

National Institutes of Health
Bethesda, Maryland 20892

May 5, 2011

Ms. Denlyn K. Atherton
Sr. Patent Administrator
Harvard University Office of Technology Development
1350 Massachusetts Ave. #727
Cambridge, MA 02138

Re: Request for Waiver of the Preference for United States Industry

EIR: 3212901-06-0093

EIR TITLE: STOCHASTIC OPTICAL RECONSTRUCTION MICROSCOPY PROVIDES SUB-DIFFRACTION-LIMIT IMAGE RESOLUTION

EIR: 3212901-07-0113

EIR TITLE: SUB-DIFFRACTION LIMIT IMAGE RESOLUTION IN THREE DIMENSIONS (Also Patent Title)

Patents and	11/605,842	Filing Date 11/29/2006	3212901-06-0093
Patent applications:	7,776,613	Issue Date 8/17/2010	3212901-06-0093
	12/012,524	Filing Date 2/1/2008	3212901-06-0093
	12/795,423	Filing Date 6/7/2010	3212901-06-0093
	12/746,784	Filing Date 6/8/2010	3212901-07-0113

NIH Funding Agreement: GM068518

Inventors' Names: Xiaowei Zhuang, Bo Huang, Wenqin Wang, Wilfred M. Bates

Dear Ms. Atherton:

This letter is in response to the US Manufacturing Waiver Request submitted by Harvard University on the above-referenced invention conceived or first actually reduced to practice through an NIH funding agreement.

Below is a summary of the scientific, commercialization and licensing reviews of the Subject Invention that is the subject of this Manufacturing Waiver; this Office concurs with those reviews and further agrees that it is in accord with the terms and conditions of the funding agreements under which it was made.

Commercialization Background and Analysis

This technology concerns sub-diffraction image resolution and other imaging techniques, encompassing resolution in three dimensions. Specifically, improved methods of imaging using fluorescence microscopy to provide enhanced resolution and permit the creation of images of bio-molecular cells and complexes as small as twenty nanometers. This is a ten-fold improvement in resolution over existing technologies.

Harvard states that approximately 95 percent of the current market in fluorescence microscopes is split among four companies, including its licensee, Nikon (Japan). However, these companies are neither U.S.-based nor do they have the capability to manufacture the technology within the U.S. Harvard explains that the addition of the technology into microscopes involves the incorporation of parts and software during the complex manufacturing process of a normal fluorescence microscopy unit. Production requires extensive quality control testing prior to integration; and similarly, research and development for the overall unit must occur in close proximity to manufacturing so that workers with the required expertise can participate in all stages. Given this, Harvard states that without a grant of the waiver of the Preference for United States Industry, Nikon would have to

establish new U.S. manufacturing facilities for the overall product into which the technology is integrated – however the microscope units would not represent a substantial source of profit to merit such an investment.

Harvard further provides that it made reasonable efforts to license the invention domestically, [REDACTED]

[REDACTED]
[REDACTED] (b)(4)

[REDACTED] (b)(4)

Summary

Based on the information you have provided about the current circumstances for this technology, your request for a manufacturing waiver has been approved to use the licensees' currently existing facilities as discussed in the waiver request. Should these existing facilities become inadequate or insufficient, manufacturing capacity in the United States must be developed or another Waiver of the Preference for United States Industry must be requested. [REDACTED]

[REDACTED] (b)(4)

All other terms and conditions of the funding agreements, with the exception of the Preference for United States Industry as outlined in this letter, remain in effect.

Please feel free to contact us should you have any additional questions regarding this issue.

Sincerely,



John Salzman
Assistant Extramural Inventions Policy Officer
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Internal document