

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TET SYSTEMS GMBH & CO. KG,

Plaintiff,

Civil Action No. \_\_\_\_\_

v.

STEM CELLS, INC., THE UNIVERSITY OF  
CALIFORNIA IRVINE and THE REGENTS OF  
THE UNIVERSITY OF CALIFORNIA,

Defendants.

**COMPLAINT AND JURY DEMAND**

Plaintiff TET Systems GMBH & Co. KG (“TET” or “Plaintiff”), by and through its undersigned counsel, Gibbons P.C., as for its Complaint against Defendants StemCells, Inc. (“StemCells”), The University of California Irvine (“UCI”) and The Regents of The University of California (“Regents”) (UCI and Regents are collectively referred to as “UC”), alleges as follows:

**THE PARTIES**

1. TET is a corporation organized and existing under the laws of Germany, having its principal place of business at Im Neuenheimer Feld 582, 69120 Heidelberg, Germany.
2. TET is the owner, by assignment, of all rights, title and interest in United States Patent No. 5,464,758, entitled “Tight Control of Gene Expression in Eucaryotic Cells by Tetracycline-Responsive Promoters” (“the ‘758 Patent”); United States Patent No. 6,914,124 entitled “Tetracycline-Regulated Transcriptional Activator Fusion Proteins” (“the ‘124 Patent”); and United States Patent No. 5,859,310 entitled “Mice Transgenic for a Tetracycline-Controlled

Transcriptional Activator” (“the ‘310 Patent”) (the ‘758 Patent, the ‘124 Patent and the ‘310 Patent may be collectively referred to as the “TET Technology” or the “TET System”).

3. On information and belief, StemCells is a corporation organized and existing under the laws of Delaware, having its principal place of business at 7707 Gateway Boulevard, Suite 140, Newark, California 94560. StemCells describes itself as a company that “is engaged in the development and commercialization of novel stem cell therapeutics and tools for use in stem cell-based research and drug discovery.” It is publicly traded on the NASDAQ Composite.

4. On information and belief, UCI is a subsumed entity of The Regents,<sup>1</sup> having its principal place of business at 510 Aldrich Hall, Irvine, California.

5. Regents is a public corporation organized and existing under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its principal place of business at 1111 Franklin Street, Oakland, California.

### **JURISDICTION AND VENUE**

6. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over StemCells by virtue of, *inter alia*, StemCells’ continuous and systematic business contacts with the State of Delaware, including StemCells’ incorporation in Delaware and its extensive intellectual property sale and licensing programs as described on its website as generating over \$400 million to date involving, on information and belief, other Delaware corporations.

8. This Court has personal jurisdiction over UCI by virtue of, *inter alia*, UCI’s continuous and systematic business contacts with the State of Delaware. UCI has an Office of

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<sup>1</sup> See [http://www.ucop.edu/general-counsel/\\_files/servproc.pdf](http://www.ucop.edu/general-counsel/_files/servproc.pdf) (accessed December 19, 2013).

Technology Alliances (“OTA”) that “exists to foster faculty/industry alliances and commercialization of UC Irvine technology.” The OTA touts that it has managed 113 active license or option agreements and has participated in founding more than 50 companies in the fiscal year of 2011 alone. On information and belief, these activities include agreements with or founding of companies located or incorporated in Delaware. AbaStarMDX, Inc., jCyte, Inc., Introspective Medical, HiperWall, Glaukos Corp., Bone-Rad Therapeutics, Magneto-Inertial Fusion Technologies, Inc., One-Cycle Control, Inc., RF Nano Corp., SoundCure, Inc., Thesan Pharmaceuticals, Inc. and ZeroWatt Technologies, Inc. are companies founded by the OTA that are believed to be incorporated in Delaware.

9. This Court has personal jurisdiction over Regents by virtue of, *inter alia*, Regents’ availing itself of this Court in other litigations. *See, e.g., Konarka Techs., Inc. v. Plextronics, Inc.*, 1-09-cv-00916 (D. Del.) and *Regents Of The University of California v. Rogan*, 1-03-cv-01133 (D. Del.). Additionally, on information and belief, Regents is vested with the legal title and the management and disposition of the property of the university and all the powers necessary or convenient for the effective administration of its trust, including the power to sue and to be sued. It is the highest administrative authority of the University of California, including UCI, and has general rule making or policy-making power in regard to UCI, and is fully empowered to operate, control, and administer UCI.

10. As stated herein, Regents and UCI are, upon information and belief, indispensable parties to this action. Joinder is appropriate under 35 U.S.C. § 299. The infringement allegations herein arise out of the same transaction, occurrence, or series of transactions or occurrences relating to the unlawful making and using of the TET Technology in commercial collaborative research between UC and StemCells.

11. Venue is proper in this district under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

## **BACKGROUND**

### **The TET Technology**

12. Dr. Manfred Gossen and Prof. Dr. Hermann Bujard, while at the University of Heidelberg, discovered a control system that allows for the regulation of expression of individual genes in eukaryotic cells, *e.g.*, mammalian cells. The invented control system utilizes tetracycline responsive promoters to provide efficient, precise and reversible control over both the timing and level of gene expression. This technology allows scientists to control the regulation of expression of an individual gene in mammalian cells.

