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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 OLIVER W. PRESS, M.D., Ph.D.

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I, Oliver W. Press, M.D., Ph.D., do hereby declare:

1. I am a Professor of Medicine and Biological Structure and am Acting Program Director of the High-Dose Chemotherapy Service of the University of Washington Medical Center. I am also an Associate Member of the Fred Hutchinson Cancer Research Center. A copy of my Curriculum Vitae is attached hereto as **EXHIBIT A.**

2. I am familiar with CellPro's CEPRATE® SC stem cell concentrator, having used that device for the treatment of selected patients over the past three or four years. I estimate that I have personally performed approximately 25 transplants using suspensions prepared using the CellPro device. Several of these transplants were performed on patients who were enrolled in NIH-funded research protocols.

3. I have found CellPro's CEPRATE® SC stem cell concentrator to be superior to heretofore conventional treatment options for many autologous transplant candidates. Specifically, these candidates are patients with evidence of tumor contamination in their blood or bone marrow. The basic approach with these patients is to prepare autologous transplant suspensions that are not only enriched in the cell population

that is necessary for long-term engraftment, but also depleted of tumor-cell contamination. I have found the CellPro device, used alone or in combination with a secondary manipulation of the suspension, to be an effective means of tumor-cell depletion.

4. To take a specific example, I have employed the CellPro device to treat a B-cell lymphoma patient in whose blood and marrow we found evidence of tumor cell contamination. The treatment was as follows: (a) we collected and apheresed mobilized peripheral blood from the patient; (b) we processed the apheresis product using CellPro's CEPRATE® SC stem cell concentrator (the effect of which was to concentrate cells, including stem and progenitor cells, which were positive for the 12.8 antibody while leaving behind, through negative selection, 12.8-negative cells including malignant B cells); (c) we myeloablated the patient by irradiation and chemotherapy; and (d) we reinfused the stem-cell enriched and B-cell depleted suspension into the patient. Engraftment was achieved and malignant B-cells were no longer detectable in the patient's marrow and peripheral blood.

5. I have also employed the CellPro device for tumor-cell-purging in patients with other lymphomas and with breast cancer. For some patients I have used a combination of anti-CD19 and anti-CD20 antibody-negative selection of tumor cells followed

by a positive selection step using the 12.8 antibody to collect CD34 stem cells. These procedures would not, in my judgement, be feasible without the availability of a clinically practical positive immunoselection device for stem and progenitor cells; and CellPro's CEPRATE® SC stem cell concentrator is presently the only such device which has FDA approval.

6. If the CEPRATE® SC stem cell concentrator were for any reason to become unavailable in the U.S. market, I believe that this would have a serious adverse impact on those patients for whom the device affords a potentially beneficial treatment option.

7. Simply substituting another stem- and progenitor-cell immunoselection device for the CellPro device would not, in my estimation, eliminate the adverse impact on these patients. No other such device, besides CellPro's, is FDA-approved. In my experience it is very difficult, if not impossible, for an institution to obtain a non-FDA-approved device unless that institution is enrolled in an FDA-approved trial which involves the use of that device. Even if the institution is involved in such a trial, patient enrollment in FDA clinical and preclinical trials is restricted, so that not every patient who might benefit will meet the criteria for inclusion in the trial. If the

patient cannot be included in the trial, the patient will be denied the treatment unless a compassionate use application is filed with, and approved by, the FDA.

8. In my experience, the preparation of a compassionate use application is enormously burdensome to the physician who wishes to use the non-approved device outside of an FDA-approved trial. I recently had occasion to prepare such an application, and it involved many hours of preparation of documents, protocols, consent forms, human subject applications, etc., an exercise that consumed nearly a full week of my time. I simply do not have the time and the resources to prepare compassionate use applications for every patient I see who might possibly benefit from the use of a non-FDA-approved device; and I believe that I am typical of physicians involved in stem-cell-transplant work when I say that the preparation of a compassionate use application is a rare and exceptional step, and one that it is quite impractical to take on a routine or even frequent basis. Hence, I believe that for so long as the CellPro device remains the only FDA-approved device of its kind, unavailability of that device on the U.S. market would mean, as a practical matter, that there would be patients for whom the

device might afford the best treatment for a life-threatening disease who would be denied access to that device.

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

Executed at Seattle, Washington, this 7th day of April 1997.

Oliver W. Press, M.D., Ph.D.

CURRICULUM VITAE

Oliver W. Press, M.D., Ph.D.

Birthdate: September 10, 1952
Birthplace: St. Louis, Missouri
Social Security Number: 486-60-0542
Residence: 11018 Exeter Ave. NE, Seattle, WA 98125
Telephone: (206)-367-6568

Undergraduate Education: Stanford University (1969-1973)
Degree: BS. (Biology)

Postgraduate Education: University of Washington (1973-1977)
Medical Scientist Training Program
Degree: PhD (Biological Structure)
Dissertation: Characterization of the phytohemagglutinin responsive population of cells in murine bone marrow

Medical Education: University of Washington (1973-1979)
Medical Scientist Training Program
Degree: MD

Postgraduate Training in Internal Medicine:

1. Internship: Massachusetts General Hospital, Boston (1979-1980)
2. Residency: Massachusetts General Hospital, Boston (1980-1982)
3. Chief Residency: University Hospital, Seattle (1982-1983)
4. Fellow in Oncology: University of Washington and Fred Hutchinson Cancer Research Center (1983-1986)

Faculty Positions Held:

1. Clinical Fellow in Medicine, Harvard Medical School (1979-1982)
2. Acting Instructor in Medicine, University of Washington (1982-1986)
3. Senior Fellow, Fred Hutchinson Cancer Research Center (1983-1986)
4. Assistant Member, Fred Hutchinson Cancer Research Center (1986-1991)
5. Assistant Professor in Medicine, University of Washington (1987-1991)
6. Adjunct Assistant Professor of Biological Structure, University of Washington (1988-1991)
7. Associate Professor in Medicine, University of Washington (1991-present)
8. Associate Member, Fred Hutchinson Cancer Research Center (1991-present)
9. Adjunct Associate Professor of Biological Structure (1991-present)
10. Acting Program Director, High-Dose Chemotherapy Unit, University of Washington Medical Center (1993-present)