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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|--------------------------|----------------------|---------------------|------------------|
| 12/821,020 | 06/22/2010 | James S. Baldassarre | 26047-0003004 | 3179 |
| 94169 Fish & Richards | 7590 01/31/201 son PC | EXAMINER | | |
| P.O.Box 1022 | NI 55440 | ARNOLD, ERNST V | | |
| minneapolis, MN 55440 | | | ART UNIT | PAPER NUMBER |
| | | | 1613 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/31/2012 | PAPER |

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.



PTOL-90A (Rev. 04/07)

| Office Action Summary | | Application No. | Applicant(s) | | | |
|---|---|---|-------------------------------|--|--|--|
| | | 12/821,020 | BALDASSARRE ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | ERNST ARNOLD | 1613 | | | |
| The MAILING DATE Period for Reply | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to com | munication(s) filed on <u>27 D</u> | December 2011. | | | | |
| 2a) This action is FINA | | action is non-final. | | | | |
| , | ,— | | | | | |
| ; the restriction | ; the restriction requirement and election have been incorporated into this action. | | | | | |
| 4) Since this application | on is in condition for allowa | nce except for formal matters, pr | osecution as to the merits is | | | |
| closed in accordance | ce with the practice under I | E <i>x parte Quayle</i> , 1935 C.D. 11, 4 | 53 O.G. 213. | | | |
| Disposition of Claims | | | | | | |
| 5) Claim(s) 31-45 is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn from consideration. 6) Claim(s) is/are allowed. 7) Claim(s) 31-45 is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 10) ☐ The specification is objected to by the Examiner. 11) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/10/12. 4) Interview Summary (PTO-413) Paper No(s)/Mail Date Notice of Informal Patent Application 6) Other: | | | | | | |

U.S. Patent and Trademark Onto PTOL-326 (Rev. 03-11)

Office Action Summary

Part of Paper No./Mail Date 20120123A



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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.



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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 negatived 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



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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 pulmenary edoma associated with a medical treatment comprising inhalation of nitric oxide gas, said method comprising:
- (a) identifying a child in need of inhated nitric oxide treatment, wherein the child is not known to be detrendent 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 bidirectional 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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