

FILED

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, )

Civil Action  
No. 94-105-RRM

v. )

CELLPRO, a Delaware corporation, )

Defendant. )

DECLARATION OF DR. JAMES JOSEPH VREDENBURGH

Submitted by:

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Baxter Healthcare Corporation

Dated: April 28, 1997

## DECLARATION OF DR. JAMES J. VREDENBURGH

I, James J. Vredenburg, M.D., hereby declare:

1. I am an attending physician in the Bone Marrow Transplant Program at Duke University Medical Center, and recently served as its Interim Director. I am a co-author of some 37 published scientific papers and several books in the fields of oncology, bone marrow transplantation, and related subjects. A copy of my Curriculum Vitae is attached hereto as Exhibit A.

2. Duke University Medical Center is one of the major stem cell transplant centers in the world. The Medical Center draws patients from all fifty states and from foreign countries. We have performed over 1200 breast cancer transplants, more than any other medical center in the world.

3. I am personally familiar with the capabilities of Baxter's Isclex® 300 Stem Cell Selection System, which we have used in treatment of breast cancer patients since mid-1996. Our use of the Isclex® 300 system is under an investigator-sponsored IDE for metastatic breast cancer, in which I am the Principal Investigator. We treat these patients with high dose chemotherapy, and then support their recovery by transplanting CD34+ peripheral blood stem cells. Approximately 15 patients are currently enrolled in this trial.

4. Initially, we used the Isclex® 300 SA device in the trial. In the fall of 1996, we obtained Baxter's newer Isclex® 300i device, which automates the process to shorten the processing time and make the system very easy to use. We then amended our IDE to substitute the 300i for the 300 SA, and we have used it in all subsequent procedures.

5. Our experience with the Isclex® 300 SA and 300i devices has been very satisfactory. We have obtained high CD34+ purities and yields, and have not observed any

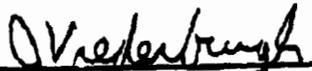
toxicities associated with use of the device. Our patients have engrafted well, with no delays.

6. I also have some familiarity with CellPro's CEPRATE<sup>®</sup> SC device.

CellPro installed the device at the Medical Center a few years ago and provided training in its use. We used it in some research experiments, but not in clinical procedures. We gave no consideration to switching to the CellPro device when it received FDA approval for autologous bone marrow transplantation in December 1996, and we have no plans to use it in the future. From my perspective as a clinician, its status as an "FDA-approved" device is not relevant to my decision as to which stem cell selection device I will use, and I am very comfortable continuing to use the Baxter device in treatment protocols requiring selection of CD34+ cells.

7. In my estimation, 85% or more of stem cell transplants being performed in hospitals today use peripheral blood, as opposed to bone marrow, as the source of stem cells.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 28<sup>th</sup> day of April, 1997.

  
James J. Vredenburg, M.D.

## CURRICULUM VITAE

**Name:** James Joseph Vredonburgh

**Social Security Number:** 108-38-6502

**Current Address:**

**Home:** 6200 Accorn Ridge Trail  
Hillsborough, NC 27278  
(919) 477-9716

**Business:** Division of Hematology/Oncology  
Box 3961  
Duke University Medical Center  
Durham, North Carolina 27710  
PH: (919) 684-8707  
FAX: (919) 684-6177

**Date of Birth:** February 17, 1957

**Place of Birth:** Mount Kisco, New York

**Current Positions:**

Associate Professor of Medicine  
Duke University Medical Center  
July 1996-present

Interim Director  
Bone Marrow Transplant Program  
Duke University Medical Center  
July 1995- Dec. 1996

Assistant Professor of Medicine  
Duke University Medical Center  
July 1990-July 1996

Director, Cryopreservation Laboratory  
Duke University Medical Center  
July 1990-present

Attending, Bone Marrow Transplant Program  
July 1990-present

Director, Clinical Laboratories  
Bone Marrow Transplant Outpatient Clinic  
July 1983-present

