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June 17, 1997

VIA FEDERAL EXPRESS

Barbara M. McGarey  
Deputy Director  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Blvd.  
Suite 325  
Rockville, MD 20852

Re: Petition of CellPro, Inc.

Dear Ms. McGarey:

Just a few days before Johns Hopkins filed its supplemental response to CellPro's petition on June 2, 1997, we received a copy of the Declaration of Larry Culver, CellPro's chief financial officer. We understand that CellPro presented the Culver declaration to the NIH in a meeting held in late May.

For your information, CellPro subsequently submitted the Culver declaration to the federal district court, for its consideration in connection with the pending motions. Plaintiffs in the federal litigation submitted, in response, the supplemental declaration of Dr. Jerry A. Hausman, a copy of which is enclosed.<sup>1</sup>

Mr. Culver's declaration argues that if CellPro does not get a "Bayh-Dole license" at a royalty rate of 4%, CellPro's only viable business strategy would be to shut down the company's business pending the outcome of its appeal. This threat, as Dr. Hausman points out, has "no basis in economic reality." The declaration is simply another tactic in CellPro's campaign to pressure the NIH into granting it a compulsory license by threatening to deprive cancer patients of

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<sup>1</sup> A copy of Dr. Hausman's initial declaration was included in the Appendix accompanying Hopkins' May 7, 1997 submission to the NIH.

treatment if CellPro does not get what it wants.

There are several reasons why the NIH should not credit this threat. It is implausible to believe that a company willing to spend more than \$10 million on litigation, lobbying and public relations and having \$54 million in cash would shut down operations pending its appeal of the district court's decision, simply because it disagrees with the court's determination of the appropriate amount of compensation for its continued use of Hopkins' patented technology.

It is noteworthy that when CellPro filed its opposition to plaintiffs' motion in late April, CellPro did not assert that the financial terms of the proposed order would force it to shut down any operations. Based upon the declaration of its expert accountant, it argued simply that the proposed minimum payment on infringing commercial sales would cause CellPro to incur an accounting loss per unit, because the proposed cost recovery did not include an allocation of various fixed overhead costs.

The focus of CellPro's opposition to the proposed order was its assertion that, as drafted, the proposed order would prohibit CellPro from continuing clinical trials using the Ceprate® SC system. As explained in Hopkins' May 7, 1997 submission, this was never plaintiffs' intent, and when the issue was raised, plaintiffs promptly modified the proposed order to clarify that there would be no such restriction pending FDA approval of an equivalent alternative system. Only then, after it recognized that the proposed order raised no genuine patient access issues, did CellPro contrive its argument that the order would force it to shut down operations and thereby "deny patients access to treatment."

When Mr. Culver's declaration is scrutinized, it becomes apparent that the amount CellPro is required to pay pending FDA approval of an alternative system is essentially irrelevant. A comparison of Mr. Culver's Exhibit A-1 (which assumes a "Bayh-Dole license" at a 4% royalty rate) and B-1 (which assumes the court enters the proposed order) shows that in either case, if CellPro's cash flow assumptions are correct, CellPro will need additional financing in 1998. Mr. Culver then offers the self-serving opinion that if CellPro has a "Bayh-Dole license" at 4%, it can obtain financing, but if it does not, CellPro will be unable to obtain financing.

As Dr. Hausman's supplemental declaration shows, CellPro's latest argument is baseless. Dr. Hausman notes that the capital markets have been willing to finance CellPro throughout its existence in the face of potentially blocking patents and despite the known risk that a court would ultimately enjoin further sales. CellPro has represented to the financial community that it intends to appeal the court's judgment and expects to win. Financial analysts continue to recommend the purchase of CellPro's stock, and investors continue to buy it. In view of the size of CellPro's current cash reserves, its assessment of its prospects on appeal, the potential size of the market for its Ceprate® SC products, and the significant upside opportunity for CellPro should it succeed in its long-term litigation strategy of invalidating the Hopkins' patents, CellPro has ample ability to finance its continued operations pending the outcome of its appeal.

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Moreover, it would be irrational and imprudent for CellPro to abandon its principal product line during its appeal and thereby run the risk of forfeiting the substantial profits that will accrue should it succeed. CellPro's argument that its obligations to its stockholders require that it shut down pending appeal has it backwards: if CellPro has a legitimate basis for pursuing its appeal, management's fiduciary obligations to stockholders require that CellPro continue to support its stem cell selection business pending the outcome of the appeal.

Significantly, CellPro's May 14, 1997 press release announcing its results for fiscal 1997 (Hausman Decl., Exh. B) described the pending litigation but contained no suggestion that entry of the proposed order would force it to shut down operations or prevent it from obtaining necessary financing. If Mr. Culver's argument were meritorious, why would he make it to the NIH and not disclose it to CellPro's stockholders?

Dr. Hausman's declaration also shows that the sales, expense, and cash flow projections which are essential to Mr. Culver's analysis are unsupported and highly questionable. Plaintiffs requested back-up documentation from CellPro to allow them to evaluate Mr. Culver's declaration (Hausman Decl., Exh. C), but CellPro has refused to produce any of the documents requested or to provide any of the explanations requested. If the NIH intends to consider Mr. Culver's declaration, it should insist that CellPro produce this information. In its absence, Mr. Culver's declaration should be given no weight.

Finally, we believe the time has come for CellPro to make some commitments of its own. CellPro created the dilemma in which it finds itself by rejecting all license offers and insisting on unauthorized use of Hopkins' patented technology. The federal court has determined that CellPro's actions represented knowing and willful violation of federal law. If CellPro is a responsible company that truly cares about the needs of cancer patients, it should proclaim publicly its commitment to continue supplying its customers, pending FDA approval of an authorized equivalent system, on whatever financial terms the federal court determines are reasonable. We urge the NIH to ask CellPro to make that commitment.

Sincerely yours,



Donald R. Ware

DRW/kaw  
Enclosure

cc.: Robert B. Lanman, Esq