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**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of Exclusive Patent License: Development and commercialization of Nitrite Salts for the treatment, amelioration, and prevention by any route of administration of Pulmonary Hypertension, including all WHO classifications of Pulmonary Hypertension, e.g., Groups 1-5.

**AGENCY:** National Institutes of Health

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung, and Blood Institute (“NHLBI”), an institute of the National Institutes of Health; an agency within the Department of Health and Human Services, is contemplating the grant of an exclusive patent license to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to United Therapeutics Corporation (“United”) located in Silver Spring, MD and incorporated under the laws of Delaware.

**DATES:** Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Cristina Thalhammer-Reyero, PhD, MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology Transfer and Development, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; Telephone: +1-301-435-4507; Fax: +1-301-594-3080; E-mail: thalhamc@mail.nih.gov.

**SUPPLEMENTARY INFORMATION:**

The following represents the intellectual property to be licensed under the prospective agreement: PCT Application Number: PCT/US2004/21985, filed 9 July 2004, and corresponding US, EP, CA, AU and JP filings; and PCT Patent Application PCT/US2004/22232 filed 9 July 2004, and corresponding issued patents in EP, CA, AU and JP, as well as US 8,927,030 issued 01/06/2015; US 9,387,224 issued 07/12/2016, and two pending US patent applications; Titled “Use of Nitrite Salts for the treatment of Cardiovascular Conditions” (NIH Reference No. E-254-2003/0,1,2,3)

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “Use of the Licensed Patent Rights for the treatment, amelioration, and prevention of any kind or nature and by

any route of administration of Pulmonary Hypertension, including all WHO classifications of pulmonary hypertension, e.g., Groups 1-5”.

The invention pertains to the unexpected finding that low, physiological and non-toxic concentrations of sodium nitrite are able to increase blood flow and produce vasodilation by infused and nebulized routes of administration.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI Office of Technology Transfer and Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License. Comments and objections to this notice submitted will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: December 21, 2016

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Cristina Thalhammer-Reyero,  
Senior Licensing and Patenting Manager  
Office of Technology Transfer and Development  
National Heart, Lung, and Blood Institute

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