DEPARTMENT OF HEALTH & HUMAN SERVICES



April 29, 1997

Public Health Division Room 2B-50, NIH Bldg. 31 31 Center Dr., MSC 2111 Bethesda, Maryland 20892-2111 (301) 496-4108 Fax (301) 402-1034

Lloyd N. Cutler, Esq. Wilmer, Cutler and Pickering 2445 M Street, N.W. Washington, DC 20037

Dear Mr. Cutler:

I am writing in response to your letter of April 24, 1997 in which you submit a memorandum supporting CellPro's petition that the Federal Government exercise its march-in rights pursuant to 35 U.S.C. § 203 in connection with certain patents owned by Johns Hopkins University and licensed to various private companies.

In your letter, you request that we proceed immediately to notify Johns Hopkins that the National Institutes of Health (NIH) is considering the exercise of march-in rights. Such action at this time would be premature. On April 23, Johns Hopkins, by telephone, sought an extension of time until May 7 to respond to CellPro's petition and confirmed that request by letter. We have agreed to this extension, consistent with the regulations at 37 CFR § 401.6(b). Under the regulations, the agency must determine within 60 days after it receives the comments of the grantee, either to initiate the march-in proceeding or notify the grantee in writing that march-in proceedings will not be initiated.

In your letter, you also renew your offer to meet in order to discuss CellPro's petition. As I advised you in my letter of March 24, 1997, I believe a meeting with you and your client would be more productive after we have received Johns Hopkins' response. At that time, we will be in a much better position to assess fully the information you, Johns Hopkins, and interested members of the public have presented and to seek clarification and further information, as appropriate.

In the meantime, we will review your submissions and include them in the administrative record.

Sincerely,

Robert B. Lanman NIH Legal Advisor