

## STATEMENT OF CONSIDERATIONS

REQUEST BY THE UNIVERSITY OF CALIFORNIA AS OPERATOR OF LAWRENCE BERKELEY NATIONAL LABORATORY FOR WAIVER OF DOMESTIC AND FOREIGN PATENT RIGHTS IN AN IDENTIFIED INVENTION, DOE DOCKET NO. S-119,945 PARTIALLY MADE UNDER A SUBCONTRACT ISSUED UNDER DOE CONTRACT NO. DE-AC02-05CH11231 WITH THE UNIVERSITY OF CALIFORNIA, W(I)2010-002, CH1556

This waiver request by the University of California (the University) is for an identified joint invention developed by a subcontractor of Lawrence Berkeley National Laboratory (LBNL) in performance of its work under its prime contract with the Department of Energy. In October 2008, LBNL entered into a Work-For-Others Agreement (WFOA LB09005060) with ProGDerm, LLC entitled "Further Investigation of Rhamm Technology for Subcutaneous Fat Regeneration." In that WFOA, LBNL identified a background invention (BIP), which ProGDerm intends to exclusively license. Since ProGDerm only wanted a license in a field of use "designated as applications that improve the appearance of human skin" for Subject Inventions, it was agreed that LBNL could retain title to inventions where the Sponsor had an option for a royalty-free exclusive license in the field of use if the Sponsor licensed the BIP. Eva Turley was under a guest agreement at LBNL and was a co-inventor with an LBNL employee for the BIP. To continue the research for this project, LBNL issued a subcontract to Lawson Health Research Institute (LHRI), a Canadian academic research institution, to obtain Eva Turley's expertise. See Petition, Answer 3. ProGDerm was informed that it should issue the subcontract directly with LHRI in order to receive clear title to any inventions by Eva Turley. However, ProGDerm wanted LBNL to issue the subcontract because ProGDerm would be getting a royalty-free exclusive license in the field of use under the WFOA.

The Subject Invention (S-119,945) entitled "Development of a 2 Dimensional Culture Screen for Factors Controlling Adipogenesis and Myofibroblase Differentiation" was developed with inventors Eva Turley (LHRI), Mina Bissel (LBNL) & Bahrami Bahram (LBNL). More specifically, the Subject Invention is an assay to determine what cellular constituents control adipogenesis and myofibroblast differentiaion. Adipogenesis is the process of producing fat cells. Myofibroblasts differential is critical step in cell growth. See Petition Answer 2.

LHRI is a Canadian organization that does not qualify as an academic or US non-profit organization for Bayh-Dole purposes to elect title to inventions. Therefore, the subcontract clause DEAR 952.227-13 Patent Rights—Acquisition by the Government applies and DOE owns an undivided interest in this invention with the University, because two LBNL employees are co-inventors and the University intends to elect title under its M&O Contract for its undivided interest in the Subject Invention. As an employee of LHRI, Eva Turley owns any intellectual

property, and therefore, could petition DOE for title. However, since two of the three joint inventors are LBNL employees and University intends to exclusively license the BIP and Subject Inventions to the Sponsor, the University is petitioning for title of Eva Turley's interest in this Subject Invention. Eva Turley has agreed to this arrangement since she will receive payment of royalties under the University's licensing program. ProGDerm is receiving a royalty-free exclusive license in a field of use; and therefore, ProGDerm's rights are protected in the Subject Invention when the Government grants this petition for the University.

Since this Subject Invention was funded under a WFOA, there is no DOE HQ Program official to approve of this transfer of DOE's interest in the invention to the University. Therefore, Berkeley Site Office's Program Analyst that reviews WFOA proposals will approve this transfer of DOE's interest in the Subject Invention. Furthermore, DOE's mission is satisfied since the technology is transferred to the University for licensing to the WFOA Sponsor and third parties. Any royalties generated from these third party licenses (in out-field of uses) will be directed to further research at the LBNL as dictated by the M&O Contract.

Grant of the waiver will not have an adverse impact on competition or on market concentration, since the University (as M&O Contractor) is subject to Public Laws 101-189 and as amended by PL 103-160 in its technology transfer activities. The technology transfer provisions of the contract further require including the Government license, march-in rights and preference for U.S. industry in its licensing activities. ProGDerm intends to make further substantial investment in the Subject Invention to commercialize the technology. See Petition Answers 8-10.

Upon evaluation of the waiver petition, in view of all the objectives and consideration set forth in 10 CFR 784, all of which have been considered, it is recommended that the requested waiver be granted.



Date: April 26, 2010

Gary R. Drew  
Assistant Chief Counsel  
Office of Intellectual Property Law  
Chicago Office

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:

APPROVAL:



Joseph Krupa  
DOE Program Analyst, Berkeley Site Office

Paul A. Gottlieb  
Assistant General Counsel for Technology  
Transfer and Intellectual Property, GC-62

Date: April 26, 2010

Date: 4-26-10