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

DECLARATION OF DR. RICHARD BURT

DECLARATION OF DR. RICHARD BURT

I, RICHARD BURT, M.D., do hereby declare:

1. I am the Director of Allogeneic Bone Marrow Transplant at Northwestern Memorial Hospital, Chicago, Illinois. Attached hereto as **EXHIBIT A** is a copy of my curriculum vitae.

2. I am familiar with the features and capabilities of CellPro's CEPRATE® SC stem cell concentrator, based on having read and heard reports of it and having observed its use over the past several years, and having employed it myself, as further described below.

3. I have recently begun using CellPro's CEPRATE® SC stem cell concentrator to prepare T-cell depleted suspensions, from peripheral blood, from fully-matched donors, for use along with bone marrow in allogeneic transplants. I have performed three such transplants and presently have two more scheduled.

4. Use of the CellPro device has made a phenomenal difference compared to our former practice in fully-matched

allogeneic transplant cases, which was to use unprocessed donor bone marrow. That technique typically produced evidence of engraftment at about day 18-21 and the patient was typically discharged from the hospital at about day 30. In contrast, with transplant suspensions prepared using the CellPro device, we are now seeing evidence of engraftment at about day 8 and patients are being discharged at about day 11. The cost savings implicit in such a dramatic shortening of hospital stays are of course great; but more important is the improvement in patient safety.

5. The time period between myeloablation (i.e., the eradication of the patient's bone marrow and, with it, his ability to make blood and immune-system cells) and engraftment (which marks the restoration of hematopoiesis, the body's ability to make blood and immune-system cells), is a time period during which the patient is without a functioning immune system. During that time period the patient is at grave peril of death from opportunistic infections. The fact that use of the CellPro device reduces this period of extreme vulnerability to about 8 days, as compared to 18-21 days, is a patient-safety benefit which I expect will reduce transplant-related mortality significantly over the long run.

6. In addition to using the CellPro CEPRATE® SC stem cell concentrator in the allogeneic transplant setting as described above, I have recently embarked on three autologous transplant studies involving use of the CellPro device for the treatment of ordinarily-fatal autoimmune diseases. Each of these studies has been granted a separate IDE by the FDA and I plan to seek "R-29" NIH funding with respect to each. The basic concept being explored in all three studies is the concept that by myeloablating the patient and reinfusing with a suspension of "naive" stem cells (prepared from the patient's marrow and peripheral blood using the CEPRATE® SC device), the patient's immune system may be created anew, in a form that no longer contains the dysfunctional immune cells that were responsible for the autoimmune attack. Said another way, the strategy is to purge the patient of the dysfunctional immune-system cells and replace them with a complement of normally-functioning immune cells, thus eradicating the autoimmune response. The three trials involve, respectively, the following autoimmune diseases:

(a) Multiple sclerosis. This autoimmune disease attacks the myelin sheaths of the nerves, causing nerve damage, paralysis and ultimately death. So far we have transplanted two

patients; and at one month and nearly four months post-transplant, respectively, it appears that the progress of the disease has been arrested, and some improvement in motor control has been observed, in both. This study is being conducted jointly with another institution that has transplanted one patient so far and has, as I am informed, observed similarly encouraging results.

(b) Systemic Lupus Erythematosus ("SLE"). This autoimmune disease is systemic, in that it attacks multiple organ systems, ultimately causing organ failure and death. Our study is, so far as I know, the second in the world and the first in the United States that utilizes myeloablative therapy for this disease. So far we have enrolled several patients, the first of whom was transplanted on April 2, 1997.

(c) Rheumatoid Arthritis. This autoimmune disease attacks the joints and connective tissues, progressively crippling and finally killing the patient. Our study is, to the best of my knowledge, the first in the world that brings myeloablative therapy to bear on this disease. The first patient for this study has been selected but not yet transplanted.

In all three of these studies, it is a criterion that patients be at high risk of death from the disease and that they have failed all conventional therapies. In other words, the patients who are and will be offered treatment under these studies are ones who are facing progressively crippling and eventually fatal diseases, against which they otherwise have no options left.

7. In addition to the above studies, I am presently at work on a protocol for a trial which will use the CellPro device to perform allogeneic transplants on leukemia patients using suspensions prepared from the peripheral blood of haploidentical (i.e., half-matched) donors. Because the CellPro device provides a clinically practical method of positive immunoselection of stem and progenitor cells, with depletion of the T-cells which mediate graft-versus-host disease ("GVHD"), the availability of the device has made it possible to transplant patients who need transplants to survive but have no fully-matched, or better-than-half-matched, donor available. Prior to the advent of the CellPro device, these patients had no transplant option because no adequate and willing donor was known, and therefore no potentially curative therapy was available to them. Haploidentical transplant, which worked poorly with prior technology, is now an area of intense interest in the

allogeneic transplant field using the CellPro device.