Family Status: Wife: Suzanne Vredenburg; 3 children

Education: B.A. Psychology  
University of Virginia  
May, 1979

M.D.  
University of Vermont  
May, 1983

Postgraduate Training: Residency in Internal Medicine  
St. Francis Hospital and Medical Center  
Hartford, Connecticut  
July, 1983-June, 1986

Fellowship in Hematology/Oncology  
Dartmouth-Hitchcock Medical Center  
Hanover, New Hampshire  
July, 1986-June, 1990

Professional Positions: Instructor in Medicine  
Dartmouth Medical School  
Hanover, New Hampshire  
1986-1990

Attending Hematologist/Oncologist  
Dartmouth Medical School  
Hanover, New Hampshire  
1990

Associate Professor of Medicine  
Duke University Medical Center  
Durham, North Carolina  
1996-present

Assistant Professor of Medicine  
Duke University Medical Center

Durham, North Carolina  
July 1990-1998

Director, Cryopreservation Laboratory  
Duke University Medical Center  
Durham, North Carolina  
July 1990-present

Director, Hilldale Clinical Laboratory  
Duke University Medical Center  
Durham, North Carolina  
May 1992-present

Attending, Bone Marrow Transplantation Program  
July 1990-present

**Board Certification  
and Licenses:**

Board Certified in Internal Medicine, 6/88  
Board Certified in Hematology, 11/89  
Board Certified in Medical Oncology, 11/89

Licensed in the states of Connecticut, New  
Hampshire, North Carolina, and Vermont

**Societies and  
Professional Affiliations:**

American Society of Clinical Oncology (ASCO), 1992  
American Society of Hematology (ASH), 1992  
American Society of Blood and Marrow Transplantation,  
1992  
International Society for Hematotherapy and Graft  
Engineering, 1993

**Awards and Honors:**

Frank N. Willard, M.D. Award  
Most Outstanding and Sensitive Physician  
St. Francis Hospital and Medical Center  
May, 1988

Tiffany Blake Fellow  
Hitchcock Clinic  
July, 1988

Dartmouth-Hitchcock Medical Center  
Most Compassionate Physician  
June, 1988

American Cancer Society Institutional Grant  
November, 1988-October, 1989

Committees and Boards: Member, Cancer Protocol Review Committee  
Comprehensive Cancer Center  
Duke University Medical Center  
September, 1990-present

Member, Standards and Accreditation Committee  
Internal Society of Hematotherapy and Graft Engineering  
1993-present

Major Research Interests:

1. Detection of submicroscopic metastases in the marrow and peripheral blood.
2. Bone marrow purging with monoclonal antibodies.
3. High-dose chemotherapy and hematopoietic support for breast and ovarian cancer.

Teaching Experience: Instructor in Medicine  
Dartmouth Medical School  
Hanover, New Hampshire  
1986-1990

Assistant Professor of Medicine  
Duke University Medical Center  
Durham, North Carolina  
1990-1996

Associate Professor of Medicine  
Duke University Medical Center  
Durham, North Carolina  
1996-present

**Principal Clinical and Hospital Service**

**Responsibilities:**

Attending Hematologist  
Dartmouth Medical School  
Hanover, New Hampshire  
1990

Attending Hematologist/Oncologist  
Bone Marrow Transplant Program  
Duke University Medical Center  
Durham, North Carolina  
July, 1990-present

**Major Administrative**

**Responsibilities:**

Interim Director  
Bone Marrow Transplant Program  
Duke University Medical Center  
Durham, North Carolina  
July 1995-Dec. 1998

Director, Cryopreservation Laboratory  
Bone Marrow Transplant Program  
Duke University Medical Center  
Durham, North Carolina  
July, 1990-present

Director, Hillandale Clinical Laboratory  
Duke University Medical Center  
Durham, North Carolina  
May, 1992-present

