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WISCONSIN ALUMNI RESEARCH FOUNDATION

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MADISON 6, WISCONSIN

September 20, 1963

Professor William H. Young
Budget Director
University of Wisconsin
20 Bascom Hall
Madison, Wisconsin

Dear Bill:

Re: Coenzyme Q Licensing Situation
(U.S. Application Ser. No. 758,838)

Pursuant to our earlier discussions relative to the above subject we have now had an opportunity to thoroughly discuss with Merck & Co., Inc. the licensing situation on Coenzyme Q in relation to the Surgeon General's determination [Case No. N-62-58 (D59)]. As you know, there were three major stumbling blocks to licensing in the Surgeon General's determination. These were:

1. The limited period of exclusivity which could be granted a licensee - this period being for five years from the patent application date (July 7, 1958) or three years from the first public use, whichever was earlier;

2. The requirement to dedicate the inventions to the public or to make licenses available upon request on a royalty-free basis beginning ten years after the filing date of the patent application;

3. The requirement that all future inventions made by an exclusive licensee be subject to the terms of the determination including the above two limitations.

At the outset, Merck had a very definite interest in Coensyme Q and in pursuing research and development work which would lead to and establish its utility through clinical studies. Merck, however, did not feel that they could accept a license from the Foundation under the terms and conditions set out in the determination, the major deterrent to such a license being the three limitations set forth above. Of these limitations the first and second were not considered as disabling to Merck's program as was the third limitation. It developed that under no circumstances did Merck feel it could enter into a licensing arrangement containing limitation 3. above. (Refer to letter from Dr. Max Tishler, President of Merck Sharpe & Dohme Research Laboratories to Dr. William C. Hendrickson of the Foundation dated August 10, 1960.) As a result, no agreement was

ever reached with Merck and no license was ever issued under the above patent application.

Our discussions with Merck further developed the fact that because of the limitations expressed in the determination, Merck's research effort was directed not to the compounds discovered at the University of Wisconsin and which were the subject of the patent application, but was directed into areas not covered by the patent application and in which there was a possibility that Merck could obtain a patent position for itself. Thus, the effect of the limitations in the determination forced Merck's research efforts away from the invention made at the University.

In spite of the large investment in time and money which Merck has made relative to this general area of investigation, there has not yet been a clear showing of clinical utility and the probabilities are, therefore, very great that no compounds of this type will be marketed prior to 1968, the year in which the Foundation's right to grant even a nonexclusive license expires. It is also significant that because of Merck's justified unwillingness to work in an area, namely, within the scope of the patent application, where no incentive was provided because of the limitations of the determination, any products which would subsequently be marketed by Merck in this general subject matter area would very probably not fall within the scope of the patent application.

In view of the above factors, Merck has now gone on record with the Foundation that, insofar as Merck's interest is concerned, they do not think that additional prosecution of the patent application, which is now in the appeal stage, is warranted. In other words, Merck is no longer interested in a license under the Foundation's patent position.

Within the limitations set by the determination, the Foundation's right to grant an exclusive license has now expired and its right to grant a nonexclusive license will expire in July 1966. In spite of the work done to date, it is still apparent that any research and development effort in this subject matter area, particularly to the point of clinical utility, will be extremely expensive and time consuming. As a consequence, the limitations in the determination do not provide for sufficient incentive for an industrial concern to enter into such a research and development program. There is, therefore, little chance that the Foundation could expect to find a licensee on a nonexclusive basis when it has been unable to obtain a licensee on an exclusive basis.

The Foundation, too, has expended a good deal of time and effort in pursuing the patent position on Coenzyme Q and also in its efforts to obtain licensees. In view of the developments in this situation as outlined above, and in view of the lack of response to the letter from the Foundation to the Surgeon General dated September 26, 1960 requesting a modification of the determination referred to above, the Foundation does not believe further expense on its part is warranted.

The patent application referred to above contains some claims which have been allowed by the Patent Office and others that are on appeal. It is now contemplated that no further appeal proceedings will be pursued and that upon receipt of Notice of Allowance from the Patent Office of the claims now in the application or within the six months' statutory period following during which the final fee to have the patent issue must be paid, the Foundation will assign all right, title and interest in the inventions disclosed and claimed in the application to the United States Government.

We, at the Foundation, believe that many valuable lessons have been learned as a result of this experience. Some of the more important of these are the following:

1. It is unrealistic for any period of exclusivity in a licensing arrangement to be based upon the filing date of an application. In most instances, and particularly in the pharmaceutical field, the research and development to bring a particular pharmaceutical preparation to the stage of clinical utility is extremely time consuming and indeterminate. Any period of exclusivity commencing with the date of patent application may well be used up, therefore, before a product has reach the market. There would, consequently, be no incentive for a manufacturer under such a situation. We feel that it is much more realistic to commence the period of exclusivity with the first marketing of a product.

2. It is also unrealistic, where patenting with licensing on a royalty basis appears to be in the best public interest, to restrict the period for such licensing using as a basis the patent application date. In this Coenzyme Q situation, it is apparent that even ten years may at times not be adequate, when measured from the patent application date, for a licensee to bring an invention to the market.

3. No commercial enterprise is willing to lose the fruits of its research and development effort, when it has financed that effort itself, by agreeing to make its inventions freely available to all comers. Of the three limitations in the determination under Coenzyme Q which were outlined above, this was indicated by Merck to be the greatest deterrent to Merck entering into some licensing arrangement with the Foundation.

It is prima facie evident from the provisions of Section 8.2(b) of the Regulations of the Department of Health, Education and Welfare that there is a recognition that in certain situations the public is best served by patenting with licensing on a royalty basis. It is also evident from the foregoing that where a determination is made under Section 8.2(b) of the Regulations which permits such patenting

and licensing, the rights granted must not be restricted by the determination to the extent of discouraging a potential licensee. We feel that the limitations outlined above removed any incentive for a licensee to enter into a licensing arrangement under the Coenzyme Q patent application and achieved an effect directly opposite to that for which Section 8.2(b) was designed.

Very truly yours,

Howard W. Bremer
Patent Counsel

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