DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. Donald S. Fredrickson
Director, National Institutes of Health

February 28, 1977

Patent Counsel
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Harvard and Monsanto: The $23 Million Alliance

This is in response to your request for comments on the Science article "Harvard and Monsanto: The $23 Million Alliance".

Dr. Henry Meadow, who negotiated this undertaking for Harvard, is the University's focal point for intellectual property matters. He has had an interface with this office for over ten years and is cognizant with Department patent policy.

It appears that your interest lies in the fact that the article indicates that the Harvard investigators in question are being funded by the National Institutes of Health, and that Monsanto wishes to secure patent rights to products or research processes emerging from their support. The consistency of possible NIH involvement and Monsanto obtaining patent rights is explained in one of three ways:

a) The NIH support to the Harvard investigators does not overlap the workscope of what is to be undertaken for Monsanto. In other words, NIH and Monsanto funds are not to be co-mingled. There is nothing in our regulations which precludes NIH investigators from accepting private funding for projects which are separable from an NIH project, absent a problem with the University's own conflict-of-interest policies.

b) If there is a co-mingling of funds or overlapping workscopes, Harvard recognizes that any future patent rights to be obtained by Monsanto are contingent on the Department of Health, Education, and Welfare's waiver of rights under our deferred determination policy. As you recall, a waiver of rights carries with it the same conditions attached to Institutional Patent Agreements (IPA), or

c) If there is a co-mingling of funds or overlapping workscopes, Harvard anticipates clearance of an HEW Institutional Patent Agreement which would permit them to guarantee a first option to future invention rights to Monsanto on the basis of Monsanto's

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cost-sharing. Harvard has made a request for an Institutional Patent Agreement, which is now in its final stage of clearance.

I believe the primary reason for Harvard's change in patent policy mentioned in the article was based on the need to meet the Department of Health, Education, and Welfare conditions for an IPA, since they have had major difficulties putting together other collaborative projects in the health area with private sponsors, due to their past inability to guarantee with certainty some rights in the end results to such private sponsors. I am in agreement with University Counsel Daniel Steiner's comment that "given the emphasis that is being placed on 'technology transfer' generally and on the realities of resources needed to take any discovery from research through development, Harvard's 'laissez-faire' patent policy was 'foolish'". I have expressed similar views to Mr. Meadow in other terms on a number of occasions when confronted with the proposed collaborative projects involving NIH funding and Harvard policy's failure to generate optimum transfer of our technology.

Although this arrangement is, indeed, a "novel and imaginative approach to innovation and technology transfer problems in today's complex society" for Harvard, it is commonplace amongst many of our Institutional Patent Agreement holders, as one of the primary features of the IPA is its ability to create "certainty" that a private collaborator's equities can be observed at the time of negotiation and prior to identification of inventions.

In 1974 when our office was last able to collect patent statistics on licensing and collaborative arrangements (the statistics Dr. Perpich is now using to support the IPA in the DNA situation), we were advised of at least seven such arrangements. From conversations with University patent focal points, I know that that figure has significantly increased.

I believe this type of arrangement is supportable whether NIH funds are involved or not on the grounds that:

a) They guarantee technology transfer on the most expeditious basis if positive findings arise as the industrial component of the delivery system has been involved from inception.

b) If NIH funds are involved, it stretches our capability to fund basic research elsewhere, since it is to be expected that the industrial component will undertake most of the applied research.

c) The University has a means (as demonstrated in the Harvard arrangement) to impress a "public interest" aspect on the technology transfer process.

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If you should wish additional information on the Harvard-Monsanto arrangement, I would be glad to speak to Dr. Meadow. I would note that Harvard is one of the last major institutions in the country to approach us for an IPA. (The list of present IPA holders is attached.)

Changing the subject slightly, Dr. Perpich recently asked for information supporting the Department's patent policy to aid your decision on patents in the DNA area. The primary statistical support is based on three separate studies conducted prior to the end of 1975, which indicated that the University sector was licensing over 30 percent of the patent portfolio they hold, while the Government's performance now indicates a licensing rate of its own portfolio of under 5 percent. Many factors enter into the Government's poor performance, but in my mind, it is primarily due to the loss of the "advocate" of the innovation when the Government retains or destroys the property rights involved. Due to Dr. Perpich's prompt need for the information, my office was only able to compile the attached sample list of some of the 30 percent of innovations licensed by the University sector. (Many of these have occurred after 1975.) It seems to me that this sampling can be viewed as a dramatic indication of the enormity of the amount of private capital flowing into the development of high-technology innovations emerging from NIH supported research which would not be duplicated under a Government licensing program which, as noted, at best licenses 5 percent of its portfolio.

The accomplishments of the University sector based on the sampling indicates to me that, given the flexibility of the Department's patent policy, the Universities have exceeded the best expectations I had when my office last reviewed their performance in 1974.

Norman J. Latker

Enclosure

cc: Dr. Harmison w/attachment (HEW) - (2)
Dr. Perpich w/attachment - 1
Dr. Malone w/attachment - 1
Dr. Jacobs w/attachment - 1
Dr. Perry w/attachment (2)
Mr. Feiner w/attachment (HEW) (2)

bcc: Dr. Heming (2)
Dr. Ringler (2)
Dr. Burton (2)

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