

STATEMENT OF CONSIDERATIONS

REQUEST BY IMAGINEERING TECHNOLOGIES INC. FOR WAIVER OF U.S. AND FOREIGN RIGHTS IN AN IDENTIFIED INVENTION, DOE DOCKET NO. S-89,856 MADE UNDER CONTRACT NO. DE-AC07-94ID13223 WITH LOCKHEED IDAHO TECHNOLOGIES CO. W(I)-08-001; CH-1432

The Petitioner, Henry Makowitz, has requested a waiver of domestic and foreign patent rights in the invention, S-89,856, "Radiodurans-suscepta-humana." The subject invention is a method of controlling the radiation resistance and susceptibility of both normal and cancerous cells by using the genetic makeup of a certain micro-organism.

The invention was made under the above identified prime contract with Lockheed Idaho Technologies Company for the management and operation of Idaho National Laboratory (INL). The purpose of this waiver is to vest Imagineering Technologies Inc. ("Imagineering") with clear title to the invention to enable Imagineering to further research and possibly commercialize the subject invention. Imagineering is managed and substantially owned by Henry Makowitz, an inventor of the subject invention.

Referring to item 2 of the waiver petition, the subject invention is at a conceptual level of development. Basically, the subject invention utilizes the genetic makeup of certain micro-organisms that exist in nature for controlling the radiation resistance and susceptibility of cells. Ideally, the invention can mature into a cancer treatment method, whereby cancer cells can be selectively targeted by radiation by either decreasing the radiation resistance of the cancer cells or increasing the radiation resistance of healthy cells. Also, according to the Petitioner, this technology could be used as a weapon, whereby a population's resistance to radiation can be weakened making them more susceptible to radiation. However, the application of the subject invention as a cancer treatment method is the thrust of the present invention. Furthermore, a grant of this waiver will not include the use of the subject invention as a weapon.

Referring to item 3 of the waiver petition, the invention was made with LDRD (lab directed research and development) funding under the management operating contract of INL in 1997. Lockheed Idaho Technologies Company, management and operating contractor of INL at the time of the subject invention, did not fund further research on the subject invention and declined title to the invention. Battelle Energy Alliance (BEA), the current contractor of INL has also declined title to the subject invention and has stated that it has no objections to the Petitioner obtaining rights in the invention. The DOE closed out the subject invention on 5/28/1998. Currently, there is no DOE funding or programmatic interest in the invention. Francisco F. Roberto, the coinventor, has stated in writing that he has no objection to the DOE waiving rights to Imagineering Tech. Inc.

Referring to items 5-9 of the waiver petition, Henry Makowitz was the Principal Investigator of the subject invention. Dr. Makowitz has over 30 years of R&D experiences and over 109 publications in various technological areas. Dr. Makowitz is the Director of the "Imagine a Cure Cancer Treatment Research Foundation", a non-profit organization working to develop technology, pharmaceuticals and tools for cancer treatment. His company, Imagineering, is currently in the processes of raising four million dollars through private placement and from various venture capital sources. Dr. Makowitz has already invested ten years of effort in the field of cancer research and cancer treatment technology and has personally invested about ten thousand dollars in this effort.

The grant of this waiver should effectively promote the continued development and commercial utilization of the subject invention since Imagineering will be able to develop the subject invention into a commercial product. Imagineering estimates that approximately twenty-five million dollars of additional spending will be needed to conduct additional research and tests. Imagineering believes it possess all skills and

facilities need to commercialize the subject technology and that the subject technology may be commercialized in as short as eight years.

The grant of this waiver will help ensure that Imagineering can realize the full potential of the subject invention through very significant future investments to allow a more rapid introduction of the technology. The Government and its contractors have no further funding or research planned, thus, the waiver is necessary for the development of the subject invention, given the size and nature of the investment necessary to commercialize the invention.

The Petitioner has agreed that this waiver will be subject to the march-in and preference for U.S. industry provisions, as well as the U. S. Government license, set out in 35 U.S.C. 202-204. Further, Petitioner has agreed to the attached U.S. Competitiveness provision (paragraph (t)). In brief, Petitioner has agreed that products embodying a waived invention or produced through the use of a waived invention will be manufactured substantially in the United States unless the Petitioner can show to the satisfaction of the DOE that is not commercially feasible to do so. The Petitioner has further agreed to make the above conditions binding on any assignee or licensee or any entity otherwise acquiring rights in the waived inventions, including subsequent assignees and licensees. Should the Petitioner or other such entity receiving rights in the waived invention undergo a change in ownership amounting to a controlling interest, then the waiver, assignment, license, or other transfer of rights in the waived invention is suspended until approved in writing by DOE.

Referring to item 10 of the waiver petition, granting this waiver will not have an adverse impact on competition. There are a plurality of methods being evaluated to combat the effects of cancer such as radiation therapy, chemotherapy, targeted therapies, immunotherapy, and hormonal therapy. The Petitioner is unaware of others investigating his proposed method. Therefore, if the subject invention matures into a viable solution, granting this waiver will spur the creation of a new industry of combating

cancer by controlling the radiation resistance and susceptibility of both normal and cancerous cells.

Considering the foregoing, it is believed that granting this waiver will provide Petitioner with the necessary incentive to invest its resources in the commercialization of the subject invention in a fashion which will make the technology available to the public in the shortest practicable time. Therefore, upon evaluation of the waiver petition and in view of the objectives and considerations set forth in 10 CFR Part 784, all of which have been considered, it is recommended that the requested waiver be granted.

[REDACTED]
Daniel D. Park
Assistant Chief Counsel
Intellectual Property Law Division

Date: 10/30/08

[REDACTED]
Michael J. Dobbs
Patent Attorney
Intellectual Property Law Division

Date: 10/30/08

Based upon the foregoing Statement of Considerations and representations in the attached waiver petition, it is determined that the interests of the United States and the general public will best be served by a waiver of patent rights of the scope described above, and therefore the waiver is granted.

CONCURRENCE:

[REDACTED]
Linda Susan McCoy, Ph.D.
LDRD Program Manager
1955 Fremont Avenue, MS 1235
Idaho Falls, ID 83402-1510

Date: 11/06/2008

APPROVAL:

[REDACTED]
Paul A. Gottlieb
Assistant General Counsel for
Technology
Transfer and Intellectual Property,
GC-62 NOV 19 2008

Date: _____

WAIVER ACTION - ABSTRACT
W(I)-08-001

REQUESTOR

CONTRACT SCOPE

RATIONALE FOR
DECISION

Imagineering

A method of controlling the radiation resistance and susceptibility of both normal and cancerous cells

Imagineering will contribute significant financial funding as well as research expertise in the subject technology. The grant of this waiver will help ensure commercialization.

(t) U. S. Competitiveness

The Petitioner agrees that any products embodying any waived invention or produced through the use of any waived invention will be manufactured substantially in the United States unless the Petitioner can show to the satisfaction of the DOE that it is not commercially feasible to do so. In the event the DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., recoupment of the Government's investment, etc. The Petitioner agrees that it will not license, assign or otherwise transfer any waived invention to any entity unless that entity agrees to these same requirements. Should the Petitioner or other such entity receiving rights in the invention undergo a change in ownership amounting to a controlling interest, then the waiver, assignment, license, or other transfer of rights in the waived invention is suspended until approved in writing by the DOE.