IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 02-148 GMS
	)	
VIACELL INC., et al.,	)	
	)	
Defendants.	)	

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Jeffrey L. Moyer, Esquire of Richards Layton & Finger, Wilmington, Delaware, Richard D. Kirk, Esquire of Morris James Hitchens & Williams LLP, Wilmington, Delaware, and Robert F. Stewart, Esquire of Dilworth Paxson LLP, Wilmington, Delaware. Counsel for Defendants. Of Counsel: Paul F. Ware, Esquire, John C. Englander, Esquire, James C. Rehnquist, Esquire, James W. McGarry, Esquire, and Elaine Herrmann Blais, Esquire of Goodwin Procter LLP, Boston, Massachussetts; William F. Abrams, Esquire, Thomas F. Chaffin, Esquire and Randal Ivor-Smith, Esquire of Pillsbury Winthrop LLP, Palo Alto, California; and James L. Rodgers, Esquire, Evelyn H. McConathy, Esquire, and Lisa Burgin Conte, Esquire of Dilworth Paxson LLP, Philadelphia, Pennsylvania.

MEMORANDUM OPINION

September 15, 2004
Wilmington, DE

SLEET, District Judge

I. INTRODUCTION

On February 22, 2002, PharmaStem Therapeutics, Inc. ("PharmaStem") filed suit against ViaCell, Inc. ("ViaCell"), Cryo-Cell International, Inc. ("Cryo-Cell"), CorCell, Inc. ("CorCell"), StemCyte, Inc. ("StemCyte"), CBR Systems, Inc. ("CBR"), Birthcells Technology, Inc. ("Birthcells"), Nustem Technologies, Inc. ("Nustem"), and Bio-Cell, Inc. ("Bio-Cell") (collectively "ViaCell" or "the defendants")[1], alleging infringement of United States Patents Nos. B1 5,004,681 ("'681 Patent") and 5,192,553 ("'553 Patent") (collectively "the Patents-In-Suit"). The Patents-In-Suit are generally directed toward cryopreserved therapeutic compositions containing hematopoietic stem cells obtained from umbilical cord or placental blood of a newborn, the '681 Patent, and methods pertaining to the therapeutic use of such compositions, the '553 Patent.

ViaCell asserted the defenses of invalidity for anticipation, indefiniteness, inequitable conduct and obviousness. The court held a *Markman* hearing and issued an order construing the disputed terms of the '681 and '553 Patents on January 13, 2003. A jury trial commenced on October 10, 2003. During trial, both parties properly moved for judgment as a matter of law ("JMOL") pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. The court reserved ruling on all JMOL motions.

On October 29, 2003, the jury returned a unanimous verdict on all claims in favor of PharmaStem. The jury found that each of the defendants infringed the claims of the '681 and '553 Patents, and that each of the defendant's infringement of those patents was willful. The jury also

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[1]A default judgment was subsequently rendered against NuStem on July 10, 2002. StemCyte and PharmaStem entered a settlement agreement before trial, and StemCyte accordingly was dismissed from this action on October 21, 2003.

upheld the validity and enforceability of the Patents-In-Suit, found that PharmaStem did not commit any anti-trust violation, and awarded PharmaStem past damages in the amount of $7,126,544.92. The court entered judgment on the verdict on October 30, 2003.

Following the jury's verdict, ViaCell filed a renewed motion for judgment as a matter of law, and, in the alternative, a motion for a new trial or for a remittitur. Defendants CBR, CorCell, and Cryo-Cell joined in Viacell's motions and submitted individual memoranda addressing issues specific to each of them. ViaCell filed another alternative motion, in which the three other defendants also joined, for findings by the court and/or to alter or amend judgment pursuant to Federal Rule of Civil Procedure 52, 59(e) and/or the court's equitable power. PharmaStem filed a motion for enhanced damages, attorneys' fees, pre-judgment interest and post judgment interest, a motion for a permanent injunction, as well as a motion to strike the affidavit of Chris Adams submitted in support of ViaCell's motion to alter or amend the judgment. Addressing these motions collectively herein, the court will enter judgment as a matter of law that defendants do not infringe the '553 patent and grant a partial new trial on the issue of infringement of the '681 Patent.

