IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation, BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation,	)	
Plaintiffs,	)	Civil Action No. 94-105-RRM
v	)	
CELLPRO, a Delaware corporation,	)	
Defendant.	)	

SUPPLEMENTAL DECLARATION OF DR. JERRY A. HAUSMAN

I, Jerry A. Hausman, D.Phil., declare as follows under penalties of perjury:

1. I am MacDonald Professor of Economics at the Massachusetts Institute of Technology. This declaration supplements my previously-filed declaration dated April 27, 1997. In preparing this declaration, I have reviewed CellPro's financial results for the fiscal year ending 3/31/97, the declaration of Larry Culver dated May 28, 1997, and the declaration of James Mack Folsom dated June 2, 1997.

2. The declarations of Mr. Culver and Mr. Folsom make the argument that if CellPro were required to pay its incremental profit to plaintiffs on infringing sales of Ceprate® SC products pending FDA approval of Baxter's Isolex® 300 system, the only economically rational

course of action for CellPro would be to go into a "shut down mode." This argument has no basis in economic reality.

3. If I accept, for purposes of argument, the sales, expense and cash flow projections contained in Mr. Culver's exhibits, it does not follow that an order requiring CellPro to pay its incremental profit on infringing commercial sales of Ceprate® SC products pending FDA approval of Baxter's system will lead CellPro to shut down its operations. As a preliminary matter, I note that under CellPro's projections, it runs out of cash in 1998 even if it obtains a compulsory license at a 4% royalty rate and wins its appeal of this Court's judgment. Thus, the amount that it is required to pay plaintiffs under the Court's order is essentially irrelevant to its cash needs. Under CellPro's projections, for CellPro to continue in business in the long term, CellPro must raise additional funds in the capital market irrespective of the terms of this Court's order.

4. The fundamental assumption in CellPro's argument is that only if it obtains a compulsory license as a result of its Bayh-Dole petition will it have access to the capital markets to raise additional funds for operation. Neither Mr. Culver nor Mr. Folsom offers any support for this assumption, and it does not reflect CellPro's statements to the financial community or the reality of how capital markets work.

5. Mr. Culver and Mr. Folsom both fail to mention CellPro's repeated assurances to its investors and to the financial analysts that CellPro intends to appeal this Court's decision and expects to win on appeal. If it has a good faith basis for this view, it will not have difficulty raising funds in the capital markets. The proof of this can be seen in CellPro's actual experience in raising funds since its formation in 1989.

6. The evidence at trial showed that when CellPro was formed in 1989, it knew of the '680 patent issued to Johns Hopkins, which covers stem cell suspensions substantially free of mature cells, and in 1990, it knew of the '204 patent, which covers the use of CD34 antibodies. Yet even in the face of these potentially blocking patents, Kleiner Perkins Caulfield and Byers, one of the largest and most prestigious venture capital firms in the world, was willing to invest millions of dollars in the company's development of its Ceprate® SC product line. Since 1992, there has been continuous litigation between CellPro and the patent holders, and the financial community has been well aware that an adverse result in the litigation could prevent CellPro from continuing to sell its Ceprate® SC products. Yet over the period of its existence, CellPro has raised over $160 million in the capital markets, despite the patent uncertainty and despite the knowledge of investors that there was significant risk a court might enjoin future sales of CellPro's principal product.

7. Even after the jury verdict for plaintiffs in March 1997, financial analysts have continued to recommend the purchase of CellPro's stock. In a March 13, 1997 report, Hambrecht & Quist gave CellPro's stock a "Strong Buy" recommendation, even though H&Q predicted that this Court would enjoin CellPro from selling its Ceprate® SC products. (Copy attached as Exhibit A.) According to H&Q, the critical investment decision regarding CellPro is not the possibility of a court-ordered injunction, but rather "the eventual size of the Ceprate business." At CellPro's current stock price of about $6.50/share, the public market puts a value on CellPro of nearly $100 million, well in excess of its book value (which includes the cash CellPro holds), despite the analysts' expectation that an injunction will be entered.