## PUBLICATIONS

1. Ramsay A, Vredenburgh J: Recognition of alcoholism among patients with psychiatric problems in a family practice clinic. J Family Practice 17:829, 1983.
2. Vredenburgh JJ, McIntyre OR, Cornwell CG III, Ball ED, Cornell JC, Mills LE, O'Donnell JF: Mitoxantrone in the treatment of relapsed or refractory acute non-lymphocytic leukemia. Med & Ped Oncol 16:187-189, 1988.
3. Ball ED, Vredenburgh J, Mills LE, Cornwell GC, Schwarz L, Howell AL, Troy K: Autologous bone marrow transplantation for acute myelogenous leukemia following *in vitro* treatment with neuraminidase and monoclonal antibodies: A case report. Bone Marrow Transplantation 6:277-280, 1990.
4. Vredenburgh JJ, Ball ED: Elimination of small cell carcinoma of the lung from human bone marrow by monoclonal antibodies and immunomagnetic beads. Cancer Res 50:7216-7220, 1990.
5. Vredenburgh JJ, Simpson W, Memoli VA, Ball ED: Reactivity of anti-CD15 monoclonal antibody PM-81 with breast cancer and elimination of breast cancer cells from human bone marrow by PM-81 and immunomagnetic beads. Cancer Res 51:2451-2455, 1991.
6. Wurster-Hill D, Vredenburgh JJ, Mills LE, Davis BH, Ball ED: Isodicentric chromosome 18q as sole abnormality in a histologically normal bone marrow from a patient with diffuse large-cell non-Hodgkin's lymphoma. Cancer Genet & Cytogenet 54:233-237, 1991.
7. Ball ED, Powers FJ, Vredenburgh JJ, Heath CA, Converse AO: Purging of small cell lung cancer cells from bone marrow using immunomagnetic beads and a flow through device. Bone Marrow Transplantation 6:35-40, 1992.
8. Bast RC Jr, Boyer CM, Berchuck A, Xu FJ, Wu S, Lidor Y, Maler LA, Crews JR, Ross M, Vredenburgh JJ, Shpall EJ, Peters WP: New strategies for the management of ovarian and breast cancer based on biology and pharmacology. Cancer Chemotherapy: Challenges for the Future 7:3-20, 1992.
9. Marks LB, Halperin EC, Prosnitz LR, Ross M, Vredenburgh JJ, Rosner GL, Peters WP, and CALGB: Post-mastectomy radiotherapy following adjuvant chemotherapy and autologous bone marrow transplantation for breast cancer patients with  $\geq 10$  axillary lymph nodes. Int J Radiation Oncology Biol Phys 23:1021-1026, 1992.

10. Peters WP, Drago S, Tepperberg M, Vredenburgh JJ: Collection, cryopreservation and use of peripheral blood progenitor cells primed with colony stimulating factor. In: Marrow Transplantation: Practical and Technical Aspects of Stem Cell Reconstitution. Eds: Sacher RA and AuBuchon JP. Arlington, VA: American Association of Blood Banks, pp. 51-67, 1992.
11. Peters WP, Kurtzberg J, Rosner G, Ross M, Vredenburgh J, Meisenberg B, Gilbert C: Comparative effects of G-CSF and GM-CSF on priming peripheral blood progenitor cells for use with autologous bone marrow after high-dose chemotherapy. Blood 81:7, 1709-1719, 1993.
12. Peters WP, Ross M, Vredenburgh JJ, Meisenberg B, Marks LB, Winer E, Kurtzberg J, Bast RC Jr, Jones R, Shpall E, Wu K, Rosner G, Gilbert C, Mathias S, Coniglio D, Petros W, Henderson IC, Norton L, Weiss RB, Budman D, Hurd D: High-dose chemotherapy and autologous bone marrow support as consolidation after standard-dose adjuvant therapy for high-risk primary breast cancer. J Clinical Oncology 11:1132-1143, 1993.
13. Peters WP, Ross M, Vredenburgh J, Hussein A, Meisenberg B, Gilbert C, Petros W, Kurtzberg J: Role of cytokines in autologous bone marrow transplantation. Hematology/Oncology Clinics of North America 7:737-747, 1993.
14. Meisenberg B, Ross M, Vredenburgh JJ, Jones R, Shpall EJ, Seigler HF, Coniglio DM, Wu K, Peters WP: Randomized trial of high-dose chemotherapy with autologous bone marrow support as adjuvant therapy for high-risk, multi-node positive malignant melanoma. J Nat Cancer Inst 85:(13), July 7, 1993.
15. Gilbert C, Meisenberg B, Vredenburgh J., Ross M, Hussein A, Perfect J, Peters WP: Sequential prophylactic Ciprofloxacin and Rifampin and empiric once daily Vancomycin and aminoglycoside for neutropenic fever after high-dose chemotherapy and autologous bone marrow support. J Clinical Oncology 12:1006, 1994.
16. Theil MC, Claccia D, Vredenburgh JJ, Peters W, Corey GR: Clostridium septicum abscess in hepatic metastases: Successful medical management. Bone Marrow Transplant 13(4):495-8, 1994.
17. Marks L, Rosner GL, Prosnitz LR, Ross M, Vredenburgh JJ, Peters WP: The impact of conventional plus high dose chemotherapy with autologous bone marrow transplantation on hematologic toxicity during subsequent local-regional radiotherapy for breast cancer. Cancer 74(11):2964-71, 1994.

