DEPARTMENT OF HEALTH & HUMAN SERVICES



National Institutes of Health Office of the Director

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Office of Extramural Research Bethesda, Maryland 20892 http://www.nih.gov/grants/oer.htm

MAY 1 5 1997

1997 MAY 19 P 1:50

Donald R. Ware, Esq. Foley, Hoag & Eliot One Post Office Square Boston, MA 02109-2170

Dear Mr. Ware:

I am writing in response to your letter of May 12 in which you request a period of thirty days to respond to CellPro's supplemental submission of April 24.

Your response to CellPro's March 3 submission was received by the National Institutes of Health (NIH) on May 7. On April 24, CellPro filed supplemental materials that you received on May 1. In light of the limited time that you had to consider CellPro's supplemental submission and its substantive nature and consistent with the requirement in 37 CFR § 401.6(b) providing for a response time of thirty days, we agree to provide you with thirty days from the date which you received CellPro's supplemental submission in which to provide a further response. Accordingly, that further response on behalf of Johns Hopkins University (JHU) is due on Monday, June 2. We will consider the response of JHU to be complete on that date or such earlier date as we receive your supplemental response, and will, within sixty days thereafter, either initiate march-in proceedings under 37 CFR § 401.6 or notify JHU that march-in will not be pursued on the basis of the available information.

An important factor in our agreeing to your request is that there currently is no restriction on the availability of the CellPro technology. In the event such a restriction is imposed, it may be necessary for the NIH to take prompt action to protect public health or safety. Thus, your response should be submitted as promptly as possible.

Sincerely,

Ball

Wendy Baldwin Ph.D. Deputy Director for Extramural Research

cc: Lloyd Cutler, Wilmer Cutler and Pickering

bcc: Ms. McGarey, OSPTT Mr. Lanman, OGC