

July 11, 1997

The Honorable Donna E. Shalala
Secretary of Health Sciences
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

There is an issue before you which could have substantial impact on the future of University Technology Transfer. My understanding is that you are currently considering a request by CellPro, Inc., to exercise "march-in-rights" under the Bayh-Dole Act in a case involving patents awarded to Johns Hopkins University for stem cell selection technology. As Vice-President for Research at the University of Utah, I strongly urge you to reject CellPro's unwarranted request.

As you know, "march-in-rights" were included in the Bayh-Dole Act of 1980 to address situations where a university or research institution failed to move forward in licensing and developing its technology and innovation. The current position does not address a situation which meets this criteria. CellPro, Inc. has attempted to circumvent the federal court decision that found them to have "willfully infringed" the Hopkins' patents by petitioning the department of Health and Human Services (DHHS) to grant them a compulsory license for patents that it did not secure through the legal patent process. They have alleged such action is necessary on the basis of public health needs and failure of Johns Hopkins University to fully exploit the innovation. However, as substantiated to the NIH and the federal courts, there is no threat to public health or access to stem cell selection technology. Further, in 1984 Johns Hopkins swiftly moved to license the technology as soon as patent applications were filed.

The Bayh-Dole Act greatly improved incentives for university and industry partnerships to bring life-saving products and services to the public. Commercialization of federally funded research is the fundamental principle underlying the Bayh-Dole Act. However, this necessary and successful process relies heavily on the protections afforded by the patent system and by assuring an exclusive licensee (who invests significant resources in product development) that its investment will be protected.

If CellPro, Inc., is granted an unwarranted license under the "march-in-rights" of the Bayh-Dole Act, it will set a very negative precedent for the future of technology transfer. Such an action will likely have a negative impact on our ability to attract private sector partners for the commercialization of research innovations. If institutions cannot offer their licensees the protections of the patent system, companies will be unwilling to make the large financial investments necessary to develop inventions into commercial products as they were before the Bayh-Dole Act. Nowhere is this more important than in developing medical products.

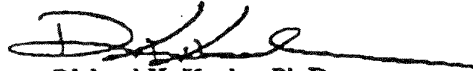
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Thank you for your considerations of my concerns. Please do not hesitate to contact me if you have any questions.

Sincerely,



Richard K. Koehn, Ph.D.
Vice President for Research

cc: Dr. Harold Varmus, Director, National Institutes of Health
Chris Jansen, Director, Technology Transfer Office