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May 31, 1985

- FEDERAL EXPRESS -

Mr. Norman Latker Director -Federal Technology Management Policy Division Office of Productivity, Technology & Innovation Department of Commerce, Room H4837 Washington, DC 20230

Re: Proposed Regulations for 37CFR Chapter IV

Dear Mr. Latker:

The purpose of this letter is to provide comments of the University of California with respect to the proposed regulations for 37CFR Chapter IV, entitled "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms", and implementing PL98-620, as published in the Federal Register at page 13524 on April 4, 1985.

The University of California is a major recipient of federal grant and contract funds for the conduct of research. It is also the operating contractor for Los Alamos National Laboratory, Lawrence Livermore National Laboratory, Lawrence Berkeley Laboratory, and a number of smaller government-owned facilities. These regulations are of direct and major concern to us.

Before commenting on specific provisions of proposed regulations, we wish to offer four general comments:

First, we request that you consider incorporating into these regulations the administrative guidance contained in Section I of OMB Circular A-124. That guidance, which resulted from wide public comment prior to adoption, is important to continue as part of the currently proposed regulations. For example, the

instructions in Section 1(b) regarding related research projects, and the use of equipment not giving rise to patent rights in the government, are extremely important to retain in any regulations issued as a results of this current implementation.

Our second general comment relates to the applicability of provisions of PL96-517 amended by PL98-620. It would be helpful if these implementing regulations urged agencies to apply provisions of the newer law retroactively. For example, when agency regulations implementing chapter IV are issued, removal of the prior 5 and 8 year exclusive period limitation on licenses to large businesses would help us by eliminating the need to petition the agency involved.

Our third general comment concerns the interpretation of PL98-620 and parts of the somewhat turbulent legislative history, with respect to inventions arising at government-owned contractor-operated laboratories. In overall context, it is clear that the intent of Congress was to create a situation for the commercialization of laboratory inventions that would benefit not only the inventor and the public, but also the contractor and the laboratory. To the extent that the regulations under consideration limit benefits to the contractor to those less than allowed by law, then the impetus for commercialization of laboratory inventions will be reduced through a reduced incentive to the contractor.

As a last general comment, we believe it may be necessary to develop alternative administrative procedures for handling sexually propagated plants as subject inventions, because their creation and testing differs from that of utility inventions. We plan to work with the United States Department of Agriculture and various university associations to see if alternative regulations for those inventions would be appropriate. When we can offer a specific proposal, we will ask that the Department of Commerce consider altering the current draft regulations.

We find the regulations well drafted and clear, but offer the following comments and suggestions on certain key points:

1. Section 401.1(a). Should not the reference to the
portion of 35USC being implemented read #200-206 and
212*?

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Section 401.2. We believe it would be highly desirable to add a definition here and at 401.14(a) for the term "government-owned contractor-operated facility." While it is clear that major research and production facilities owned by the government but operated by a contractor were being considered by Congress, Congress did not consider the smaller facilities operated for an agency by a contractor, sometimes in facilities leased by the agency from the contractor. The definition of the Department of Energy for their "GOCO" laboratories is not limited to facilities owned by the government. We doubt that Congress was considering single buildings leased or owned by an agency, but located within and dependent upon the university buildings surrounding it, as GOCO facilities. As a contractor, we need to know what is to be considered a GOCO and what is not, for the purpose of implementing certain provisions of these regulations. Otherwise, varying agency definitions will create wide diversity in the application of these regulations. For example, is a ship owned by the Navy or NOAA and operated by a university for marine or weather research a GOCO facility?

May we suggest that consideration be given to using the FAR 17.6.0 regulations as the definition for GOCO facility. That language reads as follows:

Far 17.6.0 Operating and Management Contracts:

Management and operating means an agreement under which the government contracts for the operation, maintenance or support on its behalf of a government owned or controlled research, development, special production or testing establishment wholly or principally devoted to one or more major programs of the contracting federal agency.

Sections 401.4 and 401.11. While we have no objection to the formal appeals process outlined in these sections, we would suggest that language be added to provide for a preliminary, less formal appeal process in case the agency and the contractor desire to attempt to resolve a difference outside of the formal procedures outlined. While such an informal route might not be appropriate in all circumstances, it seems to us that suggesting such an informal attempt at resolution in the regulations would be appropriate and helpful.

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Section 401.5(d). With respect to the reservation allowing the government to sub-license foreign governments pursuant to treaties or international agreements, we understand that some agencies believe the wording proposed is too restrictive. To the extent that this paragraph is modified to provide for such future contingencies, we have no objection, as long as the right of the foreign government to sub-license is restricted to governmental purposes in the country involved. We do not believe it would be appropriate for any agreement to have an open-ended future sub-licensing provision for non-governmental purposes.

Section 401.5(e). With respect to major governmentowned contractor-operated laboratories, we believe it would be appropriate in this section to provide for annual patent clearance reports from the contractor to the agency during multi-year contracts that involve an anticipated long term relationship. It would be appropriate, in our opinion, to require that the use of any such clause be limited only to major facilities with a large annual budget -- as a minimum, perhaps \$100 million per year.

6. Section 401.5(f). The draft language adds the limiting words "at the facility" to the statutory language after the word "education" in the first sentence. We ask that the phrase "at the facility" be deleted, since such an absolute limitation precludes the contractor from using any portion of royalty income at any location other than the facility. The phrase severely and unnecessarily limits a contractor's flexibility, since statute already provides that the income must be used only for named purposes. As a result of such deletion, a contractor will have the necessary incentive for developing inventions at all GOCO facilities regardless of the facility size.

Contractors should be given flexibility in how they use retained royalty income, subject only to the limits specified in the law.

> Section 401.7. This section (Small Business Preference) 7. contains language that is, to us, reasonable in light of the language of the law, the realities of technology transfer, and the need for prudent business judgment. Nonetheless, we believe there is a substantial risk in the possibility of future litigation by a small company (perhaps located thousands of miles from the origin of the invention), challenging a license to a competitor based on the fact that the litigant was never contacted and offered a license to the invention in question. It is impossible for any university, nonprofit, or small business to contact all possible potential licensees, or even a reasonable fraction of those within the small business community. It is our experienced opinion that, as long as a university shows a reasonable record of small business licensees, such a record is defensible in light of the legislation.

We believe the regulations need to reflect that no individual small business will have standing to attack any particular license agreement. More thought needs to be given to the regulations implementing this section over the next year or two, so that the clause does not have a chilling effect on licensing or cause it to be prohibitively expensive.

8. Section 401.10. We believe this language needs to be expanded so that each agency does not create a different set of regulations with respect to the co-inventions between that agency's employees and the employees of a university, small business or nonprofit. The possibility of such joint inventions arising is greater with university employees than with those of a small business or nonprofit, since many federal employees are located in facilities at or near major research universities. The Department of Agriculture and the Veterans Administration already have taken differing positions on this matter. DHHS may take a third position. There needs to be a presumption that an agency will allow its employee inventor's rights to be assigned to a university that has coinventors. Some agencies may be concerned about laws which prohibit their employees from receiving outside compensation. This problem could be resolved by providing that any inventor's shares otherwise due an employee of an agency, where that payment would be against the law

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governing that agency, would be paid to the agency or the United States Treasury by the patent assignee. It makes absolutely no sense for an agency to retain an undivided interest to an invention, transfer it to NTIS for licensing, have NTIS license a university on an exclusive basis, and have the university pay NTIS a portion of the royalty income. This creates far more paper work to accomplish the same objective which would be met by the simpler mechanism we propose. (Whatever happened to paper work reduction act?).

With respect to this subject, we suggest the Department of Commerce consider our letter of May 3, 1985, to the Administrator of Veterans Affairs. That letter comments on the VA's draft regulations to implement 35USC 202(e), (Federal Register of April 12, 1985, at page 14393). A copy of our response to the Veterans Administration is enclosed and uncorporated herein by reference.

Section 401.12. While this language substantially follows Part 15 of OMB Circular A-124, we wonder if it would not be appropriate to add language to provide for those cases where a determination by an agency requires the licensing of background rights owned by the contractor. There should be a provision expressly stating that a reasonable royalty must be paid to the contractor, that a reasonable license issue fee be paid to the contractor, and that any such forced background rights licenses for governmental purposes must be of a limited nature.

10. Section 401.13(b). Please see our comments under paragraph 5 above, on Section 401.5(e) with respect to an annual patent clearance report at major GOCO facilities.

Section 401.14. We believe the definition of a GOCO facility from Section 401.2 should also be included in this Section's Definitions when the agreement is for or concerns the operation of a GOCO facility.

In Section (c)(3) of the Patent Rights clause, we believe the language is too restrictive. The law specifies that we must file within "a reasonable time" in foreign countries. An election or decision to make such a filing is normally made nine or ten months after

> a US filing. To make a decision earlier is imprudent business judgment. We believe the regulations would meet the test of the law if the language were changed to specify that the contractor "will file or authorize the preparation and filing of patent applications in foreign countries within either ten months of the initial patent application or six months from the date permission is granted by the Commissioner...."

> With respect to Section (h) of the Patent Rights clause we believe the voluntary reporting process initiated by the Council on Governmental Relations with the concurrence of the Department of Commerce should be continued, even if such reporting is a burden, increases indirect costs for a university, and may or may not be useful to the agencies. Nonetheless, the law clearly requires annual reporting. We believe that, as all parties gain experience, the current system will become more useful and easier to carry out.

> With respect to Subsection (k)(2), please see our comments above about a contractor sharing royalties with inventors, including federal employees. We endorse the language as given at (k)(2).

We also ask Commerce and other agencies to identify existing laws that prohibit the implementation of this particular language, so that consideration may be given to remedial legislation.

Section 401.14(b). The University of California manages 12. Lawrence Livermore National Laboratory and Los Alamos National Laboratory, both multi-program laboratories with major responsibilities for nuclear weapons design and development. Hence the alternate patent clauses set forth at 401.14(b) will have a major impact on the University's ability to acquire title to inventions made under these programs. While there is no University interest in obtaining title to patents on weapons, weapon components or otherwise classified technology (such inventions normally lack commercial potential), we are concerned about the University's ability to acquire rights to inventions made in the course of support activities such as Chemistry, Material Science and Engineering. Such support inventions may have been made with some weapons funds, have no direct or only

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incidental application to weapons, but may have widespread utility in commercial areas.

We therefore propose the following amendments:

At 2.(B), after "in and to" delete the words "the subject invention" and insert: -- any subject invention that is a nuclear weapon, naval propulsion system, component thereof, or directly useful therein, --

At 2.(C), at the end of the first sentence insert: -, and whether or not the subject invention is a nuclear weapon, naval propulsion system, component thereof, or directly useful therein. --

Also in 2(B), we suggest that the words "after consideration with" be changed to "with authorization of" because the change more clearly conforms to existing contractual agreements. We do not object to replacing "and anytime" with "or within a reasonable time" provided that DOE does not construe "a reasonable time" arbitrarily.

We ask that the language of Section 401.14(b)(3) be retained in the final regulations. However, we could accept its deletion provided that there is assurance under 401.15 that a greater rights determination will be completed within 90 days after such is requested by a contractor (or employee-inventor acting with authorization of the contractor), and that if it is not completed within that time, the request will be deemed approved by the agency.

Section 401.15. We are concerned about permitting any agency to make a greater rights determination in accordance with its own waiver regulations, where such regulations provide for denials for reasons other than provided by statute. DOE currently places restrictions on its waiver process that are not based on statute. As an example, DOE will not permit a waiver to be processed when there is continued agency funding of the invention. Such a restriction is not contemplated by P.L. 98-620 and should not be permitted in regulations for implementing that law.

> Further to the same point, one reason that GOCO contractor rights to elect title were included in P.L. 98-620 was the refusal or inability of DOE to act promptly on waiver requests. Had DOE acted promptly, there would likely have been no need to provide for an election of title at GOCO facilities in P.L. 98-620. We believe that it would be inappropriate to permit DOE to continue to use its waiver process to delay decisions on greater rights requests as it did routinely under P.L. 96-517.

We would oppose any changes to Section 401.15 absent assurances from DOE that: (a) DOE's waiver regulations will contain only those restrictions contained in P.L. 98-620, and (b) DOE waiver determinations will be completed within 90 days of the time that a waiver petition is filed.

We appreciate the opportunity to comment on these very important regulations involving technology transfer, innovation, and productivity with respect to both university and the governmentowned, contractor-operated laboratory views.

If you need further information on our comments, we are prepared to provide that at your request.

> Sincerely yours, Original Signed By Roger G. Ditzel

Roger G. Ditzel Director

RGD:jmb

Enclosure