

## **PRAXAIR TECHNOLOGY, Inc.**

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Date: November 25, 2009

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**[Via E-mail: jonathan.provoost@ikaria.com](mailto:jonathan.provoost@ikaria.com)**

Dear Jonathan,

Thank you for your patience while Praxair investigates the issues surrounding our nitric oxide mix offering in México. As we discussed, Praxair has recently conducted an investigation of the regulatory and patent issues in México you raised in our telephone call of October 27, 2009.

Our investigation confirms that Praxair Mexico has the necessary authorizations from the Ministry of Health to produce nitric oxide as a medical grade gas. In addition, Praxair Mexico has made filings with the necessary authorities which allow it to sell nitric oxide mix in Mexico. Praxair Mexico expects to obtain the definitive permits and/or authorizations for the sale of nitric oxide mix in Mexico in the short term.

Specifically, in February 2005, Praxair México obtained the requisite authorization to produce nitric oxide as a Medical gas and currently has applications with the Ministry of Health seeking further regulatory approval for its' nitric oxide offerings dating back to mid 2007. In late 2007, the relevant authorities added a new requirement for the issuance of permits, the certification of Good Manufacturing Procedures ("GMP). Early in 2008 Praxair Mexico initiated the motions to obtain the GMP certification, however, up until July 2009, the relevant Mexican authorities has not appointed any entity which could issue the GMP certification. In July 2009, COFEPRIS became the only official recognized entity to issue the GMP compliance certification.

Based on these efforts and pending applications, Praxair México has the requisite authority to continue producing and selling nitric oxide mix. In addition Praxair Mexico shall continue its efforts to obtain the definitive permits from Ministry of Health and COFEPRIS on such applications.

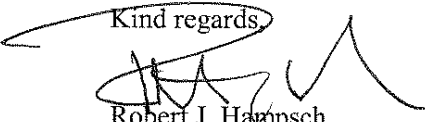
With regard to the issues concerning México Patent No 206992, we can confirm that Praxair México does manufacture nitric oxide mix as a medical gas in cylinder form from their facilities. However, there are simply no valid claims in México Patent No 206992 that would prevent Praxair (or any other gas supplier) from making or selling nitric oxide mix or the associated equipment to our customers in México.

As you know, claims 1-21 in México Patent No 206992 are directed to the use of nitric oxide as an inhalable medication. Such patent claims are contrary to Mexican law and are therefore subject to cancellation. We kindly draw your attention to Article 19, Paragraph VII of México Industrial Property Law which expressly prohibits patent protection of ‘...methods for surgical, therapeutic or diagnostic treatment applicable to the human body or animals.’ The remaining claims 22-96 are directed to an inhalation device or apparatus to introduce nitric oxide in the airways of a mammal or patient. Because such patent claims are directed to an apparatus or inhalation device, such claims are not enforceable against Praxair for its making or selling nitric oxide mix in México.

The device used to provide the nitric oxide mix is referred to as the NOMIX system. The current NOMIX system is a collection of off-the-shelf components supplied by various vendors for use by hospitals. The NOMIX system simply comprises a mixed nitric oxide cylinder (500 ppm nitric oxide gas with nitrogen gas balance) a pressure regulator, a flowmeter and PrinterNOx monitoring equipment. Our investigation also found that each of the independent apparatus claims in México Patent No. 206992 includes at least one element that is simply not present in the NOMIX system. Thus, enforcing México Patent No. 206992 against Praxair Mexico or the NOMIX system as presently configured is simply not a viable option.

We also understand that Ikaria has recently contacted the U.S. Embassy in Mexico asking for support to file actions against Praxair for patent infringement and alleged illegal sale of nitric oxide in Mexico. We believe this was an unwarranted action while Praxair was investigating the matter at your request. Therefore, we must insist that future discussions regarding this matter be directed only through our legal representative in Mexico or to me for any patent related concerns. The Praxair representative in México is Mr. Alejandro Fraga, our Legal Director who can be reached at +5281 8124 4800, e-mail [alejandro\\_fraga@praxair.com](mailto:alejandro_fraga@praxair.com).

Since there are no apparent Mexico regulatory issues or Mexican patent issues preventing Praxair Mexico from making and selling the nitric oxide mix, we consider this matter closed. Should you have any further questions or comments, please do not hesitate to contact me or Mr. Fraga directly.

Kind regards,  
  
Robert J. Hampsch  
Praxair Technology, Inc.

cc: Alejandro Fraga  
Salvador Urbina  
Jakob Janzen