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.	)	

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION

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Dated: April 7, 1997

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NATURE AND STAGE OF THE PROCEEDINGS

The Court has determined that the '680 and '204 patents are valid and infringed, and on March 11, 1997, the jury found that CellPro's infringement of the patents was willful.[1] Plaintiffs now seek entry of a permanent injunction that will bar CellPro from continued infringement of the patents and provide equitable relief with respect to past infringement. The relief requested includes, among other things, an order requiring CellPro to bring back to the United States the 12.8 hybridoma it shipped to Canada after the onset of litigation in an effort to escape this Court's jurisdiction. The proposed relief also includes an order to destroy infringing materials in CellPro's possession, custody or control. The terms of the proposed permanent injunction, and the reasons why the Court should enter it, are discussed in Part I of this brief.

Having demonstrated their entitlement to a permanent injunction, plaintiffs proceed in Part II of this brief to suggest the terms of a partial stay of the injunction, limited in time and scope and conditioned on appropriate payments to plaintiffs to ensure that CellPro will receive no financial benefit from its continuing willful infringement of the Civin patents during the period of any stay. Plaintiffs make this proposal in the interest of minimizing disruption to patients who currently are being treated using the CellPro therapeutic device and ensuring that hospitals in the United States and abroad are able to make a smooth transition to Baxter's licensed Isolex® device.

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[1]This brief assumes that, by the time the Court considers plaintiffs' request for permanent injunctive relief, it will have determined as well that the Civin patents are enforceable.

SUMMARY OF ARGUMENT

1. Under Federal Circuit law, the provision of permanent injunctive relief is the norm in patent infringement suits, since the principal value of a patent is the right to exclude others from unlicensed practice of the invention. This principle applies equally to patents involving medical products, where incentives to innovation are particularly important in light of the very substantial investments required and the delay in receiving a return on those investments. In this case, issuance of a permanent injunction serves the public interest in maintaining the integrity of the patent system, will not endanger public health, and will act as a deterrent to willful infringement.

2. The permanent injunction should prohibit CellPro from manufacturing, using, and selling infringing products, should bar the export or import of infringing products, and should require CellPro to destroy its inventory of infringing products, including the 12.8 hybridoma. These provisions are necessary to prevent future infringement and to provide a remedy for past infringement.

3. Outside the United States, where the Baxter product is approved for sale, but where CellPro has acquired a substantial market presence as a direct result of its infringing activities in the United States, CellPro should be prohibited from selling any stem cell purification product for a period of two (2) years, even if that product can be used with a CD34 antibody developed in some other country. This portion of the injunction is intended as an equitable remedy for CellPro's past and continuing infringement, and to restore to plaintiffs some portion of the market advantage they lost as a result of CellPro's infringement.

4. The permanent injunction should also require CellPro to repatriate to the United States the 12.8 hybridoma it shipped to Canada (and perhaps elsewhere) in 1993 and 1994, after issuance of the '204 patent and, indeed, after the onset of litigation with plaintiffs. Although CellPro claims to have made its "master cell bank" before issuance of the patent, its continued testing and use of the master cell bank after the issuance of the patent, as well as its export of hybridoma cells from the master cell bank after patent issuance, clearly constituted infringing uses. The Court should order the return of the hybridoma cells to ensure a meaningful remedy for that infringement. The Court should also order repatriation of any 12.8 antibodies that have produced outside the United States from the exported hybridoma, or which, if produced within the United States, have been warehoused or stockpiled outside the United States.

5. Any stay of the permanent injunction should be narrowly limited in scope and should continue only for a transitional period as needed to permit hospitals to switch to licensed products. Such a stay should be conditioned upon CellPro's payment to plaintiffs of its incremental profits from further infringing sales; CellPro should not be permitted to achieve financial gain and to support its general corporate growth on the strength of its willfully infringing sales. In addition, any stay should contain protections to prevent CellPro from abusing the stay and impairing the future market for Baxter and other licensees.

Petition of CellPro, Inc. Requesting Exercise of March-In Rights

Exhibit Volume I

Tab	Description
1.	Baxter's Motion for Entry of Permanent Injunction and Brief in Support of Plaintiffs' Motion for Permanent Injunction
2.	CellPro's Brief in Opposition to Plaintiff's Motion for a Permanent Injunction and in Support of Alternative Motion for Stay of Injunction Pending Appeal
3.	CellPro Literature Describing CEPRATE System
4.	Summary of Results from Published Studies Using the CEPRATE SC Stem Cell Concentration System for Depletion of Tumor Cells in Peripheral Blood and Bone Marrow
5.	Keith Ervin, Patent Litigation Threatens Cell-Therapy Progress, Seattle Times, April 17, 1997
6.	Summary of the Data Reported on Depletion of T-Cells from Bone Marrow and Peripheral Blood after Selection with the CEPRATE SC
7.	Investigator-Sponsored Studies Using the CEPRATE System
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9.	Research Involving CEPRATE System Sponsored by NIH/NCI Funding
10.	Abstracts From the American Society of Hematology Meeting in December 1996
11.	Flake, et al., Brief Report: Treatment of X-Linked Severe Combined Immunodeficiency by In Utero Transplantation of Paternal Bone Marrow, New England Journal of Medicine (December 12, 1996)
12A.	Transcript of Baxter Healthcare Corporation, et al. v. CellPro, Inc., March 3, 1997
12B.	Transcript of Testimony of John Osth, President of Baxter's Immunotherapy Division, Baxter Healthcare Corporation, et al. v. CellPro, Inc., March 5, 1997
13.	1996 F.D.A. Office of Device Evaluation Annual Report
14.	Baxter Literature Describing the Isolex 300SA

15. Civin et al., Highly Purified CD34 - Positive Cells Reconstitute Hematopoiesis, Journal of Clinical Oncology, Vol. 14, No. 8, August 1996

16. Baxter Literature Describing Isolex 300i

17. Boon Yap, Market Intelligence on Baxter Isolex 300 SA and Isolex 300, (November 26, 1996)

18. C. Chabannon, et al., High-Dose Chemotherapy Followed by Reinfusion of Selected CD34+ Peripheral Blood Cells in Patients with Poor Risk Breast Cancer

19. Shelly Heimfeld, Additional Information on Baxter Randomized Trial Described in ASH 1995 Abstract, (March 20, 1997) (Two Memoranda)

20. Rich van den Broek, Will the Pain Ever End?, H&Q Spot Report (March 13, 1997)

21. Facsimile from Kevin Davies, Lehman Brothers, to Richard Murdoch, CellPro (February 25, 1997)

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO A PERMANENT INJUNCTION IN THE FORM ATTACHED TO THEIR MOTION.

A. The Law Favors Issuance Of Permanent Injunctive Relief.

Once a product has been found to infringe a valid patent, the federal courts apply a very strong presumption in favor of permanent injunctive relief. See, e.g., Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1126, 1246-47 (Fed Cir.), cert. denied, 493 U.S. 853 (1989) (reversing district court's denial of permanent injunction; "[i]t is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it"); W.L. Gore & Assoc., Inc. v. Garlock, Inc., 842 F.2d 1275, 1281 (Fed. Cir. 1988) (reversing district court's denial of permanent injunction; permanent injunction should issue unless "special reason" exists for refusing it); KSM Fastening Systems, Inc. v. H.A. Jones co, 776 F.2d 1522, 1524 (Fed. Cir. 1985) ("injunctive relief against an infringer is the norm").

The presumption in favor of injunctive relief derives from the fact that "[t]he principal value of a patent is its statutory right to exclude others from the unlicensed practice of the invention." Rohm and Haas Co. v. Mobil Oil Corp., 718 F. Supp. 274, 332 (D. Del. 1989), aff'd without opinion, 895 F.2d 1421 (Fed Cir. 1990); see, e.g., Richardson, 868 F.2d at 1247; H.H. Robertson, Co. v. United Steel Deck, 820 F.2d 384, 390 (Fed. Cir. 1987); Schneider (Europe) AG v. SciMed Life Systems, 852 F. Supp. 813, 861 (D. Minn. 1994), aff'd without opinion, 60 F.3d 839 (Fed. Cir.), cert. denied, 116 S.Ct. 520 (1995); Shiley, Inc. v. Bentley Labs. Inc., 601 F. Supp. 964, 970 (C.D. Cal. 1985), cert denied, 479 U.S. 1087 (1987). As the Federal Circuit has observed, "[w]ithout the right to obtain an injunction, the right to exclude granted to the patentee would have

only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir.), cert. denied, 464 U.S. 996 (1983).

The general rule has been followed routinely in medical product cases, where patent protection provides an important incentive for research and innovation. In Eli Lilly & Co. v. Medtronic, Inc., 7 U.S.P.Q. 2d 1439, 1445 (E.D. Pa, 1988), rev'd on other grounds, 872 F.2d 402 (Fed. Cir. 1989), the infringer argued that injunctive relief should be denied in the public interest because the infringing product (a defibrillation device for treating tachycardia) provided important health benefits. The court ruled:

> While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices such as Medtronic's, Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free competition in the goods. Congress has not seen fit to differentiate between what might be referred to as lifesaving devices and those of a more trivial or less important nature.

Similar injunctive relief has been granted in other medical product cases, notwithstanding "public interest" arguments to the contrary. See, e.g., Schneider, supra, 852 F. Supp. at 861 (balloon dilation catheter for treating coronary artery disease); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 28 U.S.P.Q.2d 1362, 1370-71 (D. Del. 1993) (safety catheter designed to eliminate risk to healthcare professionals of accidental needlesticks when treating AIDS patients); Shiley, supra, 601 F. Supp. at 970 (bubble blood oxygenator for use in open heart surgery).

The district court's decision in Hybritech Inc. v. Abbott Laboratories, 4 U.S.P.Q.2d 1001 (C.D. Cal. 1987), aff'd, 849 F.2d 1446 (Fed. Cir. 1988) does not suggest a contrary ruling here. In that case, the court excluded infringing cancer and hepatitis test kits from

the scope of a *preliminary* injunction, not a permanent injunction. As to the cancer test kits, moreover, the order permitted continued sales of infringing test kits only to patients who were already being treated and monitored using those specific products. Id. at 1003. As to the hepatitis test kits, the court noted that neither the patentee nor any licensee was marketing a hepatitis test kit. The order permitted continued sales of infringing hepatitis test kits, but only until the patentee or a licensee offered a similar product capable of meeting the market demand.[2] The Federal Circuit recently cited the district court's order in Hybritech as a "rare instance" where a court exercised its discretion to deny injunctive relief on public interest grounds, based upon the "patentee's failure to practice a patented invention." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547 (Fed. Cir.), cert. denied, 116 S. Ct. 184 (1995). That is not the case here, where Baxter is actively practicing the patented inventions and has developed its own stem cell concentration device.

B. Any Assertion By CellPro That A Permanent Injunction Will Cause It Hardship Is Legally Irrelevant.

CellPro should not be permitted to "cry hardship" as a defense to the proposed injunction. Even if CellPro's business were to fail as a result of the injunction, the Federal Circuit explicitly rejected this argument:

> One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.

Windsurfing Int'l v. AMF, Inc., 782 F.2d 995, 1003 n. 12 (Fed Cir.), cert. denied, 477 U.S. 905 (1986).

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[2] In Hybritech, the patentee did not appeal from the district court's order excluding these particular kits from the scope of the injunction; the Federal Circuit's affirmance simply holds, in response to the infringer's appeal, that the district court did not abuse its discretion in granting preliminary injunctive relief. 849 F.2d at 1448, 1458.

Nor is there any basis for claiming hardship. According to its own SEC filings, CellPro is sitting on approximately $60 million in cash and marketable securities: the fruit of several successful stock offerings that raised more than $160 million on the strength of the infringing products. A.17. This golden hoard provides CellPro ample capital to develop noninfringing cell separation products in areas other than purification of stem cells. Cellpro's ample capital also provides it with the capacity to hire additional scientists to develop noninfringing products, or to license, acquire or invest in noninfringing products or technology, or to attract corporate partners or joint venturers to help it enter new markets.

C. A Permanent Injunction Serves The Public Interest.

In opposing plaintiffs' request for a permanent injunction, CellPro doubtless will contend that "the public interest" warrants denial of such relief. It will argue that its SC System is the only stem cell separation device currently approved by the United States Food & Drug Administration ("FDA") for therapeutic use in this country, and that compelling medical and humanitarian concerns require the Court to ensure the continued availability of that device.

To allay any possible public health concerns, plaintiffs have proposed a limited stay of the injunction until such time as Baxter or another authorized licensee under the patents receives FDA approval to sell a therapeutic device in the United States. It is important to recognize, however, that the public interest is not unidimensional, and CellPro's one-sided and self-serving articulation of that interest must be put in context.

First, as noted above, there is a compelling public interest in maintaining the integrity of the patent system, which would be defeated in the absence of injunctive relief.

See, e.g., Smith Int'l, Inc., 718 F.2d at 1577-78 (Fed. Cir. 1987); Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 674 F. Supp. 1074, 1077 (S.D.N.Y. 1987). As the court observed in the latter case:

> The public has an interest in the enforcement of valid patents. The assumption underlying the constitutional provision for the patent system and the statutes implementing that provision is that research, development and innovation are encouraged by granting to inventors the right to exclude others from the use of their inventions for a limited period of 17 years. This right of exclusion is their reward for the time and expense spent in research and for their public disclosure of the fruits of that research.

