

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents
March 15, 2012

ACTION REQUEST

Subject: Third Amendment to License Agreement between the University of Michigan and HistoSonics, LLC

Action Requested: Approval of Amendment to License Agreement

Preamble:

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

This proposed amendment to license agreement (“Agreements”) falls under the State of Michigan Conflict of Interest Statute because Professors Charles Cain, Brian Fowlkes, William Roberts, Zhen Xu, and Dr. Timothy L. Hall, are all employees of the University of Michigan (“University”) and partial owners of HistoSonics, LLC. 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 Fowlkes, 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 Professor of Biomedical Engineering, College of Engineering, and Dr. Timothy L. Hall, Assistant Research Scientist and Adjunct Lecturer, Biomedical Engineering, College of Engineering, are all partial owners in a for-profit company called HistoSonics, LLC (the “Company”). In 2010, the Company obtained a license to a variety of histotripsy technologies in a number of medical applications and desires to add to the license from the University of Michigan, the University’s rights associated with the following jointly invented and Michigan owned technologies:

UM OTT File No. 5112, entitled: “Lesion Generation Through Bone Using Histotripsy Therapy” (Charles Cain)

UM OTT File No. 5136, entitled: “Means for Generating Spatially Random Bubble Clouds within a Focal Volume for more effective Therapy” (Cain and Tzu-Yin Wang)

UM OTT File No. 5146, entitled: "Elastography for Assessment of Surgical Lesion Formation Produced by Histotripsy" (Cain and Wang)

UM OTT File No. 5205, entitled: "Generation of Tissue Lesions Much Smaller than the Diffraction Limit: Nanotripsy" (Cain, Zhen Xu and Adam Maxwell)

UM OTT File No. 5222, entitled: "Ultrasound Transducer Manufacturing Using Rapid Prototyping Method" (Cain, Xu, Yohan Kim and Timothy Hall)

The Office of Technology Transfer selected the Company as a University partner and negotiated the terms of the proposed Agreement in accordance with University policy and its accepted licensing principles.

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. 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 Agreement may be amended by consent of the parties, such as adding related technology. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Pecuniary Interest:

The pecuniary interests of Drs. Cain, Fowlkes 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 an amendment to the existing license agreement for patents related to UM OTT File Nos. 5112, 5136, 5146, 5205, and 5222. Pursuant to the Michigan Investment in New Technology Startups program ("MINTS") approved by the Regents on December 15, 2011, the University may invest up to \$1,000,000 per qualifying funding round up to, for purposes of this approval, a total of \$2.5 million in this Company.

Recommendations:

This matter has been reviewed and approved by the OVPR Conflict of Interest Review Committee and the Medical School Conflict of Interest Board and a plan has

been developed to manage the potential risks associated with the conflict of interest. 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 Third Amendment to License Agreement between the University and HistoSonics, LLC.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Stephen R. Forrest". The signature is written in black ink and is positioned above the printed name.

Stephen R. Forrest
Vice President for Research

March 2012