IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re. Application of:

Mark H. SKOLNICK et al.

Serial No. 08/483,554

Filed: 07 June 1995

For: 17q-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE

AMENDMENT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

In response to the Office Action mailed 27 March 1997, please amend the above-identified application as follows:

IN THE CLAIMS

Please cancel claims 39-46, 69-76 and 78-84, without prejudice to filing one or more divisional applications.

Please cancel claims 3, 6, 9-49, 23-25, 28-30, 33-35, 38, 46, and 49-68, without prejudice to filing one or more continuation applications.

In claim 31, line 1, please change “Recombinant host” to read -- Host --.
In claim 32, line 1, please change “Recombinant host” to read -- Host --.
In claim 36, lines 1 and 3, please delete each occurrence of “recombinant”.
In claim 37, lines 1 and 3, please delete each occurrence of “recombinant”.

Please amend claims 20 and 77 as follows:
Claim 20 (amended). [The] An isolated DNA [of claim 11] selected from the group consisting of:

(a) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having T at nucleotide position 4056;

(b) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having an extra C at nucleotide position 5385;

(c) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having G at nucleotide position 5443; and,

(d) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having 11 base pairs at nucleotide positions 189-199 deleted.

Claim 22 (amended). A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, [and] determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

REMARKS

Claims 39-43, 69-76 and 78-84, subject to restriction, have been canceled without prejudice to filing one or more divisional applications. Claims 3, 6, 9-19, 23-25, 28-30, 33-35, 38, 46, and 49-68 have been canceled without prejudice to filing one or more continuation applications in order to expedite the allowance of the claims which the Examiner indicated to be allowable. Claim 20 has been amended to make it independent, in view of the cancellation of the claim from which it depended. Claims 31, 32, 36 and 37 have been amended to delete the word "recombinant." Finally, claim 77 has been amended by incorporating the language "an altered BRCA1 gene causing cancer" as suggested by the Examiner and to add a step of comparing the growth rate of the transformed cells grown in the presence of the potential cancer
therapeutic to transformed cells grown in the absence of the potential cancer therapeutic. It is believed that none of these amendments constitute new matter.

The Examiner provisionally rejected claim 46 for obviousness-type double patenting over claims in applications 08/488,011 and 08/487,002. The cancellation of claim 46 obviates this rejection and its withdrawal is requested.

The Examiner rejected claims 3, 9-19, 23-25, 28-30, 33-35, 38, 49-68 and 77 for lack of enablement under 35 U.S.C. §112, first paragraph. Applicants believe that claim 6 should have been included in this rejection, since it depends from claim 3. The cancellation of claims 3, 6, 9-19, 23-25, 28-30, 33-35, 38 and 49-68 and the amendment of claim 77 as suggested by the Examiner obviate this rejection. Withdrawal of this rejection is requested.

The Examiner rejected claims 16-19, 31-38, 52, 53 and 77 for indefiniteness under 35 U.S.C. §112, second paragraph. Claims 16-19, 33-35, 38, 52 and 53 have been canceled. Claims 31m 32, 36 and 37 have been amendment to delete the objected word “recombinant.” Claim 77 has been amended to insert an appropriate control along the lines suggested by the Examiner. The cancellation of the specified claims and the amendment of the other specified claims obviate this rejection. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, it is believed that the claims satisfy the provisions of 35 USC §112 and are in condition for allowance. Since it is believed that all of the issues raised in the Office Action have been overcome, the Examiner is invited to telephone the undersigned to resolve any further issues and to expedite the prosecution of this application. Reconsideration of this application and early notice of allowance is requested.

Respectfully submitted,

Jeffrey L. Ihnen
Registration No. 28,957

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Attorney Docket No.: 24884-109347-07
Dated: 30 April 1997
DC2/29139.01
NOTICE OF ALLOWABILITY

PART I

1. This communication is responsive to Amendment filed 4/30/97.

2. All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be sent in due course.

3. The allowed claims are: 1, 2, 4, 5, 7, 8, 20, 22, 24, 27, 31, 32, 38, 39, 44, 45, 47, 48, 49.

4. The drawings filed on _____________ are acceptable.

5. Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [...] been received. [...] not been received. [...] been filed in parent application Serial No. _____________ filed on _____________.

6. Note the attached Examiner's Amendment.

7. Note the attached Examiner Interview Summary Record, PTO-413.

8. Note the attached Examiner's Statement of Reasons for Allowance.

9. Note the attached NOTICE OF REFERENCES CITED, PTO-892.

10. Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE “DATE MAILED” indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

2. APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.

   a. Drawing informalities are indicated on the NOTICE OF PATENT DRAWINGS, PTO-946, attached hereto or to Paper No. _____________, CORRECTION IS REQUIRED.

   b. The proposed drawing correction filed on _____________ has been approved by the examiner. CORRECTION IS REQUIRED.

   c. Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.

   d. Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:
- Examiner's Amendment
- Examiner Interview Summary Record, PTO-413
- Notice of Allowance
- Notice of Informal Application, PTO-152
- Notice of Patent Drawings, PTO-946
- Listing of Bonded Draftsman
- Other
NOTICE OF ALLOWANCE AND ISSUE FEE DUE

VENABLE BAETJER HOWARD & CIVILETTI
1291 NEW YORK AVENUE NW
SUITE 1000
WASHINGTON DC 20005

APPLICATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED
--- | --- | --- | --- | ---
08/483,554 | 06/07/95 | 020 | RAZZAQUE, A | 1819 | 05/09/97

First Named Applicant: SKOLNICK, MARK H.

TITLE OF INVENTION: 70-LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE

ATTY’S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE | DATE DUE
--- | --- | --- | --- | --- | --- | ---
1 | 24984-109347 | 435-069,100 | 299 | UTILITY | NO | $1290.00 | 08/11/97

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
   If the SMALL ENTITY is shown as yes, verify your current SMALL ENTITY status:
   A. If the status is changed, pay twice the amount of the FEE DUE shown and notify the Patent and Trademark Office of the change in status, or
   B. If the status is the same, pay the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

III. All communications regarding this application must give application number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents Issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee’s responsibility to ensure timely payment of maintenance fees when due.
**Inventors Name:**

VENABLE BARTJER HOWARD & CIVILETTI
1301 NEW YORK AVENUE NW
SUITE 1000
WASHINGTON, DC 20005

**Title of Invention:** 70-linked breast and ovarian cancer susceptibility gene

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**Certificate of Mailing:**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

**Received:**

MAY 14, 1997

By:

(U.S. Department of Commerce)