UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity, Technology and Innovation
Washington, D.C. 20230
(202) 377-1984

NOV 2 1987

Mr. Leroy Randall
Chief, Patents Branch
U.S. Department of Health & Human Services
Westwood Building, Room 5A03
5333 Westbard Avenue
Bethesda, MD 20912

Dear Mr. Randall:

Thank you for your letter of July 17, regarding the trade secret licensing of hybridomas. For purposes of discussion I would characterize the subject as the licensing of tangible property resulting from federally-funded research. The fact that such property may be licensed exclusively does not necessarily mean that we are dealing with trade secrets. Most investigators producing such property publish articles which teach how the property was made which eliminates the need to discuss this as a "trade secret" issue.

The issue of licensing tangible property resulting from Federally-funded research is of great concern to the Department of Commerce. In light of your inquiry, I have asked my staff to look into undertaking the development of a policy statement. After that review, I will be back in contact with you.

Sincerely,

(Signed)
D. B. Merrifield

D. Bruce Merrifield

cc: Dr. Robert E. Windom, AS, HHS (w/cc of incoming)

EA/PTI/FTMP/Norman Latker/rh 10/30/87
bc: Dr. Merrifield
Niels Reimers, Stanford University
Roger Ditzel, University of California
George Dummer/John Preston, MIT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

c/o National Institutes of Health
Westwood Building, Room 5A03
Bethesda, Maryland 20912
(301) 496-7056

July 17, 1987

Dr. Bruce Merrifield
Assistant Secretary for Productivity,
Technology and Innovation
Department of Commerce
14th Street and Constitution Avenue
Room 4824
Washington, D.C. 20230

Re: Trade Secret Licensing of Hybridomas

Dear Dr. Merrifield:

This refers to the enclosed copy of a letter dated June 17, 1987 from Dr. Ed Pandolfino of Hybritech suggesting that the Government license hybridomas as trade secrets, without filing patent applications, and to our telephone conversation of July 14, 1987 discussing this proposal.

I would appreciate your review of the suggestion from Dr. Pandolfino, and your opinion as to its merit, particularly in view of the publication requirements of the Department of Commerce regulations covering the exclusive or partially exclusive licensing of Government owned inventions (37 CFR 404). Our procedure before exclusive or partially exclusive licensing could provide for publication and an opportunity for filing written objections, if a need exists for such publication.

Before we get into the details of this type of licensing, I would appreciate your review of the merit of the basic idea.

Thanks for your cooperation.

Sincerely,

Leroy B. Randall
Chief, Patent Branch

cc: Mr. D. Grinstead, HHS
Dr. Philip Chen, NIH

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D. BRUCE MERRIFIELD

Hybritech
INCORPORATED

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June 17, 1987

Robert E. Windom, M.D.
Assistant Secretary for Health
Room 716G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Windom:

I am writing to offer a suggestion which could greatly facilitate the transfer of clinically useful government-owned technology to the biomedical industry.

During the last five years, I have been involved in licensing technology for two different biotechnology companies. One consistently frustrating aspect of my work has been the difficulty of licensing technology (particularly hybridomas) from federal institutions. Numerous investigators at NIH and CDC have developed monoclonal antibodies and other technology which could be incorporated into commercial products. The primary difficulty in making this technology available to U.S. industry appears to stem from the current federal licensing policy.

As I understand it, technology developed at government institutions cannot usually be licensed unless a decision to file a patent application has been made. In the case of most hybridomas and many other biologicals, this may not be appropriate.

Most universities and companies involved in making hybridomas have come to the conclusion that patent cliams which are restricted to a specific hybridoma are of very limited value. Patent prosecution is expensive, and requires that the hybridoma be made publically available. One must also reveal exactly how the hybridoma was generated. It is usually not difficult for someone else to produce an equivalent hybridoma which does not infringe the restricted patent claims. Also, the public availablility of the hybridoma creates the risk that others will use it without obtaining a license. Such infringement could be very difficult to detect and prove.

In light of this, many organizations active in this field (both companies and universities) often choose to protect hybridomas as they would protect trade secrets or know-how. That is, access to the hybridoma is restricted.

The hybridomas can still be made available to researchers by having them sign a 'research use only' agreement. If the organization wishes to have the hybridoma used commercially, a license agreement (very similar to a patent license) can

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be executed. This agreement typically specifies fees, royalties and limits on the licensee's rights. In most cases, the licensee is specifically precluded from transferring the hybridoma to any third parties. This sort of agreement has been common in the industry since the late 1970's and has worked quite well.

My suggestion is that a new policy be instituted which permits the licensing of government-owned hybridomas (and other biologicals) in the absence of a patent applicaton. This policy could work as described below:

1. Given a specific set of criteria, a determination would be made at a regional level that a particular hybridoma would be best treated as 'know-how' or a 'trade secret'.

2. Once that determination is made, the regional institution would be free to license the hybridoma using a standard license agreement.

3. The income from such licenses would have to be shared according to current federal policy. Hopefully, some of the revenues would remain in the institution as an incentive to future technology transfer and, perhaps, to supply funds for prosecution of patents on other types of technology.

This system would allow the biomedical industry much more efficient access to government technology of potential clinical value. It would also bring additional funds to the regional institutions without the expense associated with a patent application. The use of standard criteria and a standard license agreement means that very little administrative time would be required.

Under the current system, many valuable hybridomas are simply not made available either because they are not considered patentable or because the institution does not wish to bear the costs of patent prosecution. This situation is frustrating not only to the companies which would like to use these hybridomas, but also the investigators who would like to see their developments put to clinical use.

I hope that you will give this proposal serious consideration. I believe that a policy can be developed which is consistent with the charters of the institutions and in the best interest of the public.

Best regards,

Ed Pandolfino, Ph.D.
Licensing Manager

ERP:MG

cc: Dr. Lowell Hermison