



Association of American Universities

June 5, 1997

President:

Harold Varms, M.D.
 Director
 National Institutes of Health
 Building 1, Room 126
 Bethesda, MD 20892

Dear Harold:

I understand you are 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 transplantation technology. On behalf of the Association of American Universities, I urge you to reject CellPro's request.

As you know, the "march-in rights" provision was included in the Bayh-Dole Act only to deal with situations where the university had taken no steps to license its inventions, or its licensees had taken no reasonable efforts to develop the inventions into useful products. It is my understanding that in this case, Johns Hopkins University licensed the technology, and that an authorized licensee, Baxter Healthcare, has developed an effective product that is pending approval by the Food and Drug Administration. Since Johns Hopkins University has proposed to the court that CellPro be allowed to continue selling the technology under dispute until the Baxter system or another licensed alternative is available, CellPro's request appears to me to be unnecessary, inappropriate, and a misuse of a provision that is designed to protect the public's interest, and not designed to guarantee a company a license.

Encouraging commercialization of federally funded research is the fundamental principle underlying the Bayh-Dole Act. It creates incentives for university-industry partnerships that result in important products and services reaching the public more quickly than ever before. It does so by relying on the protections afforded by the patent system, and by assuring an exclusive licensee, who invests millions in product development, that its investment will be protected. In the case involving CellPro and Johns Hopkins University, we are assured by Johns Hopkins that no one will be denied access to the stem cell transplantation technology. However, should the Department of Health and Human Services move to a formal "march-in" procedure, I am concerned that it would have a chilling effect on future university-industry partnerships, threaten the continued success of the Bayh-Dole Act, and potentially limit the public's access to other new discoveries.

Sincerely,

A handwritten signature in cursive script that reads "Neal".

Cornelius J. Fings
 President

CJF/Mt B/llt