II. STANDARDS OF REVIEW

A. Renewed Motion for Judgment as a Matter of Law

Pursuant to Federal Rule of Civil Procedure 50, a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial, if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Walter v. Holiday Inns, Inc.*, 985 F.2d 1232, 1238 (3d Cir. 1993) (citation omitted). If the court denies a motion for JMOL during trial, the motion may be renewed within ten days of entry of judgment in the case. FED. R. CIV. P. 50(b). To prevail on a renewed motion for JMOL following a jury trial, a party "'must show

that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.,* 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d. at 893. In assessing the sufficiency of the evidence, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. *Id*.; *Richardson-Vicks Inc. v. UpJohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). The appropriate inquiry is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998). The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893.

B. Motion for a New Trial

The court may grant a new trial pursuant to Federal Rule of Civil Procedure 59 "for any of the reasons for which new trials have heretofore been granted in actions of law in the courts of the United States." FED. R. CIV. P. 59(a). A court should grant a new trial in a jury case, however, only if "the verdict was against the weight of the evidence . . . [and] a miscarriage of justice would result if the verdict were to stand." *Williamson v. Consolidated Rail Corp.*, 926 F.2d 1344, 1352 (3d Cir. 1991). In making this determination, the trial judge should consider the overall setting of the trial, the character of the evidence, and the complexity or simplicity of the legal principles which the jury had to apply to the facts. *Lind v. Schenley Industries, Inc*., 278 F.2d 79, 89 (3d Cir.), *cert. denied*,

364 U.S. 835 (1960)

III. DISCUSSION

A. Defendants' Renewed Motion for Judgment as a Matter of Law

1. The Jury's Verdict That the Patents-In-Suit Are Not Obvious, Anticipated or Indefinite Is Supported by Substantial Evidence.

a. Obviousness

The defendants contend that both the '681 and '553 Patents are invalid as obvious under 35 U.S.C. § 103. Whether or not a patent is obvious over the prior art is a question of law. *See Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1479, 1479 (Fed Cir. 1997); *see also Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1384-85 (Fed Cir. 2001). Section 103 provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S. § 103. Put simply, an invention is invalid if "the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966). Obviousness cannot be based on "the hindsight combination of components selectively culled from the prior art to fit the parameters of the invention." *ADT Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed Cir. 1998). The Supreme Court has set forth four factors relevant to determining obviousness: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4)

other secondary considerations. *Graham*, 383 U.S. at 17-18. Evaluating the *Graham* factors in view of the evidence adduced at trial, it was not unreasonable for the jury to have concluded that the Patents-In-Suit were not obvious.

Indeed, PharmaStem proffered ample evidence to support the jury's verdict. Both a suggestion to make the composition or carry out the claimed process and a reasonable expectation of success must be found in the prior art to support a conclusion that a patent is obvious. *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). At trial, PharmaStem presented testimony that there were problems associated with transplant tissues used prior to the Patents-In-Suit. Bernstein Tr. at 2035-2038. There was also tremendous skepticism in the transplant field regarding the use of cord blood as a transplant tissue, Bernstein Tr. at 2043-204, and the references ViaCell asserts (namely Koike, Knudtzon and Vidal) did not overcome this skepticism. Bernstein Tr. at 2045-2048, 2054-2060. Finally, testimony established that those in the field of transplantation were surprised at the result of the first cord blood transplant conducted by the inventors of the Patents-In-Suit. Bernstein Tr. at 2061-2062. *See also* Wagner Tr. at 1378-1379. It is true that ViaCell capably highlights record evidence as to the meaning one of ordinary skill would attach to the alleged prior art references. Base upon the record evidence, a jury could have found that the Patents-In-Suit were obvious. This jury did not, however, and the aforementioned evidence provided it with sufficient basis to reach the conclusion that, prior to the inventions of the Patents-In-Suit, those in the field of hematopoietic reconstitution would not have expected cord blood to be a successful transplant tissue.

