NW Latker
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MEMBERS OF THE RECOMBINANT ADVISORY COMMITTEE

Dear

As you may know, Stanford University and the University of California have proceeded to file a patent application on a process for forming recombinant DNA. This invention was generated in performance of an NIH grant. A number of other Universities, including the University of Alabama, may also file patent applications on derivatives of recombinant DNA research. Notwithstanding Stanford's right to file under the terms of a prior agreement with the Department, they have solicited NIH's view on an appropriate plan for administration of this invention. A copy of their letter on the matter is enclosed.

These patent activities, the certitude that other important inventions in this field are forthcoming, and the public's apprehension over control of recombinant DNA research compel inquiry into whether the Department's normal policy of allocating invention rights is consonant with the concerns about this research or whether special treatment would be more appropriate.

Invention rights are normally allocated in either of two ways under Department patent regulations:

First, if a University or other nonprofit institution seeks to enhance its technology transfer capability, the Department may enter into an Institutional Patent Agreement (IPA). This provides to the institution the first option to ownership in all inventions made in performance of Department research, subject to a number of conditions deemed necessary to protect the public interest. Some of the more important conditions are

(1) a royalty-free license permitting the Government and those functioning under Government direction to practice the invention,
(2) a limit on the term of any exclusive license granted,
(3) Department authority to withdraw specified grants from the agreement, and
(4) the right of the Department to regain ownership due to public interest considerations or the institution's failure to take effective steps to commercialize the invention.

A more detailed outline of such conditions is enclosed.

Stanford and the University of Alabama each hold one of the 65 IPA's now being administered by the Department.

Second, under grants and contracts with institutions having no identified technology transfer capability, the Department utilizes a provision deferring determination of ownership until an invention has been made. Under the deferred determination provision, an innovating institution may petition the Department for ownership of an invention after it is identified. In the past, approximately 90 percent of all such petitions have been granted on the basis of a satisfactory institution plan for development or licensing, subject, however, to conditions similar to those contained in the Department's IPA's.

The Department's normal policy of allocating invention rights is designed to facilitate the transfer of technology from the bench to the marketplace, by assuring that the innovating institution has the right to convey those intellectual property rights necessary to induce industrial investment and continued development of inventions generated with Department support. Only the IPA policy, however, assures a management focal point in the innovating institution which is trained to solicit and establish timely rights in intellectual property prior to invention.

We have been advised by the Department Patent Branch that 167 patent applications were filed from 1969 through the fall of 1974 under IPA's. Approximately $24 million is committed to the development of inventions on the basis of licenses granted under these patent applications. Meanwhile, we are advised that the Department, under the deferred determination provision, has granted 162 of the institutions' 178 petitions for ownership. Approximately $53 million was invested or committed to development under the licenses awarded. The commitment of private risk capital in these instances is viewed as evidence that a licensable patent right is a primary factor in the successful transfer of Department research results to industry and the marketplace.

It indeed appears that the incentives provided by Department patent policy have encouraged the development of new technology in general and afforded patent protection for some inventions to the economic benefit of the United States.

The control of DNA research envisioned by the guidelines, however, requires a delicate balance between need for rapid exchange of information unhampered by undue concern for patent rights and a potential for achieving uniformity in safety practices through conditions of licensure under patent agreements.

As noted, Stanford has indicated some willingness to consider modification of their IPA as it relates to such research. There are a number of possible policy options, short of the present allocation of rights under the IPA, which could be considered for discussion with Stanford and as possible alternatives to the present allocation of rights made under all other IPA's. Some of these options are as follows:

(1) Institutions could be discouraged from filing patent applications on inventions arising from recombinant DNA research. If this option were pursued, publication would be relied on to cut off all possible adverse patent claims.

(2) Institutions could be asked to file patent applications on inventions arising from recombinant DNA research and to dedicate all issued patents to the public. This would, to a greater extent than (1), block adverse patent claims.

(3) Institutions could be asked to assign all inventions made in performance of recombinant DNA research to the Department. The Department as assignee of the invention could either pursue the licensing of whatever patent applications were filed or dedicate issued patents to the public.

(4) The Department could continue to permit institutions to exercise their first option to ownership under the IPA but require that all licensing of patented inventions be approved by the Department. The Department could set certain conditions for approval, such as compliance with the NIH guidelines on recombinant DNA research.

(5) The Department could permit institutions to retain their first option as in (4), but approve only exclusive licenses. Here, as above, the Department could set out conditions to account for the special nature of recombinant DNA research, both in approved exclusive and non-exclusive licenses.

If it is determined that institutions with IPA's should be permitted to retain ownership of inventions arising from recombinant DNA research, I am concerned about the effect of the processing of patent applications on the dissemination of research information. Under United States law, an inventor has a one-year period of grace after research results are published in which to file in order to obtain a valid United States patent. However, valid protection in a number of foreign countries requires that a patent application be filed prior to publication. If one publishes first, valid patent protection cannot be obtained in such countries. Our patent people believe that any necessary patent applications can be handled expeditiously without an undue burden on disclosure. I am especially mindful

of your Committee's concern for the rapid dissemination of research results in recombinant DNA research and would especially welcome your thoughts on this matter. For example, would you view patent claims as an impediment to the operation and functions of your Committee? What experience, if any, have you or your colleagues or institution had with patent claims in this regard?

I have asked Bill Gartland to assign about an hour on the agenda of your meeting to review patent policy, and have asked Joe Perpich and Norm Latker, the Department Patent Counsel, to attend the meeting for this discussion.

I would appreciate your views on Department patent policy as it relates to the conduct of your research, the operations of your Committee, and the suggested policy options I have outlined above. I intend also to solicit advice on this matter from other interested parties in the scientific community and in the public and private sectors.

Thank you very much for your consideration of this most important matter.

Sincerely yours,

/s/ Donald S. Fredrickson, M.D.

Donald S. Fredrickson, M.D.
Director

3 Enclosures

JPerpich:hh