WISCONSIN ALUMNI RESEARCH FOUNDATION

INTER-OFFICE LETTER

TO Professor W. H. Young

FROM Ward Ross DATE August 20, 1964

Re: Several Matters

I have had occasion this week to review some of the earlier material having to do with HEW and would like in this memorandum to record a few observations.

Applicability to WARF of Section 6.3 of HEW Regulations

In rereading the Green, Crane and Lester Coenzyme Q determination by the Surgeon General of December 1959, a rather puzzling thing came to light. In Section C2, page 3, of the determination, reference is made to the Foundation issuing nonexclusive, revocable, royalty bearing licenses to "all qualified manufacturers." The same subparagraph of the determination provides, however, that the Foundation may issue an exclusive license under certain conditions "to one interested, reliable manufacturer."

Section C3 of the Coenzyme Q determination, however, provides that after ten years from the date of filing of the United States patent application, the Foundation will either effectively dedicate the invention to the public or make licenses thereon "generally available on a royalty-free nonexclusive basis."

The Coenzyme Q determination was made by the Surgeon General presumably at a time (December 1959) when Section 6.3 of the Regulations was in effect. It may be argued that in the Coenzyme Q determination the Surgeon General is interpreting his own Regulation - at least Section 6.3 - as not applying to a third party organization, such as WARF, at least during the ten year licensing period while WARF is administering the invention. WARF, during that ten year licensing period, was at least given express authorization in Section C2 of the determination to limit licenses to qualified manufacturers and was not required to license within the language of Section 6.3 "all applicants."

See further discussion of this matter in a separate memorandum to you of today regarding the Heidelberger 5-FU patents.

University of Oregon Medical School Situation

In the above situation, dealing with an invention of one Dr. Greer on the Extraction of Progoitrin, the Surgeon General made an original determination on September 6, 1962, under Section 8.1(a) of the Regulations, in the absence of any specific proposal from the Oregon Medical School which would lay a factual basis for a conclusion under Section

8.2(a) or 8.2(b) of the Regulations. The determination provided that it would become effective sixty days from date unless the Oregon Medical School submitted a proposal which would permit reconsideration of the disposition of the invention. The determination further provided that if such proposal was not made within the time specified, assignment of rights to the United States Government would have to be made. The determination then concluded with this sentence:

> "Pursuant to this assignment and in accord with the patent policy of the Department, licenses under any patent which may issue will be granted by the Department to all applicants on a nonexclusive, revocable, royalty-free basis, subject only to such controls as to condition of manufacture and quality of product as may appear needed to protect the public interest."

I would like to make two observations on the above. First, the determination seems to comply with Section 6.3 of the Regulations in stating that the Department upon taking title to the invention would license "all applicants." Second, the phraseology at the very end of the determination,

> "subject only to such controls as to condition of manufacture and quality of product as may appear needed to protect the public interest,"

seems quite inconsistent with the provisions of Section 6.3 of the Regulations that licenses

> "will contain no limitations or standards relating to the quality of the products to be manufactured, sold, or distributed thereunder."

Comments on Revised "Proposed Statement on Approval of University Patent Policies"

I agree with you that the major proposed change in the above as contained in the draft forwarded to me by Reuben Lorenz on August 12, 1964, the draft being dated August 5, 1964, is to permit universities to handle some Section 1(a) inventions (of the President's statement of October 10, 1963) in the same manner as the proposed statement permits universities to handle Section 1(c) inventions.

A couple of additonal observations:

> The attempt in several places to change "inventions" to "inventions and discoveries" seems to me accomplishes very little, if anything.

The attempt by the University people to broaden the permissive disposition of net royalty income (see paragraph D, page 4) from "research and educational purposes of the university" to "university purposes" seems to me very unwise and, furthermore, might boomerang.

Lichtenstein-Casida Development Statement

It may be that the Lichtenstein-Casida Development Statement is defective or deficient in one respect, that is, in failing to provide that at the end of some specified period, such as ten years, WARF would either effectively dedicate the invention to the public or make licenses thereunder generally available on a royalty-free and nonexclusive basis. This was a definite requirement of the Coenzyme Q determination, which is the only determination by the Surgeon General that I have ever seen which permits anyone outside of the Government to administer an invention (see Section C3, page 4, of the determination). Much more recently, namely, as late as September 25, 1962, Miss Parent pointed out in communicating with the University of Oregon Medical School that any proposal to the Surgeon General regarding consideration of the disposition of the Greer invention should include, among other things, a provision for

> "dedication of the invention to the public by making licenses generally available on a royalty-free and nonexclusive basis after a period of, say, ten years."

My impression is that Miss Parent and others have quite consistently taken the viewpoint that licensing by an outside group would be permitted for a limited period of time, of approximately ten years. I am not aware of any departure from this policy. I am pretty sure, therefore, that we are going to have to ultimately include some such limitation in the Lichtenstein-Casida Development Statement.

W. R.

WR/nmb