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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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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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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008102

PATENT NO. 5,843,780

ART UNI 3993

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	
	90/008,102	5843780	
	Examiner	Art Unit	
	Padmashri Ponnaluri	3991	

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

The request for *ex parte* reexamination filed *17 July 2006* 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)).

Padmashri Ponnaluri
Primary Examiner
Art Unit: 3991

cc:Requester (if third party requester)

DETAILED ACTION: *Reexamination: Granting of Request*

Procedural Posture:

The Third Party Request (dated 7/17/06) for *ex parte* reexamination of claims 1-11 of United States Patent Number 5,843,780 (Thomson) is acknowledged.

Decision Granting the Order

A substantial new question of patentability affecting claims 1-11 of United States Patent Number 5,843,780 (Thomson) is raised by the request for reexamination.

Information Disclosure Statement

The Information disclosure statement (PTO-1449) filed on 7/17/06 has been considered.

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 Patent No. 5,843,780 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286. The third party requester is also reminded of the ability to similarly appraise 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 (SNQ) 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, a 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 following issue raised in the request:

The `780 Patent is causing significant Public Harm (see the request pages 2-3)

The reexamination proceeding provides a complete reexamination of the patent claims on the basis of prior art patents and printed publications. 37 CFR 1.552, MPEP 2258.

The third party discussion of Harm caused by the `780 Patent (Request pages 2-3) is clearly outside the scope of reexamination and thus has no bearing on the raising of SNQ.

Priority

U.S. Pat. No. 5,843,780 is issued from application 08/591,246, filed on January 18, 1996, which is continuation-in-part of application 08/376,327 filed on January 20, 1995.

The Thomason 5,843,780 *Patented Invention*

In the Thomson `780 patent 11 claims are present, of which claims 1, 3, 9 are independent and claim 2 depends on claim 1; claims 4-8 depend on claim 3; and claims 10-11 depend on claim 9.

Independent claims 1 and 3 are drawn to a purified preparation of primate embryonic stem cells, and independent claim 9 is drawn to a method of isolating a primate embryonic stem cell line.

Documents Cited By The Requester:

1. **US Patent 5,166,065, Williams et al (Williams)** issued November 24, 1992.

2. **Robertson et al.** Teratocarcinoma Stem cells, 1983, 647-683, Cold Spring Harbor Laboratory, United States of America (**Robertson et al, 1983**).

3. **Robertson et al.** Teratocarcinomas and Embryonic Stem cells, A Practical Approach, 1987, Chapter 4: 71-112, Oxford: IRL Press, England (**Robertson et al, 1987**).

4. **Piedrahita et al,** Theriogenology, November 1990, v 34, n 5: pages 879-901 **(Piedrahita, 1990).**

5. **Declaration by Dr. Jeanne F. Loring (July 17, 2006).**

The above listed references (Williams, Robertson (1983), Robertson et al (1987) and Piedrahita et al) were not used in rejections during the prosecution of the application that resulted in the present `780 patent.

However, the third party requester notes that Piedrahita et al is "old art", and was used in a rejection in the parent application 08/376,327(abandoned) (see the request in pages 14-15).

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

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. Rather, 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. See MPEP 2242.

Piedrahita et al was considered during the prosecution of the parent application (08/376,327). Piedrahita et al was not applied in a rejection to the present claims of the `780 patent, and further Piedrahita et al is now being presented and/or viewed in a new light, or in a

different way, as compared with its use in the earlier concluded parent application examination, in view of a material new argument or interpretation presented in the request.

Discussion of the Cited Documents and an SNQ

1. **Williams** (US Patent 5,166,065) raises a substantial new question of patentability of claims of the present US Patent 5,843,780.

Williams teaches a method for isolating ES cells of various animals, including specifically humans (primate) (see column 2, lines 37-40, lines 47-50, and column 4, lines 18-19 and column 6, lines 51-66). Williams's method first isolated blastocysts and then isolated the inner cell mass (ICM), which was plated on embryonic fibroblasts (see column 5, lines 19-34 and column 6, lines 51-66). From the ICM, Williams extracted ES cell colonies and cultured them on a media suitable to support their growth while maintaining their pluripotential nature (See column 3, lines 54-55, column 4, lines 24-27, column 5, lines 19-34 and column 6, lines 51-66). Williams' ES cells retained their pluripotential phenotype and the developmental potential to differentiate into all somatic and germ cell lineages (see column 4, lines 14 and 26-27).

There is a substantial likelihood that a reasonable examiner would consider the teachings of Williams's reference important in deciding the patentability of claims of the present US Patent 5,843,780.

2. **Robertson et al (1983)** raises a substantial new question of patentability of claims of US Patent 5,843,780.

Robertson et al (1983) taught a step-by-step process for isolating pluripotential mammalian ES cells. Robertson (1983) process includes the steps of i) isolating blastocyst, ii) removing the ICM from blastocyst, iii) placing the ICM on fibroblast cells, iv) isolating the stem cells and v) maintaining the isolated ES cells on feeder layers. The ES cells taught by Robertson et al (1983) are pluripotential and are maintained over a significant time period and retained a normal euploid karyotype.

There is a substantial likelihood that a reasonable examiner would consider the teachings of Robertson et al (1983) reference important in deciding the patentability of claims the present US Patent 5,843,780.

3. **Robertson et al (1987)** raises a substantial new question of patentability of claims of US Patent 5,843,780.

Robertson et al (1987) taught a step-by-step process for isolating pluripotential mammalian ES cells.

There is a substantial likelihood that a reasonable examiner would consider the teachings of Robertson et al (1987) reference important in deciding the patentability of claims the present US Patent 5,843,780.

4. **Piedrahita et al (1990)** raises a substantial new question of patentability of claims of US Patent 5,843,780.

Piedrahita et al teaches a method of isolating murine (rodent), porcine (pig) and ovine (sheep) ES cells (see page 882-883). The blastocyst were isolated and then the cells from the

ICM were isolated. The ICM was then placed on embryonic fibroblast feeder layer. After plating, the growing ICM was dissociated and replated onto fresh feeder layer. ES cells were selected based on large nucleus and prominent nucleoli. The selected ES cells were cultured on fresh feeder layer to prevent differentiation. Piedrahita's ES cells are pluripotential, maintained for a significant time period and retained a normal euploid karyotype.

There is a substantial likelihood that a reasonable examiner would consider the teachings of Piedrahita et al reference important in deciding the patentability of claims the present US Patent 5,843,780.

5. **Declaration by Jeanne F. Loring** (July 17, 2006) does not raise a substantial new question of patentability of claims of US Patent 5,8453,780 for the following reasons.

The consideration under 35 U.S.C. 303 of a request for ex parte reexamination is limited to prior art patents and printed publications. See Ex parte McGaughey, 6 USPQ2d 1334, 1337 (Bd. Pat. App. & Inter. 1988). Thus an admission, per se, may not be the basis for establishing a substantial new question of patentability. See MPEP 2217.

The declaration by Jeanne F. Loring is neither a printed publication, nor a patent. Thus the declaration Jeanne F. Loring does not raise a substantial new question of patentability of claims of US Patent 5,843,780.

Conclusion

In view of the above, the request for reexamination is **GRANTED.**

Claims 1-11 of United States Patent Number 5,843,780 will be reexamined.

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).

Service on the Other Party (3rd Party Request)

After the filing of a request for reexamination by a 3rd party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550 (f).

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 Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Deborah Jones can be reached on 571-272-1535. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

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 to:

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Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
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Conferee:

Conferee:

Padmashri Ponnaluri
Primary Examiner
Unit 3991
22 August 2006