Ward Ross

M. D. Woerpel May 27, 1965

Re: Washington Meeting with HEW and NIH Personnel, May 19, 1965.

Present at the meeting: Mr. Hiller
Mrs. Spector
Mr. Clesner
Miss Parent
Bill Young
Reuben Lorenz
M. D. Woerpel

The initial discussion concerned the agreement between the University and WARF. This agreement had been given to Hiller and Quigley for review and approval, and by means of a non-committal letter from Hiller had been considered to have been passed on by the group. In spite of this fact, there are now four changes which are necessary as a result of the discussions in this meeting. These are:

1. A reporting requirement should be added to the agreement. They conceded that paragraph 7 of the agreement which states WARF's willingness to cooperate with the University in fulfilling all of its obligations covers this but in view of the specific reporting requirements of the President's Statement on Patent Policy, felt it should be made more specific. Bill Young and I believe this can best be accomplished by adding a sentence to paragraph 7 which will state that such reporting is specifically covered by this paragraph.

2. After considerable discussion, it was requested that we remove the word "absolute" from paragraph 3a on page 3 of the agreement.

3. They want the statement as to the inventors share of the income to be described in paragraph 6(f) as 15% of net royalties rather than total, as it now stands. There was considerable discussion of what would be an appropriate method of calculating costs on invention development for the determination of net royalties. At their request I explained the present accounting method for non-government

inventions, namely the accounting for out-of-pocket costs, sharing of income on an annual basis when aggregate licensing income exceeded the current total of out-of-pocket expenses. I pointed out that under this arrangement it is possible for an account to slide back into the red so that on an over-all basis an inventor may have participated to an extent somewhat higher than agreed upon. There appears to be an agreement that the inventor should not be asked to reimburse under these conditions and that this is an appropriate method. Bill Young, however, is very anxious for accounting procedures to show not only out-of-pocket costs but administrative overhead as well in order that the University and the government both be acquainted with the direct costs of operating a patent licensing operation. He would like very much, I am sure, to show not only administrative overhead, but the total investment in all government inventions so that royalty income on one successful one would not loom large in comparison to the total investment necessary in the many unsuccessful inventions.

4. Hiller was concerned that the agreement made no statement as to the disposition of the 85% of net income. We explained that this was not necessary in the present document because by charter the Foundation can make only one disposition of its income. Hiller understands this but wants the charter to be included either by reference or as an appendix to this agreement.

The next subject was the Lichtenstein Development Statement. After about two hours of discussion on certain lesser points, Hiller emerged from the weeds with the observation that under the terms of the President's memo, 8. 2(b) determinations are probably out of the question. It developed that the Department has not formally adopted the recommendation of the President's Statement of Patent Policy so that in fact the Surgeon General is still empowered to make 8. 2(b) determinations, as we have requested in the Lichtenstein Development Statement. It became clear, however, that Hiller did not recommend

that the Surgeon General make such a determination during the pendency of the Department's decision on the President's Memorandum. He seemed to be daring Clesner to do so.

It is Hiller's position that the language of section 1a(2), President's Statement, makes all inventions arising out of research and grants of the NIH to the University fall into the area where the government shall acquire principal or exclusive rights. They interpret that any health-related invention arising out of an NIH grant is considered as having been a purpose of the contract even though they recognize that University does not consider the purpose of the contract to be the making of inventions. Their interpretation of this point is similar to the interpretation generally made concerning an invention made by an employee. That is, any invention in the field of study supported by an NIH grant, will be construed as having been a purpose of the grant. In the case of an insecticide invention from Lichtenstein's research, it is clear that their present feeling is that it should be considered so.

