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. CLAUDIO ANASETTI

DECLARATION OF DR. CLAUDIO ANASETTI

I, Claudio Anasetti, M.D., hereby declare that:

1. I am an Associate Professor of Medicine at the University of Washington (Seattle) and an Associate Member in the Division of Clinical Research at the Fred Hutchinson Cancer Research Center ("FHCRC"). Attached hereto as Exhibit A is a copy of my Curriculum Vitae.

2. I am thoroughly familiar with the capabilities of CellPro's CEPRATE® SC stem cell concentrator, based on: (a) having been trained in its operation; (b) having read the scientific and technical literature about its capabilities; (c) having regularly worked with the device in the course of clinical trials and studies over the last four years; (d) having performed stem cell transplant procedures at the FHCRC on at least 25 patients using suspensions prepared with the device; (e) having used the device under compassionate IND protocols; (f) having published my research on the subject; and (g) being currently involved in clinical research of new therapies that utilize the CEPRATE® SC stem cell concentrator.

3. In the future, I plan on using the CEPRATE® SC device in other clinical studies requiring peripheral blood or bone marrow CD34+ selection.

4. The transplants that we have performed at the FHCRC were part of a CellPro sponsored clinical trial of allogeneic transplants using stem cell suspensions obtained from both peripheral blood and bone marrow using the CEPRATE® SC device.

5. The CEPRATE® SC device is the only FDA-approved device that, in my opinion, produces T-cell depleted stem cell suspension for allogeneic mismatched transplants.

6. The ten (10) mismatched-donor transplant patients that we treated at the FHCRC could not have been treated without the use of the CellPro CEPRATE® SC column. If not treated, these patients would have died as they were afflicted by advanced leukemias.

7. My opinion of the value of the CEPRATE® SC device in producing T-cell depleted stem cell suspensions from peripheral blood to induce graft in mismatched recipients without the risk of Graft-Versus-Host-Disease ("GVHD") is supported by a study published by Aversa, et al.'s 1994 paper in Blood.

8. In my experience, the CEPRATE® SC device is a superior product that has good reputation, is reliable, and is user-friendly.

9. In my view, there is a compelling public interest in maintaining the availability of, and access to, the CEPRATE® SC device, because patients with advanced diseases would die without the benefit of the device which makes allogeneic transplantation feasible from HLA mismatched donor. Further, there is an unquestionable benefit to be derived from keeping the device (as the only FDA-approved device) on the market as its removal would set back the development of new transplant technologies and treatment options. In the latter respect, for example, in allogeneic transplant setting, one can improve transplant outcome by the use of the CellPro device and additional study and research of pre and post transplant immunosuppression would further benefit the public.

10. I am also well-familiar with the CellPro CEPRATE® LC device and have used it in laboratory and have published my research in Rondelli, et al., Blood (1996).

11. I also believe that there is a compelling public interest in keeping available the CEPRATE® LC device (laboratory column), as the use of the laboratory column may further our confidence that a contemplated novel human study is promising and worth doing.

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

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

Claudio Anasetti, M.D.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Claudio ANASETTI	Associate Member, FHCRC

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(S)	FIELD OF STUDY
University of Perugia School of Medicine, Italy	M.D.	1980	Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. DO NOT EXCEED TWO PAGES.

1980 - 1982 Internal Medicine, University of Perugia
1982 - 1983 Fellowship in Immunology, Children's Memorial Hospital, Oklahoma City, OK.
1983 - 1985 Fellow in Oncology, Dept. of Medicine, University of Washington, FHCRC, Seattle,WA
1985 - 1987 Associate in Clinical Research, Fred Hutchinson Cancer Research Center, Seattle, WA.
1987 - 1992 Assistant Member, Fred Hutchinson Cancer Research Center, Seattle, WA.
1990 - present Director, Unrelated Donor Marrow Transplant Program, FHCRC, Seattle, WA.
1992 - present Associate Member, Fred Hutchinson Cancer Research Center
1994 - present Associate Professor of Medicine, University of Washington, Seattle, WA.

Honors:

7/89 - 6/91 ACS Career Development Award

Publications: (selected from 146)

1. Anasetti, C., Doney, K.C., Storb, R., Meyers, J.D., Farewell, V.T., Buckner, C.D., Appelbaum, F.R., Sullivan, K.M., Clift, R.A., Deeg, H.J., Fefer, A., Martin, P.J., Singer, J.W., Sanders, J.E., Stewart, P.S., Witherspoon, R.P., Thomas, E.D.: Marrow transplantation for severe aplastic anemia: Long term outcome in fifty "untransfused" patients. Ann. Intern. Med. 104: 461-466, 1986.
2. Anasetti, C., Martin, P.J., Morishita, Y., Badger, C.C., Bernstein, I.D., Hansen, J.A.: Human large granular lymphocytes express high affinity receptors for murine monoclonal antibodies of the IgG3 subclass. J. Immunol. 138: 2979-2981, 1987.
3. Anasetti, C., Martin, P.J., June, C.H., Hellstrom, K.E., Ledbetter, J.A., Rabinovitch, P.S., Morishita, Y., Hellstrom, I., Hansen, J.A.: Induction of calcium flux and enhancement of cytolytic activity in NK cells by crosslinking of the sheep erythrocyte binding protein (CD2) and the FC-receptor (CD16). J. Immunol. 139: 1772-1779, 1988.
4. Anasetti, C., Storb, R., Longton, G., Witherspoon, R., Doney, K., Sullivan, K.M., Thomas, E.D.: Donor buffy coat cell infusion after marrow transplantation for aplastic anemia. Letter to the Editor. Blood 72: 1099-1100, 1988.
5. Anasetti, C., Amos, D., Beatty, P.G., Appelbaum, F.R., Bensinger, W., Buckner, C.D., Clift, R., Doney, K., Martin, P.J., Mickelson, E., Nisperos, B., O'Quigley, J., Ramberg, R., Sanders, J.E., Stewart, P., Storb, R., Sullivan, K.M., Witherspoon, R.P., Thomas, E.D., Hansen, J.A.: Effect of HLA compatibility on engraftment of bone marrow transplants in patients with leukemia or lymphoma. N. Engl. J. Med. 320: 197-204, 1989.
6. Anasetti, C., Rybka, W., Sullivan, K.M., Banaji, M., Slichter, S.J.: Graft-v-host disease is associated with autoimmune-like thrombocytopenia. Blood 73: 1054-1058, 1989.
7. Anasetti, C., Martin, P.J., Hansen, J.A., Appelbaum, F.R., Beatty, P.G., Doney, K., Harkonen, S., Jackson, A., Reichert, T., Stewart, P., Storb, R., Sullivan, K.M., Thomas, E.D., Warner, N., Witherspoon, R.P.: A phase I-II study evaluating the murine anti-IL-2 receptor antibody 2A3 for treatment of acute graft-versus-host disease. Transplantation 50: 49-54, 1990.
8. Anasetti, C., Tan, P., Hansen, J., Martin, P.: Induction of specific unresponsiveness in unprimed human T cell by anti-CD3 antibody and alloantigen. J. Exp. Med. 172: 1691-1700, 1990.
9. Anasetti, C., Beatty, P.G., Storb, R., Martin, P.J., Mori, M., Sanders, J.E., Thomas, E.D., Hansen, J.A.: Effect of HLA incompatibility on graft-versus-host disease, relapse, and survival after marrow transplantation for patients with leukemia or lymphoma. Hum. Immunol. 29: 79-91, 1990.