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

PharmaStem Therapeutics, Inc., ("PharmaStem") is a Delaware corporation engaged in the business of cord blood banking. Cord blood banking is a process in which human stem cells are obtained and stored to be used for medical purposes. PharmaStem has obtained two patents directed to the obtainment, storing, and use of these cells. In its complaint, PharmaStem alleges, *inter alia*, that defendant NuStem ("NuStem"), a Nevada corporation, infringed and continues to infringe these patents.

On April 16, 2002, PharmaStem properly served NuStem through the Nevada Secretary of State and NuStem's registered agent for service of process in the state of Nevada. To date, NuStem has neither responded to PharmaStem's complaint nor appeared before this court. A default was entered on June 7, 2002.

Presently before the court is PharmaStem's motion for default judgment. In its motion, PharmaStem seeks a declaration that NuStem is liable for the infringement of PharmaStem's patents. This will allow PharmaStem to pursue further legal action against NuStem, including seeking an injunction to prevent NuStem from committing further infringements against PharmaStem's patents. The court will enter the requested relief for the reasons stated below.

II. BACKGROUND

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 taught methods of obtaining the abovementioned stem cells and methods for employing the cells in various medical procedures.¹

On March 25, 2002, PharmaStem filed a complaint with this court. In its complaint, PharmaStem alleges that NuStem "makes, uses and sells compositions and methods protected by the '681 Patent and the '553 Patent." (D.I. 20 at 4.) PharmaStem further alleges that NuStem 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 &

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

29.) In support of these allegations, PharmaStem asserts that NuStem has publically stated that it is in the business of "collection, processing, cryogenic storage and sale of stem cells derived from the umbilical cord of a full-term, healthy newborn baby." (D.I. 56, Exh. A.) This statement is taken directly from NuStem's website. The record evidence also consists of a press release by Thermogenesis Corp. The press release states that NuStem "collects, processes, croygenically stores, and subsequently distributes stem cells derived from the blood extracted from the umbilical cords of newborn babies following a normal, healthy live birth. NuStem has established a worldwide network of collection centers and intends to build an inventory of 50,000 cord blood units ... within a three year period." (D.I. 56, Exh. B.)

III. STANDARD OF REVIEW

When a party against whom a judgment for affirmative relief is sought has failed to plead or otherwise defend as provided by these rules, and that fact is made to appear by affidavit or otherwise, the clerk shall enter the party's default. *See* Fed. R. Civ. P. 55(a). If the plaintiff's claim against defendant is for other than a certain sum, however, the plaintiff must apply to the court for a judgment by default. *See* Fed. R. Civ. P. 55(b)(2). Once the default has been entered, the wellpleaded facts of the complaint must be accepted as true. *See Nishimatsu Const. Co., Ltd. v. Houston Nat. Bank*, 515 F.2d 1200, 1206 (5th Cir. 1975). In determining whether to enter a judgment of default, the court must set forth the factors it considered in reaching its decision. *See Emasco Ins. Co. v. Sambrick*, 834 F.2d 71, 74 (3d Cir. 1987). PharmaStem has requested relief other than a sum certain in the form of a judgment of liability. Thus, it is appropriate for the court, rather than the clerk, to enter the default judgment. Accepting the well pleaded facts of the complaint as true, the court concludes that PharmaStem's request is reasonable. The court will now set forth its reasons for its decision to grant the judgment.

IV. DISCUSSION²

Liability for infringing a patent is covered by 35 U.S.C. § 271. Section 271 states:

"(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

"(b) Whoever actively induces infringement of a patent shall be liable as an infringer. "(c) 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(a)-(c).

A finding of direct infringement can be made under section 271(a) where the infringer makes, uses, offers to sell, or sells any patented invention within the United States. PharmaStem has pleaded facts sufficient to prove direct infringement of both patents. The '681 Patent covers compositions of cryo-preserved stem cells obtained from fetuses or from the umbilical cords of newborn babies. PharmaStem has provided a copy of NuStem's website, on which NuStem clearly states that it collects, processes, cryogenically stores, and sells stem cells obtained from the umbilical cord of a healthy, newborn baby. This activity infringes the '681 Patent. The '553 Patent

²The court stresses that any presumption of validity for PharmaStem's patents and any determination of liability, infringement (either direct or contributory), or inducement to infringement is limited to this memorandum and order.

discloses the methods of obtaining these cells and methods of using these cells in therapy for humans. NuStem's website further describes the beneficial uses of stem cells for treatment of patients. Based on its statements on the website, NuStem's method of collection of these cells appears to infringe the '553 Patent. Thus, NuStem directly infringes the '681 Patent by cryogenically storing stem cells, and directly infringes the '553 Patent by using protected methods to obtain these stem cells.

A company may also be liable for contributory infringement when it sells or offers to sell components of a patented composition for use in a patented process, according to section 271(c). NuStem's website clearly states its intent to sell the collected stem cells protected by the '681 Patent. The use of the stem cells protected by the '681 Patent by NuStem's clients would constitute direct infringement under subsection (a) of §271. Thus, NuStem's sale of stem cells covered by the '681 Patent for use by one of NuStem's clients constitutes contributory infringement. From the statements on the website, it appears that the stem cells collected by NuStem would be put to use by NuStem's clients in the methods of treatment protected by the '553 Patent. Thus, NuStem's sale of the protected stem cells further constitutes contributory infringement of that patent as well.

Therefore, accepting the facts pleaded by PharmaStem as true, the court concludes that PharmaStem's request for a judgment of liability is reasonable under the circumstances. The court therefore grants PharmaStem's request for a judgment of liability. Thus, NuStem is liable for direct and contributory patent infringement under 35 U.S.C. § 271.³

³Having been found liable for infringement, NuStem may be enjoined from any infringing practices at a later date upon proper application by the plaintiff. 35 U.S.C. § 271(e)(4)(B). NuStem may also be required to pay damages to PharmaStem, with such damages to be determined at trial. 35 U.S.C. § 271(e)(4)(B). However, the court will not address the issue of damages at this time.

V. CONCLUSION

Since PharmaStem has filed a well-pleaded complaint with reasonable requests for relief and the defendant has not countered PharmaStem's allegations with any statements of its own, the court will grant the plaintiff's Motion for Default Judgment.

Therefore, IT IS HEREBY ORDERED that:

- 1. The Plaintiff's Motion for Default Judgment as to defendant NuStem (D.I. 47) is GRANTED;
- 2. Judgment BE AND IS HEREBY ENTERED in favor of the Plaintiff in the manner described in the Plaintiff's attached order (D.I. 47), also executed by the court on this date.

Dated: July <u>10</u>, 2002

Gregory M. Sleet UNITED STATES DISTRICT JUDGE