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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 DR. LEONARD SENDER

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I, LEONARD SENDER, M.D., do hereby declare:

1. I am the Director of the Hematopoietic Stem Cell Transplantation Program at St. Joseph Hospital Regional Cancer Center in Orange, California and Associate Director of the Blood and Marrow Transplantation Program at Children's Hospital of Orange County in Orange, California. A copy of my curriculum vitae is attached as Exhibit A.

2. I am familiar with the capabilities of CellPro's CEPRATE® SC stem cell selection device and am currently participating in CellPro's clinical study for "haplo-identical" transplantation. In this study, patients are children or young adults who have no suitable related or unrelated histocompatibility-matched donor available. In the past, these patients had no alternative transplantation therapies since the degree of tissue mismatch was too great that such transplantation would not be attempted due to graft failure, graft-versus-host-disease ("GVDH") or other complications. Using the CEPRATE® SC device however, we are able to use parents as donors for their children who need stem cell transplants. The CellPro device allows us to obtain such half-matched donor bone marrow or peripheral blood and then process the bone marrow or peripheral blood to select stem cells and remove a sufficient about of T cell to prevent fatal GVHD. The benefits of such a protocol to individuals without matched donors

is especially important to minority groups who are essentially discriminated against on the basis of their biology since donor pools for these individuals are limited and consequently finding suitable donors for these groups is especially difficult. The Cellpro device has opened the opportunity for transplantation to these groups who would otherwise be locked out of this lifesaving therapy.

3. Of special interest to me is the use of the Cellpro CEPRATE® device in the treatment of patients with neuroblastoma, a malignant tumor of immature nerve cells, most often affecting young children. In this disease, the bone marrow is often 80% contaminated with tumor cells. The only mechanism currently available to purge the marrow of such patients of tumor cells so that the marrow can be used for transplantation, is by sending the marrow to a select few research labs around the country. These labs process the marrow by a method not approved by the FDA by "negative selection," using a cocktail of monoclonal antibodies to remove tumor cells. Processing by this method is done only on whole bone marrow on a research basis, and this technology cannot be used for purging peripheral blood.

4. I am about to present for approval to the Children's Cancer Group ("CCG") of the National Cancer Institute, a protocol for a randomized national clinical trial whereby these neuroblastoma patients could be transplanted with stem cells using peripheral

blood purged of tumor cells using the CellPro device. The result of these studies will be a transplantation product with less volume and decreased toxicity.

5. A substantial amount of resources have been used in anticipation of the start of the neuroblastoma project. The project is six months into planning and we anticipate beginning the study within the next six months.

6. This trial will be partially patient funded, and partially funded by the CCG. I believe if the FDA approved CellPro device is not part of our protocol, that patient's medical insurance providers will not agree to pay for the transplantation because it would be considered too experimental.

7. I am distressed about any possibility of the CellPro stem selection device being removed from the market. There is no guarantee that I will be able to obtain another stem cell selection system to use in my studies. Even if Baxter had a device that could be used, because high-risk neuroblastoma is what is often called an "orphan disease", afflicting only about 200 children nationwide, and as such any non-FDA -approved device may not be made available to me. It has been my experience that because these orphan diseases do not present a big enough market they are rarely approved by manufacturers for use in investigator sponsored trials.

8. Because the CellPro CEPRATE® system is FDA approved for bone marrow transplantation protocols, I believe that this will spur other medical centers into research for other uses of the device. I believe that if such a stem cell selection device is hard to get, it will discourage centers who are not as academic from proceeding with such trials.

9. If the CEPRATE® device is removed from the market place there is no question in my mind that patients will be harmed. Ever since the promise of such a device became known in the early 1990s, everyone has been monitoring the progress of such a potentially life-saving technology. Now that the technology is available, many patients have access to a promising treatment they have waited patiently for. Patients know this technology is available. In my practice, parents of young children facing these life threatening diseases, are increasingly educating themselves, whether through the internet or their hometown medical libraries, about new treatment regimens. As part of my informed consent obligations, I also discuss with these parents the different technologies available, including the benefits of purging versus non-purging of bone marrow or peripheral blood. It would be like holding up a carrot to these parents, to confirm that you now have such promising methods that could be used to reduce the number of tumor cells in their child's marrow, but it can't be used because of a legal dispute.

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

Executed at Orange, California, this 14th day of April, 1997.

Leonard Sender, M.D.

CURRICULUM VITAE

LEONARD STANLEY SENDER, M.D.

Place of Birth:	**Johannesburg, South Africa**
Citizenship:	**United States**
Social Security #:	**552-75-5501**

EDUCATION:

1976-1982	**University of the Witwatersrand, Johannesburg, M.D.**

RESIDENCY:

1983-1986	**University of California at Irvine** **Resident in Pediatrics**
1985-1986	**University of California at Irvine** **Chief Resident, Pediatrics**

INTERNSHIP:

1983-1984	**University of California at Irvine Medical Center** **Department of Pediatrics**

FELLOWSHIP:

1986-1989	**Children's Hospital Los Angeles,** **Pediatrics Hematology/Oncology, Fellow**

ACADEMIC APPOINTMENTS:

1989-1991	**Assistant Professor of Pediatrics,** **University of Southern California,** **School of Medicine, Los Angeles, California**
1991-1994	**Assistant Professor of Pediatrics,** **University of Louisville, School of Medicine** **Division of Pediatric Hematology/Oncology** **Louisville, Kentucky**