Maintaining the integrity of the patent system requires not only that infringers (particularly willful infringers) be barred from reaping any financial reward from their misconduct, but that protection be given to the legitimate expectations and financial investments of those who, like plaintiffs, have played by the rules. Here, the longer CellPro is permitted to remain in the market, and the greater its sales, the greater the obstacles its conduct will have created for Baxter by the time Baxter begins marketing its Isolex® device in the United States. As Mr. Osth testified at trial, CellPro's unlicensed sale of its competing therapeutic device has harmed Baxter and will continue to harm Baxter by giving CellPro a market lead that will be difficult to overcome. Tr. 3/5/97 at 327-28.

Second, CellPro's attempt to suggest that only by assuring the continued availability of the CellPro product will public health needs be met is not supported by the evidence. CellPro's FDA approval in fact is limited in significant ways, including the following: (1) the FDA has authorized sale of the device for bone marrow transplantation, but not for peripheral blood stem cell transplantation; and (2) it has authorized sale of the device for

use in autologous, but not allogeneic, transplantation. DTX 1462. Even in the absence of an injunction against sales of the CellPro device, the vast majority of cancer patients who receive transplants in the next year or two will be treated by means of a procedure that does not utilize the CellPro device. Plaintiffs are not privy to CellPro's latest projections, but a recent analyst's report predicts that in the next twelve months CellPro's device will be used in only approximately 12% of the transplant procedures performed in the United States hospitals that have installed the CellPro device. A.34-35

Furthermore, as Mr. Osth testified at trial, Baxter's Isolex® 300 device has been used very successfully in a large number of clinical trials in the United States since 1993. Tr. 3/5/97 at 304-09. Additional hospitals that wish to use the Baxter device may do so by filing their own IDE's with the FDA, and Baxter is prepared to provide training and support to all such hospitals. The Baxter device has been approved as safe and effective by the European equivalent of the FDA, and Baxter has filed its request with the FDA for approval to begin marketing the device generally in the United States. Id. at 305, 311. Thus, it cannot be said that no substitute products are available to patients who need them.

Finally, in considering the equities of an injunction, the Court should take account of the compelling public interest in not rewarding willful infringement. See Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopaedic, Inc., 22 U.S.P.Q.2d 1401, 1415 (D. Minn. 1991), aff'd, 976 F.2d 1559 (Fed. Cir. 1992) ("an injunction is appropriate to 'chill' willfully infringing conduct"); Corning Glass Works, 674 F. Supp. at 1078 (arguments for denying stay and enforcing injunction immediately "are particularly strong where, as here, the infringement has been found to be deliberate and willful"); Shiley, 601

F. Supp. at 971 (defendant's argument against permanent injunction rejected, the court having "found the infringement in this case to be willful and wanton").

Here, the jury found that CellPro helped itself to a head start in the market by willfully disregarding plaintiffs' patent rights. Further, to protect that head start, CellPro repeatedly sought to delay trial of this dispute on the merits. When the Court denied those requests, CellPro engaged in litigation tactics that were deliberately calculated to further that objective. See Plaintiffs' Brief in Support of Motion for Enhancement of Damages Award.

The motive for CellPro's delaying tactics is not hard to discern: CellPro wanted to put off trial until its pending FDA application had been approved. Success in that strategy would enable CellPro to make FDA approval of its product a centerpiece of its appeal to the jury, as it did in fact, and would also put it in a stronger position to argue against injunctive relief. But for the second trial having been delayed beyond its original October 1996 date, CellPro would have been unable to make the "public interest" argument it is now asserting.

In sum, issuance of a permanent injunction would serve the public interest in maintaining the integrity of the patent system, would not endanger public health, and would act as a deterrent to willful infringement.

D. The Court Should Enjoin CellPro From Selling Any Stem Cell Purification Products Outside The United States For A Period Of Two Years.

Plaintiffs anticipate that CellPro will attempt to continue selling stem cell purification products outside of the United States by developing products (or modifying its current products) to work with a CD34 antibody that was not U.S.-developed. See A.1

(CellPro's license of Gaudernack CD34 antibody). In the long run, there may be no way to prevent CellPro from doing so. There are, however, strong equitable reasons for barring CellPro from doing so in the short run. Plaintiffs have, therefore, proposed that CellPro be barred from selling or otherwise supplying such products outside the United States for a period of two years.

First, by virtue of its infringing development and manufacturing activities in the United States, CellPro has been able to make significant sales and to acquire a substantial market presence in Europe and some other countries. Rather than being the sole supplier to the ex-U.S. market for some period of time, Baxter has been forced to share that market with an illicit participant. CellPro's sales outside the United States, which would not have occurred but for its infringing activities within the United States, have not only harmed plaintiffs in the past, but will continue to affect plaintiffs adversely for some period to come. The Court is free, in its discretion, to fashion an appropriate equitable remedy designed to restore to plaintiffs some partial measure of the exclusivity they would otherwise have enjoyed.

If CellPro were immediately enjoined from any further support of its installed base outside the United States, it might be some time before CellPro was able to qualify products for use with another antibody, and Baxter might regain a brief period of exclusivity. However, because an immediate injunction would work some hardship on CellPro's ex-U.S. customers until they can acquire and become familiar with the Baxter product, plaintiffs have proposed a one-year phase-down for sales of the 12.8 antibody in the rest of the world ("ROW"). While this phase-down period is intended to permit innocent customers to make an orderly transition from CellPro's product to Baxter's, it

should not provide CellPro with the opportunity to accomplish a relatively seamless conversion of its customer base to an alternative antibody.

E. The Permanent Injunction Should Include Provisions Barring Export Or Import Of Infringing Products And Requiring Their Destruction.

Plaintiffs' proposed form of injunction includes provisions barring export and import of CD34 antibodies, hybridoma cells that produce CD34 antibodies, or products that contain CD34 antibodies and requiring that such materials be destroyed. These provisions are necessary to remedy infringement that has already occurred and to prevent future infringement involving the use or sale of these materials.

Permanent injunctions barring the export or import of infringing products are common. See, e.g., DNIC Brokerage Co. v. Morrison & Dempsey Communications, Inc., 14 U.S.P.Q.2d 1043, 1044 (C.D. Cal. 1989) (enjoining infringer from "making, using, selling, exporting, or importing any [infringing] products"); Syntex (USA) Inc. v. Paragon Optical Inc., 7 U.S.P.Q.2d 1001, 1041 (D. Ariz. 1987) (injunction against "manufacture, use, sale, import and export" of infringing material); Beckman Inst. Inc. v. LKB Produkter AB, 703 F. Supp. 408, 410-11 (D. Md. 1988) (citing defendants for violation of injunction by exporting infringing articles rather than destroying them), aff'd in part and vac'd in part, 892 F.2d 1547 (Fed. Cir. 1989). Such injunctions not only prevent future infringement, but also, in the case of an injunction against export, ensure an adequate remedy with respect to past infringement. Plaintiffs' proposed limited stay will permit CellPro to export 12.8 antibody from the United States for a specified period, but a permanent injunction should take effect upon expiry of that stay.

An order requiring destruction of infringing products is also appropriate, in order to prevent any future use or sale of those products. E.g., Beckman, 703 F. Supp. at 410-11;

Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 1991 U.S. Dist. LEXIS 19381 (N.D. Ga. 1991) (ordering defendant to deliver all infringing master seed, working seed, and vaccine to plaintiff for destruction); Pfizer, Inc. v. International Rectifier Corp., 217 U.S.P.Q. 157, 163 (C.D. Cal. 1982) (ordering destruction of all infringing doxycycline products in custody or control of defendant); see Flanagan v. Continental Apparel Corp., 1996 U.S. Dist. LEXIS 12102 (S.D.N.Y. 1996) (whether to order destruction of infringing material within discretion of court). Upon expiration of the proposed limited stay, the order of destruction should encompass not only CellPro's inventory of 12.8 antibody, but also all 12.8 hybridoma cells from which 12.8 antibody can be produced. It should also encompass any other CD34 antibodies and hybridomas that CellPro may have produced or acquired. For the reasons discussed below, the order should include the 12.8 master cell bank created by CellPro prior to issuance of the '204 patent, based upon CellPro's infringing use thereof after issuance of the '204 patent.

F. The Permanent Injunction Should Require CellPro To Repatriate The 12.8 Master Cell Bank That It Previously Shipped To Canada.

In mid-1993, CellPro shipped vials of the 12.8 hybridoma to a contractor in Canada, Biomira, Inc., for the purpose of producing 12.8 antibody outside the United States. CellPro's motive for doing so obviously was to evade the United States patent laws and escape liability for unlicensed manufacture, use and sale of CD34 antibodies. As a remedy for CellPro's wrongful conduct, plaintiffs have included in the proposed form of injunction an order requiring CellPro to repatriate all 12.8 hybridoma cells shipped to Canada (or elsewhere) so that they will be subject to the mandatory and prohibitory provisions of the injunction.

That CellPro has the power to require return of the 12.8 hybridoma is clear: the Supply Agreement between CellPro and Biomira expressly provides that all materials, including cell banks, provided to Biomira by CellPro remain "the sole and exclusive property of CellPro." D.I. 159 at Exh. C, p. 16, § 9.1.

It is equally clear that the Court has the power to enter such an order. It is well established that the district courts have broad discretion to grant injunctions not only to prevent future infringement but also to redress past infringement. E.g., Roche Prods. v. Bolar Pharmaceutical Co., 733 F.2d 858, 865 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984); Intervet, 1991 U.S. Dist. LEXIS 19381 at *5 (ordering recall of infringing inventory shipped to defendant's distributors and requiring defendant to relinquish USDA license for manufacture and sale of infringing vaccine); Pfizer, 217 U.S.P.Q. at 163 (enjoining use of clinical data obtained using infringing products and ordering withdrawal of all pending applications to the FDA).

Here, if CellPro had not raced to ship 12.8 hybridoma outside the country prior to a judicial determination that it infringes, the Court could effectively have enjoined CellPro from exporting it, as discussed above. An order of repatriation simply restores the status quo as it existed prior to the unauthorized export, which was itself an infringing use.

In prior submissions to the Court, CellPro has argued that its export of 12.8 hybridoma to Biomira was outside the reach of the United States patent laws, on the ground that the 12.8 master cell bank, from which the cells shipped to Biomira were produced, was created prior to the issuance of the '204 patent. However, even if the 12.8 hybridoma cells shipped to Biomira were derived from the master cell bank and were "made" prior to issuance of the '204 patent, which plaintiffs do not concede, CellPro

clearly "used" the master cell bank after issuance of the patent, in violation of 35 U.S.C. § 271(a). Because that use of the master cell bank infringed the patent -- indeed, willfully infringed the patent -- the Court has ample authority to fashion an equitable remedy that will put plaintiffs in the same position they would be in today if CellPro had not disregarded plaintiffs' rights.

As demonstrated in prior briefing, CellPro's infringing use of the 12.8 master cell bank included use of the cell bank to create a "working cell bank" and additional "extended cell banks." CellPro also used the master cell bank to conduct numerous quality control tests. The official release and approval for use of the master cell bank did not occur until June 21, 1991, *after* issuance of the '204 patent, and indeed it is that date that more accurately reflects the date when CellPro accomplished the "making" of the master cell bank. Further, long after that date -- even into 1994 -- CellPro was still using the master cell bank to conduct necessary quality assurance. It also used the master cell bank in 1993 and 1994 to supply Biomira with hybridoma cells and 12.8 antibody to assist Biomira in producing 12.8 antibody in Canada. (A detailed description of CellPro's use of the master cell bank appears in D.I. 249 at pp. 4-10.)

In short, CellPro maintained and used the 12.8 master cell bank, in the United States, for numerous commercial purposes, including activities necessary to support its contractor, Biomira. The courts have consistently given a broad interpretation to the term "use" within the meaning of § 271(a). See Bauer & Cie. v. O'Donnell, 229 U.S. 1, 10-11 (1913) (interpreting "use" to include "put[ting] into service any given invention"); Olsson v. United States, 25 F. Supp. 495 (Ct. Cl. 1938), cert. denied, 307 U.S. 621 (1939) (storage of disassembled howitzers containing an embodiment of patented invention

constituted infringing use); Hughes Aircraft Co. v. United States, 215 U.S.P.Q. 787, 814 (Ct. Cl. 1982), aff'd in part and rev'd in part, 717 F.2d 1351 (Fed. Cir. 1993)(although patent for attitude control system issued after launch of spacecraft in which system was installed, availability of system for back-up after patent issued constitutes infringing use); Paper Converting Machine Co. v. Magna-Graphics Corp., 745 F.2d 11, 20 (Fed. Cir. 1984) (testing of unpatented elements of patented machine constituted infringement). Clearly, CellPro's maintenance, testing and use of the master cell bank in the United States after issuance of the patent constituted infringing use.

In addition, CellPro's 1993 and 1994 shipments of hybridoma cells from the master cell bank to Biomira constituted infringing uses in and of themselves. See Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc., 750 F.2d 1552 (Fed. Cir. 1984) (shipping display racks to customers, retaining ownership and without charge to the customer, constituted infringing use); Thorn EMI North America v. Micron Technology, 821 F. Supp. 272, 275 (D. Del. 1993) (delivery of free samples of infringing product constituted infringing use of products). Thus, assuming arguendo that the shipment of hybridoma cells to Biomira did not amount to a "sale" of infringing products, it plainly constituted a use of infringing products in violation of 35 U.S.C. § 271(a), sufficient to justify an equitable remedy.

CellPro's shipment of hybridoma cells to Biomira in Canada also appears to violate the intent of § 271(f). Section 271(f)(1) and (2) bar the export of all or substantially all of the components of a patented invention where their combination within the United States would constitute infringement. In prior submissions, CellPro took the position that § 271(f) could not apply, because the 12.8 hybridoma is itself the patented article, not a component thereof. But this interpretation would produce an irrational result that Congress

could not have intended: export of unpatented components infringes, but export of a patented article in its entirety does not. Either § 271(f) should be construed to encompass export of a patented article, or § 271(f) should be taken as confirmation of Congress' understanding that export of a patented article already constituted an infringing use under § 271(a), so that § 271(f) did not need to address an act of that character. In either case, the export to Canada in 1993 and 1994 of hybridoma cells that produce CD34 antibodies clearly constituted infringement.

Finally, in considering plaintiffs' request for an order of repatriation, the Court should take into account the jury's finding that CellPro's infringement was willful. Where a willful infringer has deliberately exported an infringing product in a scheme whose only purpose was to evade liability under the United States patent laws, the Court can and should fashion a remedy that provides plaintiffs meaningful relief.

II. IN ITS DISCRETION, THE COURT MAY STAY CERTAIN PORTIONS OF THE PERMANENT INJUNCTION, BUT ANY STAY SHOULD BE LIMITED IN TIME AND SCOPE AND SHOULD BE CONDITIONED ON CELLPRO'S PAYMENT TO PLAINTIFFS OF ITS INCREMENTAL PROFIT ON CONTINUED SALES OF INFRINGING PRODUCTS.

Plaintiffs' proposed form of injunction contains a partial stay of the injunction, limited in time and scope and conditioned upon payment to plaintiffs of CellPro's incremental profit on additional sales of infringing products during the period of the stay. Although plaintiffs believe that the Court could, in its discretion, give immediate effect to the permanent injunction in its entirety, they make this proposal in the interest of minimizing disruption to patients who currently are being treated using the CellPro therapeutic device and ensuring that hospitals in the United States and abroad are able to make a smooth transition to Baxter's licensed Isolex® device.

The proposed stay is based on the following, interrelated premises:

A. CellPro should be allowed, for a limited period of time, to continue supplying the 12.8 antibody and associated disposables to customers which, as of March 12, 1997, were already using the SC System. CellPro should not be permitted to sell or otherwise supply additional SC Systems.

B. The duration of the stay in the United States should be tied to FDA approval of the Baxter Isolex® product or another licensed device; in the rest of the world, the duration of the stay should be limited to a one-year progressive phaseout of the 12.8 antibody.

C. To the extent that CellPro is permitted to continue selling disposable products for use with its installed base of SC Systems, it should not profit from such sales, nor should any revenues derived from such sales contribute to CellPro's general corporate expenses or research and development work on other products.

D. CellPro should not be permitted to avoid the effect of the injunction by cutting the prices of its products or by entering long-term supply contracts, thereby reducing or eliminating any profit margin and destroying or impairing Baxter's future market.

Each of these basic premises is discussed below.

A. Products Subject to the Stay: The proposed stay permits CellPro to continue selling only the disposable products, including the 12.8 antibody, that are necessary to the continued use of the CEPRATE Stem Cell Concentrator (the "SC Systems"); it does not permit additional sales (or placements without charge) of the SC Systems themselves. While a supply of disposables is necessary to ensure the continued utility of the already-installed SC Systems, there is no compelling justification for permitting CellPro to expand its market base by supplying additional devices.

During the prolonged clinical trials of CellPro's SC System, and in the several months that have elapsed since FDA approval of that device, CellPro has sold or otherwise supplied a substantial number of SC Systems to dozens of cancer transplant centers in the

United States. A.26.[3] Thus, to the extent that an autologous bone marrow transplant using CellPro's SC device (as opposed to conventional therapies that do not utilize CD34 antibodies for stem cell purification) is deemed to be medically desirable for a particular patient, such treatment is already available at a significant number of institutions.

Moreover, while a certain amount of market disruption will occur whenever the permanent injunction takes full effect, such disruption will be far greater if CellPro is allowed to continue selling SC devices. First, the longer such infringing sales go on, and the larger the base of users who have invested in and been trained on the CellPro device, the greater the impact on the potential market for Baxter's legitimate, licensed products. As Judge Farnan concluded in Critikon, 28 U.S.P.Q.2d at 1370-71, substantially more customers and end users will find their activities disrupted and their expectations disappointed if an injunction is delayed until some future time. Permitting CellPro to continue supplying disposables to customers who obtained the SC device prior to the jury trial, while barring it from continuing to expand its market base, represents a reasonable compromise among competing considerations.

B. Temporal/Quantitative/Geographic Scope of the Stay: Plaintiffs propose, with respect to the United States, that the stay remain in effect only until Baxter's Isolex® product (or another licensed product) receives FDA approval, and for a phase-out period of three months thereafter. Until FDA approval, there would be no absolute limit on the quantity of disposables to be sold. However, CellPro would only be permitted to supply clinical users on an as-needed basis; it would not be allowed to sell large quantities of

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[3] CellPro's business plans reflect its expectation that the majority of its revenues would come from sales of disposables, rather than from the initial sale or installation of the SC device.

disposables in excess of the users' short range needs, thereby end-running the injunction and destroying Baxter's future market. During the three-month transition period, which is designed to permit customers to make an orderly transition to the Baxter product, CellPro would be limited to selling a specific percentage of its average quarterly sales during the prior year.

The situation in the rest of the world ("ROW") is somewhat different. There, Baxter's product is already available, and an equitably-justified injunction against CelPro's continued making, use or sale of the 12.8 antibody would effectively shut down CellPro's ROW sales in the short range. However, in order to permit ROW customers to make an orderly transition to the Baxter product, plaintiffs propose a one-year phase-out period for the 12.8 antibody. Under this proposal, CellPro would, for an initial three-month period, be permitted to continue selling disposable/antibody products at its pre-trial rate of sale; thereafter, in each of three successive quarters, it would be required to reduce those sales by an absolute 25%, and, at the end of one year, to stop selling products containing the 12.8 antibody altogether.

C. Stay Not to Produce Profits for CellPro: Any stay that permits CellPro to continue what has been adjudged to be willfully infringing activity should ensure that CellPro reaps no financial or other business benefit from its continued infringement. Specifically, plaintiffs propose that, with respect to any sales of infringing products made after the date of the jury verdict, and as a condition of any stay, CellPro be required to pay to plaintiffs CellPro's incremental profit on those sales.

Incremental profit is a concept well recognized by economists and accountants: it represents a company's net sales revenue less the variable cost of producing and

distributing the product in question. See, e.g., State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1578-80 (Fed. Cir. 1989). By definition, incremental profit is less than gross profit, because it allows for the direct cost of selling as well as the cost of manufacture, but is more than net profit, because it does not allow for general and administrative expenses, research and development expenses, or other sunk costs. Incremental profit represents the marginal cost of producing and distributing the products in question.

Requiring CellPro to pay over its incremental profit, as a condition of continued sales, represents a fair approach because it permits CellPro to recover the actual, direct cost of its sales. However, CellPro should not be permitted to finance any portion of the general costs of its corporate existence (general and administrative expenses) from the proceeds of its infringing activities, nor should it be allowed to finance its ongoing research and product development activities from those sales.

It would be specious for CellPro to argue that depriving it of a profit on its sale of infringing products would put it out of business or eliminate any motive for going to work in the morning. As CellPro has previously reported to the Court, its investors and the public, it is currently developing other, noninfringing cell separation products. Because CellPro has some $60 million of liquid assets in its accounts, it does not need to make a profit on sales of the SC device in order to finance its continued existence or the current research and development efforts. Moreover, CellPro's continued sale of disposables will enable it to stay in contact with its customer base and will provide occupation for its manufacturing and sales personnel. Finally, if CellPro believes so strongly that the public

interest requires continued availability of the SC device, it should be willing to satisfy that need on a non-profit basis.

In order to avoid future disagreements about the proper method of calculating incremental profit or of allocating expenses, plaintiffs propose a relatively simple definition that identifies specifically the categories of costs included in variable cost of sales. See Proposed Form of Injunction, paragraph 4.i. The proposed stay also includes quarterly reporting requirements with respect to CellPro's calculation of incremental profit. And, to prevent any accounting manipulation, the stay establishes a floor of $2000 for the incremental profit on disposables (slightly less than 50% of CellPro's current selling price).

D. Other Limits on the Stay: The proposed stay also includes provisions to prevent CellPro from cutting the prices on infringing products or contracting with customers for long term supplies of disposables. These provisions are necessary to prevent CellPro from eliminating its incremental profit margin in order to avoid payment to plaintiffs, and from destroying or impairing the future market for Baxter's device.

To ensure that the stay continues to serve its intended purpose and is not abused by CellPro, plaintiffs request that the Court retain continuing jurisdiction over the permanent injunction. The proposed injunction provides, in addition, that if there is any question as to whether a particular activity is permitted under the terms of the limited stay, CellPro shall first seek approval from plaintiffs' counsel and, if necessary, clarification from the Court, before engaging in such activity. Upon expiration of the stay in accordance with its terms, the permanent injunction would thereafter be in full effect, without further action by the Court.

CONCLUSION

For all the above reasons, plaintiffs respectfully request that the Court enter a permanent injunction in the form attached to their motion, and that any temporary stay of such injunction be on the conditions described therein.

Respectfully submitted,

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Dated: April 7, 1997

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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.	)	

MOTION FOR ENTRY OF PERMANENT INJUNCTION

Defendant CellPro, Inc. having been found to have willfully infringed United States Patent Nos. 4,174,680 and 4,965,204, plaintiffs hereby move for entry of a permanent injunction in the form attached hereto. The grounds for plaintiffs' motion are set forth in the Brief in Support of Plaintiffs' Motion for a Permanent Injunction filed herewith.

By their attorneys,

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PA&C/254922

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.	)	

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.

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.

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. 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.

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

PA&C/254919

CERTIFICATE OF SERVICE

I, William J. Marsden, Jr., hereby certify that on this 7th 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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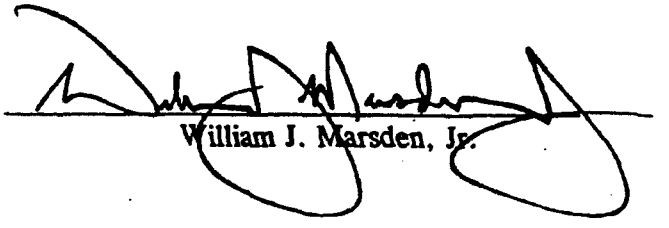

William J. Marsden, Jr.

CERTIFICATE OF SERVICE

I, William J. Marsden, Jr., hereby certify that on this 7th 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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William J. Marsden, Jr.

CERTIFICATE OF SERVICE

I, Gerard M. O'Rourke, do hereby certify that on April 21, 1997, I caused to be served copies of the foregoing CELLPRO'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INJUNCTION PENDING APPEAL upon the following counsel of record by the means indicated:

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation, BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation, Plaintiffs, v. CELLPRO, INC., a Delaware corporation, Defendants.	:	Case No. 94-105-RRM

CELLPRO'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INJUNCTION PENDING APPEAL

PREPARED BY:

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Dated: April 21, 1997

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I. NATURE OF THE CASE AND STAGE OF PROCEEDINGS

The validity and infringement of U.S. Patent Nos. 4,714,680 and 4,965,204 were determined by summary judgment, and in March 1997 a jury reached a verdict finding willful infringement and the amount of compensatory damages. However, certain defenses, including patent misuse, remain to be adjudicated.

One necessary predicate to the issuance of a permanent injunction is a final judgment. Eli Lilly & Co. v. Medtronics, Inc., 915 F.2d 670, 674 (Fed. Cir. 1990). And entry of a final judgment (even a partial final judgment under Rule 54(b)) requires that plaintiffs' infringement claim be finally adjudicated. See W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc., 975 F.2d 858, 863 (Fed. Cir. 1992).

Here, since CellPro's outstanding, bifurcated patent misuse defense is still pending, there has been no final adjudication and the final injunction cannot be entered. The Court in Virginia Panel Corp. v. Mac Panel Co., 887 F. Supp. 880 (W.D.Va. 1995) faced precisely this situation. In Virginia Panel, the defendant was found to have willfully infringed two of the plaintiff's patents; however, the defendant's patent misuse defense and antitrust claims had been bifurcated. Id. at 883. The Court found that entry of partial final judgment under Rule 54(b) was improper (Id. at 883-884) and declined to enter a permanent injunction because final judgment was not proper (Id. at 887).

