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**WISCONSIN  
ALUMNI  
RESEARCH  
FOUNDATION**

November 16, 1981

Mr. Leroy B. Randall  
Chief, Patent Branch  
Office of the General Counsel  
Department of Health and Human Services  
National Institutes of Health  
Westwood Building, Room 5A03  
Bethesda, MD 20205

Dear Mr. Randall:

Enclosed you will find copies of the reports which were sent by Dr. Charles Lowe to Dr. O'Neil, President of the University of Wisconsin, upon which some of the pertinent data requested has been entered. You will note that with regard to some of the data we have stamped it confidential so as to comport with the reporting requirements under OMB Bulletin No. 81-22, the interim final regulations issued under PL 96-517. We consider that the data supplied and so marked is privileged and confidential and should therefore not be disclosed to persons outside the Government.

To further protect our licensees, which we believe must take high precedence over supplying information for a study, we have, wherever possible, lumped total sales so that single product identification-sales will not be evident on a company-by-company basis. We have done this to preserve our working relationship with licensees and potential licensees for the reported and other technology which we may handle. This latter type of information is often sought by our licensees' competitors and, although we are willing to provide some of the information we firmly believe that the data marked confidential is of such nature as to be within the 4th exemption of the Freedom of Information Act.

Also in order is a comment on the effort that has been required to supply much of the information which we believe was already in the hands of the Agency through earlier annual reports under the IPA. The work required to respond to the request took days of the time of

*Copy to Harry Peterson*

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my secretary, who also has the responsibility for keeping our patent and licensing records, a substantial amount of time by our accounting department, to supply some of the financial data involved and at least two full days of totally unproductive review time by myself. As a matter of fact, and in reviewing the effort now in light of the total benefits which might be derived by the Government from the information, I consider the total effort unproductive and antithetical to the record keeping and regulation reduction program which is one of the primary thrusts of the current Administration.

Please also be advised that we have no available figures on the commitment of the licensee to a development program in terms of dollars. In all cases we ask for a development program and protocol by a licensee and periodic progress reports against that stated protocol to indicate whether or not significant progress has been made in the program. Lack of a showing of progress in the program can constitute breach of contract under our agreements for which termination can be invoked. In my view, the dollar figure assigned to a licensee's commitment is rather meaningless since it does not necessarily indicate any developmental progress and since any dollar commitment expressed can result from a wide latitude of interpretation of funds being utilized for development effort under the license. We firmly believe that requiring a development protocol and reports against such protocol are of much greater significance to the licensee's efforts at development. We do know that, as is the case with a number of the inventions reported, the dollar commitment is in the millions of dollars where a new chemical entity earmarked for a pharmaceutical use and eventually marketed is concerned. The estimation of that commitment by the industry runs from 30 - 50 million dollars.

The policies of the University of Wisconsin and the Wisconsin Alumni Research Foundation acting as the designee of the University under the IPA is fully documented in the Agency's files and has not changed. It is the University's obligation to obtain the necessary agreements regarding inventions under the funding proposals but, at the University of Wisconsin, there is no formal employment agreement with faculty and

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staff. The performance of the Foundation we believe is totally self-evident from the annual reports which have been supplied since the IPA first became effective as between the University of Wisconsin and the Department of Health, Education, and Welfare in 1968. Pursuant to the Foundation's function as a designee, a formal agreement was made with the University to give assurance that the Foundation would recognize the University's obligations to funding entities. That agreement is also a matter of record in the Agency's files.

Although it is at the risk of suggesting the Agency request more information it should be realized that any University which engages in a technology transfer program commits substantial monies of its own to transfer any technology through use of the patent system to the marketplace. We have in some circumstances indicated total expenditures made by WARF to indicate the significance of such expenses. In some situations the expenditure for establishing a patent portfolio on a given invention may also reflect a part of the commitment by a licensee where the licensee agrees to pay the patenting costs, U. S., foreign or both. In any event that initial commitment is the one which serves to establish a base from which the technology transfer can be made.

As a last item we look upon the request for the detailed information as burdensome and not the reasonable kind of request which should be made under the provisions and regulations of PL 96-517 or within the purview of the current Administration's efforts to reduce regulation and paper work. Moreover, the shortened reporting time does not comport with the notification (copy attached) which changed the due date of the annual report to December 31. As I mentioned before, accumulating and supplying the kind of information requested represents in our view a major nonproductive effort and the use of time which could more beneficially be applied to the technology transfer effort.

Very truly yours,

Howard W. Bremer  
Patent Counsel

HWB:rw  
Enc.

cc--Dr. Lowe; Mr. Lorenz