Ward Ross

M. D. Woerpel September 22, 1964

Re: Washington NIH Meetings

One meeting began at 9:00 in Clesner's office, where we were joined 20 minutes later by Miss Parent. This group adjourned to Dr. Price's office for a session lasting one hour. At the end of this time, Young and Lorenz went to their meeting with Quigley and Hiller. I returned to Clesner's office with him and Miss Parent.

During the first hour, Clesner showed numerous memoranda which he seemed willing for me to see, although in each case he handed the papers to Young. The purpose of these disclosures was to convince us that the real difficulty in administering the patent policy of the NIH arose because of the attitudes "up stairs". The memoranda was written by Hiller and dealt specifically with a case being handled by the University of Indiana Foundation. The department regulations have a paragraph 8.2(d) under which an invention conceded to be of doubtful importance or one in which the government has minimal equity, can be administratively left with the grantee. It appears that the Indiana invention has been conceded to be of doubtful importance at this point in time, and therefore, Clesner has proposed a determination which would leave rights with the Indiana Foundation. As nearly as I could tell after a very superficial reading, Hiller had objected to this on the ground that the invention report did not substantiate the evaluation that the invention is of doubtful importance.

Clesner now wants to use our Cannon invention which he claims has both of the qualifications which are provided as alternatives under 8.2(d). In the session when I was alone with Clesner and Parent, I asked him if he was not afraid that an invention presently defined as of doubtful importance, might later be found to have value. He said he recognized this possibility but wishes to test the regulation which only says the present evaluation of the invention is that it be of doubtful importance.

When Miss Parent joined us she wished to immediately plunge into the details of her workload. There was some discussion of the Gott-Daggett heart valve, and Clesner's question concerning the claim coverage of the Tobey-West case.

The discussion with Dr. Price was initiated by Bill Young, who stated that the University intends to comply with Price's last letter on the Coenzyme Q case. Bill told him that in the letter which will assign this invention to the government, the University will take the opportunity to make a record of what we consider to be the government's mistakes in the original determination. Bill told Price that whereas in most of the other situations that have been under discussion, the University had made certain errors of omission or commission, in this case, we feel the University and WARF did everything properly, but that the government made certain errors. These errors proved to be fatal to the successful development of the invention. Price did not object and, in fact, stated that he thought this letter would be good reading for certain of the people involved in the NIH program at this time.

Attention was then devoted to the Lichtenstein matter for the remainder of the meeting. Price asked for the reactions of Parent and Clesner to the development statement which they had studied. Miss Parent volunteered the first comments. She thought (1) the Surgeon General should have some language in the statement whereby he would have the right to review the license agreement and (2) that reports on the progress of the development program should be made by the licensee not only to WARF but to the Surgeon General. The entire meeting was spent in the discussions of these two points. We pointed out that reports from the licensee could be the avenue through which know-how would be made available to its future competitor and that a requirement for detailed reports to the Surgeon General would undoubtedly be as difficult to work with as the Coenzyme Q determination had been. All three government employees were quick to state that detailed reports were not intended and that only reports showing "diligence to achieve utilization", would be required.

At this point, Clesner asked Price whether it would not be appropriate for the development statement to provide that in the areas where government regulations is involved; i.e. drugs and pesticides, a potential competitor could begin his efforts to obtain Federal clearance prior to the expiration of the primary licensees exclusivity, without fear of prosecution by the Foundation. He stated that this was a condition which had been written into the proposed Cancer Society agreement. In the subsequent session he agreed to send the formal language which had been worked out for this provision.

I expressed a reluctance to submit license agreements to the government for review, based as much on a general reaction as to anything specific. Bill Young agreed that this was not a point which we could accept without further discussions in Madison. At this point, Dr. Price used the phrase that the requirement for review of licenses should be a "compliance review." It is my interpretation that by this he meant that the government would not be in a position of being a party to the negotiations but that the finished, fully executed document would be made available to the government to establish that all of the licensing policies stated in the development statement had indeed been adhered to.

Young asked Price the present status of institutional agreements and Price said that no new ones had been granted and no old ones had been canceled. They are waiting now for the decision which will be made by the Office of Science and Technology patent panel, which has been working with the University business officers to arrive at a suitable policy.

Miss Parent recommended that our changes to the Lichtenstein development statement be submitted as a supplement rather than redoing the entire document.

The specific suggestions which were made in my session with Clesner and Parent include the following:

1. The statement should be broadened to include synthetic myristicin.

2. The extent of other sponsorship should be determined and stated.

3. We might point out that a synthesis may have to be devised in order to achieve significant production of myristicin under 5b.

4. Under 5c we mention the possibility of different tolerances of male and female insect species. Clesner said we could strengthen this by pointing out that the differences in tolerances would have to be dealt with.

5. In our paragraph 6, we talk about the necessary <u>incentives</u> for a company to undertake the development program. Clesner suggests making this "<u>production and incentives</u>."

6. On page 8, we do not adequately support the selection of Union Carbide as the licensee, in the opinion of Clesner and Parent. I asked to what extent would we have to document our search for alternative licensees in order to satisfy this requirement. Clesner said that he had no comment and that he was sure that I understood the spirit of the requirement????

7. On page 12, paragraph g, we should state our willingness to assign either the patent or patent application to the Surgeon General.

8. WARF should state that a copy of the patent application as filed, will be provided to the Surgeon General. Also if at any time after 3 years it is the intent of WARF to abandon the prosecution, it will first offer the pending application to the government.

9. We were asked to carefully review subparagraphs e, f, g and h of the President's Memorandum and make sure that we gave these proper consideration in the development statement.

The only point at which the conversation came at all close to dealing with the question of how broadly an invention must be licensed at the expiration of exclusivity of the primary licensee, then followed. Clesner asked that we add a paragraph stating that if after expiration of the primary licensee's exclusivity there would be a complaint that the Foundation was unreasonably reluctant to grant additional licenses, then the government could grant licenses. I asked whether requiring a company seeking license to be well qualified was unreasonable reluctance and was advised that we could qualify the phrase, i.e., if there were unreasonable reluctance to license a qualified company then the government could grant the license.

Clesner offered to send us formal language on this latter point and on the matter of permitting a secondary licensee to begin proceedings prior to the expiration of an exclusive license. I asked him to direct this information to Professor Young. The proposed language is as follows:

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While there may be nothing seriously wrong with the additions to the Lichtenstein development statement which were requested by Parent and Clesner, it is my reaction that the agreement between University and government is apt to be broader in scope and much less detailed if it can be worked out at the Quigley-Hiller level, therefore, acquiescence in many of the detailed points raised by Clesner and Parent might be precedent forming and unnecessary. For this reason, I do not think we should be in a hurry to file the supplement to the Lichtenstein Development Statement, although we should undoubtedly be working on it in the event a progress report is requested.

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