18. Meisenberg B, Lassiter M, Hussein A, Ross M, Vredenburgh JJ, Peters WP: Prevention of hemorrhagic cystitis after high-dose alkylating agent chemotherapy and autologous bone marrow support. Bone Marrow Transplant 14(2):287-91, 1994.
19. Muddo R, Vredenburgh J, Paulson EK, Ross M, Meisenberg B, Hussein A, Peters WP: A radiologic syndrome after high dose chemotherapy and autologous bone marrow transplantation, with clinical and pathologic features of systemic candidiasis. Cancer 74(4):1360-1366, 1994.
20. Ghajia AA, Silva O, Vredenburgh JJ, Bast RC Jr: Advances in the detection of marrow micrometastases in breast cancer. Cancer Research, Therapy and Control 4:43-47, 1994.
21. Peters WP, Ross M, Vredenburgh J, Hussein A, Rubin P, Dukelow K, Cavanaugh C, Beauvais R, Kasprzak S: The use of intensive clinic support to permit outpatient autologous bone marrow transplantation for breast cancer. Seminars in Oncology 21(4)(Suppl 7):25-31, 1994.
22. Young ST, Paulson EK, Washington K, Gulliver DJ, Vredenburgh JJ, Baker ME: CT of the liver in patients with metastatic breast carcinoma treated by chemotherapy: Findings simulating cirrhosis. AJR 163:1385-1388, 1994.
23. Vredenburgh JJ, Peters WP: Commentary on the article, "Bone marrow micrometastases in breast cancer", written by M Osborne and P Rosen. Oncology 8:31, 1994.
24. Hussein AM, Ross M, Vredenburgh J, Meisenberg B, Hars V, Gilbert C, Petros WP, Coniglio D, Kurtzberg J, Rubin P, Peters WP: Effects of granulocyte-macrophage colony stimulating factor produced in Chinese hamster ovary cells (regranimostim), Escherichia coli (molgramostim) and yeast (sargramostim) on priming peripheral blood progenitor cells for use with autologous bone marrow after high-dose chemotherapy. European J Haematol. 54:281-287, 1995.
25. Vredenburgh JJ, Peters WP, Roemer G, De Sombre K, Johnston WW, Kamal A, Wu K, Bast RC Jr: Detection of tumor cells in the bone marrow of stage IV breast cancer patients receiving high dose chemotherapy: The role of induction chemotherapy. Bone Marrow Transplantation, 16: 815-821, 1995.
26. Hussein AM, Petros WP, Ross M, Vredenburgh JJ, Affronti ML, Jones RB, Shpall EJ, Rubin P, Elkordy M, Gilbert C, Gupton C, Egorin MJ, Soper J, Berchuck A, Clarke-Pearson D, Berry DA, Peters WP: A phase I/II study of high-dose cyclophosphamide, cisplatin, and thiotepa followed by autologous bone

marrow and granulocyte colony-stimulating factor-primed peripheral blood progenitor cells in patients with advanced malignancies. Cancer Chemotherapy and Pharmacology, 37: 561-568, 1996.

