IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the matter of:

Reexamination Control. No. 95/000,154	Art Unit: 3991
U.S. Patent No. 7,029,913	Examiner: Gary L. Kunz
Issued: April 18, 2006	
Inventor: Thomson	
For: PRIMATE EMBRYONIC STEM CELLS	

DECLARATION OF DR. CHAD COWAN, PH.D.

SIR:

I, Chad Cowan, do declare and state:

My Education and Experience Related to Human Embryonic Stem Cell Research

1. I received a B.A. in Chemistry and Biochemistry and B.S. in Cell Biology (with Honors), with honors, from Kansas University in 1995 and 1996, a Ph.D. in Cell Regulation from the University of Texas Southwestern at Dallas in 2002 and subsequently completed a postdoctoral fellowship with Professor Douglas Melton at Harvard University.

2. I am currently on the Principal Faculty of Harvard's Stem Cell Institute. I have received a number of academic honors and am an ad-hoc reviewer for various journals, including

Developmental Biology, Journal of Biological Chemistry, Developmental Cell, and Cell Stem Cell. I am also a member of the International Stem Cell Initiative.

3. Since 2000, I have performed extensive embryonic research, including research relating to human embryonic stem cells. For example, I derived embryonic stem-cell lines from human blastocysts in work that was published in the *New England Journal of Medicine*, determined that the Src family of tyrosine kinases is important for embryonic stem cell self-renewal in work that was published in the *Journal of Biological Chemistry* and investigated nuclear reprogramming of somatic cells after fusion with human embryonic stem cells in work that was published in *Science*.

4. A copy of my curriculum vitae is attached hereto as Exhibit 1.

Reexamination of the '913 Patent

5. I am familiar with U.S. Patent No. 7,029,913 to Thomson titled, "Primate Embryonic Stem Cells" ("the '913 patent").

6. I am aware that the Foundation for Taxpayers and Consumer Rights, through its counsel the Public Patent Foundation, requested reexamination of the '913 patent, that the U.S. Patent and Trademark Office granted that request and issued an Office Action on March 30, 2007, and that the owner of the '913 patent submitted a Response to the Office Action on May 30, 2007. I have reviewed the '913 patent, the Office Action and the Response. I have also specifically reviewed the '913 patent's claims as amended by the Response.

7. I am aware that the initial application leading to the '913 patent was filed on January 20, 1995.

Robertson '83 and Robertson '87

8. I am familiar with Robertson, et al., "Isolation, Properties, and Karyotype Analysis of Pluripotential (EK) Cell Lines From Normal and Parthenogenetic Embryos," *Teratocarcinoma Stem Cells*, Cold Spring Harbor Laboratory, Cold Spring Harbor, volume 10, pp. 647-663 (1983) ("Robertson '83") and Robertson, Elizabeth J., "Embryo-Derived Stem Cell Lines," *Teratocarcinomas and Embryonic Stem Cells; A Practical Approach*, Oxford: 1RL Press, Ch. 4:71-112 (1987) ("Robertson '87").

9. Robertson '83 and Robertson '87 each describe a method for deriving pluripotential mouse ES cells. The process detailed in Robertson '83 and Robertson '87 and the claims of the '913 patent differ only in that Robertson '83 and Robertson '87 isolated mouse ES cells while the '913 patent claims human ES cells. In January, 1995, it would have been obvious to those in the art of ES cell derivation that the process taught by Robertson '83 and Robertson '87 for isolating mouse ES cells could be used to isolate human ES cells. The motivation to do so would have come at least from the general understanding in the field of the applicability of mouse studies to human research. It is also common sense that methods successfully developed for deriving mouse ES cells can be expected to work to isolate human ES cells, because one of the most important reasons for performing mouse research is to apply the results of that research to humans.

Piedrahita

10. I am also familiar with Piedrahita, et al., "On The Isolation Of Embryonic Stem Cells: Comparative Behavior Of Murine, Porcine And Ovine Embryos," *Theriogenology*, 34(5):879-901

(1990) ("Piedrahita"). I have reviewed Piedrahita and specifically its teaching regarding the isolation of ES cells for several different mammalian species.

11. Piedrahita described a way to isolate murine, porcine and ovine ES cells. Piedrahita and the claims of the '913 patent differ only in that Piedrahita isolated murine, porcine and ovine ES cells while the '913 patent claims human ES cells. However, in January, 1995, it would have been obvious to those in the art of ES cell derivation that the process taught by Piedrahita for isolating murine, porcine and ovine ES cells could be used to isolate human ES cells. The motivation to do so would have come at least from the general understanding in the field of the applicability of mouse, pig and sheep studies to human research. It is also common sense that methods successfully developed for deriving murine, porcine and ovine ES cells could be expected to work to isolate human ES cells, because one of the most important reasons for performing murine, porcine and ovine research is to apply the results of that research to humans.

Robertson '83, Robertson '87 and Piedrahita

12. At the time the first application leading to the '913 patent was filed, one of ordinary skill in the art would have combined the teachings of Robertson '83, Robertson '87 and Piedrahita, as they each relate to the derivation of mammalian ES cells. Further, Robertson '87 was written by the same author as Robertson '83 and both Robertson '87 and Piedrahita expressly cite Robertson '83.

13. Robertson '83, Robertson '87 and Piedrahita combined teach virtually the same method for isolating ES cells of various mammalian species, including mouse, rodent, pig and sheep. They

only differ from the '913 patent claims in that they isolated mouse, murine, porcine and ovine ES cells while the '913 patent claims human ES cells. However, in January, 1995, it would have been obvious to those in the art of ES cell derivation that the process taught by Robertson '83, Robertson '87 and Piedrahita for isolating mouse, murine, porcine and ovine ES cells could be used to isolate human ES cells. The motivation to do so would have come at least from the general understanding in the field of the applicability of mouse, pig and sheep studies to human research. It is also common sense that methods successfully developed for deriving mouse, murine, porcine and ovine ES cells could be expected to work to isolate human ES cells, because one of the most important reasons for performing mouse, murine, porcine and ovine research is to apply the results of that research to humans.

14. In fact, I was able to successfully isolate human ES cells by merely following the methods taught for deriving mouse, rat, pig and sheep ES cells without referring to Dr. Thomson's publications or patents and I was not surprised by my ability to do so, because it is obvious that they can be used for that purpose.

In Closing

15. Dr. Thomson deserved the acclaim bestowed upon him. However, he deserves that acclaim due to the time and energy he spent getting fresh human embryos to use as starting material and enough financial support for his work, not because he invented anything or made a non-obvious discovery. It was getting those resources, which are still difficult to get today, that gave Dr. Thomson the capacity to make his accomplishment. Had other stem cell researchers been

given the same human embryos and funding, they would have done the same thing, because the technical knowledge needed to derive and culture human embryonic stem cells was obvious.

16. I have not been compensated by either the Foundation for Taxpayer and Consumer Rights, the Public Patent Foundation or any other party in exchange for this declaration, nor do I have any financial interest in the outcome of the reexamination of U.S. Patent No. 7,029,913.

17. I declare that all statements made herein of my own knowledge are true and that all statements made herein on information are believed to be true. I further declare that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment or both under Section 1001, Title 18 of the United States Code.

June 29,2007

Date

CHAD COWAN, PH.D.

EXHIBIT 1

CURRICULUM VITAE