UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a : Case No. 94-105 RRM Maryland corporation, BAXTER HEALTHCARE CORPORATION, a Delaware: corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation,:

Plaintiffs,

CELLPRO, INC., a Delaware corporation,

Defendant.

DECLARATION OF DR. EDWARD BALL

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- I, Edward Ball, M.D., do hereby declare:
- 1. I am a professor of medicine at the University of Pittsburgh Medical Center. A copy of my curriculum vitae is attached.
- 2. I am acquainted with the capabilities of CellPro's CEPRATE® SC stem cell concentrator. Indeed, the Medical Center was one of the five centers involved in the breast cancer treatment studies that led to the approval of the CEPRATE® SC device by the U.S. FDA.
- investigational protocols. The first protocol involves a treatment for Gaucher disease. Gaucher disease is a metabolic disease that, left untreated, results in the failure of a patient's bone marrow. Experimental treatment for this disease involves transferring the missing gene into CD34+ cells selected by the CEPRATE® SC device. Our studies show that, when the cells are re-infused into the patient, the previously missing gene is expressed. The second on-going investigational protocol involves a two-step procedure for treatment of acute myeloid leukemia (AML). The AML treatment protocol involves selecting CD34+ cells using the CEPRATE® SC device, and then using the CEPRATE® SC device to purge tumor cells bound by an anti-myeloid monoclonal antibody that I developed.
- 4. In the future, I plan on using the CEPRATE® SC device in other protocols requiring peripheral blood or bone marrow CD34+ selection.

- 5. I have personally evaluated the Baxter ISOLEX CD34+ selection device, and found that it was not acceptable for my needs.
- 6. If the CEPRATE® SC device were not available, it would have a significantly negative effect on my ability to carry out the current and planned investigational protocols that I have described. Indeed, with regard to the Gaucher disease study, there would be no other options and the study would have to stop.
- 7. With regard to FDA approved, non-experimental protocols using the CEPRATE® SC device, that device provides reduced toxicity compared to conventional procedures. In the conventional procedure, a "buffy coat" containing hematopoietic stem cells is prepared and preserved using DMSO. However, both DMSO and other undesired cells in the buffy coat exhibit infusion toxicity.
- 8. I have also used CellPro's CEPRATE® LC laboratory column in the initial stages of developing the investigational protocols described above. If the CEPRATE® LC laboratory column had not been available, it would not have been possible to pursue these investigational treatment options.

9. There is a compelling public interest in maintaining the availability of both the CEPRATE® SC and CEPRATE® LC devices, not only for the investigational work that I have described above, but also for protocols being developed by others for gene therapy and cancer treatment.

I further declare subject to the penalty of perjury that the foregoing is true and correct.

Executed March 24, 1997 at Pittsburgh, Pennsylvania.

Edward Ball, M.D.

BIOGRAPHICAL

NAME:

Edward D. Ball, M.D.

BIRTH DATE:

March 15, 1950

HOME ADDRESS:

9977 Parkland Drive

BIRTH PLACE:

Syracuse, NY

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CITIZENSHIP:

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SOCIAL SECURITY NO.:

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Pittsburgh, PA 15213

SPOUSE NAME:

Susan E. B. Ball

BUSINESS PHONE: (412) 648-6413

EDUCATION AND TRAINING

UNDERGRADUATE:

1968 - 1972

University of Maryland College Park, Maryland B.S., 1972

Biochemistry

with high honors

GRADUATE:

1972 - 1976

Case Western Reserve University

M.D., 1976

Medicine

Cleveland, Ohio

POST-GRADUATE:

1976-1979 Hartford Hospital

Resident, Internal Medicine

Ralph Reinfrank, MD

1979-1981 Un

University Hospitals

Fellow - Hematology

Oscar Ratnoff, MD

of Cleveland

Dartmouth-Hitchcock

& Oncology Fellow - Hematology

Gibbons G. Comwell, III, MD

Medical Center

& Oncology

APPOINTMENTS AND POSITIONS

ACADEMIC:

1982-1983

1993-Present	Pittsburgh Cancer Institute Pittsburgh, PA	Director, Bone Marrow Transplant Program
1991-1993	Pittsburgh Cancer Institute Pittsburgh, PA	Co-Director, Bone Marrow Transplant Program
	Pittsburgh Cancer Institute Pittsburgh, PA	Co-Director, Leukemia/Lymphoma Program
1991-Present	University of Pittsburgh	Professor of Medicine
	Medical Center Pittsburgh, PA	Chief, Division of Hematology/Bone Marrow Transplantation
1987-1991	Dartmouth Medical School Hanover, NH	Associate Professor of Medicine and Microbiology
1987-1991	Dartmouth Medical School Hanover, NH	Adjunct Associate Professor of Biochemistry
1986-1987	Dartmouth Medical School Hanover, NH	Adjunct Assistant Professor of Biochemistry
1983-1987	Dartmouth Medical School Hanover, NH	Assistant Professor of Medicine and Microbiology
1982-1983	Dartmouth Medical School Hanover, NH	Assistant Professor of Microbiology