UP

UNIVERSITY PATENTS, INC. · 2777 SUMMER STREET · STAMFORD, CONNECTICUT 06905 · (203) 325-2285

Cables: UPATSTAMCO

April 20, 1978

MEMORANDUM TO: FILE

FROM: GMS

RE: SUMMARY OF RECENT DEVELOPMENTS EFFECTING UNIVERSITY PATENT RIGHTS WHICH ARE RELATED TO FEDERALLY FUNDED RESEARCH

The following is provided as a summary and factual development of two basic issues which may effect the future of University technology transfer:

1. The General Services Administration's (GSA) action to delay the implementation of the New Institutional Patent Agreement (IPA) regulations.

a) On February 2, 1978, the GSA published regulations (see attachment one) authorizing the use of a "New" Institutional Patent Agreement in all agencies of the Government that do not have statutes prohibiting their use. These new regulations are the result of work begun in 1971 by an interagency committee (the Ad Hoc Subcommittee on University Patent Policy of the Committee on Intellectual Property and Information, Federal Coordinating Council for Science

Engineering and Technology) and supplemented by public comments which were solicited.

(i) Some of the Subcommittee's early thoughts were summarized in an April, 1973 article (see Attachment 2). One of the Subcommittee's basic concerns was that "Universities do not generally have an adequate patent management capability to facilitate the transfer of their inventive results," thus, it appeared essential to the Subcommittee that "the Government persuade Universities to provide a management capability within the institution that will serve as a focal point for receipt of the inventive results of institutional research for later dissemination by itself or other management organizations to those industrial concerns most likely to utilize such results." The IPA program was considered as a possible solution.

(ii) The Universities responded to the increasing pressures placed on them by the Federal Agencies to move their research results out of the laboratory and into the flow of commerce, so that the public could benefit from their tax supported research. Admittedly, few Universities in 1973 had a technology transfer capability. One of the first attempts to "educate" University administrators as to the basics of technology transfer occurred on October 15/16, 1974 at CWRU "Technology Transfer--University Opportunities and Responsibilties" (see Attachment 3).

(iii) Another result of the CWRU meeting was the formation of the Society of University Patent Administrators (SUPA). SUPA presently has over one hundred members.

b) The "New" IPA regulations published on February 2, differed from the old IPAs used by DHEW and NSF from 1968 in the following respects:

(i) The new IPA can be used to cover research funded through contracts as well as grants.

(ii) The new IPA increases the period of exclusive control that a university can give to a licensee from 3 years after the initial marketing of a product to 5 years after the initial marketing.

(iii) The time that a licensee spends trying to get a federal regulatory agency to approve the product will be exempted from the time limits on exclusive marketing.

(iv) It permits Universities to affiliate with for-profit patent management companies, which are organized to promote the licensing of University discoveries to private industry.

(v) It removes the ceiling on the amount of royalties from a discovery that can be returned to the researcher who invented it, essentially allowing each University to set its own policy on the amounts.

c) It should be pointed out that the IPA programs (both Old and New) are not founded on statutory law, but on the memoranda and policy statements of President Kennedy in 1963 and President Nixon in 1971.

d) On March 17, 1978, Senator Gaylord Nelson wrote Lester Fettig (Director, Office of Federal Procurement Policy--OMB) requesting a delay in implementing the "New" IPA regulations under public law 93-400, so that his Subcommittee (Subcommittee on Monopoly and Anticompetitive Activities of the Committee on Small Business) could hold hearings on the "history, legal basis and implications" of the New IPA (see Attachment 4).

e) On March 20, 1978, Lester Fettig wrote Joel Solomon (Director of General Services Administration) delaying the implementation of the "New IPA" regulations for 120 days (see Attachment 5). On the same day, Fettig also issued a memorandum to the agencies that during the 120 day period, they function under their old patent procedures (see Attachment 6). Further, I have included a copy (Attachment 7) of Fettig's response to Senator Nelson's March 17 letter.

f) Also of interest, is a March 20th letter from Ralph Nader and Sidney Wolfe to Jay Solomon of GSA stating that the IPA is "unconstitutional, unwise, and contrary to the public interest" (see Attachment 8). Additional press releases summarize the situation:

i) Milwaukee Sentinel (3/9)

ii) Science (3/17)

iii) Washington Post (3/21)

iv) Washington Post (3/24)

v) N. Y. Times (4/15)

g) Finally in a memorandum issued by the Association of American Universities on April 4, 1978 (see Attachment 9), one can find an indication of the types of questions that are of concern to Senator Nelson and for which his Subcommittee will attempt to establish answers:

i) Since drugs are both patentable and profitable, is it not possible that Universities are reaping unusual profits from pharmaceutical research?

ii) What do Universities do with royalties they receive from patents?

iii) Do patent marketing companies retained by Universities make an unusual profit at the expense of the taxpayers?

iv) How are principal investigators (discoverers) treated by their institutions? (The Committee staff has heard from faculty who believe they are treated unfairly.)

v) What is the relationship between the following: the IPA, tenure, peer review and the fortunes of the young investigator? (If this question and the remaining questions have significance--and they may not--it is that the hearings may open up all of the issues of federal research support, not just IPA's.)

vi) Is federal support of academic research really in the best interest of the country?

vii) What is the relationship between University patent rights and the misuse of grant and contract funds on University campuses? (Mr.Sturges will stay in touch with Representative Fountain on this issue. Mr. Fountain has proposed hearings for his House Subcommittee on Intergovernmental Relations that will deal with NIH contracting practices.)

viii) Do certain principal investigators who form private research companies reap profits at the expense of the taxpayer?

h) This series of events has lead to the following questions:

i) What is expected to be accomplished in this 120 day period?

ii) What will happen at the end of 120 days if the "New IPA" isn't implemented? Will the Agencies revert to their "Old IPAs" or will they be cancelled?

iii) Is there a relationship between Senator Nelson's action and the present DHEW review of its policy for handling patents?

iv) Will an opportunity be provided by Senator Nelson so that testimony from a "true" spokesman for the University's position can be taken? This concern is most real in light of how the December hearing was handled. It is our recommendation that at least one or more of the following individuals be included in any proceeding that purports to represent the University's viewpoint:

Niels Remers - Patent Administration for Stanford University and President of the Licensing Executives Society-(415)497-3567;

Howard Bremer - Patent Counsel for the Wisconsin Alumni Research Foundation and President of the Society of University Patent Administrators (608) 263-2831;

L. W. Miles - President of University Patents, Inc. (a for-profit University Patent Management organization) - (203) 325-2285;

Willard Marcy - Vice President of Research Corporation (a not-for-profit University Patent Management organization) - (212) 986-6622.

i) Additional background material is provided in the following three presentations:

i) "Current Trends in Technology Transfer" (Attachment 10)- Norman Latker, 2/3/75;

ii) "Reaction to the Nelson Hearing of December, 1977" (Attachment 11)- Norman Latker, 2/6/78;

iii) Letter from Niels Reimers to Griffin Bell concerning the Nelson hearing (Attachment 12) - 1/18/78.

2. The present Administraton's position with regard to the disposition of Government patent rights.

a) It is generally understood that President Carter is preparing a Presidential Patent Policy Statement. However, it is not entirely clear as to whether his position will

lean towards one where the Government would retain title (compulsory licensing) or a position in which title would reside in the contractor (the Thornton Bill - H.R.-6249). It seems to most of us involved in technology transfer that the same issue (Justice versus Commerce with regard to patent rights and licensing of Government-funded technology) has again surfaced and may well be the underlying cause of the recent developments. Since this issue, like any other is a double edged sword, rather than attempting to identify all the factors involved, I have provided background materials which, for the most part, are supportive of the University's position.

i) "A Study of Compulsory Licensing"- Sol Goldstein 6/77 (Attachment 13);

ii) "The Folly of Compulsory Licensing"- Marcus Finnegan 6/77 (Attachment 14);

iii) "From Invention to Commercialization"- Edward Klein 4/77 (Attachment 15);

iv) "Patent-Antitrust Policies in U.S."- William Baxter 4/77 (Attachment 16).

b) It has been recognized that for all practical purposes, the Thornton Bill is dead. Thus, the University community is seriously considering taking action to differentiate it from industry when contracting with the Government for research funding.

One suggested approach is the introduction of a new Bill. Several different drafts are in their formative state. (See Attachment 17.)