

April 24, 1997

Robert B. Lanman, Esquire  
NIH Legal Advisor  
National Institutes of Health  
31 Center Drive  
Building 31, Room 2B50, MSC 2111  
Bethesda, Maryland 20892-2111

Dear Mr. Lanman:

Enclosed please find a Memorandum and two accompanying Exhibit Volumes responding to your request for additional information regarding the statutory basis for granting CellPro's Petition of March 3, 1997, requesting that the Department of Health and Human Services exercise the government's march-in rights under the Bayh-Dole Act, 35 U.S.C. § 200 et seq. As explained in greater detail in the Memorandum, both of the statutory criteria upon which CellPro's request is based have been met. Urgent public health needs require that the government take action to ensure that CellPro's CEPRATE System remains on the market. Moreover, Johns Hopkins' licensees have not taken the steps necessary to develop practical therapeutic applications of the Civin patents and will not be able to do so in the near future.

We note that you forwarded our March 3, 1997, Petition to Johns Hopkins on March 21, 1997, and that the 30 day period provided for in 37 C.F.R. § 401.6(b) has now expired. We therefore respectfully request that the agency provide written notice to Johns Hopkins and its licensees pursuant to 37 C.F.R. § 401.6(c) that the agency is considering the exercise of march-in rights. The enclosed Memorandum should provide a sufficient basis to put Johns Hopkins on notice of the facts upon which march-in would be based, and we have forwarded to you extra copies in the event you wish to send them with the required notice. We propose that the field of use in which the agency should require a license for CellPro be the field of therapeutic uses at least as broad as Baxter's license. In addition, CellPro should be licensed to make any use of the patented antibodies and hybridomas that are reasonably related to basic research relevant to therapeutic applications.

Under 37 C.F.R. § 401.6(d), Johns Hopkins is entitled to a period of 30 days after the receipt of the written notice of march-in in which to submit additional information. In our view, the facts compel the government's exercise of its rights in the present circumstances, and while there may be minor questions that could be raised regarding some issues, there could not possibly be a genuine issue of a material fact that could require the kind of fact-finding contemplated by the remainder of the regulations. Accordingly, we urge the agency to act

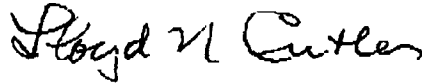
Robert B. Lanman, Esq.  
April 24, 1997  
Page 2

promptly to send the proposed notice and then to issue the direction to license CellPro promptly upon the expiration of the 30-day period provided for in the regulations.

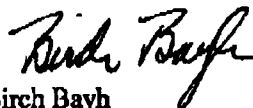
In your letter of March 24, 1997, you responded to our suggestion of a meeting by indicating that a meeting would be more productive after you had collected more information. In light of the extensive information included in the accompanying Memorandum and Exhibits and the expiration of the 30-day period of comment by Johns Hopkins on the original Petition, we would like to renew our request to meet with you to discuss CellPro's petition. Mr. Richard Murdock, who is the President and CEO of CellPro and who (as the Memorandum notes at page 17 was one of the earliest subjects of a second generation stem cell transplant) will be in Washington, D.C. next week. He would be able to provide answers to any technical questions you may have, and all three of us will be available to meet on Thursday, May 1 or Friday, May 2. If that date is not convenient for you we would be happy to find another mutually convenient date.

We look forward to hearing from you in the near future. Should you have any questions in the meantime, please contact one of us or Gary Wilson at (202) 663-6279 or Tom Connaughton at (202) 289-8660.

Very truly yours,



Lloyd N. Cutler  
Wilmer, Cutler & Pickering  
2445 M Street, N.W.  
Washington, D.C. 20037  
(202) 663-6100



Birch Bayh  
Bayh & Connaughton, P.C.  
1350 Eye Street, N.W., Suite 200  
Washington, D.C. 20005  
(202) 289-8660