8. In a press release dated May 14, 1997, CellPro's management stated that CellPro would appeal the district court's judgment vigorously and "is optimistic that it will ultimately prevail" in the dispute. (Copy attached as Exhibit B.) The Hambrecht and Quist analysts report referred to above stated, along the same lines, that the worst case scenario was that CellPro would eventually pay a modest up-front fee and royalty to Baxter, and that a more likely scenario was that CellPro would pay nothing. In short, CellPro has represented to the capital markets that it will win its appeal, and the capital markets are willing to invest in CellPro despite the known risk that CellPro's prediction will prove false. It may be that the cost of capital is greater for CellPro than it would be without the uncertainty surrounding continuing litigation, but this situation does not mean that access to capital markets is unavailable to CellPro. Indeed, although there is considerable risk attached to CellPro's stock, there is also considerable upside opportunity. CellPro has estimated the market for its Ceprate® SC products to be in the range of from $100 million to $1 billion annually, and if it is able to invalidate the patents through its litigation strategy, it will have succeeded in exploiting extremely valuable medical technology invented at Johns Hopkins (at no cost to CellPro), without having to pay any licensing fees or royalties. I am confident that the capital markets will provide CellPro funds to continue its operations as long as that prospect remains open to it.

9. In these circumstances, where CellPro intends to pursue an appeal over the next twelve months, where it has been able to persuade financial analysts that it has grounds for appeal, and where the upside opportunity is large, it would be economically irrational for CellPro to shut down operations pending the outcome of the appeal. This analysis would be true even if CellPro lost money in the short term in order to continue its clinical trial support and commercial product

sales. As Mr. Folsom acknowledges in his declaration, economic theory tells us that "a firm may sell below cost in the short run if it believes that in the long run it will make a profit that will more than offset the losses." For CellPro to do otherwise here would risk forfeiting a very profitable long run opportunity. It would also jeopardize CellPro's long term relationship with clinicians who currently use CellPro's system, particularly where they are aware that CellPro has available to it a $54 million cash position and the ability to raise additional funds if necessary to support the product.

10. Another reason for CellPro to remain actively involved in the market is to preserve its ability to exploit the market opportunity outside the U.S. CellPro has opposed any injunction that impedes its ability to sell outside the U.S. However, even if the Court imposes restrictions on foreign sales in the short term, in the long term I assume that CellPro can obtain a CD34 antibody for use with its system that was made outside the U.S. and does not infringe the Hopkins patents. It will, therefore, be able to sell ex-U.S., and it is economically rational for it to maintain operations in the short term until it has the unrestricted right to sell abroad.

11. Shutting down operations in the face of CellPro's representations about its prospects on appeal would also subject its management and directors to the risk of shareholder suits. Shareholders may already be questioning management's exercise of judgment in repeatedly turning down Baxter's 1992 offer of a license for $750,000 and an 8% royalty. In view of its substantial investment in the product line (said by CellPro to be $75 million), the size of the potential market, and CellPro's stated belief that it will prevail on appeal, shutting down operations pending appeal would be irrational and imprudent. If, on the other hand, CellPro does

not have a good faith belief that it will prevail on appeal, its public statements to shareholders have been highly misleading.

12. There are many other assumptions built into Mr. Culver's scenarios which are critical to the analysis but lack factual support. One such assumption is that it will take Baxter more than two years to obtain FDA approval of its Isolex® system. I understand that the FDA's review of Baxter's PMA application is moving at a much faster pace than is assumed in Mr. Culver's analysis, such that the FDA will have completed its clinical site visits by the end of the week of June 16 and will have presented Baxter's PMA to its Advisory Committee by the end of July, just five months after Baxter's PMA was submitted. I understand, by contrast, that it took CellPro more than two years to go from PMA submission to Advisory Committee review. I also understand that the FDA "average elapsed time" data on which CellPro relies includes data arising out of situations in which a manufacturer's PMA is not accepted for filing and the manufacturer must spend additional time preparing an acceptable PMA, situations in which the manufacturer submits a major amendment to the PMA that requires restarting the review clock, situations in which the manufacturer puts the PMA on hold to conduct additional studies, and situations in which the FDA has no prior experience reviewing a new type of drug or device. This case appears to be quite different, since the FDA has previously reviewed the clinical benefits of stem cell selection, has already accepted Baxter's PMA submission as adequate, and has not suggested that new studies will be needed prior to approval. Thus, Mr. Culver's use of unconditional "average elapsed time" data leads to a biased and unreliable prediction that undermines a critical part of his analysis.

