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,	:	Case No. 94-105 RRM
Plaintiffs,	:	
v.	:	
CELLPRO, INC., a Delaware corporation,	:	
Defendant.	:	

DECLARATION OF DR. JOHN DiPERSIO

DECLARATION OF DR. JOHN DIPERSIO

I, John DiPersio, M.D., declare as follows:

1. I am an Associate Professor of Medicine, Pathology and Pediatrics and the Chief of Bone Marrow Transplantation and Stem Cell Biology at Washington University in Saint Louis. A copy of my Curriculum Vitae is attached as Exhibit A.

2. I am well familiar with the operation and capabilities of the CellPro's CEPRATE® SC stem cell concentrator, based on my actual hands-on use of the device in performing over fifty (50) allogeneic (related, matched-unrelated and mismatched-related) and autologous transplants. I performed these transplants in connection with both investigator and CellPro sponsored phase III clinical studies using stem cells from both blood and marrow.

3. In my opinion if the CellPro device is made unavailable it would particularly adversely impact patients who undergo mismatched-related allogeneic transplants. In such transplants, the CellPro device is used as a very good method of T-cell depletion. Without the use of the CellPro device, these mismatched-related allogeneic transplant patients would otherwise die.

4. The use of the CellPro device as a superior T-cell depletion mechanism is particularly important for minority recipients because for such recipients their unrelated donor pool is very small.

5. As for autologous transplants, the availability of the CellPro device is important because it reduces toxicity of infusion for patients who receive large numbers of

stem cell products. Through the use of the CellPro device, the stem cell product is further concentrated and that in turn alleviates the storage problems.

6. Further, transplant patients with heart or kidney problems cannot tolerate large volume of infusions, and accordingly, the CellPro device offers a very good way of concentrating the stem cell product for such patients.

7. From a clinical standpoint, the CellPro device provides us with many benefits including the potential for eliminating T-cells and tumor cells from stem cell products; the potential for growing these cells outside of the body in gene therapy applications; the potential for studying the defects of stem cells; and the potential for reducing toxicity of the infusion. If the CellPro device were to be made unavailable, these potentials would become unrealized.

8. From a practical standpoint, in my view the CellPro device provides the only computerized closed, sterile system that ensures reproducibility, purification and easy of use.

9. In my experience I have found that the Baxter ISOLEX device to involve greater cost of purification and the time to do the procedure with the Baxter device is two to three times longer with the Baxter device, compared to the CellPro device.

10. Further, the CellPro device in my experience results in superior stem cell product yields which quality is critical for small-donor-large-recipient allogeneic transplant settings in which large yields are needed. This is because if the yield is below needed for engraftment count recovery, the graft could fail and the patient that could die in

the interim from infection or bleeding. Further, a good yield is also important to overcome slow engraftment in autologous transplants.

11. The availability of CellPro's FDA-approved CEPRATE® SC is also important in testing and developing novel experimental procedures. In my experience, the obtainment of approval for an experimental protocol from the FDA and/or hospital's or university's approval committee, is absolutely made easy if at least the stem-cell-enrichment and transplant step of that experimental protocol is performed with an FDA-approved device such as CellPro's CEPRATE® SC device.

12. In my clinical practice, transplant patients are told of the risks and hoped-for benefits of an experimental procedure. And the fact that at least one step of an experimental procedure is performed with an FDA-approved device makes it much easier for the patient to accept and be willing to undergo an experimental procedure.

13. Besides my ongoing clinical studies noted above, I am presently undertaking novel experimental studies that have been made possible and facilitated by the use of CellPro's device. One such novel field involves the use of genetically manipulated suicide T-cells. It is commonly accepted that T-cells are essential for certain early events in transplants. However, later in time, such T-cells may cause Graft-versus-Host Disease ("GVHD"). Thus, we are now involved in a research endeavor whereby the T-cells are genetically manipulated so that they perform these beneficial early-in-engraftment functions, but these T-cells then become inactive later in time so that they do not cause GHVD. These genetically manipulated suicide T-cells will then be added to T-cell depleted bone marrow processed by the CellPro device and transplanted into patients.

14. If the CellPro device were to become unavailable, such novel earch and therapies would be set back, because the CellPro device is a commercially ailable closed system which provides a cost-effective and efficient way of purifying these netically manipulated T-cells that express the CD34 antigen. Without the use of the llPro device, I would have to obtain INDs for several different procedures.

15. In sum, I believe there is a compelling public interest in the ailability of, and access to, the CellPro device. Owing to the medical and research mmunity's several years of experience with the CEPRATE® SC device, we can now nbark on new innovative transplantation patient care.

16. Further, if the CellPro device were made unavailable, it would versely impact my practice and research endeavor in several ways including having to .n my staff on a new device, and having to re-apply for FDA and institutional earances to perform my planned clinical studies with another device that is not FDA- proved. These hurdles would likely delay my clinical trials by about one year. Further, I n not certain that there is a substitute device that would work for my purposes.

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I further declare under penalty of perjury that the foregoing is true and orrect.

Executed at St. Louis, Missouri, this 11 day of April, 1997.

John DiPersio, M.D.