Until the patent misuse defense is adjudicated, final judgment cannot be entered, and any final injunction is premature.

II. SUMMARY OF ARGUMENT

1. The proposed injunction would violate the prohibition of 35 U.S.C. § 271(e)(3), as it would enjoin activities reasonably related to the FDA approval process. A large part of CellPro's activities have been, are now, and for the foreseeable future will continue to be related to the development of new devices and new therapeutic approaches under the § 271(e)(1) exemption from patent infringement liability.

2. Important public interests dictate that no injunction should be granted. CellPro has created and is creating unique lifesaving technologies and there is no reason to think that Baxter's device, even if the FDA some day approves it, will be technically and therapeutically equivalent for the needs of all patients.

3. If a final injunction is entered, it should be stayed in its entirety pending appeal, in view of the four-factor test of Hilton v. Braunskill, 481 U.S. 770, 776 (1987).

4. The proposed injunction would have extraterritorial effects that not only violate U.S. law but offend the free-competition policies of other countries, where plaintiffs lack patents rights. Upon principles of international comity, the Court should refuse to grant these parts of the injunction, even if they were not violative of domestic law.

5. The part of the injunction which calls for a repatriation of 12.8 hybridoma made before the patent issued but sent to Canada thereafter is legally insupportable. The shipment aboard was not an act of infringement, nor can any use of the hybridoma aboard be an act of infringement.

6. The proposed injunction is overly broad as regards the '680 patent, for its language implies that the mere sale of the device is an inducement of infringement or a contributory infringement, and it is neither.

III. FACTS

Litigation has been called a blizzard of words. In any blizzard, voices can be muffled or drowned out. Before the Court decides this most important motion, we believe that the Court needs to hear from those who have not been heard so far in this case – physicians who rely on the CellPro CEPRATE® SC Stem Cell Concentrator in their day-to-day work. Those clinicians and clinical researchers, better than anybody else, know what is at stake here.[1/]

With regard to Baxter's argument that the CellPro FDA-approved device can be withdrawn from the market without harm to patients, consider the following sworn statements by physicians involved in patient care:

> The device is the only FDA-approved device for this indication [autologous BMT for breast cancer], and removing the device from the market would withdraw from cancer patients in this country a safe and effective therapy against a widespread, and lethal, disease. – FRED LeMAISTRE, M.D. (Decl. ¶ 8(a))

[1/]The facts set forth here and elsewhere in the brief are taken from testimony and exhibits already of record, and/or from the following persons' declarations, which are being filed and served herewith: Dr. Claudio Anasetti; Dr. Kenneth Anderson; Dr. Edward Ball; Dr. Oscar Ballester; Dr. Michael Bishop; Dr. William Burns; Dr. Richard Burt; Dr. Stanley Calderwood; Dr. Richard Champlin; Dr. John DiPersio; Dr. Anthony Elias; Dr. Cesar O. Freytes; Dr. Dr. Jed B. Gorlin; Dr. Charles Hesdorfer; Dr. Helen Heslop; Dr. Kent Holland; Dr. Mary Horowitz; Dr. Cindy A. Jacobs; Mr. Edward Kenney; Dr. Monica S. Krieger; Dr. Fred LeMaistre; Mr. H. Colin Overbury; Dr. Robertson Parkman; Dr. Gordon L. Phillips; Dr. Oliver W. Press; Dr. Gary Schiller; Dr. Leonard Sender; Dr. Thomas Shea; Mr. William E. Simpson; Dr. Joseph Tarnowski; Mr. Robert Vandervelde; Mr. David F. Weeda; Dr. Andrew M. Yeager; Dr. John A. Zaia. These Declarations are hereinafter cited in the form, "Anderson Decl. ¶__," "Anasetti Decl. ¶__," etc. Of the clinicians-declarants who are quoted and/or cited herein, two (Drs. Parkman and Press) are persons who at other times have been compensated by CellPro as testifying and/or consulting experts in this litigation. No other clinician-declarant has had any prior relationship to this case; and no clinician-declarant, (including Drs. Parkman and Press) has been paid or offered any compensation in connection with these declarations. They all donated their time.

Until the CellPro device made possible these haploidentical transplants, such [pediatric cancer] patients simply had no therapeutic options; they all died. – DR. STANLEY CALDERWOOD (Decl. ¶ 7)

Prior to the advent of the CellPro device, these [leukemia] patients had no transplant option because no adequate and willing donor was known, and therefore no potentially curative therapy was available to them. – RICHARD BURT, M.D. (Decl. ¶ 7)

In a pilot study in children, we achieved survival rates in the range of 30 to 40% for these patients who underwent haploidentical transplantation using parental donor cells manipulated with the CEPRATE® device. Before, these patients had no treatment option at all; they were not transplant candidates and, without transplantation, they typically succumbed to leukemia within 3 to 6 months after diagnosis....–KENT HOLLAND, M.D. (Decl. ¶ 6)

Patients know this technology is available. In my practice, parents of young children facing these life threatening diseases, are increasingly educating themselves ..... It would be like holding up a carrot to these parents, to confirm that you now have such promising methods that could be used to reduce the number of tumor cells in their child's marrow, but it can't be used because of a legal dispute. – LEONARD SENDER, M.D. (Decl. ¶ 9)

I was asked what effect the inability to obtain the CellPro CEPRATE® device would have on our clinical research programs .... [O]ur in utero program would essentially be ended since I know of no other manufacturer that offers a system to stem cell select and T cell deplete. – ROBERTSON PARKMAN, M.D. (Decl. ¶ 8)

This past winter we initiated another clinical trial involving CellPro's second-generation ("TCD") immunoselection column.... [T]he donors are haploidentical parents and the patients are children with end-stage leukemia for whom there are no conventional treatment options available.... If for any reason the CellPro TCD device were to become unavailable, this study would need to be shut down. If that were to happen, children would die. – ANDREW M. YEAGER, M.D. (Decl. ¶ 6)

To those who would discount the miseries that patients suffer when deprived of treatment options they want, I would say that I wish they could experience what I have had to experience when explaining to a desperately sick patient why he does not meet the eligibility criteria for a limited-enrollment study which he believes might hold his best hope of a life-saving cure. I recently had to deliver such an explanation to a patient, only to be told a week later, by a relative of the patient, that his inability to enroll in the study had left him so despondent that he had tried to kill himself. – RICHARD BURT, M.D. (Decl. ¶ 10)

With regard to Baxter's argument that its Isolex 300 device is a reasonable substitute for the CellPro FDA-approved device, consider the following sworn statements by physicians involved in patient care:

> Baxter's Isolex device, according to what I have heard and read about it, lacks sufficient demonstrated T-cell depletion capability ... to be practical for my child and young-adult studies even if the device were FDA-approved. –KENT HOLLAND, M.D. (Decl. ¶ 11)

> I have personally evaluated the Baxter ISOLEX CD 34+ selection device, and found that it was not acceptable for my needs .... If the CEPRATE®SC device were not available, it would have a significantly negative effect on my ability to carry out the current and planned investigational protocols that I have described. Indeed, with regard to the Gaucher disease study, there would be no other options and the study would have to stop.– EDWARD BALL, M.D. (Decl. ¶¶ 5, 6)

> While at Johns Hopkins I saw both the CellPro and the Baxter therapeutic stem-cell selection columns in use, and based on my observations and discussions with knowledgeable persons there, I formed the impression that the CellPro device was far superior to the Baxter device. The latter was relatively slow and clumsy, requiring two persons to operate, and produced suspensions of inferior quality.... I do not regard the Baxter device as a fit or comparable substitute for the CellPro device and would not choose to use the Baxter device to treat my patients. – RICHARD BURT, M.D. (Decl. ¶ 8)

> If access by clinicians to the CellPro CEPRATE®SC stem cell concentrator were restricted in the United States, the practical availability of stem-cell-therapy options to clinicians and their patients would be diminished; and in my view it is not realistic to expect that Baxter's ISOLEX® device, or any other device that lacks FDA approval, could fully and adequately replace the CellPro device even if the therapeutic and technical equivalency of such device to the CellPro device were certain. – RICHARD CHAMPLIN, M.D. (Decl. ¶ 9)

> Even if Baxter had a device that could be used, because high-risk neuroblastoma is what is often called an "orphan disease," afflicting only about 200 children nationwide, any non-FDA-approved device may not be made available to me. It has been my experience that because these orphan diseases do not present a big enough market they are rarely approved by manufacturers for use in investigator sponsored trials. – LEONARD SENDER, M.D. (Decl. ¶ 7)

With regard to Baxter's argument that the proposed injunction would effect a "relatively seamless conversion" (Brief p. 12), consider the following sworn statements by

physicians involved in patient care as to the impact any switch would have on their ongoing clinical programs:

> Even if there are applications for which an alternate immunoselection device might be adequate, a switch over to such a device could not be accomplished without substantial delay.... [T]his delay would be fatal to the children involved in our haploidentical parent-to-child leukemia transplant studies, who are not candidates for non-immunoselected stem cell transplant and whose life expectancies (if untreated) are too short for any significant delay to be tolerable in their cases. – ANDREW M. YEAGER, M.D. (Decl. ¶ 9)

> Because the patients involved and to be involved in our autoimmune pilot studies are, by definition, persons with poor short-term prognoses, some of these patients would die, and others might become ineligible for the studies due to further deterioration in their conditions, during the period of delay that would be occasioned by a changeover (assuming that a changeover were otherwise possible) from the CellPro device to another stem-cell immunoseparation device. – MARY HOROWITZ, M.D. (Decl. ¶ 7)

> Without the CellPro device, our clinical work would be set back by up to two (2) years.... If the CellPro device is made unavailable, we would have to discard data of our clinical studies already in progress, and start over. We would further have to retrain staff to use a new device, and must reapply for FDA and institutional clearance to conduct our clinical studies with an unapproved device. Above all, I would not be certain that a substitute device would work as well for my purposes.– MICHAEL BISHOP, M.D. (Decl. ¶ 11)

> It is not clear that switching from one device to another in mid-trial would even be permitted by the FDA. Even if the FDA did not require that we discard data gathered using the CellPro device and begin anew, it would still be undesirable, from the standpoint of sound scientific methodology, to make a substitution of such an important piece of equipment in the midst of a trial. – ANDREW M. YEAGER, M.D. (Decl. ¶ 10)

> If the CellPro device were to become unavailable our clinical research and studies would be set back significantly. We would more than likely have to discard our already accumulated data, retrain staff with another device, and reapply for FDA and institutional clearances anew. I estimate that our efforts would be set back by up to two (2) years. Further, even if an alternative device were available, I would not be sure that it would work just as well for our purposes. – CHARLES HESDORFFER, M.D. (Decl. ¶ 10)

Even if the Baxter device were available, new and emerging treatments made possible by the CellPro FDA-approved device would be impacted, according to physicians involved in patient care:

> In my view, there is a compelling public interest in maintaining the availability of, and access to, the CEPRATE® SC device, because patients with advanced diseases would die without the benefit of the device which makes allogeneic transplantation feasible from HLA mismatched donor. Further, there is unquestionable benefit to be derived from keeping the device (as the only FDA-approved device) on the market as its removal would set back the development of new transplant technologies and treatment options. – CLAUDIO ANASETTI, M.D. (Decl. ¶ 9)

> Besides our own completed and planned clinical studies, I consider the availability of, and access to, the CellPro device as important to the development of other novel treatment procedures such as gene therapy. – OSCAR BALLESTER, M.D. (Decl. ¶ 6)

> My pilot study results to date suggest that the device affords a new, potentially lifesaving treatment option for multiple sclerosis patients for whom all conventional therapies have failed. – WILLIAM BURNS, M.D. (Decl. ¶ 8)

> If the CEPRATE® device were not available, the current trials regarding small cell lung cancer, as well as the future tumor purging studies, would be significantly disrupted, delaying what appear to be significant advances in the treatment of certain types of cancer. – ANTHONY ELIAS, M.D. (Decl. ¶ 8)

> I believe that FDA-approved status confers on the CellPro device what we may call a "halo effect," such that researchers are encouraged to explore new therapeutic frontiers through the use of the device because they believe that its already-FDA-approved status will facilitate expanded approval for new applications and because they believe that its widespread acceptance and wide distribution within the American medical community will help assure that any new therapies they develop, if successful, will quickly come into widespread use. – FRED LeMAISTRE (Decl. ¶ 8(b)

The CellPro FDA-approved device is an invaluable device for patient care as illustrated by the following comments of physicians involved in patient care:

> The time period between myeloablation...and engraftment...is a time period during which the patient...is at grave peril of death from opportunistic infections. The fact that use of the CellPro device reduces this period of extreme vulnerability to about 8 days, as compared to 18-21 days, is a patient-safety benefit which I expect will reduce transplant-related mortality significantly over the long run. – RICHARD BURT, M.D. (Decl. ¶ 5)

> The CellPro device in my experience results in superior stem cell product yields which quality is critical for small-donor-large-recipient allogeneic transplant settings in which large yields are needed. This is because if the yield is below that needed for engraftment count recovery, the graft could fail and the patient could die in the interim from infection or bleeding. – JOHN DiPIERSO, M.D. (Decl. ¶ 10)

> I consider the availability of, and access to, the CellPro's CEPRATE® SC device a compelling public interest. In fact, for patients afflicted with lymphoma, multiple myeloma, low grade lymphoma or breast cancer (where purging of tumor cells is potentially valuable), who are otherwise ineligible for treatment with an investigational device, the CellPro device offers the only available processing system. – GARY SCHILLER, M.D. (Decl. ¶ 9)

Any limitation on the quantity of CellPro devices would severely impact patient care as stated by the following physicians:

> If access by clinicians to the CellPro CEPRATE® SC stem cell concentrator were restricted in the United States, the practical availability of stem-cell-therapy options to clinicians and their patients would be diminished; and in my view it is not realistic to expect that Baxter's ISOLEX® device, or any other device that lacks FDA approval, could fully and adequately replace the CellPro device even if the therapeutic and technical equivalency of such device to the CellPro device were certain. – RICHARD CHAMPLIN, M.D. (Decl. ¶9)

> I understand that our supply of the CellPro device may be limited to the volume we were using as of March 1997. Such a restriction would adversely impact our ability to advance our pilot study in neuroblastoma to the randomized trial, thereby limiting the availability of this potentially life sustaining technology to these desperately ill children. – JED B. GORLIN, M.D. (Decl. ¶ 4)

> It is the only FDA-approved device which reliably prepares clinically useful volumes of concentrated stem cells. For some categories of patients, there were no practical therapeutic options available before the advent of the CEPRATE®SC concentrator and it still affords the only practical treatment option. I believe that <u>any</u> injunction, even if it contains significant exemptions and exceptions, would disserve compelling public interests. – CESAR O. FREYTES, M.D. (Decl. ¶ 3)

Baxter's argument that it would be a simple matter to initiate new IDEs with the non FDA-approved Baxter device in place of the FDA-approved CellPro device are contrary to the experience of the physicians involved in patient care:

> I find it important that the CellPro CEPRATE® SC device is the only FDA-approved stem cell concentration device, because I can use it for other clinical protocols as I deem appropriate without having to go through the cumbersome FDA approval process that would be the case with an unapproved device. Indeed, the fact that the CellPro device is FDA-approved makes it easier (in terms of cutting down the amount of red tape and institutional resistance) to get an experimental protocol approved by the FDA and/or the hospital's or university's approval committee if at least the stem-cell-enrichment and transplant step is done with an FDA-approved device. – MICHAEL BISHOP, M.D. (Decl. ¶ 8)

> In my experience it is very difficult, if not impossible, for an institution to obtain a non-FDA-approved device unless that institution is enrolled in an FDA-approved trial which involves the use of that device. Even if the institution is involved in such a trial, patient enrollment in FDA clinical and preclinical trials is restricted, so that not every patient who might benefit will meet the criteria for inclusion in the trial. – OLIVER W. PRESS, M.D., Ph.D. (Decl. ¶ 7)

To those physicians involved in patient care and to patients who are seeking treatment for their life-threatening afflictions, it makes a difference that the CellPro device is FDA-approved and the Baxter device is not FDA-approved:

> In my experience, the ability to obtain approval for an experimental protocol from the FDA and/or hospital's or university's approval committee, is made easier if at least the stem-cell-enrichment and transplant step of that experimental procedure is performed with an FDA-approved device such as CellPro's CEPRATE®SC device... – CHARLES HESDORFFER, M.D. (Decl. ¶ 7)

> [T]he CEPRATE®SC device makes it easier to obtain approval for investigational and experimental protocols incorporating that device. This is true not only scientifically, because at least one step of the process is already known to be safe and efficacious, but the availability of an approved product has the practical effect of making experimental treatments more available because of such reasons as the availability of medical insurance reimbursement. – KENNETH ANDERSON, M.D. (Decl. ¶ 7)

> Given a choice, I believe that any researcher whose goal is to see new therapeutic options become generally available would prefer to employ a device that is, or promises to be, FDA-approved and generally available. – WILLIAM BURNS, M.D. (Decl. ¶ 6)

Plaintiffs tell this Court that their proposed injunction will "allay any possible public health concerns" (Brief, p. 7); that it will "minimize] disruption to patients who currently are being treated using the CellPro therapeutic device and ensur[e] that hospitals in the United

States and abroad are able to make a smooth transition to Baxter's licensed Isolex® device" (Brief, p. 1); and that "it cannot be said that no substitute products are available to patients who need them" (Brief, p. 9). Plaintiffs suggest that their proposed injunction would leave CellPro able, until such time as another FDA-approved device may appear, to satisfy any public health need "on a non-profit basis" (Brief, p. 22) and that CellPro has no "basis for claiming hardship" (Brief, p. 7). Each of these positions is factually untenable.

The truth is that if an injunction were entered on the terms proposed by plaintiffs, there would be an immediate and dramatic chilling effect on stem-cell-therapy research in the United States, a general retardation of progress in the field, a serious disruption of clinical trials now in progress and of planned future clinical trials which, were they conducted, would be clearly within the "reasonably-related-to-FDA-approval" protection of 35 U.S.C. § 271(e)(1). The injunction would, moreover, erect geographic, economic and administrative roadblocks to patients seeking immunoselective stem-cell therapy, even if CellPro could afford to maintain supply at the rate of loss that would be imposed by plaintiffs' "incremental profits" formula.

Nor is it realistic to suppose that Baxter would be in a position any time soon (if ever) to fill the market void that would be created if the CellPro device were "frozen" at the number of U.S. installations that used it as of March 12, 1997, and if it were withdrawn for the rest of the world markets over the next twelve months. We will now examine each of these points in more detail.

Adverse Impact On Clinical Research

The granting of plaintiffs' proposed injunction, and even the threat of that injunction, would retard the pace of clinical research in numerous ways.

First, clinical researchers who undertake trials typically do so with the hope that if they discover new and better therapies, those therapies will quickly come into wide use. Obviously, if an investigator perceives that the medical device on which he contemplates building a new therapeutic approach is at risk of disappearing, that researcher will be reluctant to pursue clinical trials using that device.

Secondly, clinical researchers cannot be sure that any substitute device would be equivalent for their particular application. There is no guarantee that the Baxter device, even if it is someday FDA-approved, will prove to be as safe and efficacious as the CellPro device for every application to which it is put. In other words, there is simply no basis to assume – and even an FDA approval of the Baxter device would not afford any basis to assume – that the device can feasibly be substituted for the CellPro device in all clinical-research and patient treatment contexts.

Thirdly, if Baxter's device were to gain FDA approval, the proposed injunction would require CellPro to withdraw, rapidly, even from that limited position that it would (theoretically) be allowed to maintain pending FDA approval of the Baxter device. Clinical studies in progress at that point would need to be aborted unless they could convert over to use of the Baxter device, if feasible. But as the clinicians' quotations above (and other statements in their declarations) prove, conversion would cause delay which in some cases, would kill patients; and switching devices in mid-trial and attempting to "pool" the data pertaining to the first and the second devices is objectionable from the standpoint of sound scientific methodology, and is also frowned upon by the FDA. (Krieger Decl., ¶ 3(l).)

Yet another way in which the terms of the proposed injunction would set back clinical research involves cost. In CellPro-sponsored studies of its second generation

devices (i.e. those that combine a 12.8 antibody-based stem cell enrichment step with a T-cell depletion or tumor-purging step using another antibody), CellPro is barred by FDA regulations from charging subjects or investigators more than a cost-recovery price for the device and disposables. The injunction's prohibition against distributing goods free or at a discounted price would render it impossible to comply with the FDA regulation and would mean, presumably, that these would have to be aborted (Jacobs Decl. ¶¶ 8,9,12). Even for trials being conducted under investigator-sponsored IDEs, it is common for the manufacturer of the medical device involved in a trial to provide a measure of financial support. In a number of investigator-sponsored trials involving CellPro's stem-cell selection devices, CellPro has made commitments either to supply devices and/or disposables free of charge or to supply them at a lowered, "cost-recovery"price; and CellPro has typically undertaken to pay limited patient-care and/or administrative costs in support of the trials as well. (Jacobs Decl. ¶ 10.)

Finally, no fair consideration of adverse effects on clinical research could overlook the effects that the proposed injunction would have on the collection of scientists, medical professionals and engineers at CellPro, a group probably unrivaled in the world in terms of its focused expertise regarding stem-cells and therapies based thereon, and a group that has been a dynamic force behind the rapid expansion of the clinical utility of stem-cell therapies (Jacobs Decl. ¶ 3.) The practical barriers to conducting clinical trials under the terms of the injunction would probably force CellPro to dismantle the research, development and clinical teams it has assembled, to the great detriment of patient care and medical progress. (Jacobs Decl. ¶ 5.)

Hardships To Patients

Anything that hampers clinical research can, of course, mean hardship for patients who might benefit from the fruits of that research, but to the extent that the proposed injunction would cause interruption or abandonment of trials in progress for reasons like those discussed above, the effects on patients would be more direct, more personal, and more appalling. Only very seriously ill patients ever undergo stem cell transplantation; and in some of the studies, the CellPro device is being used where there simply is no known therapy for the target disease and no other hope for the patient.

Baxter's Inability to Fill the Void in the United States

Submitted herewith is a Declaration of David F. Weeda, Esq., former Associate Chief Counsel of the FDA, which rebuts the cardinal premise of the proposed injunction - namely, the premise that needy patients would not go without treatment if the CellPro device were enjoined because hospitals that wished to use Baxter's ISOLEX® device could do so simply by filing their own investigational device exemptions (IDEs) with the FDA. (Brief, p. 9.) For the reasons explained at length in the Weeda Declaration, the IDE procedure cannot render the still-experimental ISOLEX® 300 device a reasonable substitute for the availability of the FDA-approved CellPro device. (Weeda Decl. ¶14.)

An IDE is a

> "very narrow, controlled investigation-based exemption from the general rule that an unapproved device may not be shipped in interstate commerce for use on human subjects. It is not intended as a stop-gap for the commercialization of a device that is otherwise unapproved."

(Id. ¶3.) The IDE does not permit the investigational device to be promoted, test marketed, sold above cost, nor may the investigation be prolonged to promote the device. (Id. ¶10.)

Since the rationale of allowing an unapproved device to be used under an IDE is simply to gather data, in a carefully-controlled study, to support the device's safety and effectiveness,

> "it is quite common, for public health reasons, for FDA to limit the number of IDEs it will approve ... or the total number of clinical cites under one IDE .... It is not FDA's policy to carte blanche approve innumerable IDEs absent some unusual and urgent public health reason ...."

(Id.) If the Agency sees that the IDE procedure is being abused as a guise for commercialization of an unapproved device, it "has broad authority to withdraw approval of an IDE." (Id. ¶11.)

Moreover, the IDE application process is complex and burdensome (Weeda Decl. ¶5) and the record keeping, reporting and monitoring requirements on an investigator and sponsor under an IDE are substantial (Id. ¶6). These burdens mean, as a practical matter, that Baxter under an IDE could not supply its device to all clinicians who might wish to use it (Jacobs Decl. ¶15); that not all patients who might benefit will be eligible for the protocol (Id. ¶15 C); and that some transplant programs, especially smaller ones, will lack the wherewithal to handle the administrative burdens of obtaining and using a Baxter device under an IDE (Id. ¶15 A).

Baxter's argument that "CellPro's FDA approval ... is limited in significant ways [bone marrow but not peripheral blood; autologous but not allogeneic]" (Brief, pp. 8-9) misses the point entirely. As the Weeda Declaration explains:

> "FDA does not regulate the practice of medicine, which includes a physician's decision to use an approved medical device in a manner, or for a medical indication, that is not specifically approved for inclusion in the labeling of the device. Thus, a physician may, within his or her sound medical judgment and the bounds of state law, employ an approved device for an 'off-label' use in the treatment of a patient. Such off-label uses are quite common in many areas of medicine and the areas of cell therapy and transplantation are no exception." (Weeda Decl. ¶7.)

With an unapproved device, the physician has no such latitude. As Mr. Weeda explains:

> "[A]n investigational use of a device presents major restrictions in a physician's ability to treat a patient. .... [A] major limitation on the investigator under an IDE for the ISOLEX® 300 product would be the need to closely follow the investigational protocol submitted as part of the IDE. In the absence of a very limited, emergency use, ... if a change or deviation from the protocol may affect the scientific soundness of the investigation plan or the safety of the subjects, the sponsor of the IDE is required to submit to FDA a supplemental application for approval and to notify the IRB. Thus, if the use of the ISOLEX® 300 under an IDE were the only available option for a physician, his or her ability to use sound medical judgment in treating patients would be significantly constrained. Moreover, if Baxter shipped the ISOLEX® 300 device with knowledge that it was actually for use in a manner inconsistent with the IDE, that shipment would be in violation of the Federal Food, Drug, and Cosmetic Act. See also, 21 CFR §801.4." (Weeda Decl. ¶7)

Thus, because the CellPro device is FDA-approved, it is a comparatively simple matter for a physician to obtain it commercially and use it for an off-label indication where, in the physician's medical judgment, the treatment is appropriate for a particular specific patient (Jacobs Decl. ¶15).

As for the "very limited" emergency use policy to which Mr. Weeda refers,

> "[It] is not intended to be used to facilitate the nationwide, stop-gap use of an unapproved device by physicians, and unapproved devices cannot be shipped in anticipation of an emergency." (Weeda Decl. ¶12).

Strict criteria govern when an "emergency" exists, and if the emergency policy is abused, "FDA can take regulatory action against the device manufacturer or the physician/investigator." (Weeda Decl. ¶12)[2/] From the foregoing it should be clear that the major premise of plaintiffs' injunction rationale, the premise that

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[2/]There is a "compassionate use" procedure, but it is "enormously burdensome to the physician" and is "a rare and exceptional step, and one that it is quite impractical to take on a routine or even frequent basis." (Press Decl. ¶8)

"it cannot be said that no substitute products are available to patients who need them"

(Brief, p. 9), is, as a matter of practical reality, a false premise.

The Improbability of Baxter's Winning FDA Approval Without Long Delay

The average time from PMA-filing to approval is some 26 months (Krieger Decl., ¶ 2), and a complex device for a radical and potentially dangerous application can naturally be expected to take longer than a relatively simple device for a relatively non-dangerous use (Krieger Decl., ¶¶ 2,3.) CellPro's own PMA application took over 3 years to ripen into an FDA approval (id., ¶2), even though CellPro, as a startup enterprise, was far better motivated than the lumbering giants of the industry typically are to minimize delay. There are, moreover, many reasons to suspect that Baxter's PMA filing is of less than average quality and that it can expect to succeed only after a lengthy struggle, if it succeeds at all.

First there is the timing: after the plaintiffs' collective decade and a half of relative slumber, the PMA was suddenly filed one week before the damages trial in this case – and at a time when Baxter is rumored to be trying to sell the division that makes its still-experimental device. It is hard to believe that this timing is just coincidental. It seems obvious that the principal reason, if not the only reason, why the PMA was filed at that time was to allow Baxter to posture itself, before the jury and the Court, as offering needy patients a credible alternative to the CellPro device.

Moreover, the information that can be gleaned from public-record sources strongly suggests that Baxter's application improperly "pools" clinical data gathered using the

problem-plagued[2/] ISOLEX® 300SA device by putting it together with data gathered using the newer, ISOLEX® 300*i* device. Moreover, from what we know of the nature of Baxter's 300*i* device, it seems highly probable that the FDA will see significant safety issues, including toxicity from magnetic beads that are infused into the patient and possible allergic risks of the antibody used. (Krieger Decl., ¶ 3(iii)).

Additional Adverse Public Health Impacts on Patients in the Rest of the World

In the rest of the world, Baxter's proposed injunction would inflict a different sort of injury on the public health and a different kind of hardship on patients and clinicians. At a minimum, the harm would be that healthcare providers outside of the U.S. and their patients would be forced, because of what amounts to extraterritorial enforcement of the U.S. patent laws, to pay the same monopoly price as if Baxter's device were patented worldwide – even though it has not been and cannot be. Another harm, at a minimum, would be that European clinicians would be forced to conduct their clinical research and treat their patients with a device that they would, by a vast plurality, avoid if they had a choice. Although Baxter obtained regulatory approval in Europe earlier than CellPro did, still the CellPro device enjoys an 80% share of the market (Vandervelde Decl., ¶¶ 4-6) – a fact which seems a fair indicator of how clinicians would judge the relative merits of CellPro's and Baxter's devices in other markets if both were commercially available.

There is, moreover, reason to suspect that Baxter's proposed injunction would inflict greater harms than just thrusting an inferior product into the hands of unwilling Europeans

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[2/] We say "problem-plagued" because Baxters' own literature admits some of the shortcomings of its now-apparently-abandoned chymopapain-based release enzyme. (See Krieger Decl. ¶ 3(ii) and associated exhibits.)

at a monopoly price and disrupting their medical research and patient care preferences. There is the prospect that if the CellPro device were "phased out" of the rest of the world in 12 months, and CellPro banished from the world market for 2 years thereafter, there would be such a shortage of stem-cell immunoselection devices in Europe – and perhaps elsewhere – that needy patients would be unable to get any such treatment at all. It is reported that the CellPro's 300*i* device, although approved in Europe a year ago (Vandervelde Decl., ¶ 4) is in such short supply that Baxter has developed a reputation for unreliable delivery (id., ¶ 7). Baxter's evidence fails to show – and there is strong reason to doubt – that Baxter would have the capacity to supply enough units to meet the stem-cell immunoselective-therapy needs of Europe, even if it were to persuade this Court to sentence Europeans to monopoly pricing, as plaintiffs' proposed injunction so brazenly bids this Court to do.

Special Hardships to Patients in Canada and Australia

In Canada and Australia, where the Baxter device also has not been approved under local medical-device-regulatory laws, a phaseout of the CellPro device on Baxter's proposed one-year schedule (without regard, apparently, to whether Baxter gets approval in those countries or not) would mean that no alternative device was commercially available to clinicians and patients there. (Jacobs Decl., ¶ 13.)

IV. ARGUMENT

A. The Injunction Would Unlawfully Prohibit CellPro's FDA-Clinical Trial-Related Activities That Are Exempt From Infringement Liability Under 35 U.S.C. § 271(e)

Title 35 U.S.C. § 283 gives courts power to grant injunctions to prevent violation of "rights secured by patent." Nevertheless, despite the Court's infringement finding, the making, using, offering to sell, or selling of the 12.8 antibody, the 12.8 hybridoma or the CEPRATE® device does not violate "any rights secured by patent" when that activity is reasonably related to development and submission of information required for FDA approval. See 35 U.S.C. § 271(e)(1); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 671 (1990) ("§ 271(e)(1) permits competitors, prior to the expiration of a patent, to engage in otherwise infringing activities in order to prepare for obtaining regulatory approval.")

Indeed, Congress has forbidden the courts from enjoining such exempt, FDA related activities. 35 U.S.C. § 271(e)(3) provides:

> **No injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention [exempt under § 271(e)(1)].**

Yet plaintiffs request an injunction that would plainly violate § 271(e)(3).

Although CellPro has already received FDA approval to market its device for autologous bone marrow transplantation, CellPro is still engaged in on-going clinical trials designed to obtain further FDA approvals not only by way of label expansions for its CEPRATE® SC Stem Cell Concentrator but also for second-generation devices that combine the use of the 12.8 antibody for stem-cell concentration with other antibodies for other manipulations of the suspension (Jacobs Decl., ¶¶ 5,6,7,11,16). CellPro even plans trials in

Europe and Australia which are aimed at gathering data that are FDA-related (Id. ¶¶ 17,19). Under § 271(e) this is non-infringing activity which the Court cannot lawfully enjoin.

Despite the clear law to the contrary, plaintiffs seek to enjoin this exempt activity. See, e.g., the following portions of Plaintiffs' proposed permanent injunction:

> 1. CellPro, Inc. ... [is] 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.[4/]
>
> 3. CellPro shall promptly destroy, in the presence of a United States Marshall, all [12.8] antibodies and hybridomas ....

As should be clear from the proposed language – "for any purpose whatever" – plaintiffs are requesting that CellPro be enjoined from doing exactly what Congress, through § 271(e), permits it to do. Indeed, by seeking the destruction of the 12.8 hybridoma, plaintiffs seek to preclude CellPro from conducting clinical trials now or at any time in the future, – after the expiration of the Civin patents. Without the unique 12.8 hybridoma to produce the unique 12.8 antibody, there will be no clinical trials. Plaintiffs' proposed injunction is, on its face, broader than allowed by law.

But more fundamental than this problem of overbreadth is that . . .

B. In View Of The Public Interest, No Injunctive Relief Should Be Awarded

Plaintiffs concede, as they must, that findings of patent validity and infringement do not confer on the patentee any absolute right to permanent injunctive relief (Brief, p. 4) and

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[4/] Similar language to this paragraph appears in subparagraphs (b), (e) and (f).

that such relief may and should be denied where there is a "sound reason" for denying it (id.).

Courts can, and do, deny permanent injunctive relief to prevailing patentees when public interests–including especially public health concerns–make that course appropriate. See e.g., Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found., 146 F.2d 941, 956 (9th Cir. 1944); City of Milwaukee v. Activated Sludge, 69 F.2d 577 (7th Cir. 1934), cert. denied 293 U.S. 576 (1934).

In a similar vein are decisions which deny, or stay, injunctive relief even in situations where significant public hardship, or detriment to public health, are not evident. In Foster v. American Mach. & Foundry Co., 492 F2d 1317, 1324 (2d Cir. 1974), the court affirmed what amounted to a compulsory license–a reasonable royalty damage award without an injunction. The Court wrote:

> We do not find any difficulty in agreeing that an injunction would be an inappropriate remedy in this case. An injunction to protect a patent against infringement, like any other injunction, is an equitable remedy to be determined by the circumstances. .... Here, as the District court noted, the appellee manufactures a product; the appellant does not. In the assessment of relative equities, the court could properly conclude that to impose irreparable hardship on the infringer by injunction, without any concomitant benefit to the patentee, would be inequitable.
>
> . . . .
>
> Instead, the District Court avoided ordering a cessation of business to the benefit of neither party by compensating appellant in the form of a compulsory license with royalties. This Court has approved such a 'flexible approach' in patent litigation. Here the compulsory license is a benefit to the patentee who has been unable to prevail in his quest for injunctive relief. To grant him a compulsory royalty is to give him half a loaf. In the circumstance of his utter failure to exploit the patent on his own, that seems fair.

Similarly, in E.I. duPont de Nemours and Co. v. Phillips Petroleum Co., 835 F.2d 277, 278 (Fed. Cir. 1987), the court upheld the grant of a stay of a preliminary injunction

where duPont, the patentee, had licensed all who desired entry into the patented polyethylene business and planned to exit the market. The court observed that "harm to duPont here is of a different nature than harm to a patentee who is practicing its invention and fully excluding others." (id.)

Here, as in duPont, others beside Baxter have been licensed (actually sublicensed by Baxter itself) in the therapeutic field–namely, Applied Immune Sciences ("AIS") and Systemix (PTX 421 and PTX 836)–and although Baxter has aspirations to sell a competing therapeutic device in the United States, it is, and for the indefinite future will remain, legally inhibited from doing so because the device is not FDA approved.

Hence, granting the proposed injunction and "freezing" the number of CellPro installations at March 12, 1997 would leave American clinicians, clinical researchers and patients in a kind of limbo until the day (if it ever comes) when the FDA approves Baxter's device:[5/] CellPro would be unable adequately to serve the market despite its FDA approval, and Baxter would be unable adequately to serve the market for lack of FDA approval.

Finally, while it cannot be said that the plaintiffs are guilty of "utter failure to exploit the patent on [their] own" (Foster, supra, 492 F2d at 1324), it must be said that they have

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5/ Nor is FDA approval the all-or-nothing proposition that Baxter's proposed injunction supposes it to be. It is entirely possible that Baxter's device could gain FDA approval for some indications, on the basis of some safety or efficacy parameter, while CellPro's device would be FDA approved for other indications, based on some other safety or efficacy parameter. For example, CellPro's device is presently FDA approved for allogeneic bone marrow transplantation, the efficacy parameter being a lowering of infusional toxicity compared to conventional transplantation. Even if Baxter's device someday achieves FDA approval, it could well be for a different labeled indication and the FDA could well make different findings as to safety and efficacy advantages (or disadvantages). (See Jacobs Decl. ¶ 2.) Even if it were not naive to think that Baxter will soon have an FDA approval of some kind, it may still be naive to think that the Baxter device will ever prove to be a medically (or legally) appropriate and equivalent substitute for the CellPro device for all researchers' and patients' needs.

been guilty of extraordinary, and still-ongoing, delay in bringing U.S.-taxpayer-funded technology to the U.S. therapeutic market.[6/]

We take issue with plaintiffs' assertion that even irreparable injury to CellPro is "legally irrelevant" to the question whether permanent injunctive relief should be awarded. Clearly it is relevant. Nerney v. New York, 83 F2d 409, 411 (2d Cir. 1936), injunctive relief denied where "it was not absolutely essential to the patentee and caused the infringing defendant irreparable damage"]; Foster, 492 F2d at 1324, supra ["the court could properly conclude that to impose irreparable hardship on the infringer by injunction, without any concomitant benefit to the patentee, would be inequitable"].

Even if irreparable harm to CellPro were not relevant to the propriety of permanent injunctive relief, still it would be relevant to the issue of whether the injunction should be stayed pending appeal, an issue briefed in the following point. Hence, we discuss the issue of irreparable harm to CellPro.

[6/] Plaintiffs have indeed been remarkably slow to convert the discovery of the MY-10 antibody into a clinically practical immunoselection device. From Dr. Civin's Blood Abstract (DTX15) we know that he had the MY-10 antibody at least as early as November 1982 – about a decade and a half ago. The patent applications were filed over 13 years ago on February 6, 1984. Although Hopkins licensed BD fairly promptly after the application was filed (August 1984; see DTX980), BD sat on the license for over 6 years (until August 24, 1990) before it licensed Baxter for therapeutic applications – in the meantime failing itself to create a practical immunoselection device. Although Baxter granted sublicenses in 1992 and 1993 (PTX 421and PTX 836), both of those sublicenses apparently also failed to produce a practical device. Baxter itself has now been licensed for more than 6-1/2 years, but neither Hopkins, Baxter, nor any licensee or sublicensee under the Civin patents has yet produced an FDA-approved therapeutic device.

Although plaintiffs are fond of repeating that CellPro is ahead of them because it got an unfair "head start," plaintiffs ignore the fact that CellPro was not yet even in operation during the first half of the extraordinarily lengthy period during which the plaintiffs, collectively, have delayed developing the fruits of taxpayer-funded medical research to the level of practical therapeutic usefulness.

Even if the Court declines to award plaintiffs the direct monetary sums they seek--including a trebling of damages and award of attorney fees, for a total of some $13.9 million, still the combination of injunctive provisions plaintiffs seek would, by itself, inflict irreparable harm on CellPro. Throughout all of its corporate existence, CellPro has focused most of its effort on stem-cell therapy. Its one and only FDA-approved device is in that field, providing the one significant income stream to a company that has never made a profit and has had to depend on venture-capital investors and public stock offerings to support its endeavors. The overhang of litigation is enough of a hardship to such a company even when the litigation is at a early stage and even when the news is good; but if it should come to pass that CellPro is under Court order to phase itself out of the rest-of-the-world market (including the European market, in which it has an 80% share (Vandervelde Decl., ¶ 6); to sell temporarily at money-losing prices into a U.S. market that the Court will not let grow; and then to disappear, quickly, from that market if any Baxter device should ever become FDA-approved, it is not hard to predict what this would do to CellPro's ability to hold together the world-class team of medical, scientific and engineering professionals it has assembled, and to survive as a company. (Jacobs Decl. ¶¶ 3,4.)

The definition of "incremental profit" contained in the proposed injunction, together with the $2,000 "floor" on what CellPro would be required to pay per unit, would mean that CellPro could supply disposables only at a large loss. As appears from the Declaration of William E. Simpson, if CellPro were compelled to pay a royalty of $2,000 per unit and all appropriate costs were allocated, CellPro would loss some $1,510.81 per unit before considering fixed costs. It would, moreover, be unfair to prohibit CellPro from recovering such costs as research and development and administrative costs, as much of CellPro's

ongoing activity aims at developing new therapies and new products, which activities are § 271(e)(1) exempt. (Id. ¶¶ 17, 19).

C. If A Final Injunction Is To Be Entered, It Should Be Stayed In Its Entirety Pending Appeal

A district court "in its discretion may suspend ... an injunction during the pendency of the appeal." Fed. R. Civ. P. 62(c). Four factors are considered:

> "(1) Whether the stay applicant has made a strong showing that he is likely to succeed on the merits;
>
> (2) Whether the applicant will be irreparably injured absent a stay;
>
> (3) Whether issuance of a stay will substantially injure the other parties interested in the proceeding; and
>
> (4) Where the public interest lies."

Standard Havens Products v. Gencor Indus., 897 F.2d 511, 512 (Fed. Cir. 1990), quoting Hilton v. Braunskill, 481 U.S. 770, 776, 107 S. Ct. 2113, 2119, 95 L.Ed.2d 724 (1987). These factors do not constitute rigid, inflexible requirements; they are considered according to a sort of sliding-scale approach, such that if harm to the applicant is great enough, a court will not require a strong showing that the applicant is likely to succeed on the merits of the appeal. Standard Havens, 897 F.2d at 513; Hybritech, Inc. v. Abbott Laboratories, 849 F.2d 1446, 1451 (Fed. Cir. 1988) [the "factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested"].

Stays have been granted in cases where the applicant's showing as to one or more of the factors is wholly lacking or only weakly supportive of his position. For example, in In

re Hayes Microcomputer Products, Inc., 766 F. Supp. 818 (N.D. Cal. 1991), aff'd., 982 F.2d 1527 (Fed. Cir. 1992), the district court granted defendants' motion for a stay of the injunction although convinced that their chances on appeal were doubtful. The court reasoned that the defendants would have been put out of business or irreparably harmed pending appeal, even if ultimately not found to be willful infringers; that the plaintiff, having made a habit of licensing its technology, would not be substantially injured during pendency of the appeal; and that the public, though interested in seeing valid patents enforced, also had an interest in fostering legitimate competition by encouraging valid challenges to patents. The stay was granted on condition that the defendants deposit an amount equal to a reasonable royalty on infringing sales sold during appeal pendency.

We submit that the Hilton v. Braunskill factors all favor the granting of a stay pending appeal in this case, as follows:

1. Likelihood of Success on Merits

The principal liability and infringement issues have been thoroughly ventilated in prior briefing; we understand the Court's rulings; and we do not expect that rehashing our arguments at this late hour would change the Court's view of the merits. With respect, however, we would remind the Court that there were potentially dispositive issues that were close enough to withstand a first round of summary judgment motions, to prevail at trial, and thereafter to withstand JMOL motions.[2] This case, moreover, presents novel and

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[2] Baxter, in an issue of Blood dated four days after the jury's wilfulness finding, effectively admitted to the medical community that Baxter itself does not believe that CellPro achieves 90%-pure suspensions. Kenny Decl., ¶¶ 2-3 and Exhibit A.) The Court itself called CellPro's '204 nonenablement defense a "horse race"; and in the same

(continued...)

important policy issues as regards, for example, the appropriate scope of enablement and claim breadth which can fairly be supported by a 1-example patent, dealing with monoclonal antibody technology, a concededly unpredictable art. CellPro sincerely believes that its likelihood of appellate success is high; but even if this Court disagrees, at least it must be said that this record discloses fairly arguable and important issues for the appellate court. The likelihood-of-success factor is, in any event, not dispositive.

2. Irreparable Harm to CellPro

The lack of a stay pending appeal would irreparably harm CellPro, for the reasons mentioned above.

3. Whether Issuance of the Stay Will Substantially Injure the Other Parties Interested in the Proceeding

Because Baxter, for lack of FDA approval and possibly for other reasons, is incapable of fully supplying the needs of the U.S. market, and because Baxter's experimental device cannot lawfully command a commercial price under FDA standards, the extent to which Baxter can lose sales and revenues if CellPro continues distributing its products freely pending appeal is limited; and besides, there is ample precedent for requiring the stay applicant to deposit reasonable royalties into court pending appeal. In re Hayes Microcomputer, supra.

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[11](...continued)
statement the Court acknowledged its understanding why an accused infringer's trial strategy might reasonably differ from the defenses discussed in opinion letters--namely, that the enablement defense is typically one that does not develop until after discovery has been had (8/4/95 Tr. at 244).

Moreover, unless Baxter's patents are ultimately determined to be invalid, unenforceable or not infringed by CellPro, Baxter actually will be benefitted, not harmed, if CellPro is permitted during the appellate process to keep "growing the market" – to keep expanding the customer base, to keep sponsoring research that will broaden the range of the clinical utility of stem cell immunoselection.

Baxter's assertion that "the longer CellPro is permitted to remain in the market, and the greater its sales, the greater the obstacles its conduct will have created for Baxter by the time Baxter begins marketing its ISOLEX® device in the United States (Brief, p. 8), and its assertion that "CellPro's unlicensed sales of its competing therapeutic device has harmed Baxter and will continue Baxter by giving CellPro a market lead that will be difficult to overcome" (id.) are nonsensical in the circumstances of this case. Exactly the opposite is true: The more CellPro expands the market before Baxter wins FDA approval, the bigger Baxter's eventual windfall will be – if the Court of Appeals vindicates Baxter's position on the merits and a permanent injunction is found to be appropriate.

Baxter is helped more than it is hurt if CellPro continues to nurture and expand a market far broader than any that Baxter, without FDA approval, could efficiently develop and adequately serve, but which Baxter would "own" if CellPro were enjoined following the appeal.

4. The Public Interest

To what has already been said about the public interest, we would only add that it is clearly in the public interest that somebody, at least, continue to widen the availability, and expand the range of clinical utility, of stem-cell immunoselective therapy; and in this

country, Baxter cannot effectively do that if CellPro is enjoined pending appeal, given the FDA-related limitations on the use of Baxter's still- experimental device for human treatment.

D. The Final Injunction That Plaintiffs Seek is Too Broad and Violative of Legal and Public Policy Constraints

In addition to the overbreadth that comes of ignoring § 271(e)(l), the proposed injunction includes other features that are legally impermissible or inappropriate, as follows:

1. The Proposed Two Year Prohibition Upon CellPro Selling Foreign-Manufactured Products Abroad Would Not Only Prohibit Non-infringing Conduct But Would Also Intrude upon the Law and Policy of Other Sovereigns and Is Therefore Contrary to Applicable Principles of International Comity

In their proposed Permanent Injunction, plaintiffs seek a provision (para. 1(l)) that:

> "l. 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."

This provision would reach even products wholly made in Europe with an antibody made in Europe – a result that the Brief makes clear is intended. Such a provision would prohibit CellPro from competing with plaintiffs in the European Union, even though CellPro's competition in Europe is entirely free of any infringement of any intellectual property of plaintiff in Europe.

Plaintiffs do not cite a single authority in support of this daring provision. It is, in fact, contrary to basic principles of law and of international comity which has been endorsed by the United States Government.

a. A United States Patent Has No Force or Effect Outside the United States. An Attempt To Prohibit Conduct Outside the United States Improperly Extends the United States Patent Law beyond Its Inherent Reach.

The Federal Circuit stated it starkly in Paper Converting Machine v. Magna Graphics, 745 F.2d 11, 17 (Fed. Cir. 1984), citing Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), for the general proposition that there is a "horror of giving extraterritorial effect to United States patent protection." Deepsouth had made it clear (406 U.S. at 531) that:

> Our patent system makes no claim to extraterritorial effect; "these acts of Congress do not, and were not intended to, operate beyond the limits of the United States," [. . .] and we correspondingly reject the claims of others to such control over our markets. [. . .]. To the degree that the inventor needs protection in markets other than those of this country, the wording of 35 U.S.C. §§ 154 and 271 reveals a congressional intent to have him seek it abroad through patents secured in countries where his goods are being used.

The enactment of 35 U.S.C. § 271(f) with respect to manufacturing component parts in the United States for assembly abroad did not erode the fundamental proposition concerning extraterritoriality. See, e.g., Robotic Vision Systems v. View Engineering Inc, 39 U.S.P.Q.2d 1117, 1119 (C.D. Cal. 1995) (citing Deepsouth for proposition that it is not an infringement to make or use a patented product outside the United States, and denying an injunction of activities beyond the territorial reach of the statute.

Plaintiffs speak of an advantage supposed to have flowed to CellPro in respect of its foreign operations from CellPro's infringing conduct in the United States, saying (Brief, p. 11):

> "Rather than being the sole supplier to the ex-U.S. market for some period of time, Baxter has been forced to share that market with an illicit participant."

Plaintiffs conveniently overlook the fact that CellPro is not an "illicit participant" in competing with Baxter outside the United States. CellPro's infringement of Baxter's two United States patents concerns CellPro's conduct in the United States, which does not supply a scintilla of foundation for the assertion that CellPro's conduct in the "ex-U.S. market" constitutes the infringement of any patent right of Baxter in any such foreign jurisdiction. Plaintiffs have no patent rights in those jurisdictions, and Dr. Civin would be told that he was time-barred long ago if he sought them now.

b. The Proposed Extraterritorial Provision Would Be Contrary to the Law and Policy of the European Union.

We submit herewith the sworn statement of the Honorable H. Colin Overbury, CBE, an expert on European law and policy. Mr. Overbury was one of the highest officials in the European Commission, having served in numerous capacities in the portion of the Commission charged with competition (antitrust) responsibilities. Mr. Overbury's sworn statement sets out in detail the intrusion of the proposed extraterritorial prohibition upon the fundamental law and policy of the European Union.

For instance (Overbury para. 7),

- The terms of the proposed Permanent Injunction have the effect of preventing Cell Pro from competing with the plaintiffs in the European Union for a two year period. From the perspective of the European Union and its institutions, that would give to a United States patent an extraterritorial effect contrary to the competition law and policy of the European Union, directly impeding competition within the European Union and depriving the common market of the benefit of competition, and would be contrary to the basic tenet of the EC Treaty which renders void restrictions upon the free movement of goods within the common market.

- The only purportedly ameliorating effect of the proposed Partial Stay does not permit competition as it would be if European patent and competition law were given their normal reach, but would only have the effect of granting a license to CellPro which restricts CellPro's ability to fix its own prices, which limits the quantities CellPro can supply to its customers, and

which prevents CellPro from competing with the plaintiffs. Such restrictions are contrary to the EC Commission's Regulation on the Transfer of Technology.

- CellPro would also be prevented (subject to the terms of the Partial Stay) from reselling any of the products in question which had lawfully been placed on the market by the plaintiffs or with their consent, which contravenes the principles of the exhaustion of rights.

c. Such Intrusions Run Afoul of the Principles of International Comity.