27. Ingram SS, Samulek T, Dodge R, Prosnitz LR, Peters WP, Vredenburgh JJ. The Effects of Hyperthermia in Bone Marrow Purging of Breast Cancer. Internal Journal of Hyperthermia, 12 (1) 21-29, 1996.
28. Crews J, Vredenburgh JJ, Hussain A, Rubin P, Elkordy M, Ross M, Gockerman J, Cirincione C, Bigner S, Mills L, Peters WP: Secondary Myelodysplastic Syndrome and Acute Leukemia in Patients Following Autologous Bone Marrow Transplant. Submitted to Journal of Clinical Oncology, 1995.
29. Cohen A, Tepperberg M, Waters-Pick B, Coniglio D, Perfect J, Peters WP, Gilbert C, Morgan C, Vredenburgh JJ. The Significance of Microbial Cultures of the Hematopoietic Support for Patients Receiving High-Dose Chemotherapy. Journal of Hematotherapy, 5:289-294, 1996.
30. Rubin P, Huletta C, Khawly JMI, Elkordy M, Hussain A, Vredenburgh JJ. Ocular Toxicity Following High Dose Chemotherapy and Autologous Bone Marrow Transplantation: Case Report and Pathological Correlation. Bone Marrow Transplantation, 18:253-256, 1996.
31. Vredenburgh JJ, Silva O, Tyer CL, DeSambre K, Cook M, Layfield L, Peters WP, Best RC Jr. A comparison of immunohistochemistry, two-color immunofluorescence and flow cytometry with cell sorting for the detection of micrometastatic breast cancer in the bone marrow. Journal of Hematotherapy, 5:57-62, 1996.
32. Petros WP, Rosner G, Rabinowicz J, Gilbert C, Coniglio D, Vredenburgh JJ, Ross M, Peters WP. The Pharmacologic Effects of Recombinant, Human Colony-Stimulating Factors and Their Modulation by Theophylline. Pharmacotherapy, 16(5):742-748, 1996.
33. Cartee L, Petros WP, Rosner G, Gilbert C, Moore S, Affronti ML, Haks J, Hussain AM, Ross M, Rubin P, Vredenburgh JJ, Peters WP: Evaluation of GM-CSF Mouthwash Prevention of Chemotherapy-Induced Mucositis: A Randomized, Double-Blind, Dose Ranging Study. Cytokine 7 (5), 471-477, 1995.

34. Fisher DC, Sherrill G, Bradley, Hussein A, Rubin P, Vredenburgh JJ, Elkordy M, Ross M, Peters WP. Thrombotic microangiopathy as a complication of high-dose chemotherapy for breast cancer. *Bone Marrow Transplantation*, 18, 193-198, 1996.
35. Vredenburgh JJ, Silva O, Broadwater G, Berry D, DeSombre K, Tyer C, Peters WP, Bast RC Jr. The Significance of Tumor Contamination in the Bone Marrow from High Risk Primary Breast Cancer Patients Treated with High Dose Chemotherapy and Hematopoietic Support. Submitted to *Journal of Clinical Oncology*.
36. Elkordy M, Crump M, Vredenburgh J, Peters WP, Hussein A, Rubin P, Ross M, Gilbert C, Modlin C, Meisenberg B, Coniglio D, Rabinowitz J, Laughlin M, Kurtzberg J, Peters WP: A phase I trial of recombinant human interleukin-1-beta(OCT-43) following high-dose chemotherapy and autologous bone marrow transplantation. *Bone Marrow Transplantation*, 19, 315-322, 1997.
37. Tyer CL, Vredenburgh JJ, Heimer M, Peters WP, Bast RC Jr. Breast cancer cells are effectively purged from peripheral blood progenitor cells using an immunomagnetic technique. *Clin Cancer Res*, 2:81-88, 1996.

#### Books

1. Vredenburgh JJ, Ball ED: Lymphokines and lung cancer. In, Lung Cancer Differentiation, Bernal S, Baylin S, eds. New York: Marcel Dekker, Inc., 1992.
2. Vredenburgh JJ. Photographic Case Studies in Surgical Oncology. Diagnostic Tests for Practitioners eds. Clinical Communications, 1993
3. Vredenburgh JJ. Photographic Case Studies in Malignant Disease. Diagnostic Tests for the Practitioner. eds. Clinical Communications, 1993.
4. Seraly M, Vredenburgh J, Zwas FR. Immunocompromised Patients. A Case Study Approach. eds. Clinical Communications, vol. 1, 1995.
5. Seraly M, Skowron G, Vredenburgh JJ, Zwas F. Immunocompromised Patients: A Case Study Approach. eds. Clinical Communications, vol. 2, 1995.

**Abstracts:**

1. Vredenburgh J, McIntyre OR, Cornwell GG III, Ball ED, Cornell CJ, Mills LE, O'Donnell JF. Mitoxantrone in the treatment of relapsed and refractory acute non-lymphocytic leukemia. Leukemia 1:287, 1987.
2. Vredenburgh JJ and Ball ED: Monoclonal antibodies and immunomagnetic beads eliminate small cell carcinoma of the lung from bone marrow. Proceedings of the American Society of Clinical Oncology 8:224(No. 871), 1989.
3. Vredenburgh JJ: The detection of a low percentage of small cell carcinoma of the lung or breast cancer cells in the bone marrow by two-color flow cytometry. Submitted for presentation at the New England Cancer Society Meeting, 11/89.
4. Ball ED, Vredenburgh JJ, Crabtree GW: Monoclonal antibodies detect and eliminate breast cancer from bone marrow. UCLA Bone Marrow Transplant Symposia. J Cell Biochem 1990.
5. Powers F, Heath CA, Ball ED, Vredenburgh JJ, Converse AO. Separation of tumor cells from bone marrow using immunomagnetic beads. Presented at the Cell Separation Symposium at the ACS Meeting, Boston, Massachusetts, 4/90.
6. Simpson WA, Vredenburgh JJ, Ball ED, Memoli VA: PM-81 reactivity with normal, fibrocystic and malignant breast tissues. Presented at the United States and Canadian Academy of Pathology Meeting, Boston, Massachusetts, 1990.
7. Vredenburgh JJ, Davis B, Ball ED: The detection of low percentages of small cell carcinoma of the lung or breast cancer cells in the bone marrow by two-color flow cytometry. Proceedings of the American Society of Clinical Oncology 9:7 (No. 23), 1990.
8. Vredenburgh JJ, Ross M, Dukelow K, Johnson S, Shpall EJ, Jones RB, Best RC, Peters WP. Intravenous gamma globulin for refractory thrombocytopenia following high-dose alkylating chemotherapy and autologous bone marrow transplantation. Blood 76:410a, 1990.
9. Peterson J, Kirkpatrick G, Ross M, Vredenburgh J, Peters WP, Kurtzberg J: Growth factor primed peripheral blood progenitor cells (PBPC) are enriched for hematopoietic progenitor cells (HPC). Proceedings of the American Society of Clinical Oncology 10:78, 1991.

10. Winer EP, Gold DT, Lee J, Affronti ML, Westlund R, Ross M, Vredenburgh J, Jones R, Shpall E, Trump DL, Peters WP, Cohen HJ: Quality of life (QL) following high dose chemotherapy with autologous bone marrow support (HDC) in patients with metastatic breast cancer. Proceedings of the American Society of Clinical Oncology 10:62, 1991.
11. Peterson J, Kirkpatrick G, Ross M, Vredenburgh J, Peters WP, Kurtzberg J: Growth factor-primed peripheral blood progenitor cells (PBPC) are enriched for hematopoietic progenitor cells (HPC). Proceedings of the American Society of Clinical Oncology 10:78a, 1991.
12. Vredenburgh JJ, Ross A, Siegel MD, Ring D, Ross M, Peters WP: Micrometastatic bone marrow involvement in patients with breast cancer and 10 or more positive nodes. Breast Cancer Research and Treatment 19:171(No. 59), 1991.
13. Vredenburgh J, Ross M, Kurtzberg J, Coniglio D, Dukelow K, Gilbert C, Peters W: Phase I trial of Interleukin-1-beta (IL-1-beta) following high-dose chemotherapy and autologous bone marrow transplantation (ABMT). Blood 78:6a, 1991.
14. Peters WP, Hussein AM, Kurtzberg J, Ross M, Vredenburgh J, Gilbert C, Coniglio D, Dukelow K, Oette D: Use of recombinant human Interleukin-3 (IL-3) in patients (pts) with metastatic breast cancer receiving high-dose chemotherapy (HDC) and chemo-immunologically purged autologous bone marrow transplantation (P-ABMT). Blood 78:162a, 1991.
15. Meisenberg B, Ross M, Jones R, Vredenburgh J, Seigler H, Peters WP: Adjuvant high-dose combination alkylating agent chemotherapy (HDCAA) with autologous bone marrow support (ABMS) in multi-node positive melanoma. Proceedings of the American Society of Clinical Oncology 11:345a, 1992.
16. Vredenburgh J, Shpall EJ, Ross M, Meisenberg B, Bast R, Tyer C, Tepperberg M, Eggleston S, Peters WP: Immunopharmacologic bone marrow purging and high-dose chemotherapy with autologous bone marrow support (ABMS) for patients with metastatic breast cancer. Proceedings of the American Society of Clinical Oncology 11:58, 1992.
17. Peters WP, Ross M, Vredenburgh J, Meisenberg B, Rosner G, Marks L, Mathias B, Henderson C, Hurd D, Budman D, Norton L, Weiss RB: High-dose alkylating agents and autologous bone marrow support (ABMS) for stage II/III breast cancer involving 10 or more axillary lymph nodes (Duke and CALGB 8782). Proceedings of the American Society of Clinical Oncology 11:58, 1992.

18. Vredenburgh JJ, Ross M, Meisenberg B, Hussein A, Kurtzberg J, Gilbert C, Petros W, Peters WP: A short course of G-CSF for priming of peripheral blood progenitor cells (PBPC). Blood 80:291a, 1992.
19. Crump M, Ross M, Vredenburgh J, Meisenberg B, Dukelow K, Peters WP: Early toxicity after high-dose therapy and autologous bone marrow transplantation (ABMT) for breast cancer: Implications for outpatient management. American Society of Hematology 34<sup>th</sup> Annual Meeting, Blood 80:70a, 1992.
20. Meisenberg B, Affronti M, Ross M, Vredenburgh J, Hussein A, Kay J, Peters WP: Recombinant human macrophage colony-stimulating factor (rhM-CSF) after high-dose chemotherapy (HDC) with autologous bone marrow support (ABMS). Blood 80:417a, 1992.
21. Gupta C, Rabinowitz J, Petros W, Stuart A, Vredenburgh J, Peters WP: Interleukin-3 therapy suppresses endogenous cytokine concentrations following high-dose chemotherapy and autologous bone marrow transplantation (ABMT). Blood 80:85a, 1992.
22. Hussein A, Vredenburgh JJ, Meisenberg BR, Ross M, Petros WP, Peters WP: Protection against chemotherapy-induced alopecia by minoxidil in the newborn rat animal model. American Society of Hematology 34<sup>th</sup> Annual Meeting. Blood 80:450a, 1992.
23. Vredenburgh J, Ross M, Meisenberg B, Bast RC Jr, Gilbert C, Lawrence J, Moore S, Affronti M, Coniglio D, Mathias B, Oette D, Peters WP: Use of interleukin-3 (IL-3) and/or GM-CSF in patients with metastatic breast cancer receiving high-dose chemotherapy (HDC) and immunopharmacologically purged (IMP) autologous bone marrow support (P-ABMS). Twenty-Fourth Congress of the International Society of Haematology 24:1, 1992.
24. Peters WP, Ross M, Vredenburgh J, Winer E, Rosner G, Meisenberg B, Hussein A: High-dose adjuvant chemotherapy with autologous bone marrow support for high-risk primary breast cancer. International Conference on the Adjuvant Therapy of Cancer, March 10-13, 1993.
25. Ross AA, Cooper BW, Lazarus HM, Peters WP, Vredenburgh JJ, Mose TJ, Ciobanu N, Tallman MS, Kennedy MJ, Davidson N, Sweet DS, Di Persio JF, Klumpp TS, Jansen J, Akard L, Capelan E, Kahn DG, Winer NE: Incidence of tumor cell contamination in peripheral blood stem cell (PBSC) collections from breast cancer patients. Proceedings of the American Society of Clinical Oncology 12:69, 1993.

26. Vredenburgh J, Ross M, Meisenberg B, Mudad R, Paulson E, Hussein A, Peters WP: Hepatic, splenic and renal candidiasis following high-dose chemotherapy and autologous bone marrow support. Proceedings of the American Society of Clinical Oncology 12:456, 1993.
27. Crump M, Ross M, Vredenburgh J, Shpall E, Jones R, Meisenberg B, Peters WP: Phase I/II evaluation of high-dose thiotepa, cisplatin and cyclophosphamide with autologous stem cell rescue for patients with refractory solid tumors. Proceedings of the American Society of Clinical Oncology 12:131, 1993.
28. Vredenburgh J, Bast RC Jr, De Sombre K, Johnston W, Peters WP: Detection of tumor cells in the bone marrow or peripheral blood in breast cancer patients with 10 or more positive nodes. Proceedings of the American Association for Cancer Research 34:1130, 1993.
29. Tyer C, Vredenburgh J, Bast RC Jr, Peters WP: Two-color immuno-fluorescence improves the detection of tumor cells in the bone marrow. Fourth International Symposium on Purging and Processing 4:81, 1993.
30. Vredenburgh J, Ross M, Meisenberg B, Hussein A, Bast RC Jr, Shpall EJ, Tyer C, Heimer M, Tepperberg M, Affronti ML, Moore S, Peters WP: A phase I trial of high-dose chemotherapy and immunopharmacologically purged autologous bone marrow support for patients with metastatic breast cancer. Fourth International Symposium on Purging and Processing 4:23, 1993.
31. Tyer CL, Vredenburgh JJ, Heimer M, Bast RC Jr, Peters WP: Breast cancer cells are effectively purged from peripheral blood progenitor cells using an immunomagnetic technique. Fourth International Symposium on Purging and Processing 4:11, 1993.
32. Vredenburgh JJ, Waters-Pick B, Kurtzberg J, Drago S, Ross M, Hussein A, Peters WP: A single 6-hour (HR) steady state leukapheresis is sufficient for collection of peripheral blood progenitor cells (PBPC) after G-CSF. Blood 82:1381(a), 1993.
33. Hussein A, Ross M, Vredenburgh JJ, Meisenberg B, Gilbert C, Peters WP, Coniglio D, Kurtzberg J, Peters WP: Effects of granulocyte-macrophage colony stimulating factor (GM-CSF), Escherichia coli (E. Coli-GM) or yeast (yeast GM) on priming peripheral blood progenitor cells for use with autologous bone marrow after high-dose chemotherapy. Blood 82:1156(a), 1993.

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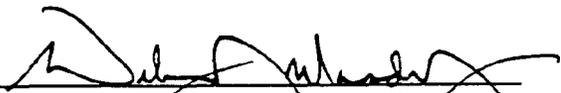
I, William J. Marsden, Jr., hereby certify that on this 28th day of April, 1997, copies of the within document were caused to be served on the attorneys of record at the following addresses as indicated:

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