13. Mr. Culver does not explain the basis for his sales projections. According to the "Major Assumptions" of his Exhibit A-1, he assumes expansion into new market opportunities, including "transplants for mismatched donors and autoimmune diseases." Yet as I understand it, CellPro's FDA approval is limited to processing of autologous bone marrow, a procedure I understand to have become essentially obsolete. It is my understanding that CellPro has not yet applied for FDA approval for any other indications. If Mr. Culver's sales projections include commercial sales of products for unapproved, "off-label" uses, those projections are in all likelihood overstated, because under FDA law CellPro's sales representatives are legally prohibited from promoting the Ceprate® SC products for such uses. Since Mr. Culver asserts that the proposed order would cause CellPro to lose money on incremental sales, a reduction in projected sales would have the effect of reducing CellPro's short term losses and improving cash flow. (I do not agree, however, that the proposed order would cause CellPro to sustain incremental losses; that is not the purpose of the proposed order, and if CellPro persuades the Court that its incremental profit is less than the $2000 suggested minimum, the solution is to adjust the minimum figure accordingly so that CellPro recovers its incremental costs.)

14. Nor does Mr. Culver explain how he calculated the "Incremental Profit Paid to Baxter" in his scenarios. He provides no breakdown as between projected commercial sales and projected delivery of supplies for use in clinical trials. It is my understanding that most of the disposable kits that CellPro currently supplies to clinicians in the U.S. are provided for use in clinical trials, not sold as commercial products. Since the proposed injunction would impose the minimum payment only on commercial sales, the breakdown between projected commercial sales and projected clinical trial supplies assumed in Mr. Culver's analysis is critical to the accuracy of

his projection of incremental profit payments. If Mr. Culver has overstated the ratio of commercial sales to clinical trial supplies, then his assumption as to the amount of CellPro's payments to plaintiffs is likewise overstated, perhaps by a considerable factor. To evaluate the validity of Mr. Culver's projected payments to plaintiffs, it would be necessary to review in detail the assumed breakdown, and to compare it with actual sales data with respect to each of CellPro's clinical sites in the U.S.

15. There are many other assumptions in Mr. Culver's scenarios that are unexplained and questionable. He assumes, for example, that R&D expenses in 1997/98 will increase by $2.5 million, even though R&D was flat the year before. He also assumes, without any explanation or justification, that general and administrative expenses (a category that includes management compensation) will jump by $5 million in the current fiscal year as compared to the last. His projections of cash flow are also questionable. He assumes that cash outflow will increase by more than $20 million in the current fiscal year, to a total of more than $41 million, even if CellPro were to obtain a compulsory license at a 4% royalty and were to win its appeal. This dramatic increase in cash outflow is critical to his assumption that CellPro must access the capital markets in 1998, yet his cash flow projection is wholly unexplained. If it is overstated, then his entire analysis is invalid.

16. Finally, Mr. Culver's projection of thousands fewer patient treatments over the next few years if the proposed order is entered makes the incorrect assumption that only CellPro is able to provide patient treatments. Mr. Culver has provided no explanation as to why those same treatments cannot be provided using Baxter's system. It may be that CellPro would provide fewer patient treatments over the next four years, but in that case, it is reasonable to assume that

Baxter will provide that many more treatments during the same period, and perhaps even increase the total number of patients treated. Mr. Culver's projections thus are meaningless.

17. In an effort to determine whether Mr. Culver's projections had any basis in fact, I asked plaintiffs' counsel to request that CellPro provide back-up documentation. A copy of counsel's letter requesting this information is attached hereto as Exhibit C. I understand that CellPro has refused to produce the documents requested.

I declare under penalties of perjury that the foregoing is true and correct. Executed this 12th day of June, 1997.

J. A. Hausman 12 June 1997

Jerry A. Hausman