13. Through the implementation of Dr. Bujard and Dr. Gossen's ground-breaking invention, higher cells and entire organisms can be used as hosts in assays, or screening tests that control target gene expression via external stimuli. In particular, cell-based screening assays can be useful in discovering and profiling the activity of chemical compounds versus medically-relevant targets. For example, antiviral activity against the Hepatitis virus was screened in cell lines in which the Hepatitis B viral ("HBV") genome was placed under the TET System control. This led to the discovery of new antiviral compounds and also proved useful for testing antiviral drugs against Hepatitis viruses. The TET Technology has been recognized in the scientific literature as a broadly and successfully applied system for controlled gene expression in eukaryotes, *i.e.*, organisms made up of cells that possess a membrane-bound nucleus containing genetic material.

14. TET's technology allows users to control the activity of a target gene both *in vivo* and *in vitro*. The TET Technology has been applied in cultured cells, as well as in a wide spectrum of organisms, from animals and plants to various unicellular systems.

15. The advantages of the TET System have provided scientists with new insights into complex biological processes of development, disease and behavior.

16. The United States Patent and Trademark Office has granted Dr. Gossen and Dr. Bujard numerous patents directed to polynucleotide molecules and methods of their use for controlling expression of genes of interest in mammalian cells including, but not limited to, the '758 Patent, the '124 Patent and the '310 Patent.

17. The '758 Patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 1995. A copy of the '758 Patent is attached hereto as Exhibit 1.

18. The '124 Patent was duly and legally issued by the United States Patent and Trademark Office on July 5, 2005. A copy of the '124 Patent is attached hereto as Exhibit 2.

19. The '310 Patent was duly and legally issued by the United States Patent and Trademark Office on January 12, 1999. A copy of the '310 Patent is attached hereto as Exhibit 3.

20. Claims of the '124 Patent cover, *inter alia*, certain fusion proteins which activate transcription.

21. Claims of the '758 Patent cover, *inter alia*, a two component system consisting of hybrid polynucleotide molecules encoding a transactivator fusion protein and a transcription unit, which is responsive to the transactivator fusion protein.

22. When polynucleotide molecules encoding the fusion protein and the responsive transcription unit, respectively, are inserted into suitable vectors and transfected into a cell, they can provide accurate and reproducible control of expression of a gene of interest using tetracycline or a tetracycline analogue as the controlling effector molecule.

23. This allows users to utilize that cell and its progeny to screen new drug compounds.

24. Claims of the '758 Patent also cover, *inter alia*, a method of using the cell transfected with a vector containing the hybrid polynucleotide molecule in a tetracycline or a tetracycline analogue medium as a means of controlling gene expression.

25. This enables users to determine the activity of compounds in the presence of stimuli, on the activity of viral proteins, required for replication and/or pathogenicity.

26. Claims of the '758 Patent further cover, *inter alia*, a kit that provides the novel reagents of the invention for convenient use by companies to set up an assay system useful to identify the activity of compounds to evaluate their potential use as drugs.

27. The '310 Patent covers a system that allows for conditional inactivation or modulation of expression of a gene of interest in a mouse. Claims of the '310 Patent cover, *inter alia*, certain transgenic mice having a transgene integrated into their genome and also having a tet operator-linked gene in the genome of the mice.

28. Claims of the '310 Patent also cover, *inter alia*, transgenic mice wherein hybrid polynucleotide molecules encoding a transactivator fusion protein comprising a tet repressor and a polypeptide which directly or indirectly activates transcription of a tet operator-linked gene are integrated into the mice's genome.

29. Claims of the '310 Patent also cover, *inter alia*, transgenic mice wherein hybrid polynucleotide molecules encoding a gene of interest that is operably linked to a minimal promoter operably linked to at least one tet operator sequence are integrated into the mice's genome.

30. Claims of the '310 Patent further cover, *inter alia*, methods of regulating the expression of a tet-operator linked gene of interest by administering tetracycline or a tetracycline analogue to a mouse of the invention.

31. TET has commercially licensed and, through a distributor sold, products and components that embody features claimed in the '124 Patent, the '758 Patent and the '310 Patent.

### **Commercialization and Licensing of the TET Technology/TET System**

32. Licenses to the TET Technology have been commercially available since 1996; first through BASF Bioresearch Corporation and then exclusively from Abbott Laboratories ("Abbott") following Abbott's acquisition of the pharmaceutical division of BASF AG in 2001. However, Drs. Gossen and Bujard wanted to ensure that the TET Technology was easily accessible to scientists conducting academic and other non-profit research around the world. So, in 2003, Dr. Bujard together with Dr. Gossen and others founded TET. One of TET's first orders of business was to effect the transfer of the entire TET IP portfolio from Abbott to TET in December of 2003. Since, TET has overseen the dissemination of products, components and reagents covered by the TET IP Portfolio, including the TET Technology, and implemented licensing policies that make the TET IP readily available to researchers worldwide. Furthermore, TET has since continued to develop the TET IP and expand the TET IP portfolio through internal development and acquisitions. To date, the TET IP Portfolio is comprised of 36 patents and 5 patent applications.

33. The licensing program implemented by TET is a simple, yet robust, licensing program that grants academic and not-for-profit researchers and institutions the right to use to the TET Technology at no cost for their internal research and development projects. TET also offers

licenses for commercial research and development under a fee schedule based on the entity's size, intended use and geographic territory.

34. To date, over 250 organizations have licensed the TET Technology, including 17 of the top 20 BIG Pharma (2006).

35. Presently, products based on, or containing components of the TET Technology are available from a number of companies, including Clontech (a commercial licensee of products such as TET System reagents), Addgene Inc. (global licensed distributor of plasmids containing components of the TET Technology that are not commercially available), Millipore (commercial licensee for the worldwide marketing of TET-inducible lentiviral iPS gene cassettes); Open Biosystems (commercial licensee for the worldwide marketing of Yeast TET-promoters), and Vectalys<sup>TM</sup> (commercial worldwide licensee for the production, concentration and the purification of lentiviral vector compositions comprising the TET Technology). Additionally, there are numerous companies, such as Sirion, genOway, inGenious Targeting Laboratory, Mirimus, Inc. and Ozgene that have been granted commercial licenses for the worldwide marketing of cell lines and transgenic mice and rat lines that contain or are produced using the TET Technology.

36. Drs. Bujard and Gossen and the TET Technology have been recognized in numerous peer-reviewed scientific journals throughout the world. The TET Technology has become the most widely applied inducible gene expression system. The use of the TET System has lead to more than 10,000 publications in peer-reviewed journals by researchers and institutions licensed under the technology.

**Defendants' Prior Dealings With TET**

37. Defendants are no strangers to TET's licensing program.



38. Defendant StemCells, at one point, was a licensee under the TET Technology. IP Merchandisers, a division of TET, and StemCells first entered into a Non-Exclusive License Agreement for Internal Research Use effective June 28, 2006 (the “TET-StemCells Agreement”).

39. The TET-StemCells Agreement limited StemCells’ use of TET Products and the rights granted under the TET-StemCells Agreement for “internal use” and in the territory of North America. StemCells was prohibited from sublicensing or assigning the rights granted it under the TET-StemCells Agreement and conducting contract research or screening.

40. The TET-StemCells Agreement also required StemCells to (i) pay an annual license maintenance fee on or before each anniversary of the effective date, (ii) “promptly cease any and all uses of the TET-System, TET Products, the intellectual property rights granted to [TET under the agreement] and/or the Patent Rights” and to “promptly destroy any such materials” upon termination of the TET-StemCells Agreement, and (iii) “promptly notify” TET if StemCells “becomes aware that any Patent Rights and the intellectual property rights granted to [TET under the TET-StemCells Agreement] are being infringed or have been infringed by any third party, or that TET Products have been misappropriated by a third party.” A redacted copy of the TET-StemCells Agreement is attached as Exhibit 4.

41. StemCells paid the licensing fee for the first two years, but failed to pay the fee in accordance with the TET-StemCells Agreement for the third year. Instead, on October 21, 2008, almost three months after the annual license maintenance fee was due, StemCells notified TET that it desired to terminate the license agreement. A copy of StemCells’ October 21, 2008 letter is attached as Exhibit 5.

42. In its termination letter, StemCells explicitly stated that “StemCells no longer uses TET Technologies for research.” Yet, shortly thereafter, as detailed below, StemCells funded and/or obtained funding for commercial collaborative research with UC that implemented the TET Technology (“the StemCells-UC Collaboration”). StemCells’ researchers participated in the research and two StemCells researchers are named co-authors on a poster presenting the results from studies conducted with the TET Technology during the StemCells-UC Collaboration. Moreover, StemCells not only failed to notify TET that it was using TET Technology again, but also failed to notify TET that UC, an unlicensed third party, was conducting activities that infringed the TET Technology and misappropriated products covered by the TET Technology as StemCells was contractually required to do under the TET-StemCells Agreement.

43. At the time StemCells sent its purported termination letter, the licensing fee for that year was due. The TET-StemCells Agreement permits StemCells to terminate the agreement upon sixty (60) days written notice and payment of any fees currently or past due under the agreement. As stated above, StemCells’ termination letter was dated almost three months after the due date for the license maintenance fee. Despite TET’s attempts to obtain the outstanding licensing fees from StemCells, the fees remain unpaid.

44. UC has also taken advantage of TET’s licensing program. Being an academic institution, UC is able to license certain materials covered by the TET Technology under TET’s form Notice and Acknowledgment agreement, which is much more limited than TET’s commercial licenses.

45. On at least two separate occasions, UC obtained materials covered by the TET Technology under TET’s form Notice and Acknowledgment agreement with effective dates of

November 16, 2005 and October 20, 2007 (the “UC Agreements”). Pursuant to the UC Agreements, TET agreed to provide UC certain TET Technology components, free of charge, for non-commercial research. The UC Agreements contain strict limitations on the use of the TET Technology. Copies of the UC Agreements are attached as Exhibit 6 and Exhibit 7.

46. The UC Agreements align with TET’s spirit, philosophy and mission that the TET Technology be available to academic researchers and institutions free of charge as long as the use is for internal research projects and not-for-profit research. The UC Agreements specifically state that the use of the TET Technology “is only valid for academic and other non-profit research.” To the extent that UC desired to use the TET System components in collaboration with any commercial entity, the UC Agreements expressly state that UC “must first obtain the approval of [TET]” and the commercial entity “would be required to obtain a Research & Development or Commercial license from [TET].” Additionally, the UC Agreements require UC to obtain TET’s prior written approval before transferring any products or agents that incorporate the TET Technology to a commercial entity.

