IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, BAXTER HEALTHCARE CORPORATION, and BECTON DICKINSON AND COMPANY,	§	
Plaintiffs,	§	
v.	§	Civil Action No. 94-105-RRM
CELLPRO,	§	
Defendant.	§	

ORDER FOR PERMANENT INJUNCTION AND PARTIAL STAY OF INJUNCTION

Defendant CellPro, Inc. having been found to have willfully infringed United States Patent Nos. 4,714,680 (the "'680 patent") and 4,965,204 (the "'204 patent"), and said patents having been found to be valid and enforceable, this matter came on to be heard upon plaintiffs' motion for entry of a permanent injunction, and upon consideration thereof, it is hereby ORDERED THAT:

(Prohibitory Portions of Injunction)

1. CellPro, Inc., its subsidiaries, affiliates, distributors and agents, and its and their officers, directors, employees, agents and servants, and all others acting in concert or participation with any of the foregoing who have actual notice of this Order, be, and they hereby are, permanently enjoined and restrained from any and all of the following:

a. From making, having made, selling, supplying, testing, evaluating or using for any purpose whatever, within the United States, and from importing to or exporting from the United States, any CD34 antibody, including but not limited to the 12.8 antibody.

b. From making, having made, selling, supplying, testing, evaluating, maintaining or using for any purpose whatever, within the United States, and from importing to or exporting from the United States, any hybridoma cells capable of producing CD34 antibodies, including but not limited to the 12.8 hybridoma cell line, and from making or having made any master cell bank or working cell bank derived from such hybridoma cells or any clone or subclone thereof.

c. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the CEPRATE LC (CD34) Laboratory Cell Separation System (the "LC34 System"), or any disposable products intended for use therewith.

d. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the CEPRATE SC Stem Cell Concentrator (the "SC System"), or any disposable products intended for use therewith.

e. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any hybridoma cells produced, subcloned or otherwise derived from the 12.8 hybridoma cell line, or any other hybridoma cells produced, subcloned or derived from hybridoma cells originally made in the United States.

f. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any 12.8 antibodies or any other CD34 antibodies produced from hybridoma cells originally made in the United States.

g. From infringing or inducing or contributing to the infringement of any of claims 1, 2, 3, 4, 5 or 6 of the '680 patent until December 22, 2004, by making, using, selling or supplying in the United states, or importing to or exporting from the United States, any infringing suspension of human cells or by making, using or selling any product designed to produce or capable of producing an infringing suspension.

h. From infringing or inducing or contributing to the infringement of claims 1 or 4 of the '204 patent until October 23, 2007, by making, using, selling or supplying in the United States, or importing to or exporting from the United States, any infringing antibody or any infringing hybridoma, or any product which utilizes, or is designed or intended for use with, an infringing antibody.

i. For a period of two (2) years from the date of this Order, from selling or otherwise supplying to customers outside the United States, any product which utilizes or is designed or intended for use with any CD34 antibody.

(Mandatory Portions of Injunction)

IT IS FURTHER ORDERED THAT:

2. CellPro shall take immediate measures to repatriate to the United States (i) all clones or subclones of the 12.8 hybridoma cell line previously exported by it, as well as any further clones or subclones produced therefrom, including without limitation the 12.8 master cell bank hybridoma cells shipped by CellPro to Biomira, Inc.; (ii) all clones or subclones of any other CD34 antibody-producing hybridoma in its possession, custody or control, which hybridoma was first made in the United States by any person,

or which, if produced from a hybridoma first made outside the United States, has been used in any way by CellPro at any time within the United States; and (iii) any CD34 antibodies that have been produced outside the United States from any CD34 hybridomas first made in the United States, or which, if produced within the United States, are currently warehoused or stored outside the United States. CellPro shall report to the Court in writing when, and under what circumstances, such repatriation has occurred, and shall certify in writing to the Court at that time that no clones or subclones of the 12.8 hybridoma cell line, or of any other CD34 antibody-producing hybridoma cell line first made in the United States and thereafter used by CellPro, exist anywhere outside the United States, or, if it is unable to so certify, shall explain in detail the reasons for its inability to do so.

3. To the extent that CellPro has possession, custody or control of any CD34 antibodies, including but not limited to the 12.8 antibody, and any hybridoma cells capable of producing CD34 antibodies, including but not limited to the 12.8 hybridoma cell line and clones and subclones thereof, CellPro shall promptly destroy, in the presence of a United States Marshal, all such antibodies and hybridomas, and shall certify in writing to the Court at that time that it no longer has any CD34 antibodies in its possession, custody or control.

(Terms and Conditions of Partial Stay)

IT IS FURTHER ORDERED THAT:

4. The effectiveness of the above Order is hereby stayed as to the following specific activities only, and such partial stay is contingent upon CellPro's good faith compliance with the conditions set forth below:

a. CellPro may continue to make, have made, use and sell disposable products (including the 12.8 antibody), within the United States, for use only with SC Systems installed at a customer location on or prior to March 12, 1997, until such time as another stem cell concentration device, manufactured under a license under the '204 and '680 patents, is approved for therapeutic use in the United States by the United States Food and Drug Administration and for a period of three months thereafter. During the term of such stay, CellPro shall sell such disposable products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such customer with any quantity of disposable products in excess of such customer's anticipated short-range needs. During the three month period following FDA approval of a licensed stem cell concentration device, CellPro's total net sales of such disposable products shall not exceed 60% of its average quarterly net sales of such products during the twelve calendar months immediately preceding such FDA approval. The foregoing volume restriction shall not apply to the provision of disposable products solely for use in clinical trials that were approved by the FDA and the applicable IRB as of March 12, 1997.

b. CellPro may continue to sell the 12.8 antibody from the United States, but from no other location, to its customers in the rest of the world outside the United States ("ROW") for use only with SC Systems installed at a customer location on or prior to March 12, 1997, for a period of one (1) year from the date of this Order. During the term of such stay, CellPro shall sell the 12.8 antibody and other disposable products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such customer with any quantity of such antibody or related disposable products in excess of such customer's anticipated short-range needs. During the first three-month period following the date of this Order, CellPro's net sales of disposable products sold for use with the SC system pursuant to this subparagraph shall not exceed its total net sales of such disposable products in the ROW during the last calendar quarter of 1996. Thereafter, such maximum permitted amount shall be reduced by an absolute 25% in each succeeding three-month period, such that in the last three months of permitted sales, CellPro's net sales of such disposable products pursuant to this subparagraph shall not exceed 25% of its total net sales of such disposable products in the ROW during the last calendar quarter of 1996.

c. CellPro may continue to make, have made, use and sell the 12.8 antibody (but no other CD34 antibody), in the United States, solely for use with the SC System in the United States or in the ROW pursuant to the terms of subparagraphs a. and b. hereof, but may not make, have made, use or sell the 12.8 antibody for any other purpose.

d. Any sales by CellPro pursuant to the terms of this partial stay shall be at prices no lower than the prices at which such products were actually sold by CellPro in the ordinary course of its business during the period January 1, 1997 to February 28, 1997 in the relevant country or region, subject to any quantity discount schedule or cash discount schedule which was actually published to customers in such country or region during that period. CellPro shall not engage in any price or other special promotions with respect to any products sold pursuant to this partial stay, nor shall it provide any customer or user with any products at no charge. The provisions of this subparagraph shall not apply to the extent the products are provided solely for use in clinical trials that were approved by the FDA and the applicable IRB as of March 12, 1997.

e. Within forty-five (45) days after the close of each of calendar quarter (commencing with the quarter ending March 31, 1997), CellPro shall provide a detailed written report to plaintiffs and the Court, which shall include at least the following information:

(1) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro for use with the SC System in the United States during said quarter;

(2) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro sold for use with the SC System in or to the ROW during said quarter; and

(3) as to any sales of the SC System or the LC34 system or disposables sold prior to the effective date of this Order, the net sales of all such devices and disposables, by number of units and dollar volume, stated separately by product code and by geographic area (i.e., US or ROW).

f. For so long as CellPro continues to make sales in the United States pursuant to subparagraph a. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net U.S. revenues from such disposable products during said quarter, but not less than $2000 per disposable product. The foregoing $2000 floor on incremental profit per disposable product shall not apply to products provided on a so-called "cost recovery" basis solely for use in clinical trials that were approved by the FDA and the applicable IRB as of March 12, 1997, and CellPro shall not be required to make any payment of incremental profit to plaintiffs in the case of disposable products that are provided solely for use in such clinical trials where the products, in their entirety, are provided to the user free of no charge. The amount of incremental profit shall be determined as provided in subparagraph i. hereof, and, except as otherwise provided in the foregoing sentence, shall be payable on all such products sold or shipped on or after March 12, 1997.

