

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
SOUTHERN DIVISION**

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NEURALSTEM, INC.,  
9700 Great Seneca Highway,  
Rockville, Maryland, 20850,  
Montgomery County,

Plaintiff,

v.

STEMCELLS, INC.; STEMCELLS  
CALIFORNIA, INC.,  
3155 Porter Drive, Palo Alto,  
California 94304;

and

NEUROSPHERES HOLDING LTD.,  
83 Heritage Medical Research Center,  
3330 Hospital Drive N.W.,  
Calgary, Alberta, T2N 4N1, Canada,

Defendants.

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Civ. No. 08-cv-1173

Jury Trial Demanded

Judge Alexander Williams, Jr.

**AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT  
UNENFORCEABILITY, INVALIDITY, NON-INFRINGEMENT, AND NON-LIABILITY  
OF TRADE LIBEL AND UNFAIR COMPETITION**

Plaintiff, Neuralstem, Inc. (“Neuralstem”), by its attorneys, alleges as follows for its Complaint for Declaratory Judgment against Defendants StemCells, Inc.; StemCells California, Inc. (collectively, “StemCells”); and Neurospheres Holding, Ltd. (“Neurospheres”) (collectively, “Defendants”):

**I. JURISDICTION, VENUE AND PARTIES**

1. This action arises under the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 1 *et seq.* Venue for this case is proper in this District and before this Court under 28 U.S.C. § 1391(b) and 1391(c).

2. Plaintiff Neuralstem is a corporation organized under the laws of the State of Maryland with its principal place of business at 9700 Great Seneca Highway, Rockville, Maryland 20850. Founded in 1996, Neuralstem is a publicly-traded biotherapeutics company whose mission is to use stem cell research and its patented human neural stem cell technology to treat diseases of the central nervous system including Ischemic Paraplegia, Traumatic Spinal Cord Injury, ALS, Stroke, and Parkinson's Disease. Neuralstem's technology was pioneered and developed by its Scientific Founder and Chairman, Dr. Karl Johe. Neuralstem's technology enables, for the first time, the ability to produce neural stem cells of the human brain and spinal cord in significant quantities, and the ability to control the differentiation of these cells into mature, physiologically relevant human neurons and glia. Neuralstem sells no commercial products embodying this technology as it is engaged in the process of gathering data for submission to the Food and Drug Administration.

3. Upon information and belief, Defendant StemCells, Inc. is a Delaware corporation, with its principal place of business located at 3155 Porter Drive, Palo Alto, California 94304. 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 and stem cell based diagnostic and screening tools.

4. Upon information and belief, Defendant StemCells California, Inc. is a wholly owned subsidiary of StemCells, Inc., with its principal place of business located at 3155 Porter Drive, Palo Alto, California 94304.

5. Jurisdiction over StemCells is proper because StemCells has availed itself of the jurisdiction of this Court by filing lawsuits alleging patent infringement in the United States

District Court for the District of Maryland, including *StemCells, Inc. v. Neuralstem, Inc.*, Case No. 06-1877, which is currently pending.

6. Upon information and belief, Defendant Neurospheres is a Canadian entity with its principal place of business at 83 Heritage Medical Research Center, 3330 Hospital Drive N.W., Calgary, Alberta, T2N 4N1, Canada. Upon information and belief, Neurospheres is an intellectual property holding company that licenses all of its patents to its exclusive/non-exclusive licensee StemCells, Inc. Upon information and belief, StemCells, Inc. has the right to sublicense the Neurospheres patents and has claimed all substantial rights in all Neurospheres patents, including the right to enforce them.

7. This court has jurisdiction over Neurospheres based on its active and ongoing relationship with its exclusive licensee, StemCells, and StemCells' extensive contacts in this judicial district including, but not limited to, StemCells' filing of at least three different lawsuits alleging patent infringement in the United States District Court for the District of Maryland for patents that are owned by Neurospheres.

### FACTUAL ALLEGATIONS

8. On April 22, 2008, the United States Patent and Trademark Office issued United States Patent No. 7,361,505 (the "'505 patent") for "Multipotent Neural Stem Cell Compositions" to Neurospheres. (*See* Exhibit A.)

9. The day after issuance, StemCells, Neurospheres' exclusive licensee for the '505 patent, issued a press release regarding the '505 patent and touting its "broad claims covering human neural stem cells derived from any tissue source, including embryonic, fetal, juvenile, or adult tissue." (Exhibit B, StemCells April 23, 2008 Press Release.) In that press release, StemCells' President and CEO, Martin McGlynn stated: "We are confident that *any third party wishing to commercialize neural stem cells as potential therapeutics or use them as drug*

*screening tools will have to seek a license* from us irrespective of how they derive the cells. *Id.* (emphasis added). According to StemCells it has granted many licenses to patents directed to neural stem cells, including licenses to Cambrex; ReNeuron, R&D Systems; and Stem Cell Therapeutics. (See Exhibit C, Amended Complaint in Case No. AW 06 CV 1877, at ¶ 10.)

10. In addition, to issuing threatening statements to the market, StemCells has a history of aggressively enforcing its exclusively licensed patents. In 2001 StemCells filed suit against Sciencell Research Laboratories (“Sciencell”) in the United States District Court for the District of Massachusetts alleging infringement of nine U.S. Patents. Civil Action No. 01-CV-11942 (REK). In 2004 and 2005, StemCells sued ReNeuron twice in the United States District Court for the District of Maryland. See Civil Action Nos. 04-CV-03973 and 05-CV-1125.

11. In 2006, StemCells filed suit against Plaintiff NeuralStem in the United States District Court for the District of Maryland alleging infringement of five U.S. Patents. Civil Action No. AW-06-CV-1877. Judge Alexander Williams, Jr. has stayed that case pending the completion of the reexaminations related to the patents-in-suit in that case. (See Exhibit D, Case No. AW 06 CV 1877, Docket No. 70.)

12. Based on its press release stating that no one can work in this field without a license from StemCells and its history of suing companies that refuse to take a license, including Neuralstem, a justiciable controversy exists between Neuralstem and Defendants regarding the ‘505 patent.

### **StemCells’ New California Action**

13. On May 7, *after* Neuralstem filed the present action, Stemcells’ filed a Complaint in the United States District Court for the Northern District of California alleging patent infringement of U. S. Patents 7,115,418 (the “418 patent”) and the ‘505 patent at issue here.

(Civil Action No. 08-cv-02364, the “California Action”). A copy of the ‘418 patent is attached as Exhibit E. On May 9, 2008, StemCells filed an Amended Complaint adding claims to the California Action for Trade Libel and Unfair Competition in violation of California Business & Professions Code § 17200 *et seq.* According to StemCells, which purport to be based on statements made by Neuralstem’s CEO concerning the reexamination of StemCells’ patents-in-suit and the present action, these common law and state law claims have “common operative facts” to its patent infringement claims. (*See* Exhibit F, Amended Complaint in California Action, at ¶¶ 2 and 22-37.)

14. In light of StemCells’ filing of the California Action, a justiciable controversy exists between Neuralstem and Defendants regarding the ‘505 patent, the ‘418 patent and the allegedly related claims for trade libel and unfair competition. Nonetheless, Neuralstem’s statements are protected by the Noerr-Pennington Doctrine, the First Amendment, and/or the litigation privilege, and consequently are immune from liability.

#### **Neuralstem’s Injury**

15. Neuralstem has suffered injury due to StemCells’ public threats of infringement and enforcement. Through its overarching threats of litigation against all neural stem cell researchers, StemCells has knowingly and willfully engaged in a course of conduct designed to improperly obtain monopoly power in the neural stem cell market and the market for innovation in the field of neural stem cell technology in the United States.

16. StemCells’ threats of infringement are designed to prevent Neuralstem from obtaining research funding and/or adversely affect Neuralstem’s financial position. On the day of StemCells’ April 23, 2008 press release, Neuralstem’s stock price dropped 10%.

17. To remedy the damage StemCells has caused and continues to cause, Neuralstem seeks declaratory judgments of non-infringement and invalidity and/or unenforceability of the '505 patent.

### **History Before the Patent Office and Inequitable Conduct**

18. On June 7, 1995, Neurospheres filed application serial no. 08/480, 172 (the '505 patent Application") with the PTO for "Multipotent Neural Stem Cell Compositions." The '505 patent application was assigned to Examiner Robert Hayes. After nearly thirteen years in prosecution and extensive appellate review, Neurospheres obtained a Notice of Allowance on January 24, 2007. On February 5, 2007, Neurospheres paid the issue fee.

19. On July 24, 2006, StemCells filed a lawsuit in this Judicial District asserting infringement of U.S. Patent Nos. 6,294,346 ("346 patent"); 7,101,709 ("709 patent"); 6,497,872 ("872 patent"); and 5,851,832 ("832 patent"). The '346, '709, '872, and '832 patents are from the same family as the '505 patent and claim similar subject matter related to neural stem cells.

20. On December 7, 2006 and April 5, 2007, Neuralstem filed reexamination requests for the '346 patent (Reexamination Control No. 90/008,367); '709 patent (Reexamination Control No. 90/008,366); '872 patent (Reexamination Control No. 90/008,581); and the '832 patent (Reexamination Control No. 90/008,580). The reexamination requests cited at least eleven prior art references that had not been previously cited in the StemCells patent family.

21. The PTO determined the reexaminations raised multiple new issues of patentability. The reexaminations were assigned to Examiners Bennett Celsa, Padmashri Ponnaluri, Sharon Turner, and Deborah Jones who operate in a special group at the PTO. Notably, the three Examiners handling the reexaminations were not the same as the Examiner handling the '505 patent application.

22. As a result of the reexaminations, StemCells and Neuralstem jointly agreed to stay the previous lawsuit between these parties.

23. While the reexaminations and the '505 patent application were assigned to different Examiners, the attorneys prosecuting both the '505 patent and the concurrent reexaminations for the '346, '709, '872, and '832 patents were the same. Moreover, the attorneys representing StemCells in *StemCells v. Neuralstem* (Civil Action No. AW-06-CV-1877) are also from the same law firm as those prosecuting patents on behalf of StemCells before the PTO. Upon information and belief, the lead prosecuting attorney maintains his law firm's relationship with both StemCells and Neurospheres. The lead prosecuting attorney participated in telephone conversations with opposing counsel regarding the *StemCells v. Neuralstem* litigation.

24. Accordingly, the attorneys prosecuting the '505 patent were fully aware of the pending litigation with Neuralstem, the reexaminations filed by Neuralstem, and the prior art cited in those reexaminations. The attorneys prosecuting the '505 patent were aware their firm was handling the concurrent reexaminations.

25. The '346, '709, '872, and '832 patents are in the same family as the '505 patent and claim similar subject matter related to neural stem cells. Accordingly, the attorneys prosecuting the '505 patent were aware that they had a duty to disclose the existence of the Neuralstem litigation and the reexaminations of the '346, '709, '872, and '832 patents to the PTO during the prosecution of the '505 patent.

26. Under the Manual of Patent Examining Procedure ("MPEP") 2001.06, Patentees have the duty to disclose "all material information they are *aware* of regardless of the source of or how they become aware of the information." MPEP 2001.06 (emphasis in original). This

also includes when “the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom *must* be brought to the attention of the [PTO].” MPEP 2001.06(c) (emphasis added).

27. The inventors and their attorneys failed to disclose the pending litigation with Neuralstem to the PTO during prosecution of the ‘505 patent.

28. On December 7, 2006, Neuralstem filed reexamination requests for the ‘346 patent (Reexamination Control No. 90/008,367) and the ‘709 patent (Reexamination Control No. 90/008,366). The PTO granted these requests on February 16, 2007.

29. The inventors and their attorneys failed to disclose Reexamination Control Nos. 90/008,367 and 90/008,366 to Examiner Hayes during prosecution of the ‘505 patent.

30. On April 5, 2007, Neuralstem filed reexamination requests for the ‘872 patent (Reexamination Control No. 90/008,581) and the ‘832 patent (Reexamination Control No. 90/008,580). The PTO granted these requests on May 10, 2007.

31. The inventors and their attorneys failed to disclose Reexamination Control Nos. 90/008,580 and 90/008,581 to Examiner Hayes during prosecution of the ‘505 patent.

32. On September 7 and 8, 2007, the PTO Examiners handling the reexaminations issued four Office Actions rejecting the claims in the ‘346, ‘709, ‘872 and ‘832 patents as unpatentable.

33. The inventors and their attorneys did not disclose the September 7 and 8, 2007 Office Actions to Examiner Hayes during prosecution of the ‘505 patent.

34. The inventors and their attorneys amended the patent claims of the ‘346, ‘709, ‘872 and ‘832 patents in their Responses to overcome the rejections in the September 7 and 8, 2007 Office Actions.



35. The inventors and their attorneys did not disclose their Responses to the September 7 and 8, 2007 Office Actions to Examiner Hayes during prosecution of the '505 patent.

36. The inventors and their attorneys did not disclose the existence of any of the four concurrently pending reexamination proceedings to Examiner Hayes during prosecution of the '505 patent.

37. Though Defendants submitted an Information Disclosure Statement ("IDS") to Examiner Hayes revealing the prior art cited in the four reexaminations on May 16, 2007, they did so after the patent issue fee was paid. (Exhibit G, May 16, 2007 '505 patent IDS Submission.)

38. The IDS is a filing with the PTO in which patent applicants bring to the attention of the Examiner any background art that bears on the patentability of the application. Patentees have a duty to disclose to the PTO any information known to the individual to be material to the patentability of a claimed invention. *See* MPEP § 609.

39. Per the PTO regulations, the Defendants' untimely IDS submission would not be considered by the examiner:

37 CFR 1.97

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

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(d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:

(1) The statement specified in paragraph (e) of this section; and

(2) The fee set forth in § 1.17(p).

Nevertheless, Defendants specifically requested “that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.” *Id.*

40. In addition to being untimely, Defendants’ IDS submission to Examiner Hayes also was incomplete and misleading because it failed to mention the pending reexaminations, the fact that four other PTO Examiners, Examiners Bennett Celsa, Padmashri Ponnaluri, Deborah Jones, and Sharon Turner had determined the prior art cited in those reexaminations raised “substantial new questions of patentability,” and that those prior art references ultimately forced Defendants to substantially amend the claims in all four patents during the course of the reexamination proceedings.

41. On January 9, 2008, Examiner Hayes sent a communication to Defendants’ attorneys stating that the May 16, 2007 IDS was non-compliant because it was submitted after the patent issue fee was paid, and therefore the IDS was not considered. (Exhibit H, ‘505 patent Examiner Response to IDS.) Though Defendants could have responded to the PTO communication and prevented the ‘505 patent from issuing so that their IDS submission and information about the reexamination proceedings and the litigation could be considered, Defendants failed to do so.

42. Although they had numerous opportunities to comply with their duty of candor before the PTO, Defendants repeatedly did not apprise the PTO of information highly material to

the patentability of '505 patent, including the pending litigation and concurrent reexamination proceedings.

43. Defendants repeated failures to disclose material information and the submission of an after-the-fact and incomplete IDS show their conduct was not a mistake, but rather, suggests an intent to deceive the PTO by concealing highly material information.

44. Defendants were aware of the adverse effect the prior art references cited in the non-compliant IDS had on the claims of the '346, '709, '872 and '832 patents during reexamination, and thus knew or should have known that those references were highly material to the '505 patent. As a result of the conduct described above, the '505 patent is unenforceable.

45. Moreover, the inventors' and attorneys' duty of candor extends throughout a patent's entire prosecution history. Under the doctrine of infectious unenforceability all of Defendants' patents in the same patent family, including the '346, '709, '872 and '832 patents, are also infected and unenforceable due to inequitable conduct in the '505 patent application.

### **COUNT I**

(Declaratory Judgment of Unenforceability)

46. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

47. Due to the failure to apprise the PTO of prior art and information highly material to the patentability of '505 patent, the '505 patent is unenforceable.

48. A judicial declaration of unenforceability is necessary and appropriate to resolve this controversy.

### **COUNT II**

(Declaratory Judgment of Non-Infringement of the '505 Patent)

49. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

50. Neuralstem's activities do not infringe, do not induce infringement, and do not contributorily infringe any valid, enforceable claims, if any, of the '505 patent.

51. Neuralstem does not infringe the '505 patent because Neuralstem's activities do not constitute patent infringement under 35 U.S.C. § 271(e)(1).

52. A judicial declaration of non-infringement is necessary and appropriate to resolve this controversy.

### **COUNT III**

(Declaratory Judgment of Invalidity of the '505 Patent)

53. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

54. Upon information and belief, each claim of the '505 patent is invalid for failure to comply with one of more of the conditions for patentability specified in Part II of Title 35 of the United States Code, including at least Sections 101, 102, 103, and 112.

55. A judicial declaration of invalidity is necessary and appropriate to resolve this controversy.

### **COUNT IV**

(Declaratory Judgment of Non-Infringement of the '418 Patent)

56. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

57. Neuralstem's activities do not infringe, do not induce infringement, and do not contributorily infringe any valid, enforceable claims, if any, of the '418 patent.

58. Neuralstem does not infringe the '418 patent because Neuralstem's activities do not constitute patent infringement under 35 U.S.C. § 271(e)(1).

59. A judicial declaration of non-infringement is necessary and appropriate to resolve this controversy.

### **COUNT V**

(Declaratory Judgment of Invalidity of the '418 Patent)

60. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

61. Upon information and belief, each claim of the '418 patent is invalid for failure to comply with one of more of the conditions for patentability specified in Part II of Title 35 of the United States Code, including at least Sections 101, 102, 103, and 112.

62. A judicial declaration of invalidity is necessary and appropriate to resolve this controversy.

### **COUNT VI**

(Declaratory Judgment of Non-Liability for Trade Libel)

63. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

64. Neuralstem has not embarked upon an intentional course of action to devalue and injure the intellectual property of Stemcells or effect the business honesty of Stemcells.

65. Neuralstem has not made and does not continue to make wrongful and false statements about the PTO's actions regarding Stemcells' patents and actions before the PTO.

66. Neuralstem's statements are protected by the Noerr-Pennington Doctrine, the First Amendment, and/or the litigation privilege, and consequently are immune from liability.

67. A judicial declaration of non-liability is necessary and appropriate to resolve this controversy.

### **COUNT VII**

(Declaratory Judgment of Non-Liability for Unfair Competition)

68. Neuralstem incorporates all preceding Paragraphs of its Complaint as if fully set forth herein.

69. Neuralstem has not and does not engage in unfair competition with regard to Stemcells, its business, or its actions before the PTO.

70. Neuralstem's actions are protected by the Noerr-Pennington Doctrine, the First Amendment, and/or the litigation privilege, and consequently are immune from liability.

71. A judicial declaration of non-liability is necessary and appropriate to resolve this controversy.

### **RELIEF REQUESTED**

WHEREFORE, Neuralstem requests that the Court enter a judgment in Neuralstem's favor and against StemCells and provide Neuralstem the following relief:

- A. Order, adjudge, and decree that Neuralstem is not infringing the '505 patent, directly or indirectly;
- B. Order, adjudge, and decree that the '505 patent is unenforceable;
- C. Order, adjudge, and decree that the '505 patent is invalid;
- D. Order, adjudge, and decree that Neuralstem is not infringing the '418 patent, directly or indirectly;
- E. Order, adjudge, and decree that the '418 patent is invalid;

- F. Order, adjudge, and decree that Neuralstem is not liable for trade libel against StemCells;
- G. Order, adjudge, and decree that Neuralstem is not liable for unfair competition against StemCells;
- H. Order, adjudge, and decree that this is an exceptional case under 35 U.S.C. § 285 and award Neuralstem its reasonable attorneys' fees; and
- I. Award such other and further relief as the Court may deem just.

**JURY DEMAND**

Neuralstem demands trial by jury.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

/s/ Michael T. Murphy

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