IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 02-148 GMS
VIACELL INC., CRYO-CELL INTERNATIONAL, INC., CORCELL, INC., STEMCYTE, INC., CBR SYSTEMS, INC. f/k/a CORD BLOOD REGISTRY, INC., BIRTHCELLS TECHNOLOGY, INC., NUSTEM TECHNOLOGIES, INC., and BIO-CELL, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. INTRODUCTION

The plaintiff, PharmaStem Therapeutics, Inc., ("PharmaStem") filed the above-captioned action against StemCyte, Inc. ("StemCyte") and eight other defendants, on February 22, 2002. In its complaint, PharmaStem alleges that the defendants are infringing U.S. Patent Nos. 5,004,681 ("the '681 patent") and 5,192,553 ("the '553 patent").

Presently before the court is StemCyte's motion for summary judgment. In this motion, StemCyte argues that it falls under the statutory exemption from infringement pursuant to 35 U.S.C. § 271(e)(1). For the reasons that follow, however, the court will deny this motion.

II. STANDARD OF REVIEW

The court may grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Boyle v. County of Allegheny, Pennsylvania*, 139 F.3d 386,

392 (3d Cir. 1998). Thus, the court may grant summary judgment only if the moving party shows that there are no genuine issues of material fact that would permit a reasonable jury to find for the non-moving party. *See Boyle*, 139 F.3d at 392. A fact is material if it might affect the outcome of the suit. *Id*. (citing *Anderson v. Liberty Lobby*, *Inc*., 477 U.S. 242, 247-248 (1986)). An issue is genuine if a reasonable jury could possibly find in favor of the non-moving party with regard to that issue. *Id*. In deciding the motion, the court must construe all facts and inferences in the light most favorable to the non-moving party. *Id*.; *see also Assaf v. Fields*, 178 F.3d 170, 173-174 (3d Cir. 1999).

With these standards in mind, the court will describe the facts that led to the motion presently before the court.

III. BACKGROUND

PharmaStem is a Delaware corporation engaged in the business of cord blood banking. Cord blood banking is a process by which human stem cells are obtained and stored to be used for medical purposes. PharmaStem possesses two patents directed to the obtainment, storage, and usage of these cells. On April 2, 1991, the United States Patent and Trademark Office ("PTO") issued United States Letter Patent No. 5,004,681. On April 11, 2000, the PTO issued Reexamination Certificate B1 5,004,681 ("the '681 Patent"). The '681 Patent disclosed the cryo-preservation of human stem cells obtained from fetuses or from the placental blood and umbilical cord of successfully delivered newborns. On March 9, 1993, the PTO issued United States Letter Patent No. 5,192,553 ("the '553 Patent"). The '553 Patent teaches methods of obtaining the abovementioned stem cells and methods

for employing the cells in various medical procedures.[1]

On March 25, 2002, PharmaStem filed the present action. In its complaint, PharmaStem alleges that StemCyte "makes, uses and sells compositions and methods protected by the '681 Patent and the '553 Patent." (D.I. 20 at 4, ¶19). PharmaStem further alleges that StemCyte has been and is still infringing directly and contributorily, and induces the infringement of both the '681 Patent and the '553 Patent "by making, using, selling and/or offering for sale compositions" claimed in both patents, and will continue to do so unless enjoined by this court. (*See* D.I. 20 at 5, ¶¶25 & 29).

StemCyte specializes in stem cell technology, focusing on "procurement, processing and storage of umbilical cord blood stem cells for transplantation – a substitute for traditional bone marrow transplantation in the treatment of many diseases . . . ." Defendant's Opening Br. at 1. StemCyte participates as an accredited blood bank in the National Marrow Donor Program ("NMDP"), which is currently awaiting Food and Drug Administration ("FDA") approval of a Phase II clinical trial. On November 19, 2001, StemCyte submitted its own Investigational New Drug Application ("IND") to the FDA, proposing a Phase II clinical trial entitled "StemCyte Umbilical Cord Blood Program – An Umbilical Cord Blood Collection, Processing, Storage & Distribution Program to Facilitate Allogeneic Umbilical Cord Blood Transplant."

On July 11, 2002, StemCyte filed a motion for summary judgment of non-infringement pursuant to 35 U.S.C. § 271(e)(1). Section 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a

[1]These patents were obtained by PharmaStem's predecessor, and PharmaStem now owns the '681 and '553 Patents.

Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

IV. DISCUSSION

In its motion for summary judgment, StemCyte asserts that the statutory infringement exemption of 35 U.S.C. § 271(e)(1) is applicable to this case because its allegedly infringing methods for collecting, processing, and storing umbilical cord blood stem cells ("CBUs") "are carried out pursuant to a current IND pending at the FDA."[2] Defendant's Opening Br. at 2. Specifically, StemCyte contends that CBUs are regulated as drugs under the Food, Drug, and Cosmetic Act ("FDCA"). Thus, according to StemCyte, because CBUs are considered drugs, the statutes and regulations pertaining to drugs, including submissions of INDs, apply to its CBU activities.

StemCyte supports its contention that CBUs are drugs under the FDCA by arguing that "'[d]rugs' are defined broadly in the FDCA as 'articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or . . . intended to affect the structure or any function of the body of man' and includes within its coverage a wide range of biological products." StemCyte further contends that "[t]he FDCA's definition of 'drug' clearly covers CBUs." *Id.* at 5 (citing *United States v. Calise*, 217 F. Supp. 705, 709 (S.D.N.Y. 1962), for proposition that blood falls within meaning of drug as defined by FDCA). In sum, StemCyte asserts that its activities fall under 35 U.S.C. § 271(e)(1) because they are "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

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[2]The court will assume, for purposes of this motion only, that StemCyte's CBU-related activities potentially infringe the patents-in-suit.

In response, PharmaStem asserts that, although the FDA is considering future federal involvement with respect to CBUs, it does not currently regulate collection, freezing, storing, and use of CBUs. In particular, PharmaStem contends that CBUs are neither drugs nor medical devices. It further asserts that, while "PharmaStem agrees that approval of the FDA is a prerequisite to the commercial manufacture or sale of any new drug in the United States that is regulated under the FDCA . . . CBUs are not a drug regulated under the FDCA and the FDA does not require any FDA approval prior to the commercial manufacture or sale of CBUs in the United States." Furthermore, PharmaStem contends that "[c]ontrary to StemCyte's allegations that 'in this case, the new drug . . . is allogeneic umbilical cord whole blood . . .,' umbilical cord blood stem cells units are not regulated by the FDCA, and therefore, as a matter of law, cannot be considered a drug." Additionally, PharmaStem asserts that "[a]lthough the FDA has been considering federal involvement in the umbilical cord blood industry since 1995, it currently is *not* regulating . . . use of cord blood." *Id.* at 5 (citing Rovner Decl., Exh. A at 5450). In essence, PharmaStem's argument is that CBUs are not regulated by the FDA, as evidenced by the fact that the FDA rules do not require submission of IND applications by cord blood establishments for any type of FDA approval. Thus, since CBUs are not regulated, they cannot be considered "drugs" under the FDCA.

In this case, the parties do not dispute that activities reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs are exempt from infringement. Rather, the real dispute here is whether CBUs are "drugs" as defined by the FDCA and thus subject to regulation by the FDA. The court concludes, however, that whether the CBUs fit within the definition of 'drugs' as defined by the FDCA is a determination that may ultimately hinge on, among other things, expert testimony or additional information adduced

at trial. Moreover, StemCyte has failed to point to any relevant case law from which the court could draw guidance in making this determination, nor did it otherwise succeed in meeting its heavy burden of demonstrating that judgment in its favor is warranted at this time. Therefore, on the record as it presently stands, a grant of summary judgment would be inappropriate

V. CONCLUSION

For the aforementioned reasons, IT IS HEREBY ORDERED that:

1. StemCyte's Motion for Summary Judgment (D.I. 67) is DENIED.

Dated: February 26, 2003

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE