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

THIRD PARTY REQUESTER'S COMMENTS ON
***INTER PARTES* REEXAMINATION COMMUNICATION**

Attn: Mail Stop "*Inter Partes* Reexam"
Central Reexamination Unit
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

The Third Party Requester in the above entitled *Inter Partes* Reexamination, the Foundation for Taxpayer and Consumer Rights ("FTCR"), through its assigned counsel, the Public

Patent Foundation ("PUBPAT"), respectfully submits these comments on the Patent Owner's Third Supplemental Amendment dated October 4, 2007 ("Third Supplemental Amendment").

COMMENTS

FTCR again thanks the Examiner for issuing the Office Action dated March 30, 2007 ("Office Action"), and agrees with each of the five separate grounds given therein for rejection of all three claims of the '913 patent. In its Third Supplemental Amendment responding to the Office Action, the Patent Owner made three substantive amendments to the claims in an attempt to overcome the Examiner's rejections. Upon review, however, none of those amendments are sufficient to overcome the Examiner's rejections. As such, the claims remain unpatentable.

First Amendment Made By Patent Owner: "pluripotent"

The first amendment made by the Patent Owner in the Third Supplemental Amendment was to amend claim 1 to recite "pluripotent". With respect to this limitation, the Examiner's finding in the Office Action that Williams '065 disclosed "pluripotential human ES cells" was entirely correct. Office Action, 10 – 11. Williams '065 extracted ES cell colonies and cultured them on a media suitable to support their growth while maintaining their pluripotential nature. 3:54-55, 4:24-27, 5:19-34 and 6:51-66. Williams '065's ES cells also "retain[ed] their pluripotential phenotype" and "the developmental potential to differentiate into all somatic and germ cell lineages." *Id.* at 4:14 and 26-27.

Further, as the Examiner found in the Office Action, the ES cells of Robertson, Hogan and Piedrahita were also all pluripotential. Robertson '83 at 647 ("isolation in culture of

pluripotential stem cell lines"), Hogan '926 at Title ("Pluripotential Embryonic Cells") and Abstract ("particular claims are drawn to human pluripotential cells"), and Piedrahita '90 at 880.

Lastly, the '913 patent concedes that, "[p]luripotent" cell lines had already been derived from several domestic and laboratory animals species. 3:50. Thus, the addition of the limitation "pluripotent" to claim 1 does not render the instant claims patentable over the cited art of record.

Second Amendment Made By Patent Owner: "derived from a pre-implantation embryo"

The second amendment made by the Patent Owner in the Third Supplemental Amendment was to amend claim 1 to recite that the cells are "derived from a pre-implantation embryo". With respect to this limitation, although the claims of Hogan '926 were limited to post-implantation embryos, its teachings were not so limited and could – in fact – be applied to any embryo, whether pre- or post-implantation. The Patent Owner's suggestion that Hogan '926's teaching should be limited to what it claims is incorrect. Regardless, there is no credible argument that the post-implantation embryos of Hogan '926's claims have any patentable difference from the pre-implantation embryos of the instant claims. This is because there is no structural or functional difference between the cells derived from either. See the Loring Declaration submitted with FTCR's Comments submitted on June 29, 2007, at 4 – 5.

Further, Robertson expressly taught ES cells derived from pre-implantation embryos. Robertson '83 at 647 ("isolation ... directly from preimplantation-stage mouse embryos"). There is also no statement or suggestion in either Williams '065 or Piedrahita '90 that

their teachings could not be applied to pre-implantation embryos.

Lastly, the '913 patent concedes that cell lines had been "derived from preimplantation embryos" of several domestic and laboratory animals species. 3:50. Thus, the addition of the limitation "derived from a pre-implantation embryo" to claim 1 does not render the instant claims patentable over the cited art of record.

Third Amendment Made By Patent Owner: "will proliferate ... in an undifferentiated state"

The third amendment made by the Patent Owner in the Third Supplemental Amendment was to amend claim 1 to recite that the cells "will proliferate ... in an undifferentiated state". With respect to this limitation, the Examiner's finding in the Office Action that Williams '065 disclosed embryonic stem cells that had the characteristic of "inhibition from differentiation" was entirely correct. Office Action, 11. Williams '065's ES cells were maintained "for a time and under conditions sufficient for the derivation and / or maintenance of said ES cells." 3:28-35. This inherently means that the cells were maintained in an undifferentiated state.

Further, as the Examiner found in the Office Action, the ES cells of Robertson, Hogan and Piedrahita were also capable of proliferation in an undifferentiated state. Robertson '83 at 649 ("lines were maintained"), Hogan '926 at 5:14-16 ("the ES cells can be capable of indefinite maintenance"), and Piedrahita '90 at 880 ("the ES cells can be maintained in culture in an undifferentiated state").

Thus, the addition of the limitation "will proliferate ... in an undifferentiated state" to claim 1 does not render the instant claims patentable over the cited art of record.

CONCLUSION

In light of the foregoing, FTCR respectfully submits that the claims as amended by the Patent Owner remain unpatentable and that the rejections made by the Examiner in the Office Action of the claims are still valid and may properly be made final.

November 2, 2007

Date

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