In light of this, the other discussion seems to have been purely academic. We did, however, discuss at length our paragraph 14(k) by means of which we included the "march in" clause which is paragraph 1(g) of the President's Memorandum. Clesner made an impassionate speech concerning the difficulties this would present in a negotiation for development activity. It is clear that the Department does consider this a "march in" clause and has done little to clarify the scope of this paragraph. Hiller suggested that statements concerning the adequacy of supply, the quality of supply, and the fairness of the price on the patented product as available from an exclusive licensee would be a basis by which to determine whether the "march in" paragraph should be exercised. This language is taken from the industry contract on the cancer chemotherapy program. He was unwilling for us to include this language in our paragraph 14(k), however, until we had negotiated or attempted to negotiate a contract including the present language. Failure on this would then be the basis for their consideration of our request to add limiting definitions to this right retained by the government. Again Clesner argued in our favor, whereupon it turned out that Hiller did not realize that Union Carbide had dropped its interest. He immediately stated that this made it different and seemed to be willing for us to now include the restrictions of the right, prior to negotiation with other companies.

It was agreed that we should request Clesner to send a copy for such restriction definitions.

After lunch, we reconvened with Clesner and Parent at which time we discussed their ability to make an 8. 2(d) determination based on the situation where the government has very little equity. An 8. 2(d) determination on the Tobey-West case should soon be made. Miss Parent showed us the draft copy she has prepared. At this point,

Bill Young introduced the new Lichtenstein invention explaining that in the University's opinion the extent of the government's contribution is minimal. He described the stockroom situation where some materials are bought on NIH funds but used on projects supported by other research and vice versa. He also explained that in this instance, one piece of apparatus bought several years earlier by NIH money had been important to the discovery. In spite of these contributions, it was clear that Clesner would not have asked for the right of determination had Lichtenstein and the college not sent in their invention report. This report has now directed sufficient attention to the subject matter that they would not give this up without going through the formality of a determination. Young is to send them a letter stating the University's position relative to the equities and they led us to believe that they will quickly make an 8. 2(d) determination.

We discussed the situation relative to Dr. Sih's invention. By prior agreement, Bill Young told them that in all probability this particular invention would be developed by someone in the industry and that the major justification for the University and WARF undertaking a patent would be to defend the patent rights of Sih against the possibility that others might file in this same subject area. We restated our belief based on the interest of many companies at this time that someone will develop the invention even though it is licensed non-exclusively. We told them, however, that we would be willing to file a development statement to this effect recommending a non-exclusive, royalty paying, licensing basis.

To our amazement both Clesner and Parent promptly reacted by suggesting that we do this. I had the strong impression that Clesner has some self-serving use of this case in mind. He happens to be very conversant with the chemistry and the industry related to the steroid field. Whether that familiarity is the only reason for his interest is hard to say. We are the ones that have to bear the costs of any experiment which Clesner may have in mind and such expenses and the imminent deadline of June 20, 1965, when Sih's next paper is to be published are both facts which make this project unattractive. On the other hand, we know that this subject matter is of real interest to the industry and there does appear to be a good possibility that foreign rights will be made available to WARF

There was an opening at the end of the morning meeting while Hiller and Spector were still with us, in which it seemed logical to ask about the matter of foreign rights. They said that they are still governed by Executive Order 9865 which states that if the government does not exercise its options on foreign rights within the 6-month period after notification, the inventor may exercise those rights. They have, at present, no mechanism by means of which to utilize or exercise any patent rights outside the U. S. and, therefore, are making such determinations. Katharine Parent said that in making a determination

on foreign rights they recognize the need for prompt filing in order to avoid loss of patentability. While I do not believe this situation is apt to exist very long in view of the changing legislative climate, I do believe that if we proceed on the Sih inventions we should make a strong effort to obtain the foreign rights from the very beginning.

We should promptly decide whether we wish to proceed and if so a letter should be written to the Surgeon General requesting a determination on the foreign rights and requesting the authority to proceed with the patent applications prior to a U. S. determination. I am not sure that Bill Young agrees, but I think we should make the price of our willingness to proceed with the U. S. case a prompt determination of the government's position on the foreign matter.

We should also file a development statement in which we state our position relative to non-exclusive licensing for this case, and Clesner suggests that we include a statement indicating that any income above costs will flow back to the same research of the U. W. There was some discussion on this point. Clesner started with the request that the funds go to the department in which the invention was made, but Young objected to this on various grounds. It was finally agreed that a statement would be used, promising that the funds would be utilized in research areas supported by the Public Health Service with special consideration to the needs of the pharmacy department.

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