g. For so long as CellPro continues to make sales in the ROW pursuant to subparagraph b. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net ROW revenues from such disposable products during said quarter, but not less than $2000 per disposable product. Such incremental profit shall be determined as provided in subparagraph i. hereof, and shall be payable on all such products sold or shipped on or after March 12, 1997.

h. With respect to any SC Systems and LC34 Systems sold or otherwise supplied to a customer anywhere in the world between March 12, 1997 and the effective date of this Order, CellPro shall, within sixty (60) days of the date hereof, pay to plaintiffs its incremental net profit on such devices. If and to the extent that any such devices were sold or otherwise supplied at a price less than the stated list price for such device in the country or region in which the customer is located, less any discount actually given pursuant to a quantity discount schedule or cash discount schedule actually published in such country or region prior to March 12, 1997, such devices shall be conclusively deemed to have been sold at the stated pre-March 12, 1997 list price for the country or region in which the customer is located. In all other respects, incremental profit shall be determined as provided in subparagraph i. hereof.

i. CellPro's incremental profit, as that term is used in subparagraphs f. and g. above shall be deemed to be CellPro's actual total revenues for the relevant products (net of separately-stated freight or insurance charges, permitted discounts, and returns) less its variable cost of sales, as herein defined. CellPro's variable cost of sales shall be deemed to be its variable cost of manufacture (determined in accordance with generally-accepted cost accounting practices, and adjusted for any actual manufacturing variations), plus its variable cost of distribution of such goods. Variable cost of manufacture shall not under any circumstances be calculated to include any general, administrative or overhead expenses, any research and development expenses, or any depreciation or amortization expenses. CellPro's variable cost of distribution for each quarter shall be deemed to include the following expenses only: actual sales commissions paid; a fairly allocated portion of the salary and benefits of any salesperson devoting substantially full time to selling the relevant products; and actual freight charges not billed to the customer.

j. CellPro shall provide plaintiffs' counsel, on a quarterly basis and at the time of payment, and separately with respect to the payments required under subparagraphs f., g. and h. above, with a detailed breakdown of its calculation of its incremental profit in accordance with the above standards, and shall, on request, provide plaintiffs' counsel with supporting documents, data and written explanations. If plaintiffs disagree with CellPro's net sales reports and/or incremental profit calculations with respect to any quarter, they shall be entitled, on request, to have a firm of independent auditors examine CellPro's books and records for the purpose of determining whether such reports and calculations are fair and correct. If in any quarter CellPro is determined to have underpaid the amount due by more than five percent (5%), CellPro shall reimburse plaintiffs for the costs associated with such audit.

k. The Court intends that the limited permission granted to CellPro by the partial stay set forth in subparagraphs a., b. and c. hereof shall be strictly and narrowly construed. If there is any question as to whether a particular activity is permitted under such partial stay, CellPro shall seek approval from plaintiffs' counsel and, if necessary, clarification from the Court, before engaging in such activity.

l. Unless modified by further order, the partial stay permitted by this paragraph 4 shall terminate in accordance with the terms hereof, and without further action by the Court, and the permanent injunction shall thenceforward be in full effect.

5. The Court will retain jurisdiction of the parties and of this matter for the purpose of enforcing and/or modifying the terms of this injunction and/or the terms of the partial stay.

Dated: _____, 1997

_____
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

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:

VIA HAND DELIVERY

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

VIA FEDERAL EXPRESS

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

William J. Marsden, Jr.

Rev. 5/7/97

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.	)	

[PROPOSED]
ORDER FOR PERMANENT INJUNCTION AND PARTIAL STAY OF INJUNCTION

Defendant CellPro, Inc. having been found to have willfully infringed United States Patent Nos. 4,714,680 (the "'680 patent") and 4,965,204 (the "'204 patent"), and said patents having been found to be valid and enforceable, this matter came on to be heard upon plaintiffs' motion for entry of a permanent injunction, and upon consideration thereof, it is hereby ORDERED THAT:

(Prohibitory Portions of Injunction)

1. CellPro, Inc., its subsidiaries, affiliates, distributors and agents, and its and their officers, directors, employees, agents and servants, and all others acting in concert or participation with any of the foregoing who have actual notice of this Order, be, and they hereby are, permanently enjoined and restrained from any and all of the following:

a. From making, having made, selling, supplying, testing, evaluating or using for any purpose whatever, within the United States, and from importing to or exporting from the United States, any CD34 antibody, including but not limited to the 12.8 antibody.

b. From making, having made, selling, supplying, testing, evaluating, maintaining or using for any purpose whatever, within the United States, and from importing to or exporting from the United States, any hybridoma cells capable of producing CD34 antibodies, including but not limited to the 12.8 hybridoma cell line, and from making or having made any master cell bank or working cell bank derived from such hybridoma cells or any clone or subclone thereof.

c. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the CEPRATE LC (CD34) Laboratory Cell Separation System (the "LC34 System"), or any disposable products intended for use therewith.

d. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the CEPRATE SC Stem Cell Concentrator (the "SC System"), or any disposable products intended for use therewith.

e. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any hybridoma cells produced, subcloned or otherwise derived from the 12.8 hybridoma cell line, or any other hybridoma cells produced, subcloned or derived from hybridoma cells originally made in the United States.

f. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any 12.8 antibodies or any other CD34 antibodies produced from hybridoma cells originally made in the United States.

g. From infringing or inducing or contributing to the infringement of any of claims 1, 2, 3, 4, 5 or 6 of the '680 patent until December 22, 2004, by making, using, selling or supplying in the United states, or importing to or exporting from the United States, any infringing suspension of human cells or by making, using or selling any product designed to produce or capable of producing an infringing suspension.

h. From infringing or inducing or contributing to the infringement of claims 1 or 4 of the '204 patent until October 23, 2007, by making, using, selling or supplying in the United States, or importing to or exporting from the United States, any infringing antibody or any infringing hybridoma, or any product which utilizes, or is designed or intended for use with, an infringing antibody.

i. For a period of two (2) years from the date of this Order, from selling or otherwise supplying to customers outside the United States, any product which utilizes or is designed or intended for use with any CD34 antibody.

(Mandatory Portions of Injunction)

IT IS FURTHER ORDERED THAT:

2. CellPro shall take immediate measures to repatriate to the United States (i) all clones or subclones of the 12.8 hybridoma cell line previously exported by it, as well as any further clones or subclones produced therefrom, including without limitation the 12.8 master cell bank hybridoma cells shipped by CellPro to Biomira, Inc.; (ii) all clones or subclones of any other CD34 antibody-producing hybridoma in its possession, custody or control, which hybridoma was first made in the United States by any person, or which, if produced from a hybridoma first made outside the United States, has been used in any way by CellPro at any time within the United States; and (iii) any CD34 antibodies that have been produced outside the United States from any CD34 hybridomas first made in the United States, or which, if produced within the United States, are currently warehoused or stored outside the United States. CellPro shall report to the Court in writing when, and under what circumstances, such repatriation has occurred, and shall certify in writing to the Court at that time that no clones or subclones of the 12.8 hybridoma cell line, or of any other CD34 antibody-producing hybridoma cell line first made in the United States and thereafter used by CellPro, exist anywhere outside the United States, or, if it is unable to so certify, shall explain in detail the reasons for its inability to do so.

3. To the extent that CellPro has possession, custody or control of any CD34 antibodies, including but not limited to the 12.8 antibody, and any hybridoma cells capable of producing CD34 antibodies, including but not limited to the 12.8 hybridoma cell line and clones and subclones thereof, CellPro shall promptly destroy, in the presence of a United States Marshal, all such antibodies and hybridomas, and shall certify in writing to the Court at that time that it no longer has any CD34 antibodies in its possession, custody or control.