The jury also received an abundance of evidence to support the secondary considerations of long felt need, commercial success, failure of others, copying, and unexpected results. *See e.g.,* Bernstein Tr. at 2036, 2060-2061; Wagner Tr. at 1187; Tr. Ex. 413. Additionally, with respect to

the '681 patent, the jury was permitted to consider the fact that the Patent and Trademark Office ("PTO") considered the alleged prior art in the reexamination and ultimate reissue of that patent. Similarly, during examination of the '553 Patent, the PTO considered the Ende, Prindull, and Knudtzon references, a fact which the jury was also entitled to consider in evaluating their combined effect on the obviousness issue. The court is not to "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893. In view of this standard, there is no basis to overturn the jury's finding that the Patents-In-Suit are not obvious.

b. Anticipation

Likewise, the jury's finding that the Patents-In-Suit are not invalid for anticipation is supported by substantial evidence. The defendants first contend that the '681 patent is anticipated by Koike because the latter discloses each limitation of the former's claims. "An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention." The '681 Patent claims a cryopreserved therapeutic composition comprising "viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a single human collected at the birth of said human, in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult." To anticipate the '681 Patent Koike must demonstrate that stem cells were present in umbilical cord blood. There is ample evidence in the record establishing that Koike did not demonstrate stem cells. For example, Dr. Wagner's cross examination testimony stated that Koike

did not prove that there were stem cells in umbilical cord blood.[2] Wagner Tr. at 1333. Dr. Bernstein also testified that the reference does not teach stem cells nor a therapeutic composition for use in hematopoietic reconstitution. Bernstein Tr. at 2053. In this regard, the jury's verdict that the '681 patent is not anticipated by Koike is supported by substantial evidence so as to preclude judgment as a matter of law on the issue of anticipation.

The court reaches the same conclusion with respect to the '553 Patent. The '553 Patent claims in pertinent part:

> A method for hematopoietic or immune reconstitution of a human comprising:
>
> (a) isolating human neonatal or fetal blood components containing hematopoietic stem cells;
>
> (b) cryopreserving the blood components; and
>
> (c) introducing the blood components into a suitable human host.

It is undisputed that Koike did not introduce cord blood into a human, which is a necessary limitation of the '553 Patent. The defendants claim that Koike's suggestion that introducing the stem cells into a human host should be done is a sufficiently enabling disclosure to warrant a finding of anticipation. Even so, the record contains substantial evidence from which a jury could find that a person of ordinary skill in the art would not have been so enabled. For example, Dr. Wagner testified that Koike did not do a transplant, Wagner Tr. at 1333, and Dr. Bernstein testified that Koike does not introduce stem cells into a human or teach hematopoietic reconstitution, Bernstein

[2]Dr. Wagner's cross testimony could be further construed to support the conclusion that Koike did not cryopreserve enough cord blood, or teach cryopreservation of enough cord blood, for hematopoietic reconstitution of a human, whether adult or child, which is another limitation of the '681 Patent's claims. *See* Wagner Tr. at 1342-1343.

Tr. at 2053-2054. Again, the jury's finding that the Patents-In-Suit are not anticipated[3] is supported by substantial evidence and the court will not overturn it on this basis.

c. Indefiniteness

The defendants also argue that the '681 Patent is invalid because it is indefinite. Claim 1 of that patent covers "stem cells" "in an amount sufficient to effect hematopoietic reconstitution of a human adult." According to the defendants, this language is indefinite as a matter of law because it is specifically drawn to an amount of stem cells, but the patent is completely silent as to a quantity. In this regard, they claim that it does not provide sufficient notice of the scope of the invention. The court is not persuaded.

Section 112 provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The statute requires the patentee to provide the public with clear notice of what activities infringe the patent. *See Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001); *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). "If

[3]Given the absence of record evidence showing that Koike's compositions contained an amount of stem cells sufficient to effect hematopoietic reconstitution of a human adult, the defendants' inherent anticipation theory is an equally unpersuasive basis on which to enter judgment as a matter of law on this issue. Although recognition of an element in the prior art before the critical date is not necessary, inherent anticipation still requires that the element necessarily be present. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

the claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *Shatterproof Glass Cor. v. Libbey-Woens Ford Co.*, 758 F.2d 613 624 (Fed. Cir. 1985) (citing *Georgia Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136 (2d Cir. 1958)). Indefiniteness is a question of law for the court. *In re Jolly*, 172 F.2d 566, 570 (C.C.P.A. 1949); *see also Union Pacific Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). "In a jury trial, if there are disputed factual issues related to indefiniteness, they may be submitted to the jury for resolution." *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, Nos. 99-274 (SLR), 99-876 (SLR), 2004 WL 1305849, *10 (D. Del. 2004) (citing *BJ Services Co. v. Halliburton Energy Serv., Inc.,* 338 F.3d 1368, 1372 (Fed.Cir.2003)). Because a patent is presumed valid, the party asserting a defense of invalidity on the basis of claim indefiniteness bears the burden of proof by clear and convincing evidence. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc. .,* 806 F.2d 1565, 1575-76 (Fed. Cir.1986).

It is true that the language of the '681 Patent does not specify an amount of progenitor cells nor a volume of cord blood, and the specification is silent as to a precise amount. However, these facts do not necessarily dictate that Claim 1 must fail for indefiniteness. Given that there is no determinate or determinable minimum amount of cord blood for therapeutic usefulness in humans, the record supports that the '681 Patent's claim language is as precise as the subject matter permits. Moreover, the record contains evidence establishing that a person of skill in the art would have understood what an amount of cord blood stem cells sufficient to effect hematopoietic reconstitution of a human adult means. *See Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 823 (Fed. Cir. 1988); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986).

Dr. Moore, PharmaStem's expert on hematopoiesis, testified that the Patents-In-Suit provide the reader with ample information to determine the amount of cord blood needed for transplantation in adults or children, and that the scientific community has in fact performed numerous transplants into adults. Moore Tr. at 340-348; *see also* Harris Tr. at 635-636 (for defendants' witness skilled in art stating that an amount sufficient for usefulness in a clinical setting would be "a sample that contained enough of those cells for a successful transplant"). Thus, the court can find no basis to overturn the jury's verdict that the '681 Patent is not invalid for indefiniteness.

2. The Jury's Verdict That the Defendants Contributorily Infringe the '553 Patent Cannot Stand.

The defendants claim that PharmaStem did not prove that they contributorily infringed the '553 Patent in that PharmaStem failed to adduce evidence that any of them sold or offered to sell cryopreserved cord blood to a transplanter or that cryopreserved cord blood was used by a single entity or group of entities acting in concert or working together to infringe the patent. The court agrees. Relevantly, the claim language of the '553 Patent requires:

> A method for obtaining human neonatal or fetal hematopoietic stem or progenitor cells comprising:
>
> > (a) isolating human neonatal or fetal blood components containing hematopoietic stem or progenitor cells;
> > (b) cryopreserving the blood components; and
> > (c) thawing the blood components, such that the stem or progenitor cells are viable.

Because none of the defendants thaw or inject cord blood, both required elements of the '553 Patent's claims, there can be no literal infringement of the '553 Patent.

PharmaStem would, however, still be entitled to a finding of infringement if the jury

reasonably could have found that the defendants contributorily infringed the '553 patent. *See* 35 U.S.C. § 271(c).

Section 271(c) states:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271. The verdict form required the jury to answer three questions in the affirmative in order to find that any of the defendants contributorily infringed the '553 patent. Consistent with the appropriate legal standard, the jury was required to find that (I) "cryopreserved cord blood has no substantial noninfringing use," (ii) "defendants and transplant physicians are acting in concert or working together to complete the process of infringement of claims 13, 19, 47, or 57 of the '553 patent by performing each and every one of the steps in any of those claims," and (iii) "a Defendant has contributorily infringed the '553 patent by selling or offering to sell cryopreserved cord blood that was actually used by a third party in the direct infringement of any of claims 13, 19, 47, 53, or 57 of the '553 patent." Jury Verdict Form, Qtn. Nos. 3, 4, and 5.

PharmaStem correctly points out the existence of evidence to support the jury's affirmative answer to questions (I) and (ii) of the verdict form. The record supports a conclusion that cryopreserved cord blood is, predominantly, useful only for transplantation therapy, or the use covered by the '553 Patent. Indeed, PharmaStem adduced evidence by which a jury reasonably could have found that cord blood was viewed as medical waste prior to the inventions of the Patents-In-Suit. *See, e.g.,* Moore Tr. at 328; Broxmeyer Tr. at 365; Wagner Tr. 1195-1196.

Moreover, the jury also could have reasonably found that each of the defendants worked together with transplant physicians to complete the patented process of the asserted claims of the '553 Patent. At trial, PharmaStem adduced evidence that the defendants test the blood samples to ensure each one is sufficient for transplantation and thereby aid transplant physicians. Tr. Ex. 103; Tr. Ex. 96; Laleman Tr. at 659. The defendants marketing materials also indicate that they work with physicians in various capacities to effectuate the transplantation process. For example, CorCell's website states "CorCell and Community Blood Services (CBS) has formed a strategic partnership devoted to expertly testing, processing and storing quality cord blood stem cells for future transplantation." Tr. Ex. 516. ViaCell's founder, Cynthia Fisher, testified that the company's mission was "to provide a niche application area between the obstetrician, the Hem/Onc and the blood banking center, as far as enabling providing cord blood stem cell banking." Fisher Tr. at 707. Cryo-Cell advertises that the units of cord blood stem cells stored at its facility are transplant-ready. Tr. Ex. 98. In addition, PharmaStem presented evidence that each of the defendants has at least one representative who liaises in some capacity with transplant physicians, i.e., Dr. Goldberg of CorCell and Dr. O'Neil of Cryo-Cell. CBR designates a Director of the Facility to oversee procedures regarding the release of cord blood units for transplantation. Tr. Ex. 110. Viacell seeks advice and counsel on nucleated cell counts and volumes useful for transplantation from its Medical Scientific Advisory Board, on which five of the seven members are prominent transplant doctors or physicians with extensive experience in hematology, oncology, and/or transfusion medicine. Tr. Ex. 253, Tr. at 1461-63; *see also* Wagner Tr. at 1389. Finally, there is also evidence in the record showing that each of the defendants maintain records and/or other materials regarding its cord blood units which it releases to physicians to assist the transplantation process. CorCell maintains records on the cord

blood units it releases, Tr. Ex. 274, and requests feedback from the transplant facility as part of its standard operating procedures, Tr. Ex. 215. Cryo-Cell provides directions to transplant physicians on how to thaw the cryopreserved cord blood unit it provides. Tr. Ex. 97. CBR has a similar document setting forth the detailed protocol between CBR and the transplant physician when a cord blood unit is requested and released. Tr. Ex. 110. In view of this evidence, it was not unreasonable for the jury to have found that the defendants and transplant physicians worked together to infringe the '553 patent.

Nevertheless, with respect to the third question on the verdict form, there is simply no evidence in the record to support the jury's affirmative answer. It is undisputed that the defendants do not own the cord blood units. Rather the units are owned by the clients, or families, and the defendants in turn provide services with respect to the processing and storing of the compositions. Although the defendants charge enrollment, processing, and banking fees with respect to their storage services, they do not *sell* or *offer to sell* the cord blood units. Indeed, the record evidence on this issue is clear that the defendants sell a service, not cord blood units. *See* Hendrix Tr. 1042; Tr. 2653; Wagner Tr. 1278.

Tellingly, PharmaStem cannot direct the court to a single fact in evidence that would support a finding that any of the defendants sell or offer to sell cord blood. PharmaStem attempts to overcome this deficiency in the record by arguing that Section 271(c) focuses on the financial benefit derived by the seller regardless of the source. But the statute could not be clearer. Section 271(c) liability is clearly dependant upon the accused infringer's selling or offering to sell a component of the patented process, here cord blood units. *See* 35 U.S.C. § 271(c). Drawing all reasonable inferences from the evidence in favor of PharmaStem, the court agrees with the

defendants that the jury's finding on the element of contributory infringement is not supported by substantial evidence. In this regard, the jury's verdict on contributory infringement cannot stand. The court finds as matter of law that the defendants' services do not infringe the '553 patent.[4]

B. Defendants' Motion for a New Trial

The defendants alternatively contend that the court should set aside the judgment and grant a new trial because the jury's verdict was against the great weight of the evidence. The court agrees with respect to the jury's finding that the 100% of the defendants' cord blood units infringe the '681 patent and accordingly will grant a partial new trial on this issue.

