INTER PARTES REEXAMINATION COMMUNICATION

BELOW/ATTACHED YOU WILL FIND A COMMUNICATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE OFFICIAL(S) IN CHARGE OF THE PRESENT REEXAMINATION PROCEEDING.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of this communication.
ORDER GRANTING/DENYING
REQUEST FOR INTER PARTES
REEXAMINATION

The mailing date of this communication appears on the cover sheet with the correspondence address.

The request for inter partes reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): □ PTO-892 □ PTO/SB/08 ✖Other: PTO-1449

1. ✖ The request for inter partes reexamination is GRANTED.
   □ An Office action is attached with this order.
   ✖ An Office action will follow in due course.

2. □ The request for inter partes reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 312(c). Requester may seek review of a denial by petition to the Director of the USPTO within ONE MONTH from the mailing date hereof. 37 CFR 1.927. EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183. In due course, a refund under 37 CFR 1.26(c) will be made to requester.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of this Order.

GARY L. KUNZ
CRU EXAMINER - AU 3991
INTER PARTES REEXAMINATION COMMUNICATION

Control No. 95/000,154
Examiner Gary L. Kunz
Patent Under Reexamination 7029913
Art Unit 3991

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

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Transmittal of Communication to Third Party Requester Inter Partes Reexamination

<table>
<thead>
<tr>
<th>Control No.</th>
<th>Patent Under Reexamination</th>
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<tbody>
<tr>
<td>95/000,154</td>
<td>7029913</td>
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<tr>
<td>Examiner</td>
<td>Art Unit</td>
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<tr>
<td>Gary L. Kunz</td>
<td>3991</td>
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the inter partes reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an ex parte reexamination has been merged with the inter partes reexamination, no responsive submission by any ex parte third party requester is permitted.

All correspondence relating to this inter partes reexamination proceeding should be directed to the Central Reexamination Unit at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.
DETAILED ACTION: Reexamination: Granting of Request

Procedural Posture:

The Third Party Request (dated 17 July 2006) for inter partes reexamination of claims 1-3 of United States Patent Number 7,029,913 (Thomson) is acknowledged.

Decision Granting the Order

A substantial new question of patentability affecting claims 1-3 of United States Patent Number 7,029,913 (Thomson) is raised by the request for reexamination.

Information Disclosure Statement

The Information disclosure statement (PTO-1449) filed on 17 July 2006 has been considered.

Ongoing Duty to Disclose

The patent owner is reminded of the continuing responsibility under 37 CFR §1.985(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,029,913 throughout the course of this reexamination proceeding. 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 §§ 2686 and 2686.04.

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 §2642.

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 `913 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 §1.906, MPEP
2658. The third party discussion of Harm caused by the `913 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. 7,029,913 issued from application 09/982,637, filed 18 October 2001; which is continuation of application 09/761,289 filed on 16 January 2001, now abandoned; which is a continuation of application 09/106,390 filed 26 June 1998, now Pat. No. 6,200,806; which is a divisional of application 08/591,246, filed 18 January 1996, now Pat No. 5,843,780; which is a continuation-in-part of application no. 08/376,327, filed 20 January 1995, now abandoned.

The Thomson 7,029,913 Patented Invention

In the Thomson `913 patent 3 claims are present, of which claim 1 is the only independent claim. Claims 2 and 3 depend from claim 1.

Independent claim 1 is drawn to an in vitro cell culture of human embryonic stem cells which possess the following four functional characteristics: (1) capable of proliferating in in vitro cell culture for over one year without the application of exogenous leukemia inhibitory factor, (2) maintain karyotype in which the chromosomes are euploid through prolonged culture, (3) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (4) are inhibited from differentiation when cultured on a fibroblast feeder layer.

Claim 2 that depends from claim1 and further requires that the stem cells of claim 1 spontaneously differentiate to trophoblast and produce chorionic gonadotropin when
cultured to high density.

    Claim 3 which depends from claim 1 further requires that the stem cells of claim
1 be negative for the SSEA-1 marker and positive for the SSEA-4 marker and express
alkaline phosphatase.

Documents Cited By The Requester:

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

2.  **Robertson et al.** “Embryo-derived stem cell lines,” Teratocarcinomas and

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

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

Discussion of the Cited Documents and Raising of an SNQ

1.  **Robertson et al.** Teratocarcinoma Stem Cells. 1983, 647 - 683, Cold Spring
    Harbor Laboratory, United States of American (**Robertson ’83**).

    The Third Party asserts that the Robertson ‘83 reference in combination
    with another reference (Robertson ’87 and Piedrahita) would render claims 1 - 3 of the
    ‘913 patent obvious.

