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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/008,139	07/17/2006	6200806		4856

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QUARLES & BRADY LLP
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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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9/29/06

THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

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PUBLIC PATENT FOUNDATION, INC.

1375 Broadway, Suite 600

New York, NY 10018

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008139

PATENT NO. 6,200,806

ART UNI 3991

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a replly has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/008,139	6200806	
	Examiner	Art Unit	
	Bennett Celsa	3991	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed _ has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO-1449, c)☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

Bennett Celsa
Primary Examiner
Art Unit: 3991

cc:Requester (if third party requester)

DETAILED ACTION: ***Reexamination: Granting of Request***

Procedural Posture:

The 3rd party Request (dated July 17, 2006: 90/008,139) for *ex parte* reexamination of claims 1-11 of U.S. Patent No. 6,200,806 (Thomson) is acknowledged.

Decision Granting the Order

A substantial new question of patentability of claims 1-11 of United States Patent No. 6,200,806 is raised by the request for reexamination.

Ongoing Duty To Disclose:

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Pat. No.6,200,806 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Substantial New Question of Patentability Raised By The Request

For "a substantial new question of patentability" to be present, it is only necessary that:

A. The prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim i.e. the prior art teaching is such that there is a substantial likelihood that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and it is not necessary that the prior art establish a prima facie case of unpatentability and;

B. The same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. See MPEP 2242.

For a reexamination that was ordered on or after November 2, 2002 (the date of enactment of Public Law 107-273; see Section 13105, of the Patent and Trademark Office Authorization Act of 2002), reliance *solely* on old art (as the basis for a rejection) does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. For example, an SNQ may be based solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s), in view of a material new argument or interpretation presented in the request. MPEP 2258.01.

Scope of Reexamination

The requester raised the issue (see request pages 2-3) of significant public harm resulting from the instant patent.

Reexamination provides a complete reexamination of the patent claims on the basis of prior art patents and printed publications. 37 CFR 1.552; MPEP2258.

Thus, the 3rd party requester discussion of public harm is outside the scope of reexamination and has no bearing on the raising of an SNQ.

The Claimed Invention

The instant claims are drawn to a purified preparation of pluripotent human embryonic stem cells (independent claims 1 and 3); a method of isolating a pluripotent human embryonic stem cell line (independent claims 9) and a resulting cell line (independent claim 11). The following claims are representative:

1. A purified preparation of pluripotent human embryonic stem cells which

(i) will proliferate in an in vitro culture for over one year;
(ii) maintains karyotype in which the chromosomes are euploid and not altered through prolonged culture;
(iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture; and
(iv) is inhibited from differentiation when cutured on a fibroblast feeder layer.

3. A purified preparation of pluripotent human embryonic stem cells wherein the cells are negative for the SSEA-1 marker, positive for the SSEA-4 marker, express alkaline phosphatase activity, are pluripotent, and have euploid karyotypes and in which none of the chromosomes are altered.

9. A method of isolating a pluripotent human embryonic stem cell line, comprising the steps of:
(a) isolating a human blastocyst;
(b) isolating cells from the inner cell mass of the blastocyte of (a);
(c) plating the inner cell mass cell on embryonic fibroblasts, wherein inner cell mass-derived cell masses are formed;
(d) dissociating the mass into dissociated cells;
(e) replating the dissociated cells or embryonic feeder cells;
(f) selecting colonies with compact morphologies and cells with high nucleus to cytoplasm ratios and prominent nucleoli;
(g) culturing the cells of the selected colonies to thereby obtain an isolated pluripotent human embryonic stem cell line.

11. A cell line developed by the method of claim 9.

Priority of the Instantly Claimed Invention

U.S. Pat. No. 6,200,806 issued from 09/106,390 (filed 6/6/98) which is:

-a Div. of 08/591,246 (filed 1/18/96) (issued as U.S. Pat. No. 5,843,780); which is a

-a CIP of 08/376,327 (filed 1/20/95)(abandoned).

Cited Documents

Newly Cited Reference(s):
***1. Williams**, U.S. Pat. No. 5,166,065 (issued Nov. 24, 1992)*
***2.* Robertson (1983),** *Teratocarcinoma Stem Cells, (Cold Spring Harbor: 1983), Vol. 10 pages 647-663*
3. *Robertson (1987),* Teratrocarcinoma and Embryonic Stem Cells; A Practical Approach, (Oxford: 1RL Press: 1987) Vol. 4, pages 71-112;

Old Reference: Previously Cited but not applied in 08/591,246 application:
4. *Piedrahita* *et al.*, Theriogenology, Vol. 34(5) pages 879-901 (1990)

Newly Cited Document:
5. Declaration of Dr. Jeanne F. Loring, Ph.D.(request appendix C)

The Raising of a Substantial New Question of Patentability

1. Williams

The newly presented *Williams* patent reference is drawn to a method of isolating embryonic stem cells from animal embryos (including but not limited to humans) *in vitro* comprising deriving the embryonic stem cells from culture medium containing leukemia inhibitory factor and maintaining the animal embryonic stem cells *in vitro* while retaining their pluripotential phenotype. See Williams Abstract; and col. 2-3.

The *Williams* patent reference raises an SNQ since a reasonable examiner would consider this reference teaching important in deciding the patentability of at least one of the instant claims.

