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,

٧.

CELLPRO, INC., a Delaware corporation,

Defendant.

DECLARATION OF DR. KENNETH ANDERSON

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- I, Kenneth Anderson, M.D., do hereby declare:
- I am a physician in the Department of Medicine, Division of Medical
 Oncology at the Dana Farber Cancer Institute. A copy of my curriculum vitae is attached.
- 2. I am acquainted with the capabilities of CellPro's CEPRATE® SC stem cell concentrator, as I have participated in a randomized clinical investigation of high dose chemotherapy treatment for multiple myeloma patients involving the CEPRATE® SC device. The Dana Farber Cancer Institute has also used the CEPRATE® SC device to purify progenitor cells for high dose chemotherapy treatment of patients with breast and lung cancer.
- 3. In the future I intend to use the CEPRATE® SC device quite frequently for selecting normal progenitor cells for reinfusion into patients after high dose chemotherapy.
- 4. The CEPRATE® SC device has the advantage of purifying desired progenitor cells, while at the same time depleting unwanted cells, including tumor cells. Additionally, when such progenitor cell suspensions are frozen, less cryoprotectant is needed, which is advantageous because the cryoprotectant itself can exhibit toxicity.
- 5. In the prior conventional multiple myeloma treatment, the progenitor cells which were reinfused into the patient were riddled with tumor cells. Use of

the CEPRATE® SC device significantly reduces infusion of tumor cells. Indeed, a published paper from UCLA regarding the treatment of 37 patients for multiple myeloma indicates that use of the CEPRATE® SC device results in up to 5 logs depletion of the undesirable tumor cells.

- 6. If the CEPRATE® SC device were not available, it would severely limit physicians' ability to treat patients with high dose chemotherapy followed by reinfusion of purified progenitor cells, since there are no other FDA approved technologies for doing this.
- 7. Moreover, having an FDA approved product available (such as the CEPRATE® SC device) makes it easier to obtain approval for investigational and experimental protocols incorporating that device. This is true not only scientifically, because at least one step of the process is already known to be safe and efficacious, but the availability of an approved product has the practical effect of making experimental treatments more available because of such reasons as the availability of medical insurance reimbursement.
- 8. I have also used the CEPRATE® LC laboratory device in experiments to assess purity of selected progenitor cell suspensions prior to incorporation of the CEPRATE® SC device into treatment protocols. The availability of the CEPRATE® LC device was important to my efforts to develop protocols for patient treatment.
- 9. There is a compelling public interest in maintaining the availability of the CEPRATE® devices, especially since the CEPRATE® SC device is the only such

device approved by the FDA. Removal of the CEPRATE® SC device would severely limit treatment of cancer patients using high dose chemotherapy.

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

Executed March 27, 1997 at Boston, Massachusetts.

Kenneth Anderson, M.D.

CURRICULUM VITAE

Name:

Kenneth Carl Anderson, M.D.

Address:

264 Weston Road, Wellesley, Massachusetts 02181

Date of Birth:

October 3, 1951

Place of Birth:

Worcester, Massachusetts

Education:

1973 B.A.

Boston University

1977 M.D.

Johns Hopkins University School of Medicine

1975-1977

Student Research Elective Oncology Division, Department of Medicine,

Johns Hopkins University School of Medicine

Postdoctoral Training:

Internship and Residency:

1977-1978	Intern in Medicine, Johns Hopkins Hospital, Baltimore, Maryland
1978-1979	Assistant Resident in Medicine, Johns Hopkins Hospital
1979-1980	Senior Resident in Medicine, Johns Hopkins Hospital

Fellowships:

1977-1980	Clinical Fellow in Medicine, Johns Hopkins Hospital
1980-1983	Clinical Fellow in Medicine, Harvard Medical School, Boston
1980-1983	Clinical Fellow in Medical Oncology, Dana-Farber Cancer Institute, Boston
1980-1983	Clinical Fellow in Medicine, Brigham and Women's Hospital, Boston
1981-1983	Fellow in Tumor Immunology, Dana-Farber Cancer Institute

Licensure and Certification:

1977	Flex Certification
1977	Maryland Licensure, Number 020872
1980	Massachusetts Licensure, Number 45550
1980	American Board of Internal Medicine, Certificate Number 7663

Academic Appointments:

1983-84	Instructor in Medicine, Harvard Medical School
1985-91	Assistant Professor of Medicine, Harvard Medical School
1992-	Associate Professor of Medicine, Harvard Medical School

Hospital Appointments:

1983-1985 1983-1985	Junior Associate Physician, Brigham and Women's Hospital Clinical Associate in Medical Oncology, Dana-Farber Cancer Institute
1984-	Medical Director, Blood Component Laboratory, Dana-Farber Cancer Institute
1984-	Attending Physician, Medical Oncology, Dana-Farber Cancer Institute
1984-	Attending Physician, Bone Marrow Transplantation, Dana-Farber Cancer Institute
1984-1988	Attending Physician, Bone Marrow Transplantation, Brigham and Women's Hospital
1985-	Assistant Physician, Dana-Farber Cancer Institute
1985-	Associate Physician, Brigham and Women's Hospital
1994-	Research Associate, Center for Blood Research, Boston