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AGA AB and The General Hospital Corporation
d/b/a Massachusetts General Hospital*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

INO THERAPEUTICS, INC., :
AGA AB and THE GENERAL :
HOSPITAL CORPORATION d/b/a :
MASSACHUSETTS GENERAL :
HOSPITAL, :

Plaintiffs, :

v. :

SENSORMEDICS CORPORATION and :
PULMONOX MEDICAL CORPORATION, :

Defendants. :
_____x

Civil Action No.: *00-6033 (AET)*

**COMPLAINT
AND DEMAND FOR JURY TRIAL.**

Plaintiffs INO Therapeutics, Inc. ("INO"), AGA AB ("AGA") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), by way of their Complaint against Defendants Sensormedics Corporation ("Sensormedics") and Pulmonox Medical Corporation ("Pulmonox"), hereby allege and aver as follows:

JURISDICTION AND VENUE

1. This is an action in which Plaintiffs are seeking pecuniary and injunctive relief from acts of the Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* Jurisdiction is proper in this United States District Court pursuant to 28 U.S.C. § 1338.

2. Venue is proper in the District of New Jersey pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400.

THE PARTIES

3. INO is a Delaware corporation having its principal place of business at 54 Old Highway 22, Clinton, New Jersey 08809.

4. AGA is a Swedish corporation having a place of business at Agavägen, 181 81 Lidingö, Sweden.

5. MGH is a not-for-profit corporation of the Commonwealth of Massachusetts having a place of business at 55 Fruit Street, Boston, Massachusetts 02114.

6. Upon information and belief, Defendant Pulmonox is a Canadian corporation having a head office address at 5243 53rd Avenue, Tofield, Alberta, Canada, T0B 4J0, and its corporate office at #107, 10835 - 120 Street, Edmonton, Alberta, Canada, T5H 3P9, and is doing business in interstate commerce in the United States, including commerce in New Jersey and in this judicial district.

7. Upon information and belief, Defendant Sensormedics is a California corporation having its principal place of business at 22701 Savi Ranch Parkway, Yorba Linda, CA 92887, and is doing business in interstate commerce in the United States, including commerce in New Jersey and in this judicial district.

CLAIM FOR RELIEF

8. Plaintiff INO is in the business of supplying nitric oxide therapy services and equipment for treating patients. INO markets and sells its nitric oxide products for inhalation and services under the name INOtherapy™, which includes INOmax® (nitric oxide drug), INOvent® (the delivery system to deliver nitric oxide), and INOcal® (the calibration gases to calibrate the delivery equipment).

9. Defendant Pulmonox manufactures and markets nitric oxide delivery equipment for the delivery of nitric oxide for inhalation by patients, which it sells under the name Acronox.

10. Defendant Sensormedics is the U.S. distributor for Pulmonox of the Acronox equipment.

11. On January 23, 1996, the United States Patent and Trademark Office duly and legally issued United States Patent No. 5,458,827 entitled "Methods and Devices For Treating Pulmonary Vasoconstriction And Asthma" ("the '827 patent"). The '827 patent is assigned to Plaintiff MGH.

12. On February 23, 1999, the United States Patent and Trademark Office duly and legally issued United States Patent No. 5,873,359 also entitled "Methods and Devices For Treating Pulmonary Vasoconstriction And Asthma" ("the '359 patent"). The '359 patent is assigned to MGH.

13. MGH is the lawful owner of the entire right, title and interest in and to the '827 and '359 patents.

14. AGA is the worldwide exclusive licensee from MGH under the '827 and '359 patents and their foreign equivalent patents. AGA has granted its exclusive rights in the United States under the '827 and '359 patents to INO.

15. On October 6, 2000, at the American Association of Respiratory Care Conference in Cincinnati, Ohio, Defendants Sensormedics and Pulmonox displayed a joint announcement, which recited (emphasis added):

Pulmonox receives U.S. Food and Drug Administration ("FDA") 510(k) approval to market the Aeronox nitric oxide delivery and monitoring system.

Sensormedics and Pulmonox are pleased to announce they will be working together to provide nitric oxide medical products worldwide.

The Aeronox is now available for immediate purchase in the United States and Canada through Sensormedics.

We are jointly committed to provide affordable access to inhaled nitric oxide products for research and clinical applications.

Please contact our representatives at booths number 213 or number 452 for further information regarding product support for your clinical use and IND studies.

16. Shortly after the October conference, INO was approached by Pulmonox to see if INO was interested in ordering Aeronox devices.

17. On November 2, 2000, Defendant Pulmonox sold one such Aeronox device to INO, part number 00-200042, S/N: IV-013, (P.O. Number 101800) and Pulmonox shipped the device to INO in Clinton, NJ.

18. On November 17, 2000, Sensormedics issued a press release which stated (emphasis added):

SensorMedics and Pulmonox to Collaborate On Nitric Oxide Delivery and Monitoring Products to Treat Pulmonary Diseases

YORBA LINDA, Calif.-Nov. 17, 2000--

SensorMedics (a wholly owned subsidiary of Thermo Electron Corp.) and Pulmonox Medical Inc., a Canadian corporation (Tofield/Edmonton) Friday announced that they have agreed to jointly develop a line of nitric oxide delivery and monitoring products to treat pulmonary diseases.

Under the terms of the agreement, Pulmonox will fund development costs for the devices. SensorMedics will enter the products into worldwide distribution through the Thermo Respiratory Group's (TRG) sales and distribution network.

"This program brings together the Pulmonox delivery and measurement technologies with our High Frequency Oscillatory Ventilation technology, the combination having been demonstrated in several studies to be an optimal approach for treating patients in need of nitric oxide therapy," said Bill Ross, president of SensorMedics Corp.

"We are very pleased to be working with Pulmonox in seeing this life saving technology brought to the medical community at a time when there is a rising interest in the application of nitric oxide for the treatment of several diseases."

"We believe that access to this technology may have significant impact for patients with pulmonary hypertension who may not be covered by insurance for this therapy," said Alex Stenzler, SensorMedics' vice president of Advanced Technologies. "With Pulmonox's AeroNOx delivery system receiving approval for sale by the FDA this past August, we expect to be able to provide a delivery system that is very competitive in a price sensitive market."

Stenzler added, "At one-quarter the weight of competitive devices, we also expect that the AeroNOx will become the delivery system of choice for transporting patients on nitric oxide."

"Between our participation in the Canadian-American trial and Alex Stenzler serving on the steering committee of Reese Clark, M.D.'s 'Low-Dose Nitric Oxide' trial (published in the New England Journal of Medicine), we have collectively been associated with the only two trials that have been used for FDA approval of nitric oxide for treating hypoxic respiratory failure in newborns," said Chris Miller, president and CEO of Pulmonox. "This experience puts us in a credible position to support research and clinical applications in this area of pulmonary medicine."

Thermo Respiratory Group is a world leader in production of respiratory care equipment, including ventilators, lung function and cardiopulmonary stress testing instruments, sleep diagnostic and therapeutic systems, and other critical-care equipment used in hospitals and intensive care units. It is one of several companies forming a medical products company that will be spun out, pending SEC approval, in early 2001 as a publicly owned Medical Products Company in an IPO by its parent, Thermo Electron.

Pulmonox Medical Inc., is a privately owned Canadian corporation based in Tofield/Edmonton, Alberta. Formed in 1993, it focuses almost exclusively on developing nitric oxide delivery and analysis medical devices for the treatment

and prevention of respiratory diseases. Pulmonox has also licensed several nitric oxide patents that may provide opportunities for their entrance into the veterinary market and treatment of lung infections such as pneumonia and tuberculosis.

For more information contact Alex Stenzler at 714/283-1830, ext. 8327 or by e-mail at alex.stenzler@sensormedics.com or Chris Miller at 780/662-3968 or by e-mail at chris@pulmonox.com.

19. On information and belief, Defendant Sensormedics has also entered into a gas supply agreement to supply nitric oxide gas as well as Pulmonox's Aeronox delivery systems.

20. Defendant Sensormedics has offered to sell, and Defendant Pulmonox has made, offered to sell, and sold, nitric oxide delivery and monitoring systems, including the Aeronox Bedside, the Aeronox Transport and the Aeronox Bagger nitric oxide delivery and monitoring systems.

21. At least as early as October 2000, Defendants Pulmonox and Sensormedics, without authorization from Plaintiffs, have engaged in acts of infringement including acts of contributory infringement and inducement to infringe the '827 and '359 patents by the aforementioned offers for sale and sale in this district and elsewhere of the Aeronox nitric oxide delivery systems in violation of Plaintiffs' patent rights.

22. Upon information and belief, Defendants are now committing the acts complained of herein and threaten to continue and expand the same.

23. Upon information and belief, the aforesaid acts of infringement by Defendants have been with full knowledge of the '827 and '359 patents and are willful and deliberate, thus rendering this action against Defendants "exceptional" as that term is used in 35 U.S.C. § 285. The acts of infringement by Defendants will continue unless enjoined by this Court.

24. By reason of the acts of Defendants complained of herein, Plaintiffs have suffered, are suffering, and will continue to suffer irreparable injury unless this Court enjoins such acts.

25. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs pray for the following relief:

A. An Order adjudging Defendants to have infringed U.S. Patent Nos. 5,458,827 and 5,873,359;

B. An Order preliminary enjoining during the pendency of this action and permanently enjoining Defendants, together with their officers, agents, servants, employees and attorneys, and those persons in active concert, privity or participation with any of them who receive actual notice of this Order by personal service or otherwise from infringing U.S. Patent Nos. 5,458,827 and 5,873,359;

C. An award of compensatory damages, trebled as provided by 35 U.S.C. § 284, together with interest and costs;

D. An award of reasonable attorneys' fees as provided by 35 U.S.C. § 285; and

E. Such other relief as the Court may deem necessary and just.

**DEMAND FOR TRIAL BY JURY
PURSUANT TO FED. R. CIV. P. 38**

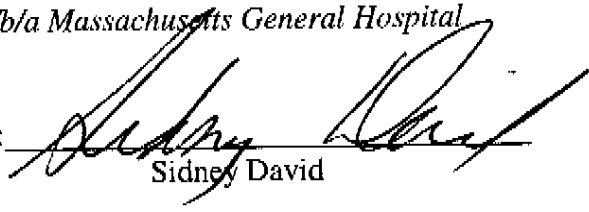
Plaintiffs demand a trial by jury of all issues in connection with the above-captioned matter.

Respectfully submitted,

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December 12, 2000

By: 
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