#### **StemCells’ and UC’s Infringing Activities**

47. In the face of these clear restrictions, TET has discovered that StemCells and UC have been using materials covered by the TET Technology in commercial collaborative research.

48. Upon information and belief, the StemCells-UC Collaboration began on or about April 2011. The purpose of the collaboration was to study the therapeutic potential of StemCells’ HuCNS-SC(R) - human neural stem cells - in Alzheimer’s disease. The HuCNS-SC cells are StemCells’ “lead product candidate.” A copy of StemCells’ April 18, 2011 press release disclosing the StemCells-UC Collaboration is attached as Exhibit 8.

49. Upon information and belief, StemCells and UC presented a poster entitled “Restoration of memory in mouse models of Alzheimer disease and neuronal loss: a new paradigm using neural stem cell transplantation” (“the UC-StemCells Reference”) at an *Alzheimer’s Association Annual Meeting*. The UC-StemCells Reference discloses that the HuCNS-SC cells restored memory and enhanced synaptic function in two animal models. The UC-StemCells Reference discloses that CaM/Tet-DT<sub>A</sub> mice were one of the animal models used in the StemCells-UC Collaboration. A copy of the UC-StemCells Reference is attached as Exhibit 9. A copy of StemCells’ April 11, 2013 press release describing the presentation of the UC-StemCells Reference by Dr. Matthew Blurton-Jones (“Dr. Blurton-Jones”) is attached as Exhibit 10.

50. Dr. Blurton-Jones is an assistant researcher at UCI working in the laboratory of Dr. Frank M. LaFerla’s (“Dr. LaFerla”).<sup>2</sup> Dr. LaFerla is the Director of UCI’s Institute for Memory Impairments and Neurological Disorders and Chancellor’s Professor, Neurobiology and Behavior in the School of Biological Sciences at UCI. Additionally, Dr. LaFerla was a recipient of material covered by the TET Technology under the October 20, 2007 UC Agreement that was executed by UC on the behalf of Dr. LaFerla.

51. Drs. Blurton-Jones and LaFerla are two of six (6) UC researchers named as co-authors of the UC-StemCells Reference along with two (2) researchers from StemCells. Dr. Blurton-Jones is listed as the lead author of the poster.

52. From the UC-StemCells Reference, TET has learned that UC and StemCells have been performing collaborative research using CaM/Tet-DT<sub>A</sub> mice. The CaM/Tet-DT<sub>A</sub> mice are transgenic mice that are covered by the TET Technology and/or were produced from or

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<sup>2</sup> See [http://neurobiology.uci.edu/faculty/laferla/Frank\\_LaFerla/People.html](http://neurobiology.uci.edu/faculty/laferla/Frank_LaFerla/People.html)

incorporate components of the TET Technology. Therefore, the CaM/Tet-DT<sub>A</sub> mice and their use fall within one or more claims of the '124 Patent, the '758 Patent and/or the '310 Patent.

53. From the UC-StemCells Reference, TET was also able to ascertain that the StemCells-UC Collaboration was for commercial purposes. The research described in the UC-StemCells Reference involved administering StemCells' lead commercial product candidate HuCNS-SC cells to the transgenic CaM/Tet-DT<sub>A</sub> mice covered by the TET Technology.

54. StemCells and UC neither had a license to use the TET Technology in the StemCells-UC Collaboration nor had TET's consent to engage in such activities.

55. And thus, StemCells' representation that it no longer uses the TET Technology (*see* ¶42 above) is not true. StemCells had an obligation to notify TET when it began using TET Technology in collaboration with UC. Additionally, Section 5.2 of the TET-StemCells Agreement requires StemCells to "promptly notify" TET if StemCells "becomes aware that any Patent Rights . . . are being infringed or have been infringed by any third party, or that TET Products have been misappropriated by a third party." This provision survived termination of the TET-StemCells Agreement and, therefore, was in effect when the UC-StemCells Collaboration began.

56. Upon information and belief, UC is a third party not authorized to make and/or use the CaM/Tet-DT<sub>A</sub> mice covered by the TET Technology. To the extent UC is licensed to use the CaM/Tet-DT<sub>A</sub> mice, its license is limited to internal research use only. In either case, UC is a third party infringing the TET Technology and is misappropriating products covered by the TET Technology. However, StemCells never notified TET of UC's unauthorized, infringing use of the TET Technology as StemCells was contractually required to do.

57. Regardless of StemCells' contractual obligations, UC should have notified TET itself that it was using TET Technology in collaboration with a commercial entity. UC is fully aware of the obligations and restrictions under which TET licenses the TET Technology. UC had previously obtained materials covered by the TET Technology under the UC Agreements. UC knows, or at least should know, that the same restrictions apply to the CaM/Tet-DT<sub>A</sub> mice, and yet it too has chosen to ignore them.