2. Robertson (1983)

The newly presented *Robertson (1983)* reference teaches a process for isolating pluripotential mammalian embryonic stem cells comprising: (i) isolating a blastocyst; (ii) removing the ICM from the blastocyst; (iii) placing the ICM on fibroblast cells; (iv) isolating stem cells once they became apparent; (v) maintaining the isolated embryonic stem cells on feeder layers. See *Robertson (1983)* at pages 647, 649, 654 and 660.

The *Robertson (1983)* reference raises an SNQ since a reasonable examiner would consider this reference teaching important in deciding the patentability of at least one of the instant claims.

3. *Robertson (1987)*

The newly presented Robertson (1987) reference teaches a method for isolating mammalian embryonic stem cells including the preparation of feeder layers, the collection of blastocyst stage embryos, transferring the embryos into culture, culturing the blastocysts, disaggregating the inner cell mass (ICM) of the embryo, identifying ICM-derived colonies, expanding embryonic stem cells and culturing embryonic stem cells. See *Robertson (1987)* at pages 76-94.

The *Robertson (1987)* reference raises an SNQ since a reasonable examiner would consider this reference teaching important in deciding the patentability of at least one of the instant claims.

4. *Piedrahita*

The 3rd Party asserts that the *Piedrahita et al.* reference taken alone (request at pages 12-14), or in combination with *Williams, Robertson (1983) or R*obertson (1987) (request pages 4-11) raises an SNQ with regard to obviousness.

The 3rd party points out that the *Piedrahita et al.* reference is "old art" (see MPEP 2242) which nevertheless raises an SNQ since the *Piedrahita et al.* reference:

a. was raised in an obvious rejection in the grandparent 08/376,327 application (office action dated Jan. 17, 1996) which was subsequently made final in an office action dated July 23, 1996; and

b. the *Piedrahita et al.* reference was not cited nor made of record in the subsequent 08/591,246 CIP application; and although cited in the most recent 09/106,390 application (which issued as the instant reexam patent), was never discussed.

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. MPEP 2200. An SNQ may be based solely on "old art" where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s), in view of a material new argument or interpretation presented in the request. MPEP 2242. An SNQ is raised when "old art" is combined with *newly presented* (never before the examiner) prior art reference(s) i.e. the "old art" is being presented/viewed in a new light or in a different way. *In re Hiniker* Co., 150 F.3d 1362,1367, 47 USPQ2d 1523,1527 (Fed. Cir. 1998).

Accordingly, for "a substantial new question of patentability" to be present, it is only necessary that:

(A) The prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the prior art patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and

(B) The same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a

final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. MPEP 2642.

The presented *Piedrahita et al.*,reference teaches a method of isolating murine (mouse), porcine (pig) and ovine (sheep) embryonic stem cells comprising

i. isolating blastocysts and their inner cell mass (ICM) embryonic cells;

ii. placing and plating the ICM on an embryonic fibroblast feeder layer (i.e. STO and HEF);

iii. dissociating the growing ICM and replating onto fresh feeder layers;

iv. selecting embryonic stem cells based on a large nucleus and prominent nucleoli; and

v. culturing the selected cells on a fresh feeder layer to prevent differentiation.

See *Piedrahita et al.*, at pages 882-884 and 888.

(A) The *Piedrahita et al.*reference raises an SNQ since a reasonable examiner would consider this reference, taken separately, or in combination with the *Williams*, *Robertson (1983)* or R*obertson (1987)* references, important in deciding the patentability of at least one of the instant claims.

(B) Additionally, the same question of patentability as to the instant claims has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. In this regard, it is noted that the *Piedrahita et al.* reference is being presented/viewed in a new light, or in a different way by the 3rd party requester, as compared with its use in the earlier concluded examination(s) since this reference is being viewed in combination with the newly presented *Williams*, *Robertson (1983)* or

R*obertson (1987)* prior art references. Additionally, reexamination of the *Piedrahita et al.* reference alone is not precluded by the previous examination of the 09/106,390 application (which issued as the instant patent) since it was never discussed by the Examiner or patent applicant during the prosecution of this application.

5. Declaration of Dr. Jeanne F. Loring

The *Dr. Loring declaration* provides an opinion regarding obviousness (items 1-11), conversations with other people (items 12-15) and a notebook page memorializing conversations (request Exhibit 2).

A reexamination proceeding provides a complete reexamination of the patent claims on the basis of prior art patents and printed publications. The submitted Declaration and notebook entry is not a prior art patent or printed publication.

Accordingly, the *Dr. Loring declaration* fails to raise an SNQ since a reasonable examiner would not consider this Declaration important in deciding the patentability of at least one of the instant claims.

Extensions of Time

Extensions of time under 37 CFR 1.136 (a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to an applicant and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be concluded with special dispatch" (37 CFR 1.555(a)). Extensions of time in ex parte reexamination proceedings are provided for in 37 CFR 1.550(c).

Patent Owner Amendment

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on M-F from 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached at 571-272-1535.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

All correspondence relating to this ex parte reexamination proceeding should be directed:

By Mail to: Mail Stop ex parte Reexam
Central Reexamination Unit
Office of Patent Legal Administration
United States Patent & Trademark Office
P.O. Box 1450 Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
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Bennett Celsa
Primary Examiner
Art Unit 3991

Conferee:

Conferee: