

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,	:	
	:	
	:	
v.	:	
	:	
CELLPRO, INC., a Delaware corporation,	:	
	:	
Defendant.	:	
	:	

STATEMENT OF DR. ANTHONY ELIAS

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I, Anthony Elias, M.D., do hereby state that:

1. I am an Assistant Professor of Medicine and Clinical Director STAMP at the Dana Farber Cancer Institute. A copy of my curriculum vitae is attached.
2. I am familiar with the capabilities of the CEPRATE® SC stem cell concentrator, and I am using that device in an on-going clinical trial for the treatment of small cell lung cancer. This clinical study is, in part, funded by the NIH.
3. Patients with small cell lung cancer typically have tumor contamination of their peripheral blood and bone marrow. Peripheral blood stem cell or bone marrow transplantation thus involves the risk of tumor reinfusion and reoccurrence of the cancer. In our experience, high dose therapy for small cell lung cancer supported by bone marrow and peripheral blood stem cells results in reoccurrence rates of 47%.
4. In the current study, stem cells are mobilized and peripheral blood containing the mobilized stem cells is processed by the CEPRATE® SC device. Before processing, the peripheral blood tumor contamination typically ranges from one cell per million to 1500 cells per million. Processing of the peripheral blood with the CEPRATE® SC device results in substantial reduction in tumor contamination. In one patient tumor contamination was reduced from 170 cells per million to zero. Even in the patients that do not experience a reduction in the percentage of tumor cell contamination, the total tumor cell contamination is still

significantly reduced (by approximately 2 logs) because of the significant cell depletion generally provided by the CEPRATE® SC column.

5. Conclusive results are not yet available from the current small cell lung cancer study. Nevertheless, we have so far treated 14 patients (out of 30 planned), and two patients have relapsed. If, after two years from transplantation, this relapse rate continues, then tumor purging using the CEPRATE® SC device will have proven a significant and exciting advance compared to the conventional cellular support.

6. We are currently looking at undertaking additional trials involving the CEPRATE® SC device. These trials would include CD34+ selection using the CEPRATE® SC device, followed by negative selection of tumor cells for additional purging. Such protocols hold the possibility of significant reduction, if not elimination, of tumor reinfusion, with a resulting reduction in reoccurrence of the cancer.

7. Having a commercially available and FDA approved product for CD34+ selection, such as the CEPRATE® SC device, makes it much easier to pursue these important investigational treatment options. It is extremely difficult to combine more than one investigational agent/device.

8. If the CEPRATE® SC device were not available, the current trials regarding small cell lung cancer, as well as the future tumor purging studies, would be significantly disrupted, delaying what appear to be significant advances in the treatment of certain types of cancer.

Executed April 5, 1997 at Boston, Massachusetts



Anthony Elias, M.D.

CURRICULUM VITAE

Name: Anthony David Elias

Address: 39 Nonantum Street, Newton, MA 02158

Date of Birth: September 9, 1954

Place of Birth: New York, New York

Education:

1976 A.B. (cum laude) Princeton University, Princeton, NJ
1980 M.D. New York University School of Medicine, New York, NY

Postdoctoral Training:

Internship and Residency:

1980-1981 Intern in Medicine, Johns Hopkins Hospital,
Baltimore, MD
1981-1982 Junior Assistant Resident, Johns Hopkins Hospital
1982-1983 Senior Assistant Resident, Johns Hopkins Hospital

Clinical Fellowships:

1983-1986 Clinical Fellow in Medicine,
Harvard Medical School, Boston, MA
1983-1986 Fellow in Medical Oncology,
Dana-Farber Cancer Institute, Boston, MA
1983-1986 Clinical Fellow in Medicine,
Brigham & Women's Hospital, Boston, MA

Licensure and Certification:

1983 Massachusetts License Registration # 50827
1983 American Board of Internal Medicine # 090773
1985 American Board of Internal Medicine,
Oncology Subspecialty Boards
1987 Advanced Cardiac Life Support Certification

Academic Appointments:

1986-1990 Instructor in Medicine, Harvard Medical School
1990- Assistant Professor in Medicine, Harvard Medical School

Hospital Appointments:

1986- Associate in Medicine, Beth Israel Hospital
1986- Associate Physician, Brigham and Women's Hospital
1986-1990 Clinical Associate in Medicine, Dana-Farber Cancer
Institute
1990-1992 Assistant Physician, Dana-Farber Cancer Institute
1992- Assistant Professor of Medicine, Dana-Farber Cancer
Institute