

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents
November 19, 2009

ACTION REQUEST

Subject: License and Non-Disclosure Agreements between the University of Michigan and Histosonics, LLC

Action Requested: Approval of License and Non-Disclosure Agreements

Preamble:

A statutory conflict of interest situation was identified by the Office of Technology Transfer while reviewing the technology transfer agreements. This then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by this Committee.

The proposed license and non-disclosure agreements ("Agreements") fall under the State of Michigan Conflict of Interest Statute because Professors Charles Cain, Brian Fowlke, William Roberts, and Dr. Zhen Xu and Dr. Timothy L. Hall, are all employees of the University of Michigan ("University") and partial owners of Histosonics, LLC ("Company"). The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan.

Background:

Dr. Charles Cain, Professor of Biomedical Engineering and Professor of Electrical Engineering and Computer Science, College of Engineering, Dr. Brian Fowlke, Professor of Radiology, Medical School and Professor of Biomedical Engineering, College of Engineering, Dr. William Roberts, Associate Professor of Urology, Medical School and Associate Professor of Biomedical Engineering, College of Engineering, Dr. Zhen Xu, Assistant Research Scientist, Biomedical Engineering, College of Engineering and Dr. Timothy L. Hall, Research Fellow in Urology, Medical School, are all partial owners in a for-profit company called Histosonics, LLC. The Company is interested in commercializing histotripsy technologies in a variety of medical applications and desires to obtain a license to the following technologies from the University:

UM File No. 1103, entitled: "An Ultrasound Phased Array Noninvasive Cardiac Ablation System" (Adam Strickberger, Charles Cain, Emad Ebbini)

UM File No. 1218, entitled: "High Power Phased Array Therapy System" (Cain)

- UM File No. 1329, entitled: "Novel Methods for Ultrasound Surgery Using Cavitation: Microbubble Applications for Lesion Localization and Threshold Stabilization (Brian Fowlkes, Cain)
- UM File No. 1329p1, entitled: "Method and Assembly for Performing Ultrasound Surgery Using Cavitation (Cain and Fowlkes)
- UM File No. 3207, entitled: "Feedback Methods and Systems for Determining Therapy Beam Positioning and Therapeutic Efficacy Before, During and After Ultrasound Cavitation Therapy" (Timothy Hall and Cain)
- UM File No. 3294, entitled: "Ultrasound Assisted Drug Delivery (Cain and Fowlkes)
- UM File No. 3343, entitled: "Apparatus and Methods for Performing Non-invasive Vasectomies" (Adam Strickberger, Cain, Matthew O'Donnell)
- UM File No. 3767, entitled: "Minimally Invasive Therapeutic Methods" (Cain)
- UM File No. 3916, entitled: "Histotripsy for Thrombolysis" (Cain, Zhen Xu, Hitinder Gurm, Adam Maxwell)
- UM File No. 4078, entitled: "Multiple Transducer Interactions for Aberration Corrections and for Other Enhancements for Therapeutic and Diagnostic Procedures in Clinical and Other Applications" (Cain)
- UM File No. 4116, entitled: "Gel Phantoms for Testing Cavitation Ultrasound Transducers" (Cain, Zhen Xu)
- UM File No. 4426, entitled: "Sheath Design and Methods of Use for Prostate Stabilization and Manipulation During Histotripsy" (Roberts and Hall)
- UM File No. 4456, entitled: "Devices and Methods for Using Controlled Bubble Cloud Cavitation in Fractioning Kidney Stones"(Xu, Roberts, Hall, Fowlkes, Cain)
- UM File No. 4457, entitled: "Concentric Compression Assembly of Ultrasound Transducer Elements" (Cain)
- UM File No. 4458, entitled: "Acoustic Reflectors for Scanned Positioning of Histotripsy Foci in a Treatment Volume" (Cain)

Parties to the Agreement:

The Regents of the University of Michigan and Histosonics, LLC.

Agreement Terms:

Agreement terms include giving the Company an exclusive license with the right to grant sublicenses in the field of use of medical devices. The Company will reimburse patent costs, pay milestone and annual minimums and royalties on sales. The University will retain ownership of the licensed technology and may continue to further develop it and use it internally. No use of University services or facilities, nor any assignment of University employees, is obligated or contemplated under the agreement. Standard disclaimers of warranties and indemnification apply, and the contract may be amended by consent of the parties. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate. The non-disclosure agreements provide for confidential information relating to business plans, technologies, engineering drawings, etc., to be disclosed between the University and the Company as well as its partners under the same obligation of confidentiality.

Pecuniary Interest:

The pecuniary interests of Drs. Cain, Fowlke, Roberts, Xu and Hall arise from their ownership interest in Histosonics, LLC.

Net Effect:

The Office of Technology Transfer has negotiated and finalized the terms of a license agreement for patents related to UM OTT File No. 1103, 1218, 1329, 1329p1, 3207, 3294, 3343, 3767, 3916, 4078, 4116, 4426, 4456, 4457, and 4458 in medical device applications. A companion series of non-disclosure agreements will also be completed.

Recommendation:

This matter has been reviewed and approved by the OVPR Conflict of Interest Review Committee. In light of this disclosure and our finding that the agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the Agreements between the University and Histosonics, LLC.

Respectfully Submitted,



Stephen R. Forrest
Vice President for Research

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