IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

STEMCELLS, INC. and STEMCELLS CALIFORNIA, INC., 3155 Porter Drive Palo Alto, California 94304,))))) CIVIL ACTION NO. AW 06 CV 1877
Plaintiffs,)
VS.)
NEURALSTEM, INC., 387 Technology Drive College Park, MD 20742,)))
Defendant.))

AMENDED COMPLAINT

(Patent Infringement)

Plaintiffs StemCells, Inc. and StemCells California, Inc. (collectively, "StemCells") allege against Defendant Neuralstem, Inc. ("Neuralstem") as follows:

JURISDICTION

1. This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

VENUE

2. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b) because defendant's acts of patent infringement are occurring within this judicial district, and defendant is subject to personal jurisdiction in this judicial district.

THE PARTIES

- 3. Plaintiff StemCells, Inc. is a Delaware corporation, with its principal place of business located at 3155 Porter Drive, Palo Alto, California 94304.
- 4. Plaintiff StemCells California, Inc. is a California corporation wholly owned by StemCells, Inc., with its principal place of business located at 3155 Porter Drive, Palo Alto, California 94304.
- 5. StemCells is in the business of stem cell based treatments of diseases and conditions characterized by damage to or degeneration of the central nervous system ("CNS"), liver, pancreas and other tissue.
- 6. On information and belief, Neuralstem is a privately held biopharmaceutical company with headquarters at 9700 Great Seneca Highway, Rockville, Maryland 20850. Upon further information and belief, Neuralstem is in the business of developing nervous system stem cell technology to treat CNS, neurodegenerative and neurological disorders of the brain and spinal cord.
- 7. Upon information and belief, Neuralstem has been and still is actively offering for sale or license products and services within the District of Maryland and elsewhere. For instance, in Neuralstem's recent Form SB-2 Registration Statement filed with the Securities and Exchange Commission, dated March 31, 2006, Neuralstem admitted:
 - "Using the Company's proprietary, patented human neural stem cells, the Company has conducted its own drug discovery program funded primarily by the U.S. Department of Defense, and has produced a group of lead neurogenic compounds. These lead compounds have demonstrated both neurogenic and/or neuroprotective potency in both *in vitro* and *in vivo* tests. The Company has out-licensed these compounds for further development toward various CNS diseases. This license includes both

- royalty and milestone payments, as these compounds make their way through the clinical trial process to commercialization." (SB-2 p. 5.)
- "The Company originally pursued three independent commercialization strategies based on different uses of the cells; genomics, drug discovery, and cell therapy. The Company's technique for growing virtually unlimited numbers of functional, physiologically relevant human neurons in dishes lent itself to creating in vitro models for experiments in gene expression (i.e., the ability of a gene to produce a biologically active protein). In 2001, the Company was paid a license fee of \$7.5 million by Gene Logic, Inc., payable over three years, to create a database using these in vitro models. Also, in 2001, the Company also received a Defense Department contract to do drug screening using the cells, in the amount of \$2.5 million over 18 months. Finally, during this period, the Company was pursuing its own research into transplanting the cells to cure disease." (SB-2 p. 22.)
- "The Company has used its human neural stem cells from the hippocampus to identify a group of small molecule compounds with the potential to enhance the survival of the endogenous stem cells residing in adult hippocampus. These compounds may be developed to treat a variety of central nervous system indications such as depression, diabetic complications of the nervous system, mild cognitive impairment, stroke, and Alzheimer's disease. This program was funded by a grant from the Department of Defense." (SB-2 p. 23.)
- "While Neuralstem believes that it has demonstrated the value of its proprietary drug discovery platform, the Company's current plan is to license out the existing library of lead compounds in order to focus all of its resources and energies toward development of cell therapeutics. The Company believes that after one of its neurogenic compounds completes human clinical trials, it will be in a position to consider additional ways to extract value from its drug discovery platform." (SB-2 p. 23.)
- "[T]he Company has also developed immortalized human neural stem cells from hard-to-obtain areas of the brain for *in vitro* uses which it has used in a significant commercial collaboration to mine gene content for Gene Logic, Inc." (SB-2 p. 24.)
- "Neuralstem could potentially sell its human immortalized neural stem cells to academia and industry partners for drug target discoveries and drug screening programs on a simple fee-for-purchase basis." (SB-2 p. 24.)
- 8. In addition, Neuralstem participated in the research and writing of a publication entitled <u>Combined Immunosuppressive Agents or CD4 Antibodies Prolong</u>

Survival of Human Neural Stem Cell grafts and Improve Disease Outcomes in ALS

Transgenic Mice, which was published by AlphaMed press on line on April 27, 2006.

That article demonstrates clearly Neuralstem's continued use of neural stem cells.

- 9. Neuralstem does not have a license with StemCells to commercialize products such as neural stem cells.
- directed to neural stem cells including certain of the following patents: United States

 Patent Nos. 5,851,832 (attached hereto as Exhibit 1); 6,103,530 (attached hereto as

 Exhibit 2), 6,497,872 B1 (attached hereto as Exhibit 3) and 6,294,346 B1 (attached hereto
 as Exhibit 4) 7,101,709 B2 (attached hereto as Exhibit 5) (collectively, the "Neural Stem
 Cell Patents"). Licensees to some of the Neural Stem Cell Patents include the following:
 Stemcell Technologies, Inc.; Biowhittaker (now Cambrex); Reneuron; R& D Systems;
 and Stem Cell Therapeutics. In addition, in 2002, StemCells filed suit against Sciencell
 Research Laboratories ("Sciencell") in the United States District Court for the District of
 Massachusetts (StemCells, Inc. v. Sciencell Research Labs., Civ.A.No. 01-CV-11942
 (REK)) alleging infringement of nine (9) United States Patents; two of which (U.S.
 Patent Nos. 5,851,832 and 6,103,530) are asserted in this lawsuit against Neuralstem.
 Sciencell entered into a Consent Judgment with StemCells, wherein Sciencell admitted
 that the patents asserted in that suit were valid and enforceable.

COUNT I

(Infringement of United States Patents)

11. The Neural Stem Cell Patents, for neural stem cell culture compositions, genetically modified neural stem cell cultures, methods of proliferating and

differentiating such cultures *in vitro* and *in vivo*, as well as culture media and uses of the foregoing cultures, are assigned to or exclusively licensed in all fields, with rights of enforcement, to StemCells. Since issuance of the Neural Stem Cell Patents, StemCells has been and still is the assignee or exclusive licensee of those patents.

- 12. On information and belief, Neuralstem has been and still is infringing, contributing to the infringement of, and/or inducing the infringement of the Neural Stem Cell Patents by making, selling, using and/or offering for sale or license neural stem cell products that practice the Neural Stem Cell Patents in this judicial district and elsewhere and will continue to do so unless enjoined by this Court.
- 13. Neuralstem's infringement of the Neural Stem Cell Patents has been and continues to be willful, entitling StemCells to enhanced damages.
- 14. Neuralstem's infringement of the Neural Stem Cell Patents has caused reparable and irreparable harm and damage to StemCells, which will continue unless enjoined by this Court.

WHEREFORE, StemCells prays for judgment and relief as follows:

- A. A finding by the Court that Neuralstem has infringed, contributed to the infringement and/or induced the infringement of the Neural Stem Cell Patents;
- B. A finding by the Court that Neuralstem's infringement of the Neural Stem Cell Patents is willful, and an award of enhanced damages of up to three times the amount found or assessed under 35 U.S.C. § 284;
- C. A temporary, preliminary and permanent injunction against Neuralstem's continued infringement, inducing of infringement, and contributing to infringement of the Neural Stem Cell Patents, including any such infringement by Neuralstem's parents,

subsidiaries, affiliates, divisions, officers, agents, servants, employees, directors, partners, representatives, shareholders and all parties in active concert and/or participation with it;

- An award of damages in favor of StemCells and against Neuralstem D. sufficient to compensate StemCells for Neuralstem's infringement of the Neural Stem Cell Patents, and an assessment of prejudgment and post-judgment interest;
 - E. A finding by the Court that this case is exceptional under 35 U.S.C. § 285;
- An award to StemCells of its reasonable expenses, including attorneys' F. fees, and costs of this action; and
 - G. Such other and further relief as the Court finds just and proper.

Respectfully submitted,

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Dated: September_, 2006

DEMAND FOR JURY TRIAL

Plaintiff StemCells, Inc. hereby demands a trial by jury on all issues so triable.

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Attorney for Plaintiff StemCells, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Plaintiffs' Amended Complaint was served upon counsel for the defendant on this day of September 2006, by telefax and U.S. Mail.