1. Inventorship

The defendants first claim that a new trial is warranted because the great weight of the evidence established that the Patents-In-Suit are invalid for failure to name one of the inventors, Dr. Pablo Rubinstein. The court does not agree.

Every patent receives the presumption that its inventors are the true and only inventors. *See e.g., Acromed Corp. v. Sofamor Danek Grp., Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001). Invalidity for failure to name an inventor must be established by clear and convincing evidence. *See id.* at 1379. To be a joint inventor, one must "contribute in some significant manner to the conception of the invention." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Specifically, each person claiming to be an inventor must have contributed to the conception of the invention. *Acromed*, 253 F.3d at 1379. Beyond conception, the purported inventor must demonstrate that he

[4]Because the court finds that the defendants do not infringe the '553 Patent, it will not address the issue of willful infringement with respect to that patent.

made "a contribution to the claimed invention that is not insignificant in quality, when contribution is measured against the dimension of the full invention, and [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Id.* at 1379.

Although the defendants point to evidence from which a jury could have found Dr. Rubinstein's contributions to be significant, PharmaStem adduced at least an equal amount of evidence that his contribution did not rise to the level of inventorship. Indeed, a jury could conclude from the record that Dr. Rubinstein provided consultation on cryopreservation methods which were already available in the art. *See* Bernstein Tr. at 1176-1177. Moreover, Dr. Rubinstein admitted that he published his cryopreservation techniques more than one year prior to the inventions of the Patents-In-Suit, Rubinstein Tr. at 1176-1177, which would allow a jury to conclude that any contribution he made was rendered prior art by the time of the patenting of the invention. *See* 35 U.S.C. § 102; *Hess v. Advanced Cardiovascular Syss.*, 106 F.3d 976, 981 (Fed. Cir. 1997). In light of these significant pieces of evidence supporting the jury's finding that Dr. Rubinstein was not improperly omitted as an inventor, the court finds no basis to grant a new trial on the issue of invalidity for failure to name an inventor.

2. Inequitable Conduct

The defendants also argue that the jury's finding that PharmaStem did not engage in inequitable conduct before the PTO in the procurement of the '681 and '553 Patents is against the great weight of the evidence. The court, however, is not persuaded that the jury's finding on this issue warrants a new trial. The burden is on the party seeking to invalidate the patents to prove inequitable conduct by clear and convincing evidence. In view of the defendants' burden, the jury's verdict was not against the great weight of the evidence.

As evidence of PharmaStem's alleged inequitable conduct, the defendants point to the PharmaStem's failure to disclose two pieces of information to the PTO. First, after PharmaStem had presented its arguments to the PTO in reexamination, but several months before the '681 Patent reissued, the European Patent Office ("EPO") denied PharmaStem's European counterpart application, rejecting its argument that Koike does not teach stem cells. PharmaStem did not bring the EPO's rejection of its argument to the attention of the PTO before reissue. Second, in its opinion, the EPO cites the 1997 Broxmeyer article for the proposition that relevant scientific community considered progenitor cell assays to be reliable assays for stem cells. In view of these facts, the defendants argue that the jury's finding that PharmaStem did not engage in inequitable conduct before the PTO is against the great weight of the evidence.

"One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." *Molins*, 48 F.3d at 1178; *accord Rockwell Techs., LLC v. Spectra Physics Lasers, Inc.*, 2002 WL 531555, at *3 (D. Del. Mar. 26, 2002). "Materiality and intent to deceive are distinct factual inquiries, and each must be shown by clear and convincing evidence." *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1324 (Fed. Cir. 2000); *accord Isco Int'l, Inc. v. Conductus, Inc.*, 2003 WL 22006253, at *6 (D. Del. Aug. 21, 2003). Patent applicants have a duty to disclose to the PTO "any material prior art or other information cited or brought to their attention in any related foreign application." Manual of Patent Examining Procedure § 2001.06(a) (4th ed., rev. 8, Oct. 1981). However, a finding of inequitable conduct for nondisclosure of information requires proof that the applicant made a deliberate decision to withhold

a known material reference from the PTO. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995).

Given the controlling standards, PharmaStem adduced significant evidence to rebut the defendants' inequitable conduct case. Specifically, the EPO's decision applied European, as opposed to United States, patent laws, and examined different claims than the ones at issue before the PTO in the reexamination. Tr. Ex. 1013. Moreover, there is no dispute that PharmaStem disclosed Koike to the PTO in the reexamination, and that the PTO came to its own conclusion as to what the reference taught. With respect to the Broxmeyer article, it was published nearly ten years after the initial filing of the Patents-In-Suit, and therefore not a prior art reference. Tr. Ex. 1015. Further lending credence to PharmaStem's view that the article was not material, the EPO characterized the Broxmeyer article as "indirect evidence" and cited it in the portion of the opinion on novelty, which was not at issue in the reexamination before the PTO. Tr. Ex. 1013. When viewed as a whole, the record more than supports a conclusion that PharmaStem did not possess the requisite intent to deceive the PTO and therefore did not engage in inequitable conduct.

3. Infringement of the '681 Patent

a. Dr. Hendrix's Testimony

As one of the bases for their motion for a new trial on infringement of the '681 Patent, the defendants contend that Dr. Mary Hendrix, PharmaStem's infringement expert, should not have been permitted to testify. During the pretrial stage of proceedings, the defendants objected to Dr. Hendrix's testimony in a motion *in limine* and then again at the close of trial moved to strike the doctor's testimony. The court denied both of these motions, but will revisit its rulings in light of the evidentiary record now before it.

Rule 702 has three requirements as to expert opinions: 1) the witness must be an expert; (2) the witness must testify to scientific, technical, or other specialized knowledge; and 3) the testimony must assist the trier of fact. *See United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995) (citations omitted). The U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), established a gatekeeping role for trial court judges in determining the admissibility of expert testimony on scientific evidence. When an expert bases opinion testimony on scientific knowledge, the testimony will not be admitted unless it is derived by the scientific method and is supported by "appropriate validation." *Daubert,* at 590. This standard of evidentiary reliability focuses on the scientific validity of the expert's methods rather than the soundness of his specific conclusions. *Id. at 589* ("[the] inquiry into the reliability of scientific evidence . . .. requires a determination as to its scientific validity."); *see also Oddi v. Ford Motor Co.,* 234 F.3d 136, 145 (3d Cir. 2000); *United States v. Shea*, 957 F. Supp. at 337. An expert's opinion is reliable if it is based on the "methods and procedures of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his or her belief. *See Daubert*, 509 U.S. at 589.

The defendants contend that the subject of Dr. Hendrix's testimony was not one for which expertise was necessary in that she based her infringement opinion entirely on an analysis of the defendants' marketing materials, without ever considering any data regarding the composition of the defendants' cord blood units. Dr. Hendrix is an accomplished stem cell biologist, but is not qualified as an expert in marketing or advertising. Moreover, her so-called analysis of the defendants' marketing materials was well within the jury's common knowledge, common sense and common experience. *See United States v. Stevens*, 935 F.2d 1380, 1399-1400 (3d Cir. 1991)

(upholding Federal Rule of Evidence 403 exclusion of expert testimony regarding eye witness identification where the evidence was susceptible of elucidation without specialized knowledge and jury could have ascertained through common sense). In view of these considerations, the court is persuaded that Dr. Hendrix's conclusion, evidenced in her expert report and adduced through her testimony, that 100% of the defendants' cord blood units infringe the '681 Patent was based upon a legally improper methodology that was unreliable as a matter of law under *Daubert*.