Such intrusions upon the law and policy of another sovereign are contrary to the "longstanding principle of American law 'that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States.'" EEOC v. Arabian American Oil Co., 499 U.S. 244, 248 (1991). If this Court were to accept plaintiffs' proposed extraterritorial provision, this Court would be compelling CellPro to refrain from competition that it would otherwise have provided in the European Union. CellPro could not voluntarily agree with Baxter not to compete and thereby to provide Baxter with the monopoly it so brazenly claims as its birthright; a court of the United States ought not compel conduct of a party that would violate foreign law and policy.

The authorities uniformly condemn such efforts and commend adherence to principles of international comity. E.g., Subafilms, Ltd. v MGM-Pathe Communications, 24 F.3d 1088 (9th Cir. 1994), expressing concern at the "international discord" that could arise if United States courts attempted to affect acts in other countries and to displace those countries' law "in circumstances in which previously it was assumed to govern." (24 F.3d at 1097.) Similarly, in Mannington Mills, Inc. v. Congoleum Corp., 595 F.2d 1287 (3d Cir. 1979), the court required careful attention to principles of international comity before

extending Walker Process antitrust liability to acts of fraudulent procurement of patents abroad. Cf., Nintendo of America, Inc. v. Aeropower Co., Ltd., 34 F.3d 246 (4th Cir. 1994) (in the context of trademark infringement); Timberlane Lumber Co. v. Bank of America, N.T. & S.A., 549 F.2d 597 (9th Cir. 1976)[8/].

Moreover, as Mr. Overbury explains, the United States Government has expressly agreed with the European Council to avoid enforcement actions which raise such issues. (Overbury para. 17.)

We respectfully submit that this Court ought not frame relief in such a way as to extend that statutory reach of the United States patent law, particularly where the proposed provision would so severely intrude upon important law and policy of a foreign sovereign, contrary to fundamental principles of international comity.

2. The 12.8 Hybridoma Outside the U.S. is Non-Infringing And Beyond The Court's Jurisdiction, and the Proposed Provision Requiring its Repatriation and Destruction is Legally Insupportable

a. The 12.8 Hybridoma is a non-infringing product

Plaintiffs have no patent coverage outside the U.S., and they lacked any patent claim to any hybridoma before October 23, 1991; yet they seek to expand the temporal and geographic scope of their patents by requesting that the Court order CellPro to bring 12.8

[8/] In Timberlane the Ninth Circuit held that, in order to allow extraterritorial application of the antitrust laws, (1) there must be some effect on American foreign commerce; (2) the effect must be sufficiently great to present a cognizable injury, and (3) the interests of and links to American foreign commerce must be sufficiently strong in relation to those of other nations to justify an assertion of extraterritorial authority. Star-Kist Foods, Inc. v. P.J. Rhodes & Co., 769 F.2d 1393, 1395 (9th Cir. 1985, Kennedy, J.), summarizing Timberlane, 549 F.2d at 613-615, and upholding district court's decision to exclude wholly foreign commerce from the scope of its injunction enforcing the Lanham Act.

hybridoma, made prior to the issuance of the '204 patent and located outside of the U.S., back to the United States to be destroyed. Plaintiffs' request is based on misstatement of the facts and misrepresentation of the law.

The 12.8 hybridoma was created in the early 1980's at the Fred Hutchinson Cancer Research Center. Under licence from the Hutchinson Center, 12.8 hybridoma was transferred to CellPro. In July 1990, CellPro created a "master cell bank" of 12.8 hybridoma by freezing about 100 vials. The '204 patent, with the first hybridoma claims, issued in October 1991. Thereafter, six of the frozen hybridoma vials were shipped to Canada. See generally D.I. 158 and 261; Tarnowski Declaration, filed herewith.

From these facts plaintiffs weave a series of convoluted and seriously erroneous arguments. First, plaintiffs argue that CellPro "used" 12.8 hybridoma master cell bank after the '204 patent issued in a way that infringed the patent. In arguing this, plaintiffs conveniently ignore the fact that that CellPro's "master cell bank" is not a single entity, but rather a collection of separate and distinct vials each containing hybridoma cells.[9/] As plaintiffs acknowledge, hybridoma that they say was "used" to make "working cell banks" and "extended cell banks" after issuance of the '204 patent was not the same hybridoma shipped to Canada:

> Mr. Bordonaro stopped recording withdrawals from the Master Cell Bank ... on December 9, 1991 [after the alleged extended and working cell banks were allegedly created], when there were only 82 vials left. However, after that date, cells from the master cell bank continued to be removed ...

9/ Indeed, plaintiffs have acknowledged and argued this very fact in an earlier brief. "The master cell bank originally contained approximately 100 vials of frozen hybridoma cells." D.I. 249 at pp. 4-10, Plaintiffs Opp. Mem. to CellPro's Motion for Partial Summary Judgment on Non-infringement (citing (Bordonaro Tr. 777-78, Appendix B, p. B117-118; Plaintiffs' Dep. Ex. 836, Appendix B, Ex. E).

> for shipment to Biomira in Canada... [and o]n or about July 19, 1993, CellPro sent six vials of cells from its master cell bank to Biomira in Canada.

D.I. 249 at p.8-9.

Plaintiff thus acknowledge that the hybridoma shipped to Canada was made before the '204 patent issued, stored separately from the hybridoma later used by CellPro in the U.S., and was never itself ever used in the U.S. The frozen hybridoma at issue was simply never tested or profiled or used in any way after the issuance of the '204 patent.

Plaintiffs' argument that the act of shipping alone was a "use" has been rejected by the courts. See Amgen, Inc. v. Elanex Pharmaceuticals, Inc., 1996 WL 84590, *3-4 (W.D. Wash. 1996) (shipment of frozen cells outside U.S. is not infringement); Fausett v. Pansy Ellen, Inc., 19 U.S.P.Q.2d 1228, 1230 (N.D. Ga. 1990) (importation and exportation of alleged infringing product are not infringement).

Even the cases plaintiffs cite make it clear that shipment alone is not an infringing "use." The Supreme Court, in Bauer & Cie. v. O'Donnell, 229 U.S. 1 (1913), defined "use" as "put[ting] into service any given invention." Id. at 10-11. A hybridoma is "put into service" by making monoclonal antibody, and the 12.8 hybridoma shipped to Canada was never so "put into service" in the U.S.[10/]

The cases cited by plaintiffs to support their argument that shipment is use are clearly not on point. In Trans World Mfg. Corp. v. Al Nyman & Sons, Inc., 750 F.2d 1552,

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[10/] Olsson v. U.S., 25 F. Supp. 495 (Ct. Cl. 1938), Hughes Aircraft v. U.S., 215 U.S.P.Q. 787 (Ct. Cl. 1982), and Paper Converting Machine Co. v. Magna-Graphics Corp., 745 F.2d 11 (Fed. Cir. 1984) are not to the contrary. In Olsson the howitzers were "put into service" for deterrence; in Hughes the attitude control system was installed in an operational satellite; and in Paper Converting the machine was operated for testing. Nothing even remotely similar occurred with respect to the 12.8 hybridoma at issue here.

1564 (Fed. Cir. 1984), the "use" of the patented invention was aiding customers to sell eyeglasses in the U.S. by providing them with infringing racks. As such, the racks were "put into service" in the U.S. Similarly, in Thorn EMI North America v. Micron Technology, 821 F. Supp. 272, 275 (D. Del. 1993), the patented article was shipped into Delaware "in an attempt to solicit business." Again, the invention was "put into service" in the U.S. On the other hand, here, the shipped hybridoma was not "put into service" in the U.S. ,but rather in Canada, a country in which plaintiffs have no patent rights.

b. 35 U.S.C. § 271(f) Does Not Apply

Since the facts plainly reveal that the 12.8 hybridoma shipped to Canada was not infringing, plaintiffs resort to arguing that CellPro's shipment of hybridoma cells to Canada "appears to violate the intent of § 271(f)." Even under the broadest possible reading of § 271(f) this cannot be true. The plain language of § 271(f) is limited to "components" of patented inventions.

The 12.8 Hybridoma shipped to Canada is not "a component of a patented invention" and is furthermore not "uncombined in whole or in part." Rather, the 12.8 hybridoma is a complete and whole product with respect to the claims of the '204 patent. The legislative history of § 271(f) further supports its inapplicability here. Section 271(f) was enacted in 1984 to legislatively overrule Deepsouth Packing Co. v. The Laitram Corp., 406 U.S. 518 (1992), in which the Supreme Court held that the defendant, who had manufactured parts of a patented product within the United States during the patent term and then shipped them overseas for final assembly into the patented product, was not liable

for infringement because the defendant did not "make" the patented invention within the United States. Id. at 527.

> This proposal [§271(f)] responds to the United States Supreme Court decision in Deepsouth Packing Co. v. The Laitram Corp., 406 U.S. 518 (1972), concerning the need for a legislative solution to close a loophole in patent law.

U.S. Code Congressional and Administrative News, Vol. 5, p. 5828, 1984 98th Cong., 2nd Session. And the courts have also recognized this narrow purpose:

> This section [271(f)] of the patent law amendment was proposed in response to the [Deepsouth] decision... which corrected a loophole in prior patent law, allowing copiers to avoid liability for products patented in the United States, by shipping the... [un]patented components for combination in foreign countries.

T.D. Williamson, Inc. v. Laymon, 723 F. Supp. 587, 592 (N.D. Okl. 1989); aff'd, 18 U.S.P.Q.2d 1575 (Fed. Cir. 1990).

Plaintiffs argue that failing to apply §271(f) here would produce an "irrational" result, namely that unpatented components cannot be exported but patented articles can be. But this argument overlooks the temporal limitations on a patent: the 12.8 hybridoma is not "a patented article" because it was made prior to the issuance of the '204 patent. 35 U.S.C. § 271(a) unambiguously provides that only making, using and selling during the term of a patent is an infringing act, and 35 U.S.C. § 271(f) unambiguously provides that only exporting of components during the term of a patent is an infringing act. Neither section applies to CellPro's shipment of the 12.8 hybridoma. Thus, that shipment was not a "violation of a right secured by a patent" which can be subject to injunction under 35 U.S.C. § 283.

3. The Injunction is Overboard in Regard to the '680 Patent

Subparagraph 1(g) at page 3 of plaintiffs' proposed permanent injunction it could be read to imply that "making, using or selling any product designed to produce or capable of producing an infringing suspension" is an infringement, inducement of infringement, or contribution to infringement of the '680 patent. To the extent to which this provision is meant to apply to the CEPRATE® SC Stem Cell Concentrator, it is legally impermissible in its breadth. Even if a device is capable of producing an infringingly-purer suspension,[11/] that is not the legal test of inducement Joy Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement"); and supplying the device cannot constitute contributory infringement if the device has a substantial noninfringing use. In re Certain Molded-In Sandwich Panel Inserts, 218 U.S.P.Q. 832, 836 (U.S. I.T.C. 1982).

As a result of the Court's June 28, 1996 decision which ruled that a suspension is within the '680 Patent claims if it is ninety percent free of mature cells, CellPro added a customer notice to its product literature (See Declaration of Ed Kenney, ¶ 4 and Exhibit B) which warns against operating the device in such a manner as to achieve ninety percent purity. Baxter, for its part, now advertises to the trade that CellPro's device cannot achieve ninety percent purity. In an advertisement for Baxter's ISOLEX® 300*i* device, appearing in the March 15, 1997 issue of Blood, Baxter asserts that CellPro's purity data are below ninety percent (See Declaration of Edward Kenney, ¶ 3 and Exhibit A.)

[11/] CellPro does not concede that the device is even capable of achieving ninety percent purity, if the calculation includes counting all cells in the suspension.

Given that CellPro's promotional literature recommends that customers not make suspensions over 90% pure – assuming they even could if they wanted to – and that Baxter's own promotional literature is broadcasting the idea that the CellPro product is incapable of making a ninety percent pure suspension, there is simply no basis to believe that CellPro's present sales of the device are made under conditions that could amount to inducement of infringement. See Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (Specific intent to induce infringement required.)

Particularly since Baxter itself is now conceding, in statements published to potential users of the CellPro device, that it cannot infringe the '680 Patent, no injunction against inducement is appropriate; and certainly would be inappropriate for the Court to sign any injunction that includes language which could imply that the mere act of selling the device constitutes an inducement to infringe the '680 Patent.

The same must be said of contributory infringement. Even if it were true – although Baxter itself now agrees that it is not – that the CellPro device is capable of infringing use, there is no doubt that it is at least capable of substantial non-infringing use. This being so, sale of the device by CellPro cannot, as a matter of law, be contributory infringement. Hence, any injunction stating or implying that sale of the CellPro device constitutes inducement of infringement or contributory infringement is impermissibly broad as it would prohibit non-infringing activity.[12/]

[12/] As to contributory infringement, CellPro notes a further objection: Plaintiffs, as the Court has found (June 28, 1996 Order (p.35), have abandoned any contributory infringement claim. They should not be permitted to seek injunctive relief on a claim they abandoned.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for permanent injunction should be denied. If any injunction is granted, it should be stayed pending appeal.

Dated: April 21, 1997 By: Gerard M. O'Rourke

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April 20, 1997 (7:22pm)