

# Genentech, Inc.

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Arthur D. Levinson, Ph.D.  
President and  
Chief Executive Officer

July 1, 1997

Hon. Donna E. Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Ave., S. W.  
Washington D. C. 20201

Dear Secretary Shalala,

I am concerned about a recent chain of events that I believe may significantly threaten the future of medical technology transfer and ultimately patient care in the U.S. I understand 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 President of Genentech, I 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 petition 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 court, there is no threat to public health or access to stem cell selection technology. Further, in 1984 John 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

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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, needed investments necessary to take medical innovations through the product development, clinical trials, and FDA approval processes will cease to exist.

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

Sincerely,



Arthur D. Levinson, Ph.D.  
President and CEO

ADL:rp