



MASSACHUSETTS INSTITUTE OF TECHNOLOGY

77 Massachusetts Avenue Room E32-300
Cambridge, Mass. 02139

TECHNOLOGY LICENSING OFFICE

TELEPHONE (617) 253-6966
TELEX 921473 MITCAM

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D. Bruce Merrifield
Assistant Secretary of Productivity
Technology and Innovation
U.S. Department of Commerce
Room 4824, 14th & Constitution, N.W.
Washington, DC 20230

Dear Bruce:

This is in response to your forwarding of the letter from Ed Pandolfino of Hybritech to Dr. Windom on the subject of licensing of hybridomas and other biologicals. Dr. Pandolfino makes some interesting points. Our experience at M.I.T. supports most of his views, while differing from others. Specifically:

1. The decision whether to file a patent on a hybridoma should rest on whether the patent is able to get broad claims of the use of a class of hybridomas/antibodies, of which the specific hybridoma/antibody is just one example (and perhaps one subordinate claim of the patent.) In that case, the specific hybridoma would be deposited at the ATCC and available publicly once the patent had issued, but later, possibly improved hybridomas would be covered by the patent but need not be deposited. In that case, a patent would probably be warranted, and the later hybridomas could be kept and licensed as proprietary "tangible property."

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We agree with Dr. Pandolfino, that if the patent would cover only the specific hybridoma, then filing of a patent is probably not warranted, since any improved hybridoma would not be covered, and the specific hybridoma would be publicly available.

2. We agree that non-patented hybridomas and other tangible biological property should be available. We routinely make such property available to researchers at nonprofit institutions at no cost under a simple letter agreement. The researchers must agree to use it for research purposes only and not to distribute it to third parties.

Distribution to researchers at industrial organizations is made under a research license agreement. A nominal fee (usually \$2000 to \$5000) is charged. No license at that time is given for product development or manufacture, since the licenses for such "commercial" uses are often granted exclusively.

In all, we distinguish very little between that biological property which is covered by patents and that which is treated only as proprietary tangible property, assuming that the latter material is also thought to have commercial value.

We are enclosing a standard research license agreement which we use for transfer to industrial concerns. This one covers material for which a patent application has been filed, but it is applicable also to simple proprietary material by deleting all mention of patent rights.

Revenue from such licensing agreements (whether or not covered by patents) is split between the inventors, the department, and M.I.T.'s "general fund". Thus, it is to the researchers' and departments' advantage that the material be made widely available.

We agree also with Dr. Pandolfino that the availability of biological property should be increased by a standard, streamlined process. The administrative group should be close to the researcher developing the material: either at a local or, at most, a regional office. Rapid communication between the institution providing the material and the institution requesting it is critical to making the process work.

Finally, you will note that we have not used the term "trade secret" in this discussion and have referred to "Proprietary tangible property" instead. This is because

a major difference between "tangible property" and "trade secrets" is that openness in describing tangible property through publications and meetings does not devalue the intellectual property, whereas such openness on trade secrets totally devalues the intellectual property. We at M.I.T. believe that openness through publications and meetings is crucial to our main mission. However, the requirements for openness does not mean we should provide unlimited access to our tangible property. Such unlimited access could inhibit the commercialization of the technology, much like failing to limit licenses to a patent often kills the incentive to commercialize that patent. Furthermore, the distribution of tangible property should be limited for safety and public health reasons.

Please let us know if we can be of further help.

Sincerely,

Lita Nelsen

Lita L. Nelsen
Technology Licensing Officer

John T. Preston
John T. Preston
Director

LLN/lgc
Enclosure