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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,955	04/20/2010	5925803	00383/005002	5754

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 06/07/2010

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



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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/010,955.

PATENT NO. 5925803.

ART UNIT 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 reply 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. 90/010,955	Patent Under Reexamination 5925803	
	Examiner BRENDA BRUMBACK	Art Unit 3991	

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

The request for *ex parte* reexamination filed 20 April 2010 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/SB/08, 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)).

/BRENDA BRUMBACK/ Primary Examiner, Art Unit 3991		
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cc:Requester (if third party requester)

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Decision on Ex Parte Reexamination Request

The Request filed by Third Party Requester on 04/20/2010 for *ex parte* reexamination of claims 1-3 of U. S. Patent No. 5,925,803 (the '803 patent), issued to Leder *et al.* on 07/20/99, is acknowledged. A substantial new question of patentability affecting claims 1-3 of United States Patent Number 5,925,803 is raised by the present request for *ex parte* reexamination.

Procedural Posture

The reexamination of U.S. Patent No. 5,925,803 is assigned control number 90/010,955.

Status of Claims

Claims 1-3 are present in the '803 patent.

Claims 1-3 are currently subject to reexamination proceedings.

The '803 Patented Claims

The '803 patent consists of claims 1-3 drawn to a method of testing a material suspected of being a carcinogen comprising exposing a transgenic mouse to the material and detecting neoplasms as an indication of carcinogenicity and to a method of testing a material suspected of conferring protection against the development of neoplasms comprising treating a transgenic mouse with the material and detecting a reduced incidence of neoplasms as an indicator of protection.

Claims 1 and 2 are representative.

1. A method of testing a material suspected of being a carcinogen, comprising exposing a transgenic

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mouse to said material and detecting neoplasms as an indication of carcinogenicity, wherein the germ cells and somatic cells of said mouse contain an activated oncogene sequence introduced into said mouse, or an ancestor of said mouse, at an embryonic stage.

2. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising

(1) providing a first and a second transgenic mouse, the germ cells and somatic cells of which contain an activated oncogene sequence introduced into said mice, or an ancestor of said mice, at an embryonic stage,

(2) treating said first mouse with said material, and

(3) detecting, as an indication of said protection, a reduced incidence of development of neoplasms in said first mouse, compared to the incidence in said second mouse, which is not so treated.

Priority and Patent Term

US Patent No. 5,925,803 issued from Application No. 07/750,518 filed on 09/19/91, which is a continuation of application Serial No. 07/171,806, filed 03/22/88 (parent Patent No. 5,087,571), which is a divisional of application Serial No. 06/623,774, filed 06/22/1984 (grandparent Patent No. 4,736,866). Therefore, the '803 patent presently under reexamination claims and is entitled to priority to the filing date of grandparent application Serial No. 06/623,774, (now U.S. Patent No. 4,736,866), which was filed on 06/22/84.

It is noted that parent application Serial No. 07/171,806 (parent Patent No. 5,087,571) was voluntarily filed as a divisional of grandparent application Serial No. 06/623,774; it was not filed as a divisional in response to any restriction requirement made in the grandparent application. During the prosecution of application Serial No. 07/171,806 (the parent '571 patent), claims (13, 18, and 19) directed to testing procedures using transgenic non-human mammals were rejected under obviousness type double patenting over claims 1-12 of grandparent U.S. Patent 4,736,866, which are drawn to a transgenic non-human mammal or more specifically to a transgenic mouse. In response, Patent owner filed a Terminal Disclaimer to

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overcome the obviousness type double patenting rejection (see the 07/171,806 IFW, specifically the Non-Final Rejection mailed 11/14/1988 and the Terminal Disclaimer filed 11/10/1989). The following is an excerpt from that Terminal Disclaimer:

Your petitioner, President and Fellows of Harvard College, hereby disclaims any portion of any patent granted on the above-identified application or on any application which is entitled to the benefit of the filing date of this application under 35 U.S.C. §120 not extending the term of any patent granted on that application beyond the term of issued U.S. Patent No. 4,736,866 issued April 12, 1988.

In an amendment filed by Patent Owner on 08/09/1991, claims 13, 18, and 19 were subsequently canceled; however, the Terminal Disclaimer remained of record and disclaims any portion of any patent granted on any application which claims and is entitled to benefit of the grandparent filing date. The grandparent patent 4,736,866 expired on 04/12/2005 (17 years from the issue date of 04/12/1988). Consequently, due to the Terminal Disclaimer filed in parent application Serial No. 07/171,806 (the parent '571 patent), **U.S. Patent No. 5,925,803**, which is currently under reexamination and which claims benefit and is entitled to the filing date of the grandparent patent, also **expired on 04/12/2005**.

Substantial New Question of Patentability

The presence or absence of "a substantial new question of patentability" (SNQ) determines whether or not reexamination is ordered. 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 new question of patentability for at least one claim, such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim was patentable. A SNQ may be based on

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newly cited art or even 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 earlier concluded examination(s), in view of a material new argument or interpretation presented in the request. (MPEP 2242)

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, after appeals, or time for such have expired.

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.

Documents Cited in the Request as Raising an SNQ

U.S. Patent 4,736,866 issued 04/12/1988 to LEDER *et al.* (hereinafter, "the '866 grandparent patent")

U.S. Patent 4,360,510 issued 11/23/1982 to PROCTOR *et al.* (hereinafter, "Proctor")

WARD *et al.*, *The Mouse Liver Tumor as an Endpoint in Carcinogenesis Tests*, Toxicol., Appl. Pharmacol., 51:389-397 (1979) (Appendix 5 of the Request; hereinafter, "Ward").

SCHACH *et al.*, *The Redundancy of Mouse Carcinogenicity Bioassays*, Fund. Appl. Toxicol., 3:631-639 (1983) (Appendix 6 of the Request, hereinafter "Schach").

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SCHWAB *et al.*, *Hypersensitivity for Carcinogenesis Resulting from Species Hybridization Impairing Control of Cellular Oncogenes as Tool Towards Tailoring Test Animals Suitable for Monitoring Carcinogens*, EPA-600/9-82-013, Sym: Carcinogen, Polynucl. Aromat. Hydrocarbons *Mar. Environ.*, 212-32 (1982). (Appendix 7 of the Request, hereinafter "Schwab").

JAENISCH *et al.*, *Simian Virus 40 DNA Sequences in DNA of Healthy Adult Mice Derived from Preimplantation Blastocysts Injected with Viral DNA*, PNAS, USA, 71(4):1250-1254 (1974) (Appendix 12 of the Request, hereinafter, "Jaenisch").

Discussion of Documents Cited

1. The request indicates that Requester considers claims 1-3 to be unpatentable over U.S. Patent 4,736,866 (the '866 grandparent patent), either alone or in combination with one of Ward, Schach, or Proctor (SNQ #'s 1-3).

It is agreed that consideration of the '866 grandparent patent raises a substantial new question of patentability for claim 1. As pointed out on pages 23-26 of the request, the claims (1-12) of the '866 grandparent patent are drawn to a transgenic non-human mammal, or more specifically to a transgenic rodent or mouse, all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of the mammal, at an embryonic stage.

The teachings of the '866 grandparent patent were not considered during the prosecution of the application which became the '803 patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not claims 1-3 are patentable. Accordingly, the '866 grandparent patent, either alone or in combination with one of Ward, Schach, or Proctor raises a substantial new question of patentability for claims 1-3.

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2. The request indicates that Requester considers claim 1 to be unpatentable over Ward in combination with the '866 grandparent patent (SNQ #1).

It is agreed that consideration of Ward, in combination with the '866 grandparent patent, raises a substantial new question of patentability for claim 1. As pointed out on page 26 of the request, Ward teaches methods of testing a material suspected of being a carcinogen by exposing a mouse to the material and observing the development of tumors in the mouse.

This substantial new question of patentability is based on a printed publication already considered in an earlier concluded examination of the patent being reexamined. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

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 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.

In the present instance, there exists an SNQ based on the combination of Ward with a new reference, the '866 grandparent patent. Ward was used alone in an obviousness rejection during the prosecution of the application which issued as the '803 patent; however, it is being

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viewed herein in a new light due to its combination with a new reference, the '866 grandparent patent. There is a substantial likelihood that a reasonable examiner would consider the teachings of Ward, when viewed in this new light, important in deciding whether or not claim 1 is patentable. Accordingly, Ward, in combination with the '866 grandparent patent, raises a substantial new question of patentability for claim 1.

3. The request indicates that Requester considers claim 1 to be unpatentable over Schach in combination with the '866 grandparent patent (SNQ # 1).

It is agreed that consideration of Schach raises a substantial new question of patentability for claim 1. As pointed out on page 26 of the request, Schach teaches methods of testing chemicals for carcinogenic potential comprising exposing a rat or mouse to the chemical and observing the development of neoplasms in the rat or mouse.

Schach was used alone in an obviousness rejection during the prosecution of the application which issued as the '803 patent; however, it is being viewed herein in a new light due to its combination with a new reference, the '866 grandparent patent. There is a substantial likelihood that a reasonable examiner would consider the teachings of Schach, when viewed in this new light, important in deciding whether or not claim 1 is patentable. Accordingly, Schach, in combination with the '866 grandparent patent, raises a substantial new question of patentability for claim 1.

4. The request indicates that Requester considers claims 2-3 to be unpatentable over Proctor in combination with the '866 grandparent patent (SNQ # 3).

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It is agreed that consideration of Proctor raises a substantial new question of patentability for claims 2-3. As pointed out on pages 28-31 of the request, Proctor teaches a method of testing a material suspected of conferring protection against the development of neoplasms comprising treating a test mouse with a candidate anti-tumor agent, and comparing the test mouse to a control mouse not treated with the anti-tumor agent, wherein both the test mouse and the control mouse are administered radiolabelled tumor cells.

The teachings of Proctor were not considered during the prosecution of the application which became the '803 patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not claims 2-3 are patentable. Accordingly, Proctor raises a substantial new question of patentability for claims 2-3.

5. The request indicates that Requester considers claims 1-3 to be unpatentable over Schwab (SNQ #4).

It is agreed that consideration of Schwab raises a substantial new question of patentability for claims 1-3. As pointed out on pages 31-32 of the request, Schwab teaches methods of testing water for the presence of carcinogens comprising exposing the freshwater fish *Xiphophorus* to the potential carcinogens, wherein the genotype of the fish is altered to render it hypersensitive to carcinogens.

While considered during the prosecution of the parent and grandparent applications, the teachings of Schwab were not considered during the prosecution of the application which became the '803 patent. There is a substantial likelihood that a reasonable examiner would

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consider these teachings important in deciding whether or not claims 1-3 were patentable.

Accordingly, Schwab raises a substantial new question of patentability for claims 1-3.

6. The request indicates that Requester considers claims 1-3 to be unpatentable over Jaenisch in combination with Proctor, Ward, or Schach (SNQ #'s 5 and 6).

It is agreed that consideration of Jaenisch raises a substantial new question of patentability for claims 1-3. As pointed out on pages 32-36 of the request, Jaenisch teaches a transgenic mouse, wherein SV40 DNA is injected into the mouse at the preimplantation blastocyst stage of the mouse embryo and wherein the SV40 DNA persists in cells of the adult mouse.

The teachings of Jaenisch were not considered during the prosecution of the application which became the '803 patent. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not claims 1-3 were patentable. Accordingly, Jaenisch in combination with Proctor, Ward, or Schach raises a substantial new question of patentability for claims 1-3.

Conclusion

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

Claims 1-3 of United States Patent Number 5,925,803 will be reexamined.

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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. 5,925,803 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Waiver of Right to file Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R 1.550(f).

Amendment in Reexamination Proceedings

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 Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brenda Brumback** whose telephone number is **571-272-0961**. The examiner can normally be reached on Monday through Thursday from 7:00 a.m. to 5:30 p.m. If the attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Deborah**

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Jones can be reached by dialing **571-272-1535**. The official fax number for the organization where this application 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 as follows:

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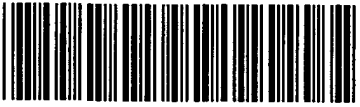
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Signed:

/Brenda Brumback/
Primary Examiner CRU
Art Unit 3991


PADMASHRI PONNALURI
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DEBORAH D. JONES
CRU SPE-AU 3991


Search Notes 	Application/Control No. 90010955	Applicant(s)/Patent Under Reexamination 5925803
	Examiner BRENDA BRUMBACK	Art Unit 3991

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Reviewed IFW 07/750,518 (PN 5,925,803); 07/171,806 (PN 5,087,571), & 06/623,774 (PN 4,736,866)	06/01/10	/BB/

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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Reexamination 	Application/Control No. 90010955	Applicant(s)/Patent Under Reexamination 5925803
	Certificate Date	Certificate Number

Requester Correspondence Address: **Patent Owner** **Third Party**

GONZALES, ELLEN,
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Case Name		Director Initials
None		<i>BBW</i> 6/14/10

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	NUMBER
1. None	

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