8. In choosing the CellPro device for the above-described trials and studies, I was motivated in part by the reputation of the CellPro product compared to the alternatives available. While at Johns Hopkins I saw both the CellPro and the Baxter therapeutic stem-cell selection columns in use, and based on my observations and discussions with knowledgeable persons there, I formed the impression that the CellPro device was far superior to the Baxter device. The latter was relatively slow and clumsy, requiring two persons to operate, and produced suspensions of inferior quality. As a result of using the CellPro device, I have been impressed with its smooth and simple functioning, its ability to produce suspensions that promote very rapid engraftment, and the quality of factory technical support, which I would rate as excellent, both in terms of knowledgeability and responsiveness. I do not regard the Baxter device as a fit or comparable substitute for the CellPro device and would not choose to use the Baxter device to treat my patients.

9. I strongly believe that if the CellPro device were for any reason to become unavailable for my use, my research

pursuits would suffer a serious setback and the interests of my patients would be compromised -- fatally, in some cases. Substituting another immunoselection device, such as the Baxter device, would not be a practical option. In addition to the fact, noted above, that I regard the Baxter product to be far inferior on the merits, additional drawbacks to substituting that device would include the long delay in switching over. I would estimate that my trials would be shut down for at least a year due to the regulatory and administrative delays which a changeover would entail. In addition, since the Baxter device is not FDA-approved, it could not be used (even assuming it were technically acceptable) without cross-referencing Baxter's IDE with Baxter's consent. If that consent were not forthcoming, the trials simply could not be done.

10. To those who would discount the miseries that patients suffer when deprived of treatment options they want, I would say that I wish they could experience what I have had to experience when explaining to a desperately sick patient why he does not meet the eligibility criteria for a limited-enrollment study which he believes might hold his best hope of a life-saving cure. I recently had to deliver such an explanation to a patient, only to be told a week later, by a relative of the patient, that

his inability to enroll in the study had left him so despondent that he had tried to kill himself. To deprive investigators like myself, and their patients, of the right to carry out potentially life-saving therapies using the FDA-approved medical technology of their choice would be a devastating blow not only to the hopes of patients searching for potentially life-prolonging or curative treatments of fatal diseases, but also to investigators who have dedicated years of their lives planning out and conducting experimental treatments in pursuit of cures for the diseases from which those patients suffer.

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

Executed at Chicago, Illinois, this 7th Day of April, 1997.

Richard Burt MD

RICHARD BURT, M.D.

CURRICULUM VITAE

NAME:	Richard K. Burt, M.D
ADDRESS:	680 N Lake Shore Drive, #2400 Tower, Chicago, Ill 60611
TELEPHONE :	312-266-0341
DATE OF BIRTH:	October 20, 1956
PLACE OF BIRTH:	Billings, Montana
CITIZENSHIP:	United States

EDUCATION:

1976-1980	B.S. Chemistry, University of Missouri, Magna Cum Laude
1980-1984	M.D., St. Louis University School of Medicine, Cum Laude

EXPERIENCE:

11/94 - Present	Director, Allogeneic Bone Marrow Transplantation, Assistant Professor, Northwestern University, Chicago, Illinois
1993-11/94	Attending, Bone Marrow Transplantation Unit, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, Maryland
1991-1993	Clinical Associate, Clinical Hematology Branch, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, Maryland
1992	Visiting Fellow, Bone Marrow Transplantation, Fred Hutchinson Cancer Center, Seattle, Washington (3 months) and Johns Hopkins Hospital, Bone Marrow Transplant Unit, Baltimore, Maryland (2 months)
1990-1991	Clinical Associate, Medical Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1987 - 1990	Biotechnology Training Fellow, Laboratory of Experimental Carcinogenesis, National Cancer Institute, National Institutes of Health, Bethesda, Maryland
1988	Chief Resident, Medicine, Baylor College of Medicine, Houston Texas
1984-1987	Resident, Baylor Clinical Investigator Pathway, Baylor College of Medicine, Houston, Texas
1980-1984	Medical School, Saint Louis University
1981	Unclassified Resident (summer), St. Louis State Mental Hospital