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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. WILLIAM BURNS

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I, William Burns, M.D., do hereby declare:

1. I am a Professor of Medicine and Microbiology and the Director of the Bone Marrow Transplant Program at the Medical College of Wisconsin. Attached hereto as **EXHIBIT A** is a copy of my curriculum vitae.

2. I am currently involved in a pilot study that is being conducted jointly between my institution and the Northwestern University Medical School. The study explores the usefulness of the CellPro CEPRATE® SC stem cell concentrator in the therapy of life-threatening autoimmune disease. Specifically, our pilot study aims at arresting and reversing the progress of severe multiple sclerosis. The candidates for the study are young adult patients who are afflicted with an especially aggressive form of the disease against which all conventional therapies have failed. These patients typically have declined from ostensibly normal condition to wheelchair-bound or near-wheelchair-bound status within a few years and have very limited prognoses.

3. Our approach in these studies is to use the CellPro CEPRATE® SC stem cell concentrator to prepare stem-cell-enriched and lymphocyte-depleted suspensions from autologous bone marrow and/or peripheral blood, ablate the patient's immune system, and then reinfuse the suspension to restore hematopoiesis. In the process, we hope to eliminate the lymphocytes that mediate the disease. For purposes of the pilot study, we plan to treat a total of 20 patients, 10 at each of the two participating institutions.

4. So far, I have transplanted one patient using the CellPro device. She is now approximately four months post-transplant, and it appears not only that the progress of her disease has been arrested, but that her symptoms are actually decreasing in severity. It is too early to foretell what this patient's long-term result will be; but my colleagues and I are excited, indeed elated, with her progress to date. If events continue to unfold as we now have reason to hope they will, we will have discovered an effective therapy against this particularly dreadful autoimmune disease. Although use of the CEPRATE® SC stem cell concentrator for the treatment of autoimmune diseases is still at a pioneering stage, there is reason to hope that this treatment approach will have efficacy beyond multiple sclerosis and will be a widely useful addition to the armamentarium of therapeutic options against severe, life-threatening autoimmune diseases.

5. Before selecting the CellPro CEPRATE® SC stem cell concentrator as the device we would use to prepare the transplant suspension, we considered, and rejected, other immunoseparation devices including the Baxter Isolex device. Based on inquiries made of numerous persons working in the bone marrow transplant field, I formed the impression that the CellPro device was not only closer to FDA approval than other possibly available devices but also was technically easier to use.

6. Both ease of use and closeness to FDA-approved status were important considerations to me, and I believe my views in this regard are typical of medical researchers planning experimental studies and protocols. Ease of use lessens the difficulty of training staff in the correct operation of the device to be used in the study,

and potentially lessens the risks of failure-producing mistakes. As for closeness to FDA approval, this was significant to me because my goal in conducting this experimental study was to develop a therapeutic option whose use would not be limited to my own practice but would be widely and generally available. Given a choice, I believe that any researcher whose goal is to see new therapeutic options become generally available would prefer to employ a device that is, or promises to be, FDA-approved and generally available. For the converse reason, a device that is not generally available and appears far from FDA approval is less attractive. A researcher who marshals the economic and personnel resources, and the commitment of his patients, to develop a new therapy will naturally prefer, as I did, to avoid the risk that the public benefit that flows from his work will be curtailed by limitations on the availability of the device on which the therapy depends. The fact that the CellPro device appeared to be close to FDA approval was a fact that I judged to bode favorably for the general availability of the device and, therefore, the general availability of any useful therapy I might develop through the use of the device.

7. While the ability of an immunoseparation system to deplete T-lymphocytes is generally thought to be much more important in the allogeneic than in the autologous transplant setting, I expect that this will <u>not</u> hold true for autoimmune-disease therapies similar to the one we presently have under study. Although that therapy uses a suspension prepared from the patient's own blood or marrow -- in other words, an autologous suspension -- the depletion of T-lymphocytes and other immune system cells is important, since the goal of the therapy is to eliminate the cells that are involved in the

autoimmune response. In this regard, I understand that CellPro has in development a second-generation device which follows the stem-cell-enrichment step with a second step, utilizing a different antibody, to further deplete T-lymphocytes. If and as the role of autologous bone marrow and peripheral blood transplantation in the treatment of autoimmune disease becomes broader, I expect that the importance of CellPro's technology for further depletion of T-cells will increase commensurately.

8. For the foregoing reasons, I believe that the public interest would be seriously harmed if the CellPro CEPRATE® SC stem cell separator were for any reason removed from the United States market. My pilot study results to date suggest that the device affords a new, potentially lifesaving treatment option for multiple sclerosis patients for whom all conventional therapies have failed. In addition, I believe that any threat that the CellPro device will become unavailable through injunction has an inhibitory effect on the willingness of patients to submit to experimental therapies using that device, and on

the willingness of medical researchers to employ it in their efforts to expand the therapeutic usefulness of stem-cell transplantation techniques.

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

Executed at Milwaukee, Wisconsin, this 24th day of March. 1997.

William Burns, M.D.

CURRICULUM VITAE

Date: February 1997

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Date, Place of Birth: July 11, 1943; Macon, Georgia

Marital Status: Single

Education:

1961-1965	B.S., Biochemistry, Yale University New Haven, Connecticut
1965-1970	M.D., Harvard University Boston, Massachusetts

Postgraduate Training and Fellowship Appointments:

1970	Researcher with Dr. Anthony C. Allison, "Immune Responses to Viral Infections" Mill Hill, London
1970-1971	Intern, Department of Medicine Stanford University Hospital Palo Alto, California
1971-1972	Junior Resident, Department of Medicine Stanford University Hospital Palo Alto, California
1972-1975	Research Associate, "Immune Responses to Viral Infections," National Institutes of Health (NIDR), Bethesda, Maryland