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President



ASSOCIATION OF  
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May 30, 1997

Harold Varmus, M.D.  
Director  
National Institutes of Health  
Building One, Room 126  
9000 Wisconsin Avenue  
Bethesda, MD 20892

Dear Harold:

The Association of American Medical Colleges strongly urges you not to exercise "march-in rights" under the Bayh-Dole Act in the licensing and patent dispute between Johns Hopkins University and CellPro, Inc. Hopkins has aggressively licensed the invention under dispute and has provided solid assurances that it will take no action that would endanger the public health or remove infringing products from the market before viable alternative and approved products are available to clinicians and patients.

In March, 1997, a federal district court determined that for more than six years CellPro, Inc. has willfully infringed two patents owned by Johns Hopkins University that have practical application in stem cell transplantation. As you know, stem cell transplantation is an innovative technology that is used in the treatment of many types of cancer. We understand that a federal district court shortly will consider the appropriate form of injunction against CellPro's continuing patent infringement.

In order to circumvent the court decision, Cell Pro has petitioned you to exercise "march-in rights" under the provisions of the Bayh-Dole Act that would grant it a license for the patents that it could not secure through other lawful means. CellPro asserts that public health needs require that it be provided a license.

However, in order to minimize any disruption to patients currently being treated from products derived from CellPro's therapeutic device and to ensure a smooth transition to licensed products, Johns Hopkins University has proposed to the court that CellPro be allowed to continue selling its infringing device to those clinicians who currently use it until the FDA approves a licensed system for sale in the U.S. This proposal will ensure that public health needs are fully satisfied.

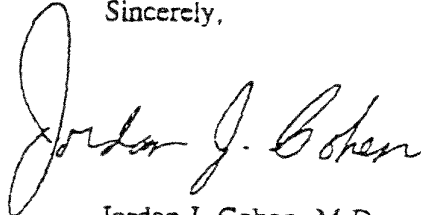
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The exercise of "march-in rights" in this case would be unjustified and is unnecessary. Johns Hopkins' licensees have aggressively developed this technology and have negotiated licenses in good faith to companies that have developed an equivalent therapeutic product.

There are important reasons not to permit the Bayh Dole Act to be used to achieve through administrative action what could not be secured through good faith license negotiations with the rightful patent owners. Such a result would have a negative impact on the ability of nonprofit institutions to achieve practical application of their inventions through patent licensing to private industry. 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 dry up. In the end, if "march-in rights" are exercised in this case, incentives for developing critical technologies in the fight against disease will be diminished and, in the long run, the public will lose out.

We appreciate your consideration of our views.

Sincerely,



Jordan J. Cohen, M.D.