

IN THE 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,)

Plaintiffs,)

v.)

CELLPRO, a Delaware corporation,)

Defendant.)

Civil Action
No. 94-105-RRM

DECLARATION OF DR. KENNETH CORNETTA, M.D.

Submitted by:

POTTER ANDERSON & CORROON
William J. Marsden, Jr. (#2247)
Joanne Ceballos (#2854)
P.O. Box 951
350 Delaware Trust Building
Wilmington, Delaware 19899
(302) 984-6000
Attorneys for Plaintiffs

OF COUNSEL:

Steven J. Lee
KENYON & KENYON
One Broadway
New York, New York 10004
(212) 425-7200
Attorneys for Plaintiffs

Donald R. Ware
Peter B. Ellis
FOLEY, HOAG & ELIOT LLP
One Post Office Square
Boston, Massachusetts 02109
(617) 832-1000 Attorneys for Plaintiffs

Michael Sennett
BELL, BOYD & LLOYD
Three First National Plaza
70 West Madison Street
Chicago, Illinois 60602
(312) 807-4243
Attorneys for Plaintiff
Baxter Healthcare Corporation

Dated: April 28, 1997

DECLARATION OF DR. KENNETH CORNETTA

I, Kenneth Cornetta, M.D., hereby declare:

1. I am Director of Bone Marrow Transplantation in the Department of Medicine at Indiana University in Indianapolis, Indiana. I am a co-author of some 49 published (or submitted for publication) scientific papers in the area of bone marrow transplantation, gene therapy, and related fields. A copy of my Curriculum Vitae is attached hereto as Exhibit A.

2. I am personally familiar with the capabilities of Baxter's Isolex® 300 Stem Cell Selection System, which we have used extensively in treating cancer patients in our center. We began using the Isolex® 300 in clinical trials in 1994 under an investigator-sponsored IDE for autologous bone marrow transplantation in breast cancer patients. More recently, in 1996, we began using Baxter's Isolex® 300i device, which is an automated version of the earlier 300 model. I am personally familiar with the capabilities of the 300i as well.

3. In all, we have participated in three FDA-approved breast cancer trials, involving approximately 40-50 patients, using the Baxter devices. Initially, the transplants used bone marrow, in 1996, we switched to using Baxter's 300i device, at which time we began transplanting peripheral blood stem cells.

4. In addition to the breast cancer trials, we are currently participating in two FDA-approved clinical trials for allogeneic transplantation, and one such trial for autologous transplantation for multiple myeloma patients. The allogeneic trials have involved approximately 30 patients to date, and the multiple myeloma trial has involved 17 patients to date.

5. We have been very satisfied with the results achieved using the Baxter devices. Both the 300 and the 300i have provided satisfactory purity and yield of CD34+ cells for

transplantation, and our patients have experienced rapid engraftment.

6. Our center does not use CellPro's CEPRATE® SC stem cell concentrator and has no plans to do so.

7. It is my expectation that our center will continue to use Baxter's 300i device in future treatment protocols requiring CD34+ selection of bone marrow or peripheral blood.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 2nd day of April, 1997.


Kenneth Cornetta, M.D.

CURRICULUM VITAE - April 1997

NAME: Kenneth Cornetta, M.D.

HOME ADDRESS: 235 Woodstock Ct.
Zionsville, IN 46077
(317) 873-0595

PROFESSIONAL ADDRESS: Indiana University
Department of Medicine
Section of Hematology/Oncology
Med. Research & Library Bldg. Rm 442
975 West Walnut Street
Indianapolis, IN 46202

DATE AND PLACE OF BIRTH: August 18, 1956
Flushing, New York.

CITIZENSHIP: United States

EDUCATION:

1978 - 1982	M.D.	Albany Medical College, Albany, NY
1974 - 1978	B.S.	Biological Sciences State University of N.Y. at Albany

PROFESSIONAL EXPERIENCE:

1995 -	Coordinating Director, National Gene Vector Laboratory
1995 -	Associate Professor of Medicine and of Medical and Molecular Genetics, Indiana University
1994 -	Director, Indiana University Vector Production Laboratory
1994 -	Graduate School Faculty, Indiana University
1994 -	Director, Bone Marrow Transplantation, Department of Medicine, Indiana University, Indianapolis, IN
1993 - 1995	Assistant Professor of Medical and Molecular Genetics, Indiana University, Indianapolis, IN
1991 - 1995	Assistant Professor of Medicine, Indiana University, Department of Medicine, Section of Hematology/Oncology Indianapolis, IN

1990 - 1991 Clinical Instructor, Section of Hematology,
University of Wisconsin, Madison, WI

1989 - 1990 Hematology Fellow, Section of Hematology,
University of Wisconsin, Madison WI

1986 - 1989 National Research Service Award Fellow,
Molecular Hematology Branch, NHLBI, NIH

1985 - 1986 Chief Resident, Department of Medicine,
Indiana University, Indianapolis, IN

1982 - 1985 Resident, Internal Medicine, Indiana
University, Indianapolis, IN

1975-77, 1979 Research Student with Stanley Zucker, M.D., VA
Medical Center, Northport, N.Y./State
University of New York at Stony Brook

AWARDS:

New York State Regents Scholarship
National Research Service Award
American Cancer Society Junior Faculty Award

MEDICAL LICENSE:

Indiana

CERTIFICATION:

American Board of Medical Examiners, 1983.
American Board of Internal Medicine, 1986.
ABIM Board in Hematology, 1990.

ASSOCIATIONS:

American Society of Hematology
International Society of Experimental Hematology
American Federation of Clinical Research
AAAS
Sigma Xi Scientific Research Society

EDITORIAL BOARD:

Cancer Gene Therapy
Gene Therapy

GRANT SUPPORT:

Chairman's Gift Fund 7/91-6/92 Total \$50,000

American Cancer Society Junior Faculty Award - 7/91 to 6/94
Principal Investigator Total \$90,500

Indiana University Biomedical Research Committee Type I Award
7/92 to 6/93 Principal Investigator Total \$20,000

NIH P01 CA59349 Dose Intensification by Gene Transduction in
Cancer. Principal Investigator, Project III - Gene Therapy
for Chronic Myelogenous Leukemia. Principal Investigator
10/92 to 9/96. Total \$946,203

American Cancer Society Institutional Grant Award.
Gene Therapy for Breast Cancer. Principal Investigator
7/93 - 6/94 Total \$10,000

Baxter Healthcare Corporation. Use of Isolated CD34 Cells
from Marrow of Matched Related and Unrelated Donors for
Allogeneic Bone Marrow Transplantation. 9/94-9/95 Principle
Investigator. Total \$47,100.

NIH P50 DK49218 Genetic Modification/Alternative Sources of
Stem Cells (Centers of Excellence). Core B Vector Production
Facility. Core Leader. 9/94-9/99.

Baxter Healthcare Corporation. Peripheral Blood Stem Cells or
Isolated CD34+ Cells from Mobilized Peripheral Stem Cell
Collections for Hematologic Rescue of Advanced Breast Cancer
Patients Treated with High-Dose Chemotherapy. 12/94-1/96
Principle Investigator. \$38,730

NIH P01 HL53586 Gene Replacement Therapy in Hematopoietic
Stem Cells. Core B Vector Production Facility. Core Leader.
12/94-11/98. Total \$263,276

Baxter Healthcare Corporation. CD34+ Cells from Mobilized
Peripheral Stem Cell Collections for Hematologic Rescue of
Patients Treated with High-Dose Chem/Radiotherapy for B-Cell
Malignancies. 3/95-12/96 Principle Investigator. Total
\$30,000

NIH U42 RR11148 National Gene Vector Laboratory. Principle
Investigator. 8/1/95-7/31/00. Total direct costs \$3,698,461.

Cathy Peachy Breast Cancer Foundation. 5/96-4/97 Principle
Investigator. FLT-3 Ligand in Breast Cancer. Total \$10,000

PUBLICATIONS

1. Lysik, R.M., Cornetta, K., DiStefano, J.F. and Zucker, S.: Bone marrow cytotoxicity induced by hepatoma, teratocarcinoma and transformed fibroblasts. *Cancer Research* **39**, 30-34, 1979.
2. Cornetta, K. and Zucker, S.: Organ distribution of circulating very low density lipoproteins (VLDL): Fate of hematopoietic growth inhibitory VLDL in the rat. *Exp. Hematol.* **11**, 275-283, 1983.
3. Zwiebel, J.A., Freeman, S.M., Kantoff, P.W., Cornetta, K., Ryan, U.S. and Anderson, W.F.: High-level recombinant gene expression in rabbit endothelial cells transduced by retroviral vectors. *Science* **243**, 220-222, 1989.
4. Cornetta, K. and Anderson, W.F.: Protamine sulfate as an effective alternative to polybrene in retroviral-mediated gene transfer: Implications for human gene therapy. *J. Virol. Meth.* **23**, 187-194, 1989.
5. Cornetta, K., Wiader, R. and Anderson, W.F.: Gene transfer into primates and prospects for gene therapy in humans. *Progress Nucleic Acid Res.* **35**, 311-322, 1989.
6. Kasid, A., Morecki, S., Aebersold, P., Cornetta, K., Culver, K., Freeman, S., Director, E., Lotze, M.T., Blasse, R.M., Anderson, W.F. and Rosenberg, S.A.: Human gene transfer: Characterization of human tumor infiltrating lymphocytes as vehicles for retroviral mediated human gene transfer in man. *Proc. Natl. Acad. Sci. USA*, 473-477, 1990.
7. McLachlin, J.R., Cornetta, K., Eglitis, M.A. and Anderson, W.F.: Retroviral-mediated gene transfer. *Progress Nucleic Acid Res.* **38**, 91-135, 1990.
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10. Zwiebel, J.A., Freeman, S.M., Cornetta, K., Forough, R., Maciag, T., and Anderson, W.F.: Recombinant gene expression in human umbilical vein endothelial cells transduced by retroviral vectors. *Biochem. Biophys. Res. Comm.* **170**, 209-213, 1990.
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16. Cornetta, K., Morgan, R., and Anderson, W.F.: Safety issues related to retroviral-mediated gene transfer in humans. *Human Gene Therapy* **2**, 5-14, 1991.
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19. Cornetta, K.: Safety aspects of gene therapy. *British J. Haematol* **80**, 421-426, 1992.
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46. Braun, S. E., Chan, K., Battiwalla, M. and Cornetta, K. Gene therapy strategies for leukemia. *Molecular Medicine Today* 3: 39-46, 1997.
47. Traycoff, C. M., Srour, E. F., Dutt, P., Fan, Y., and Cornetta, K. The 30/35 kD chymotryptic fragment of fibronectin enhances retroviral-mediated gene transfer in purified chronic myelogenous leukemia bone marrow progenitors. *Leukemia* 11: 159-167, 1997.
48. Orazi, A., Hromas, R. A., Neiman, R. S., Greiner, T. C., Lee, C. H., Rubin, L., Haskins, S., Heerema, N. A., Gharapure, V., Abonour, R., Srour, E. F., Cornetta, K. Posttransplantation lymphoproliferative disorders in bone marrow transplant recipients are aggressive diseases with high incidence of adverse histologic and immunobiological features. (in press, *Amer. J. Clin Path*).
49. Veena, P., Cornetta, K., Davidson, A., Agüero, E., McMahon, J., Traycoff, C. M., Srour, E. F. Preferential sequestration in vitro of BCR/ABL negative hematopoietic progenitor cells among cytokine nonresponsive CML marrow CD34+ cells. (in press, *Bone Marrow Transplantation*).

CERTIFICATE OF SERVICE

I, William J. Marsden, Jr., hereby certify that on this 29th day of April, 1997, copies of the within document were caused to be served on the attorneys of record at the following addresses as indicated:

VIA HAND DELIVERY

Gerard M. O'Rourke, Esquire
Connolly, Bove, Lodge & Hutz
1220 Market Street
Post Office Box 2207
Wilmington, Delaware 19801-2207

VIA FACSIMILE AND FEDERAL EXPRESS DELIVERY

Coe A. Bloomberg, Esquire
Lyon & Lyon
633 West Fifth Street, 47th Floor
Los Angeles, California 90071



William J. Marsden, Jr.