#### **Funding Obtained For the UC-StemCells Commercial Collaboration**

58. Following Dr. Blurton-Jones' July 2012 presentation, StemCells and, upon information and belief, UC, were able to secure significant funding for the commercial development of the HuCNS-SC cells. On or about July 26, 2012, StemCells "and its collaborators," *i.e.*, UC, were awarded up to \$20 million by the California Institute for Regenerative Medicine ("CIRM") "to fund preclinical development of StemCells' proprietary HuCNS-SC® product candidate . . . for cervical spinal cord injury." Shortly thereafter, on or about September 6, 2012, the CIRM awarded StemCells another \$20 million to "evaluate its HuCNS-SC cells as a potential treatment for Alzheimer's disease in collaboration with Frank LaFerla, Ph.D. . . . ." In total, following Dr. Blurton-Jones' presentation of the research results stemming from UC's and StemCells' use of the TET Technology, StemCells and UC were awarded over \$40 million to fund the commercial development of StemCells' HuCNS-SC® product candidate. Copies of the July 26, 2012 and April 11, 2013 StemCells press releases are attached as Exhibits 11 and 12.

59. The funding provided by CIRM is "in the form of unsecured, non-recourse, interest-bearing, term loans, which will be forgivable in the event the funded research fails to result in a commercialized product." However, "should the product be successfully

commercialized, CIRM would earn milestone payments depending on how successful the product becomes.” CIRM would “participate handsomely on the upside” should the product be commercially successful, yet TET will have received nothing for the contribution that the TET Technology played in the commercial development of StemCells’ HuCNS-SC® product. A copy of the StemCells press release addressing the terms of the funding provided by CIRM is provided as Exhibit 13.

60. Thus, without informing TET or obtaining TET’s prior approval, UC and StemCells engaged in commercial collaborative research using the TET Technology. Upon information and belief, StemCells and UC used the results of that research in its applications for funding to further the UC-StemCells Collaboration and the commercialization of StemCells HuCNS-SC® product candidate.

61. UC and StemCells conducted the commercial collaborative research using the TET Technology despite knowing that such collaborative research required a license from TET. However, neither UC nor StemCells are lawfully licensed under the TET Technology to conduct collaborative research utilizing the TET Technology. UC’s and StemCells’ unauthorized uses of the TET Technology are acts of infringement. Furthermore, because StemCells and UC were aware of the restrictions under TET’s licensing program, StemCells’ and UC’s infringing activities have been willful.

**TET’s Good Faith Efforts to Avoid Litigation and Defendants’ Continued Willfulness**

62. After learning of StemCells’ and UC’s infringing activities, in a letter dated November 7, 2012, TET reminded UC that its collaborative activities with StemCells using the TET Technology required the prior approval of TET and that “commercial entities, such as

StemCells, Inc., are required to obtain a Research & Development or Commercial license from TET.” A copy of TET’s November 7, 2012 letter is attached as Exhibit 14.

63. Further, in an attempt to amicably resolve the issue, TET offered to discuss terms and conditions under which UC could license the TET Technology to continue its collaborative research with StemCells.

64. On November 19, 2012, UC responded to TET’s letter. In its letter, UC professed that it was “diligently looking into [the issues raised in TET’s letter]” and that it would “respond when it has had adequate time to evaluate the situation.” A copy of UC’s November 19, 2012 letter is attached as Exhibit 15.

65. Hearing nothing further from UC, on December 4, 2012 TET wrote again to UC asking UC when a meaningful response would be forthcoming. A copy of that correspondence is attached as Exhibit 16. UC replied on December 7, but again, failed to provide a substantive response. UC completely failed to acknowledge the existence of the UC Agreements and the terms and restrictions placed on the use of the TET Technology. Instead, it patronized TET with an empty discussion on the relevance of the patents referenced in TET’s November 7 letter. A copy of UC’s December 7 letter is attached as Exhibit 17.

66. For instance, UC stated that “[b]ased on a preliminary analysis, [UC has] not been able to identify the relevance of these patents.” UC’s statement is not credible. UC is a sophisticated entity with the resources and know-how to identify what patents apply to the StemCells-UC collaboration. Likewise, UCI is equally sophisticated. Its OTA manages over one hundred license or options agreements covering UCI IP and has established numerous companies to commercialize the UCI IP. Clearly it has the capability to perform the due



diligence to ascertain the patent landscape involving tetracycline-controlled transcriptional activators and their use in transgenic mice. UC's feigned ignorance is incredulous.

67. Dismayed by UC's approach, on December 13, 2012, TET requested to speak with UC directly. Subsequent correspondence was exchanged between TET and UC, however, TET's last email of January 10, 2013 went completely ignored. To date, UC has yet to substantively address the issues first raised in TET's November 7, 2012 letter.

68. After being ignored by UC, TET attempted to contact StemCells to address the matter. On February 20, 2013, TET wrote StemCells regarding the collaboration between StemCells and UC. TET informed StemCells that the transgenic CaM/Tet-DT<sub>A</sub> mice used in StemCells' commercial collaboration with UC "are covered by TET's [patents]." TET further informed StemCells that "[StemCells'] activities with [UC] require the approval of TET" and that "commercial entities, such as StemCells, are required to obtain a research and development or commercial license from TET." A copy of TET's February 20, 2013 letter is attached as Exhibit 18.

69. In its February 20, 2013 letter, TET also attached the earlier correspondence between TET and UC regarding the StemCells-UC Collaboration and noted UC's broken promise to provide a meaningful response. TET also offered to discuss terms and conditions with StemCells under which StemCells could again license the TET Technology and continue its research with UC.

