COUNCIL ON GOVERNMENTAL RELATIONS
Eleven Dupont Circle, Suite 480 Washington, D.C. 20036 202-861-2595

September 11, 1981

TO: Patents, Copyrights and Rights in Data Committee

FROM: George B. Bush

SUBJECT: NIH Implementation of P.L. 96-517

Milton's memorandum of August 24, 1981 furnished a letter from Princeton University, attaching a letter from the Chairman, NIH Patent Board.

Enclosed is a letter from the new patent manager at Oregon State University, on the same subject. I have suggested that he reply along the lines of his third page.

Recommendations of your committee would be appreciated.

Enclosure

cc: William S. Lovell, Oregon State University
Sam Price, University of Maryland Central Administration
Allen J. Sinisgalli, Princeton University
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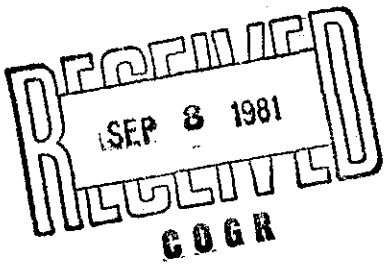

Dear Mr. Goldberg:

I would like to seek your counsel on a matter relating to agency administration of the new Public Law 96-517. I called your office there yesterday, and found that you were meeting in Colorado. (You should find a message there requesting that you return my call.) Given this opportunity, I thought it appropriate to send this letter outlining the details of the problem so you will know the reason for my contact.

The problem arises from the Department of Health and Human Services of the National Institute of Health, and no doubt stems from differing interpretations of the effect of PL 96-517. Specifically, and with reference to the Institutional Patent Agreement (IPA), the agency has stated the matter as follows: "You are no doubt aware that the reporting requirement stipulated in your IPA became a matter of statutary mandate as of July 1, 1981 (PL 96-517). For universities, the practical effect of PL 96-517 is to make the IPA, which has been an elective option in the past, into law applicable to all federally assisted research and development activities."

In a similar vein, that agency also states that the Office of Management and Budget (OMB) has recently published a bulletin setting forth proposed policy and procedures governing such patent agreements. What that Bulletin 81-22 actually says, however, is that "after July 1, 1981, this bulletin and 35 USC 200-206 (PL 96-517) shall take precedence over any conflicting agency regulations or policies" (which indeed does comply with PL 96-517).

As you are no doubt aware, PL 96-517, and the implementing regulations appearing in the July 2, 1981, Federal Register, include a number of reporting requirements along with the principle function of modifying the terms of future federal contracts as they relate to patents. These reporting requirements concern not only the reporting of inventions themselves, but also certain administrative matters, which are set forth in paragraph 5 and 6 of bulletin 81-22,

as follows:

> (5) Reporting on Utilization of Subject Inventions. Paragraph h of the Patent Rights clause in Part 5c of this Bulletin provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies shall obtain such information from their contractors. * * *
>
> (6) Additional Administrative Requirements. To the extent not required by other provisions of the funding agreement, agencies may add additional subparagraphs to paragraph (f) of the Patent Rights clause in Part 5c to require the contractor to do one or more of the following:
>
> > (i) Provide periodic (but no more frequently than annually) listings of all subject inventions required to be disclosed during the period covered by the report;
> >
> > (ii) Provide a report prior to the close-out of a funding agreement listing all subject inventions;
> >
> > (iii) Provide notification of all subcontracts for experimental, developmental or research work; and
> >
> > (iv) Provide, upon request, the filing date, serial number, and title; a copy of the patent application; and patent number and issue date for any subject invention in any county (sic) in which the contractor has applied for patents.

As opposed to those rather simple requirements, the agency in question has requested the following: (1) whether or not there have been changes in our institution's formal patent policy, and if there were any what they were and when they were implemented, (2) this institution's practices in identifying and reporting inventions and in evaluating inventions for inclusion in the required report, (3) whether faculty agreements have been assigned indicating researchers obligations regarding the disclosure and patenting of inventions made at our institution, (4) whether our organization has a patent committee, who its members are, and what is the established schedule of meetings for this committee, (5) description of any organized effort to bring to the market place inventions for which title has been retained by the institution. (Included here there is to be the amount of capital committed by any licensees to the development of the patent.) (6) whether our institution has any formal agreements with any patent management organizations, (7) identification of all components of the institution that are addressed by the report.

An enclosed computer form also requests licensing information including identification of licensee, the date license agreement was signed, the license number, the license type, the dollar capital commitment by the licensee to develop the patent, the date of the first commercial sale, gross sales by the licensee in the current year, gross sales by licensee total to date, gross royalties

by licenser (sic), and finally, total gross royalties by licenser (sic). An additional comments column asks for further patent applications information under the following code: (a) dropped, (b) foreign patents applied for, (c) foreign patents granted, (d) negotiating with potential licensee, (e) U.S. patent application pending, (f) U. S. patent application rejected licensee, (g) under evaluations/testing, (h) U. S. patent application will not be filed, (i) licensee awaiting FDA approval, (j) licensee to government, (k) license terminated, (1) university rights relinquished.

The above information rather exceeds the scope of what is required by OMB Bulletin 81-22, appears to violate the regulations announced July 2nd to implement PL 96-517, and very likely violates the Paperwork Reduction Act of 1980 (PL 96-511). If the agency is relying on the above paragraph (5), it must at least be said that they have run amok.

As you know, one reason for assigning the drafting of the July 2, 1981 Regulation to OMB was to achieve uniformity of practice among the innumerable federal agencies that administer research contracts and grants. This institution indeed has such contracts and grants from a wide variety of federal agencies. However, it is only from NIH that we have received any such request as I have described. Is this a local aberration of a particular subagency?

I will be very pleased to know if any other university of which you are aware has encountered this problem, and if so, what action they took, and in any event, what my response ought to be. I am, of course, inclined to answer back that their information requests are not strictly in accordance with the law, or words to that effect.

Your assistance in this matter would be very much appreciated.

Sincerely yours,

William S. Lovell
Patent Manager

WSL:mh

cc: Dick Perry
Bob Gutierrez
Bill Millison