

## Statement of Considerations

REQUEST BY VARIAN MEDICAL SYSTEMS FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN RIGHTS IN AN IDENTIFIED INVENTION (S-105,965) MADE IN THE COURSE OF OR UNDER BWXT Y-12, LLC SUBCONTRACT NO. 4300039024 UNDER PRIME CONTRACT NO. DE-AC05-00OR22800; DOE WAIVER DOCKET W(A)2004-075 [ORO-791]

Varian Medical Systems (Varian) has made a timely request for an advance waiver to worldwide rights in an identified invention made in the course of or under BWXT Y-12, LLC Subcontract No. 4300039024 entitled, "Prototype Megavoltage X-ray Sensor Array with High Spatial Resolution" under BWXT Y-12, LLC Prime Contract No. DE-AC05-00OR22800. This invention relates to a prototype megavoltage X-ray sensor array with high spatial resolution (67 micron pixels) with an active area of 21x28cm for use in cone beam CT imaging for non-destructive testing and characterization of dense objects.

Varian originally requested an advance waiver of patent rights to all subject inventions made under the above subcontract. However, Varian subsequently agreed by email dated August 11, 2005 to limit the scope of the request to the patent rights in the referenced identified invention. This invention, S-105,965, entitled, "Megavoltage Imaging with a Photoconductor Based Sensor" was disclosed to DOE on August 10, 2005 following the filing of the invention in the US Patent and Trademark Office on July 29, 2005. This invention was conceived by Varian prior to the subcontract, but is expected to be first actually reduced to practice under the subcontract.

The work is sponsored by the NNSA Office of Nuclear Weapons Stockpile (NA-122).

The dollar amount of the subcontract is estimated at \$498,993.41, with no cost-share by Varian. The period of performance is approximately three years through FY07. The prototype will be delivered to Y-12. After prototype delivery in FY07, no further Government funding is expected. Although Varian is not providing cost share under this subcontract, the work being done under this subcontract is of great benefit to NNSA because the work helps ensure that the nuclear warheads and bombs in the U.S. nuclear weapons stockpile are safe, secure, and reliable.

Varian's experience and expertise will contribute substantially to the development of the invention made under the subcontract. Varian is the world's leading manufacturer of integrated megavoltage X-ray sources and imaging systems for medical, industrial and non-destructive-testing applications with over \$1.2 billion in annual sales world wide. Last summer, Varian reported one of the first applications of its megavoltage sources and imagers to provide precise cone beam CT images of malignant lesions in lung cancer patients at the Memorial Sloan-Kettering Cancer Center in New York. Over eight technical publications have been made on this technology in the last four years, and since 2002, Varian has been awarded five U.S. Patents on its advanced X-ray sensor technology with numerous other patent applications in the field still pending in the U.S. Patent and Trademark Office. Furthermore, Varian has pioneered the use of flat panel array sensors to acquire X-ray projection images in digital electronic form.

With respect to Varian's financial commitment to commercialize the technology, Varian has spent in excess of over \$50 million of its funds and committed well over 100 man-years of high level technical and R&D labor over the last ten years in developing the advanced megavoltage, digital imaging, flat plate technology and introducing it commercially into both the medical and

industrial marketplace. If the prototype developed under the above subcontract is successful, Varian intends to commercialize the technology with its own resources and supporting technology. Varian has recently made the investment to expand the Security and Inspections part of its business in Las Vegas, NV, and already has the sales, support, manufacturing, and distribution channels to rapidly introduce this product commercially.

Varian has agreed to accept the attached DOE waiver terms and conditions if the requested waiver is granted. Specifically, Varian agrees to abide by the conditions set forth at 35 U.S.C. §202-204 relating to the Government license, march-in rights, preference for U.S. industry, as well as U.S. Competitiveness.

Varian 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 Varian can show to the satisfaction of DOE that it is not commercially feasible to do so. In the event 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. Varian further agrees to make the above condition binding on any assignee or licensee or any entity otherwise acquiring rights to any waived invention, including subsequent assignees or licensees. Should Varian or other such entity receiving rights in any 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.

Granting of the waiver should have little effect on competition since there are several technology options, this being one of many previously or yet-to-be developed in the marketplace. Thus, there should not be undue market concentration of Varian products.

Therefore, in view of the lack of any Government funding beyond FY07 or plans to further develop the invention, the incentive to private commercialization which would result from the grant of the waiver request, Varian's plans and intentions to patent and commercialize the invention and the objectives and considerations for waivers set forth in 10 CFR 784, all of which have been considered, it is recommended that an advance waiver of U.S. and foreign patent rights in the above-identified invention be granted.



Emily G. Schneider  
Assistant Chief Counsel for  
Intellectual Property

Based on the foregoing Statement of Considerations and the representations in the attached Waiver Petition, it is determined that the interest of the United States and the general public will best be served by a waiver of U.S. and foreign patent rights in the above identified invention, and therefore, the waiver is granted, subject to the conditions recited herein.

CONCURRENCE:



Theodore D. Sherry  
Manager  
Y-12 Site Office

12/6/06  
Date

APPROVAL:



Paul A. Gottlieb  
Assistant General Counsel for Technology  
Transfer and Intellectual Property

12/15/06  
Date