Significantly, Dr. Hendrix's admitted that she did not review or analyze any of the defendants' cord blood samples in reaching her opinion. Hendrix Tr. at 1038. Moreover, she explicitly testified that her opinion that all of the defendants' cord blood units infringe the '681 Patent was based on the fact that the defendants "promise stem cells for pediatric and adult transplantation." Hendrix Tr. at 1021. In this regard, her opinions are not based upon any methods or procedures of science in general and certainly not upon her specific expertise as a stem cell biologist, no matter how knowledgeable she may have been in that field. The court therefore determines that her opinion of infringement is no more than a lay-person's interpretation of the defendants' marketing materials. The materials relied upon by Dr. Hendrix may be persuasive on the issue of infringement, but permitting PharmaStem to couch its presentation of this evidence in the form of an expert opinion was an error.

b. The Lack of Record Evidence that 100% of the Defendants' Units Infringe the '681 Patent

Claim 1 of the '681 Patent covers compositions containing stem cells "in an amount sufficient to effect hematopoietic reconstitution of a human adult." To prove infringement, therefore, PharmaStem was required to adduce evidence that the defendants cord blood units contained an amount of stem cells sufficient for transplantation into an adult. In the absence of Dr.

Hendrix's testimony, the record is void of any proof to support a finding that 100% of the defendants' cord blood units infringe the '681 Patent. To the contrary, the record overwhelmingly indicates that cord blood units will *not all* contain sufficient cells to reconstitute an adult. *See* Wagner Tr. at 1270; *see also* Tr. Ex. 1370 at 30 (PharmaStem telling the PTO that cord blood units "are highly variable in their stem cell content such that any particular cord blood collection may have low or no stem cells"). The jury's finding that *all* of the defendants' cord blood units infringe the '681 Patent, consequently, was against the great weight of the evidence.

At the same time, however, the record suggests that at least some of the defendants' cord blood units infringe in that there is evidence of successful transplants of the defendants' compositions into human adults. *See, e.g.,* Tr. Ex 115 (circumstantial evidence in the form of statements on CBR's website that a "newborn's cord blood stem cells were transplanted to her mother to treat chronic myelogenous leukemia," and that other transplants have occurred for the newborn's mother father and cousin); Tr. Ex. 103 (draft of ViaCord's private placement memorandum acknowledging that adult transplants have occurred). As a result, the court will grant a new trial, excluding Dr. Hendrix's expert testimony, on the issue of infringement of the '681 Patent and the resultant damages therefrom.[5]

IV. CONCLUSION

For the aforementioned reasons, the court will enter judgment as a matter of law that the defendants do not infringe the '553 Patent and grant a new trial on the issue of infringement and damages with respect to the '681 Patent. In all other aspects, the motions filed by the parties are

[5]Again, in light of its granting a new trial on the infringement issue, the court will not rule on the issue of willful infringement with respect to the '681 Patent.

denied. An order to this effect will accompany this opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 02-148 GMS
	)	
VIACELL INC., et al.,	)	
	)	
Defendants.	)	

ORDER

For the reasons set forth in the court's memorandum opinion issued contemporaneously herewith, IT IS HEREBY ORDERED that:

1. Joint Renewed Motion by ViaCell, Inc, Cyro-Cell, Inc, CorCell, Inc, CBR Systems, Inc. for Judgment as a Matter of Law or in the Alternative, for a New Trial (or for Remittitur) (D.I. 448) is GRANTED IN PART.

2. PharmaStem, Inc.'s Motion for Enhanced Damages, Attorneys' Fees, Pre-Judgment Interest and Post Judgment Interest (D.I. 446) is DENIED.

3. PharmaStem, Inc.'s Motion for a Permanent Injunction (D.I. 447) is DENIED.

4. PharmaStem's Motion to Strike the Affidavit of Chris Adams (D.I. 487) is DENIED as moot.

5. The clerk shall enter judgment in favor of the defendants and against the plaintiff on the claim of infringement of U.S. Patent No. 5,192,553.

6. A new trial shall be held on the issue of infringement and damages with respect to U.S. Patent No. 5,004,681.

Dated: September 15, 2004

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE