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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. RICHARD CHAMPLIN

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I, RICHARD CHAMPLIN, M.D., do hereby declare:

1. I am the Chairman of the Department of Hematology (ad interim) and the Chief of the Bone Marrow Transplant Service of the M. D. Anderson Cancer Center of the University of Texas, located in Houston. Attached hereto as **EXHIBIT A** is a copy of my curriculum vitae.

2. I have been using CellPro's CEPRATE® SC stem cell concentrator since about 1992, when I became involved as an investigator in the pivotal breast cancer trial that led to CellPro's recent FDA approval. To date our Center has performed approximately 40 transplants on human patients using the CellPro device.

3. One application for which I have used the CEPRATE® SC stem cell concentrator is for the treatment of leukemias by marrow-and-CGSF-mobilized-peripheral-blood allogeneic transplant between related persons (parent-to-child, child-to-parent, and sibling-to-sibling) who are half-matched ("haploidentical"). Prior to acquiring the CellPro device, we did not have a practical transplant option for these patients at the M. D. Anderson Cancer Center. We had attempted such transplants with conventional

methods, but we had found the results to be so uniformly poor (the survival rate being close to zero) that we judged those transplants not to be a practical therapeutic option with then-available technology, and we stopped doing such transplants until after the CellPro device became available for that purpose.

4. With the CellPro device we have so far treated nine leukemia patients with haploidentical transplants, and one patient is alive in remission as a result. While one of nine may not seem impressive, it should be appreciated that these nine were desperately sick, late-stage patients with no conventional treatment options, and that without the CellPro device, the remission rate would have been zero. It is possible that with a supplemental T-cell depletion step we could see further improved results in this heretofore untreatable population of patients. We are beginning a new protocol which would use the CellPro device to achieve stem-cell enrichment followed by an additional step for further T-cell depletion, for haploidentical transplant of leukemia patients.

5. In addition, I am involved in a series of studies aimed at exploring the usefulness of "CD4 infusions" in the treatment of relapsed patients with chronic myelogenous leukemia ("CML"). This treatment involves the allogeneic transplant into the patient of CD4+ cells, which are immune cells that attack the patient's malignant cells but are believed to contribute little, or

not at all, to graft-versus-host disease (GVHD). In a pilot study of 17 patients (in which we concentrated CD4+ cells by negative selection via CD8-antibody depletion) we observed that only 2 of the 17 patients developed significant GVHD, whereas 80% of chronic-phase patients in the study went into remission. CellPro is developing a CD4-antibody-based positive-selection system, which I understand will run on the same "platform" as the stem cell concentrator, with which I hope, by mid-year, to begin transplanting patients as part of a Phase-II clinical trial.

6. In addition, I have used CellPro's CEPRATE® SC stem cell concentrator to isolate stem cells for allogeneic transplant to "boost" previously-transplanted patients who are showing poor engraftment. The device affords an effective means to perform a therapeutic step that can benefit patients who, post-transplant, appear to be at peril of death from graft failure. There is no other FDA-approved device available for this purpose. This is a potentially life saving use of this device.

7. Approximately two years ago I had the opportunity to work with a Baxter ISOLEX® device in treating a small number of patients. I found that while the device did work and did produce a usable end product, it was slow and cumbersome to use in comparison to the CellPro device, which is better-engineered for simplicity, ease, and convenience of use. In addition, I had concerns about possible risks to patients of allergic reaction to

chymopapain, an enzyme which the Baxter device used as an agent for releasing bound stem cells. The CellPro device, in contrast, does not use chymopapain, but instead accomplishes release of the bound stem cells by simple mechanical agitation, without the need to employ any chemical release agent.

8. If the CellPro CEPRATE® SC stem cell concentrator were taken off the U.S. market, one result would be a major disruption of my clinical research plans involving stem-cell therapies; and I believe that in this regard I am typical of clinical researchers who are using the CellPro device in this country in pursuit of new and expanded clinical applications of stem-cell therapy. It would also deprive patients of an important therapy which can currently only be provided with the CEPRATE® device.

9. If access by clinicians to the CellPro CEPRATE® SC stem cell concentrator were restricted in the United States, the practical availability of stem-cell-therapy options to clinicians and their patients would be diminished; and in my view it is not realistic to expect that Baxter's ISOLEX® device, or any other device that lacks FDA approval, could fully and adequately replace the CellPro device even if the therapeutic and technical equivalency of such device to the CellPro device were certain. The basis for this view is as follows:

(a) CellPro's device is the only stem-cell selection device that is FDA approved for therapeutic use, and therefore the only such device that can be commercially purchased in the United States.

(b) No alternative stem cell selection device is available in this country for commercial purchase; and so if a clinician wants access to an alternative device, he or she cannot gain such access if he or she is not enrolled as an investigator in an FDA-sanctioned study or trial which utilizes the device.

(c) Such enrollment, however, presupposes that the manufacturer of the alternative device is willing to accept that particular clinician as an investigator and enter into the necessary agreement with him or her, and that the manufacturer has enough of the devices on hand to be able to furnish one to that particular clinician. To date Baxter has not been willing to provide Isolex devices for our recent and planned clinical trials.

(d) In my experience, FDA trials are always of a limited-enrollment nature, as to: (1) the number of investigators who can be enrolled; (2) the number of patients who can be enrolled: and (3) the criteria that determine patient eligibility for enrollment.

(e) Hence, it follows that the number of clinicians who can practically gain access to a non-FDA-approved device will necessarily be limited by the fact that such devices are only furnished in connection with FDA-sanctioned trials.

(f) Even if a clinician does gain access to such a device, the kinds, categories and numbers of patients who can be treated with it will be limited by the details of the trial protocol, including the patient-eligibility criteria.

For these reasons, I believe that the numbers of non-FDA-approved stem cell selection devices in the hands of U.S. clinicians realistically will always remain rather limited, and the purposes for which they can practically use those devices will always more restricted than the purposes for which they could use an FDA-approved stem cell selection device.

10. Hence, I believe that important public health interests would be seriously compromised if clinicians' and researchers' access to CellPro's CEPRATE® SC stem cell concentrator were curtailed or restricted. Reducing, or preventing an increase in, the number of such devices in clinicians' and researchers' hands would not only have the effect of restricting patients' access to treatment, but would also have the effect of slowing the

rate of development of new stem-cell-therapy-based approaches to the experimental treatment of life-threatening diseases, including some that are not successfully treatable with any therapy yet known.

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

Executed at Houston, Texas, this 15 Day of April, 1997.

RC Champlin MD

RICHARD CHAMPLIN, M.D.

CURRICULUM VITAE

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