70. To date, StemCells has also completely ignored TET's overtures.

71. Because StemCells and UC have outright ignored TET's good faith efforts to resolve this dispute, TET is now forced to seek this Court's intervention.

**COUNT I: DIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(a)**  
**(STEMCELLS)**

72. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

73. In violation of 35 U.S.C. § 271(a), upon information and belief and as evidenced above, StemCells has infringed, literally or under the doctrine of equivalents, each of the elements of one or more claims of the '758 Patent, the '124 Patent and/or the '310 Patent, without a license from TET, by, *inter alia*, making, using, offering to sell, or selling the TET Technology or cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate the TET Technology or components thereof.

74. Upon information and belief, StemCells' infringement has been knowing and willful.

75. TET is entitled to recover from StemCells the damages sustained as a result of StemCells' infringing acts.

**COUNT II: DIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(a)**  
**(UC)**

76. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

77. In violation of 35 U.S.C. § 271(a), and as evidenced above, UC has infringed, literally or under the doctrine of equivalents, each of the elements of one or more claims of the '758 Patent, the '124 Patent and/or the '310 Patent, without license from TET, by, *inter alia*, making, using, offering to sell, or selling the TET Technology or cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate the TET Technology/TET System or components thereof.

78. Upon information and belief, UC's infringement has been knowing and willful.

79. TET is entitled to recover from UC the damages sustained as a result of UC's infringing acts.

**COUNT III: INDIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(b) and (c)**  
**(STEMCELLS)**

80. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

81. Upon information and belief, in violation of 35 U.S.C. § 271(b), as evidenced above, StemCells has induced infringement of the '758 Patent, the '124 Patent and/or the '310 Patent by actively, intentionally, and/or knowingly causing UC to use products and/or agents, such as CaM/Tet-DT<sub>A</sub> mice, which are covered by and/or incorporate the TET Technology/TET System, in a manner that infringes the '758 Patent, the '124 Patent and/or the '310 Patent.

82. StemCells intended UC to make and/or use products and/or agents which are covered by and/or incorporate the TET Technology/TET System during the commercial collaborative research between StemCells and UC. UC's activities during the commercial collaborative research constitute direct infringement under §271(a).

83. Upon information and belief, in violation of 35 U.S.C. § 271(c), StemCells has contributorily infringed the '758 Patent, the '124 Patent and/or the '310 Patent by supplying UC with products and/or agents, knowingly that such products and/or agents would be used in a manner that infringes the '758 Patent, the '124 Patent and/or the '310 Patent.

84. StemCells knew that the supplied products and/or agents which incorporate components of the TET Technology/TET System were not simply staple products and/or agents and that the products and/or agents did not have substantial non-infringing uses.

85. TET is entitled to recover from StemCells the damages sustained as a result of StemCells' infringing acts.

**COUNT IV: INDIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(b) and (c)**  
**(UC)**

86. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

87. On information and belief, in violation of 35 U.S.C. § 271(b), UC has induced infringement of the '758 Patent, the '124 Patent and/or the '310 Patent by actively, intentionally, and/or knowingly causing StemCells to use products and/or agents, such as CaM/Tet-DT<sub>A</sub> mice, which are covered by and/or incorporate the TET Technology/TET System, in a manner that infringes the '758 Patent, the '124 Patent and/or the '310 Patent.

88. Upon information and belief, UC intended StemCells to make and/or use products and/or agents which are covered by and/or incorporate the TET Technology/TET System during the commercial collaborative research. StemCells activities during the commercial collaborative research constitute direct infringement under §271(a).

89. On information and belief, in violation of 35 U.S.C. § 271(c), UC has contributorily infringed the '758 Patent, the '124 Patent and/or the '310 Patent by supplying StemCells with products and/or agents which incorporate components of the TET Technology/TET System, actively, intentionally, and/or knowingly that such products and/or agents would be used in a manner that infringes the '758 Patent, the '124 Patent and/or the '310 Patent.

90. UC knew that the supplied products and/or agents which incorporate components of the TET Technology/TET System were not simply staple products and/or agents and that the products and/or agents did not have substantial non-infringing uses.

91. TET is entitled to recover from UC the damages sustained as a result of UC's infringing acts.

**COUNT V: BREACH OF CONTRACT**  
**(STEMCELLS)**

92. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

93. On June 28, 2006, TET granted StemCells a non-exclusive license to utilize the TET Technology for transgenic organisms.

94. The TET-StemCells Agreement prohibited StemCells from sublicensing or assigning the rights granted it under the Agreement.

95. The TET-StemCells Agreement prohibited contract research or screening.

96. The TET-StemCells Agreement limited StemCells' use of TET Products and the rights granted under the TET-StemCells Agreement for "internal use."

97. The TET-StemCells Agreement required StemCells to pay a yearly license maintenance fee on or before each anniversary of the effective date of the TET-StemCells Agreement.

98. The TET-StemCells Agreement required StemCells, upon any termination, to "promptly cease any and all uses of the TET-System, TET Products, the intellectual property rights granted to [TET under the TET-StemCells Agreement ] and/or the Patent Rights" and to "promptly destroy any such materials."

99. The TET-StemCells Agreement requires StemCells to "promptly notify" TET if StemCells "becomes aware that any Patent Rights and the intellectual property rights granted to [TET under the TET-StemCells Agreement] are being infringed or have been infringed by any

third party, or that TET Products have been misappropriated by a third party.” This obligation survived the purported termination of the TET-StemCells Agreement.

100. StemCells breached the express and implied terms of the TET-StemCells Agreement by, upon information and belief, providing TET-System components and TET-Products to UC and funding commercial collaborative research with UC utilizing the TET-System components and TET-Products.

101. StemCells breached the express and implied terms of the TET-StemCells Agreement by: (a) failing to pay a yearly license maintenance fee on or before each anniversary of the effective date of the TET-StemCells Agreement; (b) failing to “promptly cease any and all uses of the TET-System, TET Products” and other rights granted under the TET-StemCells Agreement; (c) upon information and belief, not “promptly destroy[ing] any such materials”; and (d) not “promptly notify[ing]” TET if StemCells “becomes aware that any Patent Rights and the intellectual property rights granted to [TET under the TET-StemCells Agreement] are being infringed or have been infringed by any third party, or that TET Products have been misappropriated by a third party.”

102. TET has suffered and will continue to suffer substantial and foreseeable damages as a result of these breaches of contract by StemCells.

**COUNT VI: UNFAIR COMPETITION**  
**(STEMCELLS and UC)**

103. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

104. StemCells’ and UC’s above actions rise to the level of unlawful, unethical and immoral business practices, all designed to gain an unfair competitive advantage.

105. StemCells' and UC's actions also constitute unlawful and common law unfair competition.

106. StemCells, seeking to gain an unfair competitive advantage, prematurely terminated the TET-StemCells Agreement entered in June 2006. StemCells unethically and immorally terminated that agreement on the false pretense that it no longer uses the TET Technology, all devised to avoid paying licensing fees to TET. Subsequently, StemCells entered into a commercial collaborative relationship with UC that implemented TET Technology.

107. UC, seeking to gain an unfair competitive advantage, used TET Technology in commercial collaborative research with a commercial entity without obtaining a license to engage in such activities. UC is aware of TET's licensing program and the restrictions TET places on the use of the TET Technology, particularly the limitations regarding research collaborations with commercial entities. Despite knowing that the CaM/Tet-DT<sub>A</sub> transgenic mice constitute TET Technology and are produced with and/or incorporate TET Technology, UC unlawfully, unethically and immorally used the CaM/Tet-DT<sub>A</sub> transgenic mice anyway in collaboration with a commercial entity.

108. StemCells' and UC's unlawful, unethical and immoral use of TET Technology, upon information and belief, contributed to StemCells and UC being awarded millions of dollars in funding for their research. Additionally, upon information and belief, UC received funding from StemCells for its role in performing the study described in the UC-StemCells Reference. StemCells and UC used the TET Technology without paying any licensing fee to TET.

109. StemCells' and UC's unfair competitive business practices have unjustly harmed TET and minimized its competitive advantage, diminished the value of the TET Technology, and have caused and are causing TET to suffer other damages.

110. StemCells' and UC's actions were deceptive and dishonest.

111. As a result of StemCells' and UC's unfair competitive business practices, TET has suffered and will continue to suffer substantial and foreseeable damages.

**COUNT VII: UNJUST ENRICHMENT/QUANTUM MERUIT**  
**(STEMCELLS)**

112. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

113. As evidenced above, a license is required for an entity to practice under the TET Technology. StemCells was and is aware of TET's licensing restrictions.

114. Without obtaining a license, StemCells conducted commercial collaborative research with UC that utilized the TET Technology.

115. StemCells' commercial collaboration with UC, upon information and belief, contributed to StemCells being awarded millions of dollars in funding for their research.

116. TET has not received payment for the value of StemCells' use of the TET Technology. Further, TET is still owed licensing fees under the TET-StemCells Agreement.

117. StemCells has improperly and deceitfully received a benefit, *i.e.* the use of the TET Technology in the development of its HuCNS-SC® product without paying a license fee, for its own commercial advantage and at TET's expense and to its detriment.

118. StemCells' receipt and improper use of the TET Technology through funding and commercial collaboration with UC, and the fruits thereof, is a benefit that constitutes unjust enrichment. It would be inequitable and unjust for StemCells to retain those benefits without payment of their fair and reasonable value to TET.

119. Because of StemCells' unjust enrichment, TET has suffered and will continue to suffer substantial damages.



**COUNT VIII: UNJUST ENRICHMENT/QUANTUM MERUIT**  
**(UC)**

120. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

121. As evidenced above, UC engaged in unauthorized commercial collaborative research with StemCells that utilize the TET Technology. Upon information and belief, UC accepted funding from a commercial entity in exchange for performing research utilizing products and agents that are covered by and/or incorporate the TET Technology.

122. UC then used those results to obtain millions of dollars in additional funding to continue its unauthorized collaborative research with StemCells.

123. UC has improperly and deceitfully received a monetary benefit for an unauthorized use of the TET Technology without paying a license fee, for its own commercial advantage and at TET's expense and to its detriment.

124. UC's receipt of monetary funding for its improper use and transfer of the TET Technology is a benefit that constitutes unjust enrichment. It would be inequitable and unjust for UC to retain those benefits without payment of their fair and reasonable value to TET.

125. Because of UC's unjust enrichment, TET has suffered and will continue to suffer substantial damages.

**COUNT IX: BREACH OF DUTY OF GOOD FAITH AND FAIR DEALING**  
**(STEMCELLS AND UC)**

126. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

127. Implied in the parties' dealings and agreements was a covenant of good faith and fair dealing.

128. StemCells' and UC's actions, all as alleged herein, constitute a breach of their covenant of good faith and fair dealing.

129. TET has suffered and will continue to suffer substantial and foreseeable damages as a result of StemCells' and UC's breach of their covenant of good faith and fair dealing.

**COUNT X: DECLARATORY JUDGMENT**  
**(STEMCELLS)**

130. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

131. Disputes exist between TET and StemCells regarding whether StemCells has directly and indirectly infringed claims of the '758 Patent, the '124 Patent and/or the '310 Patent, breached the TET-StemCells Agreement, been unjustly enriched by engaging in unauthorized commercial collaborative research, engaged in unfair competitive acts and breached its duty of good faith and fair dealing. As a consequence of these disputes, an actual and justiciable controversy exists between TET and StemCells.

132. For all of the reasons set forth more fully above, TET seeks a declaratory judgment that StemCells has directly and indirectly infringed claims of the '758 Patent, the '124 Patent and/or the '310 Patent, breached the TET-StemCells Agreement, been unjustly enriched by engaging in unauthorized commercial collaborative research, engaged in unfair competitive acts, and breached its duty of good faith and fair dealing.

**COUNT XI: DECLARATORY JUDGMENT**  
**(UC)**

133. TET incorporates by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

134. Disputes exist between TET and UC regarding whether UC has directly and indirectly infringed claims of the ‘758 Patent, the ‘124 Patent and/or the ‘310 Patent engaged in unfair competitive acts, been unjustly enriched by engaging in unauthorized commercial collaborative research and breached its duty of good faith and fair dealing. As a consequence of these disputes, an actual and justiciable controversy exists between TET and UC.

135. For all of the reasons set forth more fully above, TET seeks a declaratory judgment that UC has directly and indirectly infringed claims of the ‘758 Patent, the ‘124 Patent and/or the ‘310 Patent, engaged in unfair competitive acts, has been unjustly enriched by engaging in unauthorized commercial collaborative research, and breached its duty of good faith and fair dealing.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, TET respectfully requests that this Court award TET the following relief:

- (a) A judgment and decree that StemCells has infringed one or more claims of the ‘758 Patent, the ‘124 Patent and/or the ‘310 Patent;
- (b) A judgment and decree that UC has infringed one or more claims of the ‘758 Patent, the ‘124 Patent and/or the ‘310 Patent;
- (c) An award of damages for StemCells’ infringement, which should be trebled pursuant to 35 U.S.C. § 284;
- (d) An award of damages for UC’s infringement, which should be trebled pursuant to 35 U.S.C. § 284;
- (e) That this case be declared “exceptional” and award TET its reasonable attorney fees, expenses, and costs in this action pursuant to 35 U.S.C. § 285;

(f) An order directing StemCells and UC to return to TET all unlicensed cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate and/or are covered by the TET Technology, and to require StemCells and UC to certify under oath that any and all copies thereof, including electronic records, have been destroyed in their entirety;

(g) A disgorgement of any monies, funding, or other compensation StemCells and/or UC have received to date from any entity, including but not limited to CIRM, regarding the unauthorized use of any cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate the TET Technology.

(h) An order directing StemCells and UC to complete and transfer to TET any and all trade secrets, inventions, patent applications and/or patents derived or relating to the collaboration between StemCells and UC and the use of any cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate the TET Technology.

(i) In the alternative, an order and judgment directing StemCells and UC to pay TET license fees and a premium royalty for any use of any cell lines, plasmids, vectors, receptors, promoters, embryos, animals, chemical entities, pharmaceuticals, and/or other products or agents which incorporate the TET Technology in the course of UC's and/or StemCells' development of tools and technologies for use in research or drug development;

(j) A declaratory judgment that StemCells has breached the TET-StemCells Agreement;

(k) A judgment in TET's favor compensating TET for all the damages caused by UC's and StemCells' foregoing acts, including without limitation, an accelerated payment of all licensing fees that would have been otherwise due and payable to TET under the Non-Exclusive License Agreement For Internal Research Use or any other Research & Development or Commercial license that would have been required had UC obtained lawful access to the TET Technology under a Notice and Acknowledgment Agreement, and had UC and StemCells in good faith performed its obligations under those agreements;

(l) A judgment in TET's favor for attorneys' fees and costs;

(m) An award of punitive damages in an amount no less than three (3) times the amount of all licensing fees that would have been otherwise due and payable to TET under the Non-Exclusive License Agreement For Internal Research Use or any other Research & Development or Commercial license that would have been required had UC obtained lawful access to the TET Technology under a Notice and Acknowledgment Agreement, and had UC and StemCells in good faith performed its obligations thereunder; and

(n) Such other and further relief as the Court may deem just and proper.

Dated: December 20, 2013

Respectfully submitted,

GIBBONS P.C.

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**JURY DEMAND**

TET hereby demands a jury on all issues so triable in this action.

Dated: December 20, 2013

GIBBONS P.C.

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