(Terms and Conditions of Partial Stay)

IT IS FURTHER ORDERED THAT:

4. The effectiveness of the above Order is hereby stayed as to the following specific activities only, and such partial stay is contingent upon CellPro's good faith compliance with the conditions set forth below:

a. CellPro may continue to make, have made, use and sell SC Systems and disposable products (including the 12.8 antibody) for use with SC Systems, within the United States, until such time as an alternative stem cell concentration device, manufactured under a license under the '204 and '680 patents, is approved for therapeutic use in the United States by the United States Food and Drug Administration (the "FDA Approval Date") and for a period of three months thereafter. During the term of such stay, CellPro shall sell such disposable

products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such customer with any quantity of disposable products in excess of such customer's anticipated short-range needs. During the three month period following FDA approval of a licensed stem cell concentration device, CellPro's total net sales of such disposable products shall not exceed 60% of its average quarterly net sales of such products during the twelve calendar months immediately preceding such FDA approval. The foregoing volume restriction shall not apply to the provision of disposable products solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date.

b. CellPro may continue to sell the 12.8 antibody from the United States, but from no other location, to its customers in the rest of the world outside the United States ("ROW") for use only with SC Systems installed at a customer location on or prior to March 12, 1997, for a period of one (1) year from the date of this Order. During the term of such stay, CellPro shall sell the 12.8 antibody and other disposable products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such customer with any quantity of such antibody or related disposable products in excess of such customer's anticipated short-range needs. During the first three-month period following the date of this Order, CellPro's net sales of disposable products sold for use with the SC system pursuant to this subparagraph shall not exceed its total net sales of such disposable products in the ROW during the last calendar quarter of 1996. Thereafter, such maximum permitted amount shall be reduced by an absolute 25% in each succeeding three-month period, such that in the last three months of permitted sales, CellPro's net sales of such disposable products pursuant to this subparagraph shall not exceed 25% of its total net sales of such disposable products in the ROW during the last calendar quarter of 1996.

c. CellPro may continue to make, have made, use and sell the 12.8 antibody (but no other CD34 antibody), in the United States, solely for use with the SC System in the United States or in the ROW pursuant to the terms of subparagraphs a. and b. hereof, but may not make, have made, use or sell the 12.8 antibody for any other purpose.

d. Any sales by CellPro pursuant to the terms of this partial stay shall be at prices no lower than the prices at which such products were actually sold by CellPro in the ordinary course of its business during the period January 1, 1997 to February 28, 1997 in the relevant country or region, subject to any quantity discount schedule or cash discount schedule which was actually published to customers in such country or region during that period. CellPro shall not engage in any price or other special promotions with respect to any products sold pursuant to this partial stay, nor shall it provide any customer or user with any products at no charge. The provisions of this subparagraph shall not apply to the extent the products are provided solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date.

e. Within forty-five (45) days after the close of each of calendar quarter

(commencing with the quarter ending March 31, 1997), CellPro shall provide a detailed written report to plaintiffs and the Court, which shall include at least the following information:

(1) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro for use with the SC System or with any other device that utilizes CD34 antibodies in the United States during said quarter;

(2) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro sold for use with the SC System or with any other device that utilizes CD34 antibodies in or to the ROW during said quarter; and

(3) the net sales of all SC Systems and other devices that utilize CD34 antibodies, by number of units and dollar volume, stated separately by product code and by geographic area (i.e., US or ROW), during said quarter.

f. For so long as CellPro continues to make sales in the United States pursuant to subparagraph a. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net U.S. revenues from such disposable products during said quarter, but not less than $2000 per disposable product. The foregoing $2000 floor on incremental profit per disposable product shall not apply to products provided on a so-called "cost recovery" basis solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date, and CellPro shall not be required to make any payment of incremental profit to plaintiffs in the case of disposable products that are provided solely for use in such clinical trials where the products, in their entirety, are provided to the user for no charge. The amount of incremental profit shall be determined as provided in subparagraph i. hereof, and, except as otherwise provided in the foregoing sentence, shall be payable on all such products sold or shipped on or after March 12, 1997.

g. For so long as CellPro continues to make sales in the ROW pursuant to subparagraph b. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net ROW revenues from such disposable products during said quarter, but not less than $2000 per disposable product. Such incremental profit shall be determined as provided in subparagraph i. hereof, and shall be payable on all such products sold or shipped on or after March 12, 1997.

h. With respect to any SC Systems, LC34 Systems and any other devices that utilize CD34 antibodies that are sold or otherwise supplied to a customer anywhere in the

world after March 12, 1997, CellPro shall, within sixty (60) days of the date hereof, pay to plaintiffs its incremental net profit on such devices. If and to the extent that any such devices were sold or otherwise supplied at a price less than the stated list price for such device in the country or region in which the customer is located, less any discount actually given pursuant to a quantity discount schedule or cash discount schedule actually published in such country or region prior to March 12, 1997, such devices shall be conclusively deemed to have been sold at the stated pre-March 12, 1997 list price for the country or region in which the customer is located, provided, however, that this sentence shall not apply to SC Systems supplied solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date. In all other respects, incremental profit shall be determined as provided in subparagraph i. hereof.

i. CellPro's incremental profit, as that term is used in subparagraphs f. and g. above shall be deemed to be CellPro's actual total revenues for the relevant products (net of separately-stated freight or insurance charges, permitted discounts, and returns) less its variable cost of sales, as herein defined. CellPro's variable cost of sales shall be deemed to be its variable cost of manufacture (determined in accordance with generally-accepted cost accounting practices, and adjusted for any actual manufacturing variations), plus its variable cost of distribution of such goods. Variable cost of manufacture shall not under any circumstances be calculated to include any general, administrative or overhead expenses, any research and development expenses, or any depreciation or amortization expenses. CellPro's variable cost of distribution for each quarter shall be deemed to include the following expenses only: actual sales commissions paid; a fairly allocated portion of the salary and benefits of any salesperson devoting substantially full time to selling the relevant products; and actual freight charges not billed to the customer.

j. CellPro shall provide plaintiffs' counsel, on a quarterly basis and at the time of payment, and separately with respect to the payments required under subparagraphs f., g. and h. above, with a detailed breakdown of its calculation of its incremental profit in accordance with the above standards, and shall, on request, provide plaintiffs' counsel with supporting documents, data and written explanations. If plaintiffs disagree with CellPro's net sales reports and/or incremental profit calculations with respect to any quarter, they shall be entitled, on request, to have a firm of independent auditors examine CellPro's books and records for the purpose of determining whether such reports and calculations are fair and correct. If in any quarter CellPro is determined to have underpaid the amount due by more than five percent (5%), CellPro shall reimburse plaintiffs for the costs associated with such audit.

k. The Court intends that the limited permission granted to CellPro by the partial stay set forth in subparagraphs a., b. and c. hereof shall be strictly and narrowly construed. If there is any question as to whether a particular activity is permitted under such partial stay, CellPro shall seek approval from plaintiffs' counsel and, if necessary, clarification from the Court, before engaging in such activity.

l. Unless modified by further order, the partial stay permitted by this paragraph 4 shall terminate in accordance with the terms hereof, and without further action by the Court, and the permanent injunction shall thenceforward be in full effect.

5. The Court will retain jurisdiction of the parties and of this matter for the purpose of enforcing and/or modifying the terms of this injunction and/or the terms of the partial stay.

Dated: _____, 1997

_____
UNITED STATES DISTRICT JUDGE

Supplement

(Kristen F. Houser)

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, BAXTER HEALTHCARE CORPORATION, and BECTON DICKINSON AND COMPANY,	§	
Plaintiffs,	§	
v.	§	Civil Action No. 94-105-RRM
CELLPRO,	§	
Defendant.	§	

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR A PERMANENT INJUNCTION

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Dated: April 28, 1997

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I. INTRODUCTION

In its brief in opposition to plaintiffs' motion for entry of a permanent injunction, CellPro plays out the final piece of the litigation strategy devised by Thomas Kiley in 1992 when he elected to sue rather than to negotiate a license under the patents. That strategy had as its premise that CellPro would never be enjoined from selling infringing products, because those products are used in treating cancer patients. According to this strategy, a finding of infringement would be merely an inconvenience, and the "worst case scenario" would be having to pay a "stiff royalty" on the infringing sales. PTX 79.

The Court should not let CellPro succeed in this cynical strategy. Were it to do so, companies in the medical products field could disregard patents with impunity. Even an award of treble damages and attorneys' fees will have little impact on a company that was able to raise $160 million by exploiting Dr. Civin's patented inventions and was willing to spend $10 million or so on its bad faith challenge to the patents.

Enforcing plaintiffs' patent rights here will not "kill cancer patients," as CellPro would have the Court believe. Plaintiffs are three distinguished and responsible institutions that have devoted themselves to saving the lives of patients over the course of this entire century. In their dedication to patient care, they stand second to none. Although legally they are entitled to an immediate permanent injunction against any further sales of CellPro's infringing products, they have worked hard to craft a form of injunction and temporary stay to assure that no patient in need will be deprived of the technology that Dr. Civin discovered and made available to the public by the disclosure of his inventions.

Contrary to CellPro's assertions, plaintiffs do not propose to shut down CellPro's current clinical trials, nor have they ever suggested that CellPro should "confiscate"

CEPRATE® SC devices currently installed in hospitals, as CellPro has recently asserted in press releases aimed at cancer patients currently enrolled in those trials. As discussed below, plaintiffs do not object to the completion of CellPro's clinical trials, and the two dozen clinician declarations that CellPro obtained even before plaintiffs filed their injunction papers were entirely unnecessary.

CellPro cannot, however, expect to go on selling infringing products forever. Whatever the final form of the injunction, and whatever the scope and timing of any stay, the end point must be a permanent injunction. CellPro is not the only company in the United States capable of producing a safe and effective stem cell selection device, and where a licensee under the patents has itself developed such a product, CellPro must be required, following an appropriate transition period, to cease infringement.

II. SUMMARY OF ARGUMENT

1. Plaintiffs' do not propose to curtail CellPro's provision of disposable products to clinicians engaged in ongoing clinical trials that have received FDA and IRB approval. CellPro should not be allowed, however, to supply products for new clinical trials, where Baxter's product is equally available for use.

2. CellPro's argument that the Court should deny injunctive relief on public interest grounds is untenable. The partial stay proposed by plaintiffs fully addresses the short-term concerns raised by CellPro by providing a reasonable transition period to Baxter's licensed product. CellPro's disparaging comments about Baxter's product are unsupported by competent evidence, and are contradicted by the testimony of reputable clinicians in the United States and abroad. Indeed, a number of clinicians who have used both CellPro's SC device and the current version of Baxter's Isolex® system attest to the fact that Baxter's system is easier to use and provides superior results. Baxter has filed

a comprehensive PMA with the FDA requesting FDA approval of its product, and the prospects of approval within a reasonable time frame are excellent. CellPro's arguments for denying injunctive relief are transparently self-serving and cast aside entirely the public interest in enforcing valid patents against willful infringers.

3. CellPro's objections with respect to the scope of the injunction and the terms of the partial stay, including the calculation of incremental profit, are unfounded.

4. The proposed two-year restriction on sales of infringing products outside the United States is well within the Court's equitable powers to remedy past infringement and restore plaintiffs to the position they would have enjoyed had the infringement not occurred.

5. The Court likewise has power to order the return of the 12.8 hybridoma that CellPro shipped out of the country in 1993, after the '204 patent issued, in a misguided attempt to evade the United States patent laws.

6. The Court should proceed to enter a final judgment, including a permanent injunction. If CellPro refuses to withdraw its baseless patent misuse defense, the Court should establish a briefing schedule to dispose of it as a matter of law.

7. The Court should not stay the injunction pending appeal. CellPro should not be permitted to forestall the grant of equitable relief after willfully infringing the patents for more than a third of their lives. The partial stay proposed by plaintiffs adequately protects the public and represents a reasonable accommodation of competing interests.

III. ARGUMENT

A. Under the Proposed Stay of the Permanent Injunction, CellPro Will Be Permitted to Continue its Current Clinical Trials.

CellPro's brief in opposition to plaintiffs' motion for a permanent injunction focuses almost entirely on the effect of the injunction on its clinical trials. In support of its brief, CellPro submitted two dozen declarations of clinicians involved in clinical trials attesting to the importance of the trials (the majority of them signed before plaintiffs had even submitted their proposed injunction), and suggesting that there would be practical difficulties in substituting Baxter's Isolex® system for the CellPro device in the midst of those trials. These arguments are irrelevant, because plaintiffs do not object to the clinicians completing their current clinical trials.

In general, the proposed stay of the injunction was designed to permit CellPro to continue selling disposable products to existing users of its SC device pending FDA approval of Baxter's device, conditioned upon payment to plaintiffs of CellPro's incremental profit in order to prevent CellPro from benefitting financially from its continued willful infringement. Out of concern that CellPro might decide to dump its product on the commercial market at a much reduced (or nonexistent) price in order to avoid payments to plaintiffs, plaintiffs' proposed order included a restriction against selling the product at prices below the prices at which such products were sold in the ordinary course of business in January and February 1997. [Proposed] Order for Permanent Injunction and Partial Stay of Injunction (hereafter, "Proposed Order"), ¶ 4.d.[1] Subparagraph 4.d. of the Proposed Order also included language to forbid granting special discounts to customers or providing them with the product at no charge.

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[1] A copy of the Proposed Order is attached to plaintiffs' motion (D.I. 860).

These price-cutting protections were drafted having in mind CellPro's commercial sales of the SC device. In drafting the language, it was not plaintiffs' intent to preclude the continued use of CellPro's SC device in ongoing FDA-approved clinical trials, where CellPro is required to provide products either for free or at a so-called "cost-recovery" price. To avoid any misunderstanding, plaintiffs have revised the Proposed Order to make clear that under the stay, CellPro can continue to supply products for use in current clinical trials, where the trial has already received FDA and IRB (institutional review board) approval. (A copy of the Proposed Order, as revised, is attached hereto as Exhibit A.)

Plaintiffs do not agree, however, that from this point forward, CellPro should be permitted to sponsor or participate in new clinical trials, not yet approved by the FDA. An investigator who is considering investigation of the efficacy of stem cell selection for indications that are not encompassed by CellPro's FDA approval has a choice of two products that can be used under an approved IDE to perform the CD34+ selection step: CellPro's product or Baxter's product. There is no compelling reason why the investigator must submit an IDE for CellPro's device rather than Baxter's device, since the latter is equally available and in fact is already in use in numerous FDA-approved clinical trials. Indeed, a review of the sites currently conducting clinical trials using CellPro's device reveals that at least thirteen of the institutions have participated in or are currently conducting a clinical trial using Baxter's device. Compare Jacobs Decl., Exh. B with Declaration of Kristin F. Houser (submitted herewith), ¶ 9. These institutions thus are in possession of, and fully trained on, the Baxter system, and there is no reason they cannot use it in future trials.

Moreover, if CellPro were permitted indefinitely to sponsor IDE's for use of its infringing product in clinical trials, then even after Baxter's product receives FDA approval, CellPro would be in a position to disrupt the market for Baxter's product for years to come. It could simply treat its SC device as a loss leader, making it available to clinicians for use in a never-ending series of clinical trials for free or at a cost recovery price. The result would be to limit the training of additional clinicians on Baxter's device and effectively to undermine Baxter's ability to sell its product to clinicians at commercial prices.

In short, under plaintiffs' Proposed Order, CellPro will be permitted to continue through completion all current FDA- and IRB-approved clinical trials. CellPro should not, however, be permitted to initiate new clinical trials for which Baxter's product is equally available.[2]

B. The Proposed Order Is Carefully Tailored to Protect the Public Interest.

CellPro's argument that no injunctive relief should be awarded on public interest grounds is self-serving and unfounded. Its attempts to disparage Baxter's Isolex® product and its wishful speculation that the product will not be approved by the FDA have no basis in fact. And its self-appointed role as protector of the public interest completely ignores the public interest in maintaining the integrity of the patent system.

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[2] If a showing is made that the Baxter device cannot be used in a particular clinical trial hereafter proposed, plaintiffs are prepared to consider a stay of the injunction as to that trial in order to permit CellPro to sponsor and support the proposed trial under the terms of the Proposed Order.

1. Plaintiffs' Proposed Order Satisfies the Public Health Concerns Raised by CellPro.

CellPro has attempted to cloud the issue of injunctive relief by filing a blizzard of declarations from clinicians currently using CellPro's SC device in clinical trials. For several reasons, the Court should give these declarations no weight in considering plaintiffs' Proposed Order. Even if they are considered, the Proposed Order satisfies the very concerns they raise.

First, as discussed in plaintiffs' accompanying motion to strike, the declarations are not properly before the Court. The declarants were not disclosed as witnesses in the Pretrial Order, nor were the facts upon which they rely. They have never been subjected to cross examination. There was never any suggestion from the Court that the matter of injunctive relief was to be decided on the basis of new testimonial evidence not presented during the trial and not disclosed in the Pretrial Order. Further, although CellPro obtained many of the declarations as early as March, it withheld them from plaintiffs for weeks so as to leave plaintiffs with only three business days to respond to them — yet another instance of CellPro's abusive litigation tactics. In these circumstances, the Court should disregard them. See Shiley, Inc. v. Bentley Labs. Inc., 601 F. Supp. 964, 970 (C.D. Cal. 1985), cert denied, 479 U.S. 1087 (1987).

Second, the declarations are beside the point. They nearly all focus on the potential hardship of an immediate injunction shutting down current clinical trials, which plaintiffs are not requesting.

Third, for the most part, the substance of the declarations amounts to nothing more than a statement that stem cell selection is valuable for cancer treatment — a proposition with which plaintiffs do not disagree — and an endorsement of CellPro's

product as suitable for that use. Only a handful of the clinicians purport to have any knowledge concerning Baxter's product; the rest say nothing to suggest that the needs they describe could not equally be met by the Baxter product, assuming adequate time to make the transition. The Proposed Order satisfies the latter concern by permitting CellPro to continue supplying its current SC customers pending FDA approval of Baxter's device, and by permitting the clinicians to complete all currently-approved clinical trials.

No doubt there are some clinicians who have become accustomed to using the CellPro device and would prefer not to make a switch. But the issue before the Court is not how many doctors would vote to keep the CellPro device on the market given the choice. Such preference is not a valid basis for permitting a willful infringer to escape enforcement of the patent laws.

2. CellPro's Disparagement of Baxter's Isolex® System Lacks Any Factual Basis.

Throughout its brief, CellPro refers to Baxter's Isolex® system as "still experimental" and disparages it as "problem-plagued" in ways that sound suspiciously like the tactics employed by CellPro's sales representatives in the field. These allegations are wholly unfounded and should be disregarded in considering plaintiffs' right to injunctive relief.

As noted above, of the twenty-six clinician declarations filed by CellPro, the vast majority offer no testimony at all about the capabilities of the Baxter device. Many of those who do comment on the Baxter device provide no foundation to show that they are competent to testify about it. Dr. Burns, for example, states that he "formed an impression" based on "inquiries" of unidentified persons in the field. The declarations

of several others who offer opinions on the Baxter device similarly fail to show actual hands-on experience with it in clinical treatment procedures.

Those that comment on the Baxter device assert mainly that it was slower and more labor intensive than CellPro's SC device. (Burns Decl. ¶ 5; Burt Decl. ¶ 8; Calderwood Decl. ¶ 9; Champlin Decl. ¶ 7; DiPersio Decl. ¶ 9; Hesdorffer Decl. ¶ 5). These assertions are irrelevant. Speed and ease of use implicate labor cost and convenience, not public health. Moreover, it is apparent from the declarations that in each instance, the declarant is referring to the earlier version of the Isolex® system, the 300 SA. In submitting these declarations, CellPro omits mention of the fact (well known to CellPro) that in 1996, Baxter replaced the 300 SA version of the product with a much faster, automated version, the 300i, which is not mentioned in any of CellPro's declarations.

As explained in the declaration of Dr. Bonnie J. Mills, filed herewith, the 300i automates the cell processing to reduce the processing time and make the system easier to use. Mills Decl. ¶ 4. Baxter has in fact substituted the 300i for the old 300 SA in all United States sites. Id. In doing so, it amended the applicable IDE's without objection from the FDA, since the amendment raised no issues of safety or efficacy. Id. Contrary to CellPro's assertions, Baxter has ample supply of 300i devices. Houser Decl. ¶ 8.

To ensure that the record does not reflect the false impression that CellPro has sought to leave with the Court, plaintiffs are submitting the declarations of several clinicians who have actual hands-on experience with the Isolex® 300 system, including both the earlier 300 SA version and the current 300i version, in clinical treatment of

cancer patients.[3] These declarations were obtained on very short notice, plaintiffs' counsel having received CellPro's declarations only three business days ago. If the Court believes it would be helpful, plaintiffs are prepared to submit additional ones. These declarations are based on the clinician's actual use of Baxter's Isolex® system in both autologous and allogeneic transplant procedures. Moreover, several of the clinicians have used both the Baxter and the CellPro systems in clinical procedures and can attest to the comparative attributes of the two.

Dr. Robert A. Preti, for example, has used both versions of the Isolex® system in stem cell transplants at the New York Blood Center and the Hackensack Medical Center, including use of the system in four different FDA-approved clinical trials in which he is the Principal Investigator or Laboratory Investigator. He states:

> My experiences with the two Baxter devices have been entirely satisfactory. We have seen no delayed engraftment following any of the procedures. Yields and purities of CD34+ cells have been very good with the exception of one procedure that produced very high yield (82%) at the expense of relatively poor purity (77.8%). In recent trials using the 300i with breast cancer patients mobilized with chemotherapy, we have achieved CD34+ purities in the range of 95-99.5%.

Preti Decl. ¶4.

Dr. James Vredenburgh, of Duke University Medical Center, has used both the 300 SA and the 300i in treatment of breast cancer patients. Vredenburgh Decl. ¶ 3. Duke Medical Center has performed more transplants in breast cancer patients than any other medical center in the world, and draws patients from all fifty states and foreign

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[3] In submitting these declarations, plaintiffs do not waive their objection to the Court's consideration of CellPro's declarations, for the reasons stated above.

countries. He describes the 300i as "very easy to use." Id. ¶ 4. He adds that Duke Medical Center's experience with the Baxter 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.

Id. ¶ 5. Similar statements are made in declarations of Dr. Kenneth Carnetta, Dr. Bo Björkstrand, and Dr. Joan Garcia Lopez. Each of the declarants expects to continue using the Baxter product, notwithstanding CellPro's recent FDA approval for use of the SC device in autologous bone marrow transplantation in the United States and the availability of the SC device in Europe.

Dr. Preti has also used CellPro's SC device in transplant procedures. Based on his comparison of the SC and the 300i, his preference is for the Baxter device:

> In comparing the Isolex®300i with the CEPRATE® SC, I would say, first, that the overall processing time is virtually identical. The advantage of the Baxter device is that it is more fully automated than the CellPro device, which requires some additional manual operations that must be performed by a technician. This difference in automation frees up an additional 2 hours of technician time, during which the operator is able to perform other laboratory functions. Further, the Baxter device in our hands has more consistently provided high purities and recoveries of CD34+ cells. For these reasons, my preference is to use the Baxter device rather than the CellPro device in future procedures.

Preti Decl. ¶ 5.

Dr. Björkstrand has also used both companies' products. In fact, his hospital is currently conducting a pilot program to compare the results of CellPro's SC device and Baxter's Isolex® 300i in treatment of patients with neuroblastoma, acute lymphoblastic leukemia, multiple myeloma, and breast cancer. For each patient, the hospital processed

one-half of the aspirated blood or bone marrow in the CellPro device and one-half in the Baxter device, and Dr. Björkstrand thereby compared the performance and capabilities of both systems. His conclusion:

> As far as ease of use, the Baxter system is more fully automated and easier to use than the CellPro system. As far as purity and yield of CD34+ cells, our experience has been that the Baxter system consistently provides higher purity and yield than the CellPro system.

Björkstrand Decl. ¶ 6. He adds that neither system has presented toxicity problems; as to CellPro's conjecture that the paramagnetic beads used in the Baxter system might be toxic to patients, he states that he has "no concern" in this regard. Id. at ¶ 7. Even though his hospital has used the CellPro system since 1992, his ultimate conclusion is that the Baxter system "gives us better results" and that "we expect to continue using the Baxter system in the future." Id. ¶ 8.

In its brief, CellPro argues that FDA approval of its system gives it advantages to clinicians, such as the possibility of using it for "off-label" indications. CellPro is not legally permitted to market its system for off-label use. Moreover, Dr. Preti points out that in view of the very narrow indication for which the CellPro device was approved, "it is not yet clear that the FDA approves of the off-label use of this device for stem cell sources and/or indications for which it has not been approved." Preti Decl. ¶ 6.[4] Dr. Vredenburgh of Duke Medical Center adds that even though CellPro installed its SC device at Duke in 1995 and provided training in its use,

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[4] CellPro's SC device is approved only for autologous transplants using bone marrow. As Dr. Vredenburgh notes, more than 85% of transplants performed today use peripheral blood, not bone marrow, as the source of stem cells. Vredenburgh Decl. ¶ 7.

> [w]e gave no consideration to switching to the CellPro device when it received FDA approval 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.

Vredenburgh Decl. ¶ 6.[5]

In addition to the clinician declarations, Baxter has also provided the Court a list of more than forty sites in North America that have obtained Baxter's Isolex® system for use in stem cell selection procedures. These sites include, for example, Columbia Medical Center, Children's Memorial Hospital in Chicago, MD Anderson Cancer Center in Texas, UCLA Medical Center, Yale University School of Medicine, the National Institutes of Health, and the Fred Hutchinson Cancer Research Center, the very institution in which CellPro's avidin-biotin technology was developed. Houser Decl. ¶ 9. CellPro's attempt to disparage the quality of the Isolex® system has no basis in fact.

3. CellPro's Speculation that Baxter's Isolex® System Will Not Receive FDA Approval is Unfounded.

CellPro's brief also offers speculation and rumor that Baxter's device is unlikely to obtain FDA approval for years to come, if ever. In addition to disparaging the product itself, CellPro suggests that Baxter filed its PMA with the FDA in February in

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[5] CellPro's argument about the difficulty in getting clinicians to use a device that is not FDA-approved overlooks, of course, the fact that CellPro's device was not FDA-approved until December 1996, yet all of CellPro's declarants sought and obtained FDA authorization to use it. It also ignores the fact that clinicians still need to obtain FDA authorization to use CellPro's device in trials for non-approved indications, which remain "experimental" from the FDA's perspective. In this respect, both CellPro and Baxter are in the same boat.

as a mere litigation ploy, and that the quality of the filing is poor. CellPro has no foundation whatsoever for these allegations, which are simply wishful thinking.

So that the record is clear, plaintiffs have submitted the declaration of Baxter's Dr. Bonnie Mills, who addresses the FDA filing. CellPro's suggestion that the filing occurred hastily for purposes of litigation is preposterous in the circumstances: as Dr. Mills explains, the PMA submission consists of 56 volumes of text and data, amounting to 20,000 pages of information. Baxter in fact made the decision to proceed with a PMA submission following a meeting with FDA officials in May, 1996, and originally hoped to file the PMA by the end of the year. Baxter delayed the filing in order to review with FDA staff, including an FDA statistician, the methodological approach which Baxter planned to use in analyzing the data supporting its PMA. In November 1996, the FDA accepted in principle Baxter's statistical model and its proposed use of data from a randomized breast cancer study as the basis for PMA approval. Baxter then proceeded with the data analysis and filed the PMA as soon as possible after completing the analysis and assembling the massive supporting information and data that underlay the submission. Mills Decl. ¶¶ 5-6.

CellPro's insinuation that the filing is of poor quality and unlikely to be accepted was made with no knowledge of the background of the submission or Baxter's extensive discussions with the FDA. Id. ¶ 5. Had the FDA agreed with CellPro's assessment of the filing, it could have rejected the filing as insufficient to permit substantive review. It did not. As Dr. Mills explains:

> Baxter's approach, involving extensive advance discussions with the FDA concerning Baxter's clinical data and its proposed statistical model for data analysis paid off earlier this month. By letter dated April 9, 1997, the FDA formally accepted Baxter's PMA submission as sufficient to permit substantive review as is, with February 24 as the filing date. As we

> understand it, the PMA will go through a review cycle of approximately six months. Consistent with this understanding, the FDA has advised Baxter that it will conduct a mid-cycle review meeting concerning Baxter's PMA in May. We believe, based upon our informal discussions with FDA staff, that the PMA is on track for approval by the end of 1997.

Id. ¶ 7.

CellPro next argues that even FDA approval is not good enough, because the approval might be for some indications only. Br. at 22 n.5. CellPro is talking out of both sides of its mouth. CellPro's device itself is approved only for autologous transplants, and only for transplants of bone marrow, a very narrow indication given that 85% or more of transplants today use peripheral blood stem cells rather than bone marrow. Vredenburgh Decl. ¶ 7. Yet CellPro touts its own FDA approval as offering clinicians the ability to use the device for "off-label" indications of every sort. CellPro cannot have it both ways.

Finally, CellPro's speculation about the timing of FDA approval is beside the point. If the FDA approval is delayed, the full force of the injunction will simply be stayed that much longer. Clearly this is not a case where the licensee is not practicing the patent, or where the chances of the licensee's obtaining approval to sell its product are remote. CellPro's insinuations do not support denial of injunctive relief.

4. CellPro Ignores the Strong Public Interest in Enforcing Patent Rights Against Willful Infringement.

As expected, CellPro's brief gives short shrift to the public interest in enforcing patents, particularly against willful infringers. Plaintiffs discussed the case law at length in their opening brief, including cases granting even preliminary injunctions against infringing sales of medical products that provided important public health benefits.

CellPro chooses to ignore all these cases, and instead reaches back to the 1930s and 1940s to find cases — easily distinguishable from this one — denying injunctive relief to patentees for public health reasons. The fact is, courts in the modern era simply do not grant compulsory licenses to infringers.[6] CellPro has only itself to blame for not recognizing the risk it assumed in 1992 when it made a calculated business decision to pursue a "winner-take-all" litigation strategy, instead of negotiating a license and agreeing to pay royalties to assure its ability to provide patient care. Based on the evidence from that time period, it appears that when it adopted that strategy, the patient-centered philosophy it espouses today took back seat to the lofty financial objectives of CellPro's investors.

C. CellPro's Objections to the Scope of the Injunction and the Terms of the Partial Stay Within the United States are Groundless.

1. Objections relating to CellPro's clinical trials.

Most of CellPro's brief is devoted to its misplaced alarm about the effect of the Proposed Order on ongoing clinical trials. As noted above, plaintiffs have revised the form of the order to make clear that it is not intended to prevent CellPro from continuing to supply clinicians for currently approved clinical trials using CellPro's SC device.

In addition to its public interest argument, CellPro asserts that any injunction affecting its clinical trials is barred by 35 U.S.C. § 271(e)(3). This argument is spurious,

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[6] CellPro cites Foster v. American Mach. & Foundry Co., 492 F.2d 1317, 1324 (2d Cir. 1974), a case that precedes the creation of the Federal Circuit by nearly a decade. That case is no help to CellPro; the rationale for permitting a compulsory license there was that the patentee had "utterly failed" to exploit the patent on his own. E.I. duPont de Nemours and Co. v. Phillips Petroleum Co., 835 F.2d 277, 278 (Fed. Cir. 1987), also cited by CellPro did not involve a compulsory license, but only the stay of an injunction pending appeal based on a balancing of harms in the short term.

because CellPro never asserted a § 271(e) defense with respect to its provision of products for use in clinical trials.

CellPro's argument overlooks the fact that § 271(e) is a defense to liability that must be pleaded and proved. CellPro elected not to raise a § 271(e) defense in its answer to the amended complaint (D.I. 621 Nov. 1996), and it did not assert a § 271(e) defense in the Pretrial Order (D.I. 714). As its counsel conceded in a written filing on March 13, 1997, "CellPro has not asserted a defense to liability or damages on the basis of § 271(e)(1)." D.I. 846. CellPro waived any right to contend that its clinical trial activities are protected under § 271(e)(1), and therefore § 271(e)(3) is inapplicable.

CellPro cannot seriously mean to suggest that it should be permitted to present evidence to contest the scope of the injunction under § 271(e) in yet another trial. CellPro was well aware during the recent trial of its need to offer evidence on defenses that were to be decided by the Court rather than the jury. With respect to the scope of injunctive relief, CellPro expressly listed in the Pretrial Order, in its Statement of Issues of Law to be Tried, "Whether, in view of the nature of CellPro's products any injunction is warranted and, if so, the appropriate scope of that injunction." D.I. 714, Tab 4, ¶ 7. The scope of the injunction was thus plainly an issue for trial, yet nowhere did CellPro preserve the right to offer proof that any of its activities were noninfringing under § 271(e). See Eli Lilly & Co. v. Medtronic, Inc., 915 F.2d 670, 674 (Fed. Cir. 1990) (where defendant has raised § 271(e) defense, court must make liability determination as to whether activities are exempt prior to entry of injunction).

It should be noted that evaluating the applicability of § 271(e) to particular activities requires a detailed factual inquiry; § 271(e) does not come into play merely because an infringer files an IDE with the FDA. By its express terms, § 271(e) applies

only if the defendant proves that it has made, used or sold the patented invention "solely" for uses reasonably related to the development and submission of information required for FDA approval. This question presents an issue of fact. See Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989) (remanding to district court for determination of fact issue of whether "Medtronic's use of its devices was 'solely for purposes reasonably related to submission of information' to the FDA"), aff'd 496 U.S. 661 (1990); Amgen, Inc. v. Elanex Pharmaceuticals, Inc., 1996 WL 84590 at *4 (W.D. Wash. 1996) (§ 271(e) requires proof that defendant's activities are "solely for purposes of seeking FDA approval); Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (holding that defendant's uses of the patented invention, which included development of commercial-scale manufacturing process, were not "solely related" to meeting FDA requirement).

Here, had CellPro raised a § 271(e) defense, it could not have prevailed as a factual matter. For several years now, CellPro's making and using of the 12.8 antibody has supported various uses unrelated to FDA reporting requirements. These include sales of the SC device in Europe, where CellPro has derived most of its revenue, and more recently commercial sales in the United States pursuant to the FDA's approval. In these circumstances, CellPro's use of the patented inventions was not "solely" for uses related to FDA reporting requirements, and CellPro wisely decided not to pursue that claim at trial.

2. Objections relating to the injunction against infringement of the '680 patent.

CellPro argues that the proposed injunction is overly broad with respect to the '680 patent because CellPro has added a customer notice to its product literature recommending

that customers not operate the SC device "to obtain cell suspensions of 90% or greater purity." Br. at 38 and Kenney Decl. ¶ 4. According to CellPro, this means that CellPro is no longer inducing infringement of the '680 patent.

Since every sale includes a sale of the 12.8 antibody and thereby infringes the '204 patent as well, this issue is purely hypothetical. CellPro's argument, however, is specious. CellPro has done nothing to alter the device itself, nor has it changed the operating instructions or given the user any information that would permit operation of the device in a manner that would reduce the purities of the cell suspensions. Users are motivated to obtain the highest purity possible, and by offering a device that has been shown to produce infringing cell suspensions, CellPro is clearly inducing these users to infringe.[7] Inducement of infringement cannot be overcome by a wink and a nod where both CellPro and the user know it will have no effect on actual infringing uses of the device. See, e.g., American Standard Inc. v. Pfizer, Inc., 722 F. Supp. 86, 103 (D. Del. 1989) ("it is well settled that the mere labeling of a product to advise customers of an allegedly noninfringing use of the product is insufficient as a matter of law to avoid infringement").

3. Objections to plaintiffs' proposal that CellPro pay them CellPro's incremental profit on infringing sales made pursuant to any stay.

If and to the extent that the Court permits CellPro to continue selling 12.8 disposable products for therapeutic uses,[8] CellPro should be required to pay to plaintiffs

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[7] There is no merit to CellPro's contention that Baxter "concedes" CellPro cannot infringe the '680 patent. Br. at 39. The Baxter advertisement in question merely quotes CellPro's own assertions to support Baxter's advertising claim that the performance of the Isolex® 300i "compares favorably with any existing commercial product." Kenney Decl. ¶ 3 and Exh. A.

[8] CellPro has not attempted to justify continued sales of other infringing products, such as the LC34 laboratory column, that are sold for non-therapeutic uses.

its incremental profit on those sales. As is explained in the Declaration of Professor Jerry A. Hausman, filed herewith, incremental profit is determined by subtracting from the revenues received an amount equal to the average incremental cost (AIC) of the particular sales in question. As Professor Hausman points out, allowing CellPro to recover its average incremental cost will ensure that it is not "net out of pocket"; conversely, if the stay were more generous, any additional amount would contribute to the costs of CellPro's overhead, research and development, and other operations. See Hausman Decl. at ¶¶ 12-13. Plaintiffs submit that CellPro should receive no economic benefit from a stay.[9]

The "contribution margin" figures proposed by CellPro's expert William E. Simpson in his declaration are inaccurate, and should not be relied on by the Court. First, Simpson has included an entire year's worth of costs in his calculation, ignoring the fact that CellPro was only selling therapeutic products in the United States for the last quarter of the fiscal year. This oversight has the effect of significantly overstating CellPro's current per-unit cost of sales. Hausman Decl. at ¶¶ 7-9. In addition, the cost data used by Simpson relate to all 12.8 products, not only the 12.8 therapeutic disposables: i.e., they include the total cost of manufacturing the CEPRATE SC device itself, the LC34 laboratory column and disposables, disposables being supplied to researchers and clinicians free of charge, as well as any other CD-34 based products which CellPro may be manufacturing. These costs are not relevant to the incremental cost of making and selling 12.8 disposables for therapeutic uses. Hausman Decl. ¶ 9 (second bullet). The

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[9] Where CellPro is supplying disposables to a clinician on a "cost recovery" basis, and the amount it receives exceeds the AIC of products supplied, it *should pay its* incremental profit to plaintiffs just as it would in the case of a commercial sale.

Simpson calculations also include virtually all costs associated with CellPro's sales and marketing organization, including costs which are clearly part of sales and marketing overhead, as well as the substantial cost associated with CellPro's practice of giving away CEPRATE SC devices to develop a market for the disposable products. These costs are not direct costs of making and selling the 12.8 disposables. Hausman Decl. ¶ 9 (final bullet). CellPro's average revenue data also appear to be inaccurate; at the very least the figure given is inconsistent with the revenue data previously supplied to plaintiffs in the document admitted as PTX 913. Hausman Decl. ¶ 10.[10]

In fact, the Simpson declaration simply confirms CellPro's disposition to play "accounting games." It was this concern which prompted plaintiffs to propose that CellPro be required to pay a minimum of $2,000 for each therapeutic disposable product sold pursuant to a stay. As Professor Hausman states, even the incomplete data provided by Simpson suggest that the $2,000 minimum is a reasonable one. Hausman Decl. ¶ 11.[11]

Finally, Professor Hausman addresses the issue of whether CellPro will have any incentive to continue selling if it is limited to recovering its incremental cost on sales of the therapeutic disposables:

> CellPro has substantial business and market incentives to continue selling therapeutic disposables to the U.S. therapeutic market even if those sales make no contribution

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[10] Plaintiffs' critique of the Simpson declaration could be further extended -- it is based for example, on the arbitrary assumption that manufacturing and selling costs are constant as to all of CellPro's products -- but submit that Professor Hausman's declaration is sufficient to show the inherent unreliability of the calculations made by Mr. Simpson.

[11] Plaintiffs' proposed injunction does not place any cap on the amount CellPro can charge for its product.

> to R&D or to corporate overhead expenses. Companies with $50-$60 million in cash that find themselves blocked in one endeavor do not typically go out of business; rather, they seek to develop other, related products or services which build on the technological and human capital they have already developed, or they acquire new product lines or technology through purchase, licensing or joint venture. While this transition is taking place, however, CellPro has a very strong incentive to remain active and visible in the marketplace, developing and cementing relationships with researchers, customers and potential customers, as well as public awareness of the company. Consequently, provided CellPro does not suffer any direct, immediate loss as a result of each incremental sale (i.e., if its recovers its incremental cost), CellPro has a significant economic incentive to continue selling its therapeutic disposable products.

Hausman Decl. ¶ 14.

D. The Court May Properly Grant Equitable Relief, Limited in Duration, that Restricts CellPro's Sales Outside the United States as a Remedy for Past Infringement in the United States.

In objecting to the proposed two-year injunction against sales of CD34 products outside the United States, CellPro claims that plaintiffs improperly seek to extend their U.S. patent rights to foreign countries. This is a purely rhetorical argument, and is based on a misapprehension of the legal and practical premises of plaintiffs' contention.

First, plaintiffs do not seek to, and indeed cannot, acquire corresponding patent rights in any foreign country. Any person or entity, other than CellPro or someone acting on its behalf, is entirely free to make and sell CD34 products anywhere outside the United States.

Second, except with respect to sales of the 12.8 antibody, which is dealt with in a separate provision of the Proposed Order, plaintiffs do not seek ex-U.S. relief as an injunction against future infringement by CellPro. Rather, this request for relief is addressed to the Court's general equitable powers to provide redress for past wrongdoing.

The equity powers of a federal court are not confined to prohibition of future wrongdoing; rather, they are broad and remedial in nature, and may be used creatively in an effort to restore the parties to the position they would have been in had the wrongdoing not occurred.[12]

This case provides particularly compelling circumstances for use of the Court's equitable powers. Through willful infringement of the Civin patents, including research and development of the infringing products, and their subsequent manufacture and export abroad, CellPro's infringing acts in the United States have enabled it to make substantial inroads into foreign markets. But for CellPro's infringing conduct in the United States, CellPro would not have been able to develop its products or obtain regulatory approval and market acceptance in the rest of the world. Under that circumstance, and given that no other competitor has emerged to date, Baxter would not in fact have faced competition outside the United States for its own CD34 based products.

Had CellPro not engaged in willful patent infringement in this country, it would have to start its efforts to manufacture and sell abroad from scratch. But if CellPro is now permitted without interruption to manufacture and sell abroad, or to convert its unjustly-obtained foreign customers to a system manufactured outside the United States that uses a CD34 antibody other than the 12.8 antibody, it will be building on (i) an

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[12] In trade secret cases, for example, it is common not only to permanently enjoin future use of misappropriated information, but to temporarily bar the defendant from selling even independently-developed products for a period of time equal to the head start which the defendant improperly obtained. E.g., General Elec. Co. v. Sung, 843 F. Supp. 776, 778-81 (D. Mass. 1994) (granting "production" injunction); Lamb-Weston, Inc. v. McCain Foods Ltd., 941 F 2d 980, 974 (9th Cir. 1991) (upholding worldwide inunction "to eliminate any head start the defendant may have gained"); Viscofan S.A. v. Int'l Trade Comm'n, 787 F. 2d 544, 550-551 (Fed. Cir. 1986) (upholding ten-year exclusion order for misappropriation of trade secrets).

already-developed technological base, (ii) regulatory approvals previously obtained, and (iii) an existing market presence and sales base, all of which were made possible by infringing activity in the United States in willful defiance of United States patent law.[13] In order to remedy this improper head start, to restore competitive balance, to provide Baxter with some modicum of the de facto exclusivity that would have accrued to it had CellPro not infringed, and to deter future infringers, the Court should grant the relief requested.

CellPro's self-serving appeals to public policy and "international comity" are based on the fallacious notion that the requested injunction constitutes an "extraterritorial extension of U.S. patent rights." In fact, the proposed injunction is limited in duration, and affects only CellPro's right to sell, not that of any foreign (or indeed, other U.S.) companies. By CellPro's reasoning, if a company were enjoined for some period from selling a particular product internationally, where its product development was based in part on theft of a U.S. trade secret, the free flow of goods in the European Union would be unreasonably impeded. Here, if CellPro is permitted to manufacture and sell abroad without restriction, it will no longer be directly infringing plaintiffs' patent rights, but its sales efforts will take advantage of the technical developments, the premarketing approvals and the customer acceptance which were obtained by infringing those rights. Ultimately, the issue is one of equity between the parties, both of which are U.S.-based entities, and the proposed restraint is not an unreasonable interference with international trade.

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[13] It should be noted that CellPro has not stated that it plans to engage in ex-U.S. manufacture and sale of its products, nor has it provided any information as to how soon it will be in a position to do so. Similarly, it has not suggested that it has any intention of offering a CD34 antibody other than the 12.8 antibody for use with its SC device outside the United States. Without providing any such information, it cannot assert that the proposed injunction will have any actual impact, much less result in irreparable harm.

Finally, CellPro's characterization of the injunction as "thrusting an inferior product into the hands of unwilling Europeans at a monopoly price," Br. at 17, has no basis in fact. CellPro has submitted no declarations of any European clinicians to this effect. As noted earlier, Dr. Björkstrand in Sweden has done a side-by-side comparison of the competing products which shows that Baxter's Isolex® system provides superior results, and his hospital intends to use the Baxter system in the future even though it was among the first European hospitals to obtain the CellPro system. Björkstrand Decl. ¶¶ 2, 6, 8. Another European clinician, Dr. Garcia in Barcelona, affirms his department's very satisfactory experience using the Baxter system in both autologous and allogeneic transplants, and states that the department intends to continue using it. Garcia Decl. ¶¶ 4-8. As to CellPro's reliance on market share data, CellPro's claim of an 80% share is overstated and fails to mention that Baxter has converted 28 of CellPro's European customers to the Isolex® system since Baxter's launch of the 300i in late 1996, despite CellPro's head start in the market. Houser Decl. ¶ 7. Contrary to CellPro's insinuation, there is no shortage in supply of the 300i system. Id. ¶ 8. As to monopoly pricing, CellPro's real complaint has been that Baxter is *under*pricing CellPro. Tr. 3/10/97 at 1360. In fact, as CellPro's Dr. Jacobs points out, the price at which stem cell concentration systems can be sold to clinicians is constrained by competition from conventional therapy involving the use of unpurified bone marrow. Jacobs Decl. ¶ 20.

E. The 12.8 Hybridoma Shipped Outside the United States By CellPro is Not Beyond the Court's Jurisdiction.

Plaintiffs' request that the Court order CellPro to bring its 12.8 hybridoma cells back to the United States is not an effort to expand the temporal and geographic scope of the patents, but rather an effort to obtain a meaningful remedy for CellPro's infringing

activities within the United States during the term of the patents. The relief requested is no different than an order requiring a U.S. company to bring back to the United States trade secrets that it stole in the United States and smuggled out of the country in an effort to escape the jurisdiction of United States courts.

Here, the evidence shows that CellPro used the 12.8 hybridoma within the United States during the term of the '204 patent. See D.I. 861 (Pl. Inj. Br.) at 13-17. CellPro's argument to the contrary is that the 12.8 master cell bank is "not a single entity, but rather a collection of separate and distinct vials each containing hybridoma cells" and that the hybridoma CellPro used in the United States was not the same hybridoma it shipped to Canada. This argument, on its face, is untenable. The whole point of a hybridoma cell line is that every cell is identical. When CellPro uses a vial of cells to test the cell bank, that test pertains to the entire cell bank, not just the cells in the particular vial used for the test. Testing or other use of any part of the 12.8 hybridoma is infringing, whether the hybridoma cells are stored in one vial, a hundred vials or a thousand vials. The Court's equitable powers clearly permit it to order a remedy of repatriation with respect to that part of the 12.8 hybridoma which was shipped outside the United States (but remained within the control of CellPro) after the patent issued and after CellPro commenced infringing use of the 12.8 hybridoma.

In its brief, CellPro cites Amgen, Inc. v. Elanex Pharmaceuticals, Inc., 1996 WL 84950, *3-4 (W.D. Wash. 1996) for the proposition that shipping of cells alone is not a "use" under § 271(a). That case holds, however, that the defendant nevertheless used the cells, and infringed the patent, because the cell line was "maintained for a contemplated use" in the United States. Amgen at *3. The defendant's activities in maintaining the cell line included such activities as thawing cells, decontaminating them and allowing them

to grow, just as CellPro did with its 12.8 cell bank. The maintenance activities also included training of foreign personnel to use the cell line (at its facility in Bothell, Washington no less!) and contracting with another company to conduct tests on the cell line. Amgen at *1. The Amgen case strongly supports the conclusion that CellPro's maintenance of the 12.8 hybridoma cell line at its facility in the United States after issuance of the patent was an infringing use.[14]

CellPro's argument that 35 U.S.C. § 271(f) is inapplicable does not come to grips with the irrationality of the outcome that results from CellPro's argument. It is undisputed that CellPro sent the 12.8 hybridoma to Canada during the term of the '204 patent. This activity must be covered either by § 271(a) or by § 271(f). If it is not, it would mean that export of unassembled components of a patented invention is forbidden, but export of the assembled whole is not. There is no reason to believe that Congress intended such an anomaly within the same section of the patent laws. Whether under subparagraph (a) or subparagraph (f), the export alone constituted infringement, independent of and in addition to, CellPro's infringing use of the hybridoma within the United States.

F. The Court Should Enter Final Judgment of a Permanent Injunction.

CellPro argues that no permanent injunction can be ordered until the entry of final judgment, and that no final judgment can be entered in view of the pendency of CellPro's patent misuse defense. The simple answer to this objection is that the Court should promptly dispose of CellPro's patent misuse defense.

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[14] To the extent Amgen holds that export alone is not infringement, it offers no persuasive reasoning and should not be followed.

At this stage of the proceedings, CellPro's patent misuse defense could not withstand a Rule 11 motion, and if CellPro does not withdraw the defense voluntarily, plaintiffs intend to file one. CellPro's patent misuse defense asserts, first, that plaintiffs sought to enforce the '204 patent knowing of Hopkins' inequitable conduct during prosecution of the patents. D.I. 621, Twelfth Affirmative Defense, ¶ 29. Because the Court has determined that there was no inequitable conduct, this theory of the patent misuse necessarily fails.

CellPro's alternative theory asserts that Baxter improperly sought to extend the reach of the patents by "demand[ing] rights, in exchange for a license under the '204 and '680 patents, to CellPro's technology outside the United States." D.I. 621, ¶ 30. CellPro has made clear in prior proceedings that this allegation is based upon Baxter's April 15, 1992 letter to CellPro (DTX 709) proposing an agreement that included exclusive distribution of CellPro's infringing products in Europe. This allegation does not support a defense of patent misuse. First, there is no case law support for the conclusion that a patent license which includes a right to distribute the infringer's otherwise infringing product constitutes patent misuse. Second, nothing materialized from the request, apart from CellPro's ill-considered lawsuit. A mere proposal in the course of business negotiations which is rejected by the other side does not constitute patent misuse. Finally, it is black letter law that even where patent misuse is found to have occurred, the equitable bar to enforcement of the patent disappears when the restrictive practice ceases and the misuse is thereby "purged." United States Gypsum Co. v. National Gypsum Co., 352 U.S. 457, 465 (1957); see, e.g., Virginia Panel Corp. v. Mac Panel Co., 1996 WL 335381 at *11 (W.D. Va. 1996). As the Court is well aware, by letter dated July 22, 1992 (DTX 637), CellPro reinstated its original offer of a license on the same terms

proposed in January, with no accompanying right of distribution. If there were any patent misuse — and there was not — it was purged in July 1992.

If CellPro is unwilling to stipulate to an order denying CellPro's patent misuse defense, the Court should establish a short briefing schedule so that plaintiffs can seek judgment as a matter of law on the defense. The Court should then proceed to enter final judgment.

G. The Court Should Not Stay the Permanent Injunction Pending Appeal.

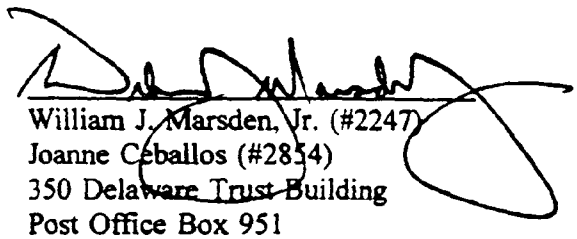
CellPro recently filed a separate motion requesting a stay of the injunction pending appeal. Plaintiffs' opposition to the motion is not yet due. They will prepare an opposition if necessary, but plaintiffs' response should be self evident. The Proposed Order already includes a stay, which permits CellPro to continue selling infringing products until Baxter's product receives FDA approval. If CellPro's predictions are correct, such approval will not occur prior to the completion of any appellate proceedings. In the circumstances of this case, where CellPro has been infringing for some six or seven years with no good faith basis for doing so, a stay of the injunction in its entirety pending appeal is unwarranted. The proposed partial stay represents a reasonable accommodation of competing interests, and it fully protects the public interest. CellPro's request for a total stay pending appeal should be denied.

CONCLUSION

For all the above reasons, and for the reasons set forth in plaintiffs' opening brief, the Court should grant a permanent injunction in the form attached hereto, and any stay of the injunction should be on the terms specified therein.

Respectfully submitted,

POTTER ANDERSON & CORROON



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