

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.	:	
	:	

DECLARATION OF DR. HELEN HESLOP

DECLARATION OF DR. HELEN HESLOP

I, Helen Heslop, M.D., declare as follows:

1. I am an Associate member in the Division of Bone Marrow Transplantation at the St. Jude Children's Research Hospital and an Associate Professor at the Department of Pediatrics, University of Tennessee in Memphis. A copy of my Curriculum Vitae is attached as Exhibit A.
2. My practice at the hospital concerns bone marrow transplantation for children afflicted with malignant diseases such as leukemias and brain tumor as well as non-malignant diseases such as the sickle cell disease.
3. I am well acquainted with the capabilities of both the CellPro CEPRATE® SC and the CellPro CEPRATE® LC devices.
4. I have used the LC column for over four years now in my preclinical work in marking studies for gene transfer clinical applications. Specifically, I have used the LC column in connection with my studies with transduction (i.e., transferring of a new gene into a cell) efficiency. In undertaking these studies I utilized NIH funding.
5. I have used the SC column for transplantation in one patient. That patient had a mismatched transplant with a poor graft function. Accordingly, I determined that that patient must be given extra stem cells that were T-cell depleted. I used the patient's sibling's GCSF mobilized blood. Because of the high numbers of T-cells in that product, I used the SC column to process that product and deplete the T-cells from it. The patient was successfully transplanted with the cell suspension produced by the SC column.

6. Currently, I have planned investigator-sponsored clinical protocols using the SC column and I have obtained an NIH grant for these planned clinical protocols. These planned clinical protocols involve autologous transplantation utilizing cell suspensions processed by the SC column from both peripheral blood and bone marrow.

7. It is my opinion that for the patient above who was transplanted with the T-cell depleted product processed by the CEPRATE® SC column, the CellPro device provided the most optimal treatment option, as the other techniques had a higher risk of Graft-versus-Host-Disease ("GVHD"). Further, alternative techniques may have damaged the transplanted stem cells. I also believe that, with respect to my planned clinical protocols, the CellPro CEPRATE® SC column provides the most optimal treatment option.

8. For some applications, such as gene therapy, the CellPro CEPRATE® SC column provides a marked improvement over the traditional procedures (such as unpurified Buffy coat progenitor cell transplant), because the CellPro SC device reduces toxicity.


9. I chose the CellPro CEPRATE® SC and LC devices for my work because in addition the CellPro devices are reliable and have a good reputation.

10. If the CellPro CEPRATE® SC and LC devices were to become unavailable, it would adversely impact my practice and research endeavors as I would have to reapply for FDA and institutional clearances of the clinical protocols that I have planned and for which I have obtained an NIH grant. This would delay my clinical transplant protocol work for likely a year.

11. I believe that there is a compelling public interest in keeping the CellPro CEPRATE® SC and LC products available because access to these devices is important for novel applications such as gene therapy, and more importantly, for patients who are not eligible for experimental clinical protocols (such as the mismatched transplant patient I described above), the CellPro CEPRATE® SC product, as the only FDA-approved product, provides the only optimal remedy. The traditional remedies, as I stated above, involve higher risks of GVHD and may involve other serious risks.

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

Executed this 8th day of April, 1997, at Memphis, Tennessee.



Helen Heslop, M.D.

CURRICULUM VITAE

NAME HELEN ELISABETH HESLOP

SOCIAL SECURITY NUMBER 410-63-9317

DATE & PLACE OF BIRTH: November 28, 1956; London, England

CITIZENSHIP: New Zealand/Great Britain

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ACADEMIC DEGREES:

MB, ChB	1980	Otago University Medical School, New Zealand
FRACP	1987	
FRCPA	1987	
MD	1990	Otago University Medical School, New Zealand (With Distinction)

PROFESSIONAL APPOINTMENTS:

1980-81	House Officer, Christchurch Hospital; Princess Margaret Hospital; Ashburton Hospital, New Zealand
1981-82	Senior House Officer, Christchurch Hospital; Princess Margaret Hospital, New Zealand
1982-84	Medical Registrar, Princess Margaret Hospital; Christchurch Hospital, New Zealand
1984-85	Senior Registrar in Haematology, Christchurch Hospital, New Zealand
1986-89	Honorary Lecturer in Haematology, Royal Free Hospital, London, England
1989-91	Research Fellow, Departments of Hematology-Oncology and Biochemistry, St. Jude Children's Research Hospital, Memphis, Tennessee
1991-94	Assistant Member, Division of Bone Marrow Transplantation, St. Jude Children's Research Hospital, Memphis, Tennessee
1991-94	Assistant Professor, Department of Pediatrics, University of Tennessee, Memphis, College of Medicine, Tennessee
1994 to present	Associate Member, Division of Bone Marrow Transplantation, St. Jude Children's Research Hospital, Memphis, Tennessee
1994 to present	Associate Professor, Department of Pediatrics, University of Tennessee, Memphis, College of Medicine, Tennessee