

UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.
Petitioner

v.

INO THERAPEUTICS, LLC. d/b/a IKARIA, INC.
Patent Owner

CASE IPR: UNASSIGNED
U.S. PATENT NO. 8,291,904

DECLARATION OF ROBERT T. STONE, PH.D

I, Robert T. Stone, Ph.D, do hereby declare and say:

1. I am over the age of twenty-one (21) and competent to make this declaration. I am also qualified to give testimony under oath. The facts and opinions listed below are within my personal knowledge.

2. I am being compensated for my time in this proceeding at my standard consulting rate of \$350.00/hr. My compensation in no way depends on the outcome of this proceeding or the content of my opinions. I am not employed by, nor receiving grant support from, Praxair Distribution, Inc., which I refer to as “Praxair”, or any of its related companies. I am receiving compensation from Praxair solely for my involvement in this matter and based only on my standard hourly consulting fees.

3. I have been asked to review certain documents, including U.S. Patent No. 8,291,904 (which I refer to as the ‘904 Patent) (Ex. 1001), and to provide my opinions on what those documents disclose. I was also asked to review and provide opinions regarding four other U.S. Patents. Specifically, I was asked to review and provide my opinions regarding U.S. Patent No. 8,573,209, U.S. Patent No. 8,573,210, U.S. Patent No. 8,776,794, and U.S. Patent No. 8,776,795. I have provided opinions specific to those patents in separate declarations. The documents I was asked to review include those addressed in more detail in the rest of this declaration and in the declarations related to the four other U.S. Patents I mentioned above.

4. Of particular relevance to the '904 Patent, I have reviewed and am familiar with the following documents:

a. U.S. Patent No. 7,114,510 to Peters et al., which is marked as Ex. 1004. I refer to this document as the '510 Patent.

b. U.S. Patent No. 5,558,083 to Bathe et al., which is marked as Ex. 1005. I refer to this document as the '083 Patent.

c. The figures and English-language translation of French Patent Publication No. 2 917 804 to L'Air Liquide Societe Anonyme Por L'Etude et L'exploitation des Procedes Georges Claude. The document I relied on, which includes both the French-language version and the English-language translation, is marked as Ex. 1006. I refer to this document as the FR '804 Publication.

d. ISO/IEEE 11073-30300, titled "Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless," an ISO/IEEE standard marked as Ex. 1007. I refer to this document as the "IR Standard."

e. U.S. Patent No. 6,811,533 to Lebel et al., which is marked as Ex. 1008. I refer to this document as the '533 Patent.

f. U.S. Patent No. 4,462,398 to Durkan et al., which is marked as Ex. 1010. I refer to this document as the '398 Patent.

g. A marketing brochure for the Air Liquide OptiKINOX inhaled Nitric Oxide delivery system, dated 2009, which is marked as Ex. 1011.

h. A document titled “Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer,” issued January 24, 2000 by the U.S. Department of Health and Human Services, Food and Drug Administration, which is marked as Exhibit 1012. I refer to this document as the FDA guidance document.

i. U.S. Patent No. 4,308,865 to Hay, which is marked as Ex. 1013. I refer to this document as the ‘865 Patent.

5. I provide my conclusions regarding the disclosures of the documents I reviewed as applied to the ‘904 Patent below.

6. I was also asked to provide my opinion on the technical feasibility of combining certain aspects of certain documents. I have offered my opinion on the feasibility of these combinations in this declaration. I have also offered my opinions about what a person of skill in the art would understand about certain aspects of the resulting combinations of documents.

7. I am not offering any conclusions as to the ultimate determinations I understand the Patent Trial and Appeals Board will make in this proceeding. Specifically, I am not offering opinions on ultimate issues of validity or claim

construction. I am simply providing my opinion on the technical aspects of the documents and on the combinability of the concepts disclosed in those documents from a technical perspective.

BACKGROUND

8. A copy of my curriculum vitae is attached to this declaration as Ex. 1003.

9. I received my B.S. in Electrical Engineering from Virginia Polytechnic Institute and State University in 1977, my M.S. in Electrical Engineering from Virginia Polytechnic Institute and State University in 1979, and my Ph.D. in Electrical Engineering from Stanford University in 1981. My studies focused on electronics and signal processing.

10. I have over thirty years of academic and industry experience in the field of medical electronics systems and instrumentation. I have extensive experience in the design of medical devices designed to communicate with remote computers, such as for control and monitoring of the delivery of treatment. I have experience designing the hardware interfaces of those systems, as well as designing the software executed on treatment delivery devices and control and monitoring hardware. I am presently the CEO and Founder of Medical Design Solutions, Inc., which is a consulting firm focusing on all aspects of medical device research and development.

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