    Robertson ‘83 reference was neither cited nor used in a rejection in the
    application which issued as the ‘913 patent.
Robertson '83 teaches a step-by-step process for isolating pluripotent mammalian ES cells. The Robertson '83 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 '83 are pluripotent and are maintained over a significant time period and retained a normal euploid karyotype.

The Robertson '83 reference raises an SNQ since there is substantial likelihood that a reasonable examiner would consider the Robertson '83 reference teaching to be important in deciding if one or more claims of the '913 patent are patentable. Accordingly, Robertson '83 raises a substantial new question of patentability as to claims 1 - 3, which question has not been decided in a previous examination of the 7,029,913 patent.


The Third Party asserts that Robertson '87 in combination with other teaching (Robertson '83 and Piedrahita et al.) would render claims 1 - 3 of the '913 patent obvious.

The Robertson '87 reference was neither cited nor used in a rejection in the application which issued as the '913 patent.

Robertson '87 teaches a step-by-step process for isolating pluripotent mammalian ES cells.
Robertson '87 reference raises an SNQ since there is substantial likelihood that a reasonable examiner would consider the Robertson '87 reference teaching to be important in deciding if one or more claims of the '913 patent are patentable. Accordingly, the Robertson '87 reference raises a substantial new question of patentability as to claim 1 - 3, which question has not been decided in a previous examination of the '913 patent.

3. Piedrahita et al., Theriogenology, November 1990, v34, n5; pages 879 - 901.

The Third Party requester asserts that Piedrahita alone or in combination with other reference teaching (Robertson '83 and Robertson '87) renders claims 1 - 3 of the '913 patent obvious.

The Piedrahita reference was cited in a rejection in the parent application 08/376,327 (abandoned) (see the request at pages 10 - 11). However, Piedrahita was not applied in a rejection to the present claims of the '913 patent, and further Piedrahita 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.

"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, determination or 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 teaches a method of isolating murine (rodent), porcine (pig) and ovine (sheep) ES cells (see page 882-883). The blastocyst are isolated and then the cells from the ICM are isolated. The ICM is then placed on embryonic fibroblast feeder layer. After plating, the growing ICM is dissociated and replated onto fresh feeder layer. ES cells are selected based on large nucleus and prominent nucleoli. The selected ES cells are cultured on fresh feeder layer to prevent differentiation. Piedrahita’s ES cells are pluripotent, maintained for a significant time period and retained a normal euploid karyotype.

The Piedrahita reference raises an SNQ since there is substantial likelihood that a reasonable examiner would consider the Piedrahita reference teaching to be important in deciding if one or more claims of the ’913 patent are patentable. Accordingly, the Piedrahita reference raises a substantial new question of patentability as to claims 1-3, which question has not been decided in a previous examination of the ’913 patent.

4. Declaration by Dr. Jeanne F. Loring (17 July 2006)

The Third Party asserts that the Loring declaration in combination with other references (Robertson ’83, Robertson ’87, and Piedrahita) would render claims 1-3 of the ’913 patent obvious.
The Loring declaration was neither cited nor used in a rejection in the application which issued as the '913 patent.

The Loring declaration does not raise an SNQ because this declaration is neither a printed publication nor a patent and a reasonable examiner would not consider this declaration of Loring in deciding the issue of patentability.

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 decisions cited in MPEP 2258 and 2258.01 for determining the presence of absence of a ‘substantial new question of patentability’ in ex parte reexamination proceedings apply in inter partes reexamination proceedings, since the statutory language relied upon in those decisions, which is taken from the ex parte reexamination statute, is also found in the inter partes reexamination.” See MPEP §2658(i.)

Conclusion

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

A substantial new question of patentability affecting claims 1-3 of United States Patent Number 7, 029,913 B1 is raised by the present request for inter partes reexamination.

Claims 1 - 3 of United States Patent Number 7,029,913 will be reexamined.

An Office action on the merits does not accompany this order for inter partes Reexamination. An Office action on the merits will be provided in due course.
Extensions of Time

Extensions of time under 37 CFR §1.136 (a) will not be permitted in *inter partes* reexamination proceedings because the provisions of 37 CFR §1.136 apply only to “an applicant” and not to the patent owner in a reexamination proceeding. Additionally, 35 U.S.C. §314(c) requires that *inter partes* reexamination proceedings “will be conducted with special dispatch” (37 CFR §1.937). Extensions of time in ex parte reexamination proceedings are not available for third party requester comments, because a comment period of 30 days from service of patent owner’s response is set by statute. 35 USC §314(b)(3)

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. 37 CFR 1.903; MPEP 2666.06.

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). See MPEP 2250 for guidance as to the manner of amending.
Future Correspondence

All correspondence relating to this inter partes Reexamination proceeding should be directed to:

By Mail to: Attn: Mail Stop “Inter Partes Reexam”
Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By Hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

Conferee: [Signature]

Gary L. Kunz
Primary Examiner
Art Unit 3991