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May 3, 1985

Administrator of Veterans Affairs (271A)
Veterans Administration
810 Vermount Avenue NW
Washington, D.C. 20420

Dear Administrator:

This letter is in response to the Veterans Administration's request for comments on the draft regulations for 38CFR Part 1, entitled "Inventions Made by VA Employees as Co-inventors in Research Supported by Nonprofit Organizations and Small Businesses", as published in the Federal Register of April 12, 1985, at page 14393. The University of California has a substantial interest in this matter, with five medical schools associated with VA hospitals.

The thirty day comment period ending May 13, 1985, provided by the VA is inadequate to allow us to provide as thorough a response as we would like. For that reason we ask that we be permitted to supplement this response after May 13.

Concurrent with the response period referred to above, the Department of Commerce has published draft regulations (FR13524 of April 4, 1985) implementing PL98-620, which modifed PL96-517. In those draft regulations Section 401.10 deals with the same section of the law (35USC 202(e)) as does the VA draft regulations. We believe it is inappropriate for the VA to propose an implementation of Section 202(e) prior to the final issuance of government-wide regulations by the Department of Commerce.

We ask that: a) the VA not issue final 38CFR Part 1 regulations until the Commerce regulations have been finalized, b) the VA publish a revised proposed 38CFR Part 1 in the Federal Register for further public comment, and c) that revision not be inconsistent with 37CFR 401.10.

We are pleased to offer the following comments on the current draft regulations of the VA so that our concerns can be considered in any revision:

1. The Background Information, Section 1.637, and other portions should be revised to incorporate reference to PL98-620 and the proposed 37CFR 401.10 as the current applicable authority.

2. Section 1.636(g) provides that, by definition, any "without compensation" (WOC) employees are considered to be federal employees as if they were fully paid and compensated by the federal government. A very substantial number of university researchers and faculty members, working in conjunction with VA employees but not themselves compensated by the VA, sign "without compensation" forms for the primary purpose of providing for liability insurance while they are in a VA facility. These university employees are paid by the university and their research funding comes from either the university or a grant from a third party. We believe it is far beyond the intent of Congress for the VA to define these university employees as being federal employees, thus capturing inventions made by those individuals for the VA.

Many VA hospitals were built next to university medical schools and operate under Affiliation Agreements with those institutions for mutual benefit. Perhaps unintentionally, these draft regulations would make all such WOC individuals VA employees for the purposes of these regulations, given the definition of "funding agreement" under 1.636(a) since Affiliation Agreements could be construed as Cooperative Agreements even though no funding is provided by the VA to the university.

Is it the VA's position that any invention made by an employee of a university's medical school, where that employee-inventor also has a WOC appointment (but may not have even entered the VA facility), must be assigned to the VA? We believe this is inappropriate, was never intended by Congress and hope such was not intended by the VA.

We suggest that section 1.636(g) be reworded to define employees, for the purposes of this Regulation, as those that are either fully salaried by the VA, or are salaried by the VA for that portion of their employment under which any subject invention arose. "Without compensation" employees should <u>not</u> be

considered VA employees, nor should interns and residents of VA Affiliated university medical schools who do not have salaried VA appointments.

From our reading of the authority cited (38USC 210(c)), it appears clear that the Administrator of Veterans Affairs is not required to define WOC individuals as "government employees".

3. We believe an intent of Congress under 35USC 202(e) was to provide that when a university employee's research was funded by one federal agency, and during the conduct of that research an invention arose with a federal employee co-inventor not working under that funding agreement, and who was not an employee of the funding agency, that the non-funding agency could agree to assignment of the federal employee's right in the invention to the university contractor. The premise used in drafting these regulations appears to be that the VA co-inventor employee would be working under a specific funding agreement with a non-VA employee. The proposed regulations address only the latter situation; they should also address the first situation.

4. With respect to Section 1.639, we believe the reporting and waiver request provisions should not be inconsistent with the disclosure and election requirement provisions contained in 35USC 202(c) with respect to time constraints. The deadlines proposed in the current draft regulations are not reasonable in light of the many facts that often must be checked prior to our being able to make a reasonable determination on whether to request a waiver or assignment of VA rights. Disclosure should be required only within 60 days after the invention becomes known to those contractor personnel responsible for patent matters, and two years should be allowed for a waiver request. Other provisions of 37CFR Chapter IV should also be observed.

5. With respect to Section 1.640(c), the concept of "preponderant contribution" may sound reasonable, but will be extremely difficult to implement since the phrase is not defined and subject to widely differing interpretations. If there were also a presumption for VA to waive in all cases <u>absent</u> an <u>overriding</u> preponderance of VA contribution, then what is suggested may work. But what if VA does contribute most? Will not a university still have a better chance to commercialize the invention? And how is "contribution" to be defined, and over what period of time?

6. We believe it is inappropriate for the VA to refuse to recognize a contractor's investment of patent prosecution expenses "except when immediate action is necessary to avoid bars to filing", as proposed in Section 1.641. Our experience in obtaining responses from the VA on patent matters has taught us that two years is often required for the VA to respond to waiver requests. If that continues to be true, in almost every case of a university invention (because of prompt publication) a bar to patenting will arise before a VA response can be expected. It is unreasonable, in our opinion, for the VA not to consider such expenditures as a part of the contractor's contribution in determining rights when no immediate filing bar exists.

We can understand why the VA would not want to be liable for reimbursing all prosecution costs on joint inventions, but we cannot understand why, if the VA retains an undivided interest, the VA should not be responsible for paying its proportionate share of prosecution expenses. For the VA to take an opposite position would be emminently inequitable, and cause a contractor to have a negative incentive for filing patent applications on subject inventions. We urge the VA to reconsider its position on this point, and encourage contractors to file patent applications using their own risk capital on joint inventions.

7. Section 1.642(b) would require a university, which had paid for all patent prosecution expenses and had paid for the cost of finding a licensee, to pay a VA employee $300 each year even though it had received no income at all from a royalty-bearing license. (We understand that the concept of a $300 payment is based on what NTIS will pay federally-employed inventors when NTIS has a royalty bearing license, and that that amount of money comes from the U.S. Treasury.) Universities have no reservoir of funds to pay VA employees. Further, this requirement would cause a university to have to give "favored treatment" to a VA co-inventor. This clearly was not contemplated by law or Commerce regulations. VA inventors should stand in no better position as co-inventors than those co-inventors employed by a university. We urge this section be revised to provided that the VA employee receive an inventors share from the university equivalent to that paid to other co-inventors, pursuant to that university's policy. We urge that Section 1.642(b) be deleted from any final regulations.

8. The regulations are silent on what VA will do with its patent rights if it does not waive them to the contractor. Should this situation not be addressed?

We appreciate the opportunity to comment on the proposed regulations. Should you desire further information or application on our comments we would be pleased to provide such to you upon your request.

Sincerely yours,
Original Signed By
Roger G. Ditzel

Roger G. Ditzel
Director

RGD: jns