



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/483,554	06/07/95	SKOLNICK	M 24884-109347

18N2/0106
VENABLE BAETJER HOWARD & CIVILETTI
1201 NEW YORK AVENUE NW
SUITE 1000
WASHINGTON DC 20005

EXAMINER

RAZZAQUE, A

ART UNIT PAPER NUMBER

1819

13

DATE MAILED: 01/06/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on _____
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.**

A shortened statutory period for response to this action is set to expire 2 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-84 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims 1-84 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
 - received.
 - received in Application No. (Series Code/Serial Number) _____
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- Interview Summary, PTO-410
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1819

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-38 and 44-45, drawn to a DNA which encodes a BRCA1 polypeptide, a vector containing the DNA, host cells transformed with the recombinant DNA, a method of producing BRCA1 polypeptide and primers for determination of BRCA1 gene, classified in class 435, subclass 69.1+.
 - II. Claims 39 and 40, drawn to a preparation of BRCA1 polypeptide, classified in class 530, subclass 350.
 - III. Claims 41-43, drawn to an antibody against BRCA1, classified in class 530, subclass 387.1.
 - IV. Claims 46-48, drawn to a method for identifying a mutant BRCA1 nucleotide sequence in a suspected mutant BRCA1 allele, classified in class 435, subclass 6.
 - V. Claims 49-68, drawn to a method of gene therapy by introducing into the cell all or part of the BRCA1 gene, classified in class 514, subclass 44.
 - VI. Claims 69-74, drawn to a method of administration of BRCA1 protein into a cell which has lost said gene function, classified in class 514, subclass 2.
 - VII. Claim 75, drawn to a method of screening potential cancer therapeutics comprising : combining a BRCA1 binding partner, a BRCA1 polypeptide and a compound suspected of being a cancer therapeutic, classified in class 435, subclass 7.1.

Art Unit: 1819

- VIII. Claim 76, drawn to a method of screening potential cancer therapeutics comprising : combining a BRCA1 binding partner and a compound suspected of being a cancer therapeutic, classified in class 435, subclass 4.
- IX. Claim 77, drawn to a method of screening potential cancer therapeutics comprising: growing a transformed cell containing a BRCA1 gene in the presence of a compound suspected of being a cancer therapeutic, classified in class 435, subclass 7.21.
- X. Claim 78-84, drawn to a transgenic animal containing an altered BRCA1 allele and a method screening potential cancer therapeutics comprising: administering a compound suspected of being a cancer therapeutic to the transgenic animal, classified in class 800 subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct because they are drawn to compositions having materially different chemical structures,, physical properties and utilities, requiring separate searches and raising different issues of enablement. The compositions of I are not required to make or use the proteins of II and the proteins of II are not required to make or use the compositions of III. There is nothing on the record that the two compositions are obvious variants. Therefore the two inventions are deemed patentably distinct.

Serial Number: 08/483554

Page 4

Art Unit: 1819

Inventions I and each of V and X are related as product and methods of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the method for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different composition of using that product (MPEP § 806.05(h)). In the instant case the DNA of I can be used for many patentably distinct purposes: biosynthesis of BRCA1, diagnostic methods, gene therapy of V or the production of the animal of X.

Group I is distinct from each of III, IV and VI-X because compositions of I are not required to make or use the antibody of III and the methods of IV and VI-X, and the antibody of III and methods of IV and VI-X are not required to make or use the compositions of I. The inventions require different searches and are not obvious variants.

Group II is patentably distinct from III because the polypeptide and the antibody are materially different compounds with different structures, biological properties and utilities requiring different searches. They are not obvious variants. Furthermore, there is nothing on the record to indicate that the two inventions are obvious variants.

Inventions II and each of VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit: 1819

§ 806.05(h)). In the instant case the polypeptide of II can be used in two distinct processes, the therapeutic method of VI and the screening method of VII .

Group II is patentably distinct from each of IV, V and VIII-X because the protein of II is not required for the animal or methods of IV, V and VIII-X and the animal or methods of IV, V and VIII-X are not required to make or use the protein of II. They require separate searches and are not obvious variants.

Group III is patentably distinct from each of IV-X because the antibody of III is not required for the methods of IV-X and the methods of IV-X are not required to make or use the antibody of III. The inventions require separate searches and are not obvious variants.

Group IV is patentably distinct from each of V-X, because the methods and animal of V-XI are not required to practice the method of IV and the methods of IV are not required to practice or use the methods or animal of V-XI. Each of the methods uses different starting materials, different procedures to achieve divergent ends.

Group V and VI are patentably distinct from each of VII-X because they use different procedures and reagents to achieve different ends. Group V and VI involve methods therapy and VII-X involves methods of screening cancer therapeutics. They require different searches and are deemed patentably distinct.

Group V is patentably distinct from each of VI because they use different starting materials and procedures, and require different searches. Group V supplies nucleic acid and group VI supplies proteins as therapeutic agent to a cell. These therapeutic agents have different chemical,

Serial Number: 08/483554

Page 6

Art Unit: 1819

physical and biological properties and functions. Successful use of one would not predict success with the other. Therefore, these are not obvious variants.

Group VII-X are distinct, each from the others, because each method uses different compositions and starting materials and each claims to identify different results. Group VII uses a combination of BRCA1 binding partner, BRCA1 polypeptide and a suspected therapeutic compound, VIII uses a combination of BRCA1 binding partner and a suspected compound, IX uses a BRCA1 gene transformed host cell and a suspected therapeutic compound, and X uses a suspected therapeutic compound to a transgenic animal. The various methods also claim to achieve different results such as determining the amount of binding of the BRCA1 polypeptide, measuring the biological activity of the binding partner, rate of host cell growth and growth of a lesion. Each of the methods requires different searches. Therefore, groups VII-X are deemed patentably distinct.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Jeffrey L. Ihnen on September 26, 1996 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Serial Number: 08/483554

Page 7

Art Unit: 1819

Applicant is reminded that upon the cancellation of claims to a nonelected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Abdur Razzaque, whose telephone number is 703-305-4061. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00 (Eastern time).

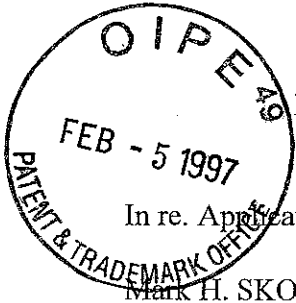
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine C. Chambers, can be reached on 703-308-2035. The FAX phone number for art unit 1804 is 703-308-0294.

Any inquiry for a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

AR
Abdur Razzaque

December 23, 1996

BRUCE R. CAMPBELL
PRIMARY EXAMINER
GROUP 1800



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

RECEIVED

FEB 06 1997

GROUP 1800

Group Art Unit: 1819

Examiner: A. Razzaque

14
KD

2-21-97

RESPONSE TO RESTRICTION REQUIREMENT

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

Sir:

Applicants respectfully traverse the Restriction Requirement mailed 6 January 1997. In this Restriction Requirement the Examiner divided the 84 claims into ten Groups. These 10 Groups are classified in only four classes, which Applicants believe is ample demonstration that the subject matter of the claims are sufficiently related, and recognized within the art to be sufficiently related, such that a restriction of the subject matter into fewer groups is more appropriate for the present case.

Applicants note that the present invention is directed to the discovery of a breast and ovarian cancer susceptibility gene called BRCA1. Applicants discovered that a BRCA1 gene is altered in the germline of patients and that such alteration represents a predisposition to breast and ovarian cancer. Only with the discovery of a BRCA1 gene sequence is it possible to determine or detect altered or mutant BRCA1 nucleic acids. The discovery of a BRCA1 gene sequence provides the basis for a sequence of a BRCA1 polypeptide and the subsequent production of antibodies to a BRCA1 polypeptide. The sequence of a BRCA1 polypeptide provides the basis for protein therapy and drug screening using the protein. The discovery of a BRCA1 gene sequence provides the basis for transgenic animals with altered sequences, gene therapy using a BRCA1 gene sequence and drug screening with transformed hosts or transgenic animals. Thus, it is clearly evident that the subject matter of the Groups proposed by the

Examiner have a close technical relationship among themselves, are therefore closely related and should not be restricted, at least in the manner proposed by the Examiner.

Applicants believe that a more proper restriction of the subject matter of the present application is as follows:

Group Ia - claims 1-38, 44, 45-48 and 77-84;

Group IIa - claims 39-43;

Group IIIa - claims 49-68;

Group IVa - claims 69-74; and

Group Va - claims 75 and 76.

Alternatively, Applicants believe that a more proper restriction of the subject matter of the present application is as follows:

Group Ib - claims 1-38, 44, 45 and 79-84;

Group IIb - claims 39-43;

Group IIIb - claims 49-68;

Group IVb - claims 69-74;

Group Vb - claims 75 and 76;

Group VIb - claims 77 and 78; and,

Group VIIb - claims 46-48.

Applicants believe that claims 46-48 properly belong with the claims of Examiner's Group I. Specifically, claim 46 relates to a method for identifying a mutant BRCA1 nucleotide sequence. This identification cannot be accomplished without the DNA sequence of claim 1, since the nucleotide sequence of the suspected allele is compared to the DNA sequence of claim 1. Claim 47 belongs with this Group since it contains the primers which are referred to in claim 44. Claims 46-48 are classified in class 435 (the same class as the Examiner's Group I), subclass 6. The inclusion of these claims in Group I would only require the search of one additional subclass -- not an undue burden on the Examiner. Furthermore, the search for each would require the consideration of the BRCA1 gene, and thus the claims are sufficiently related to be examined together. OK

A similar analysis is also applicable to claims 77-84. Claim 77 is directed to drug screening using a transformed cell containing an altered BRCA1 gene, and it is classified in class 435 (the same class as the Examiner's Group I), subclass 7.21. The inclusion of this claim OK

in Group I would only require the search of one additional subclass -- not an undue burden on the Examiner. Claims 79-84 are directed to transgenic animals containing an altered BRCA1 gene. These claims are not a method of use as asserted by the Examiner in the Restriction Requirement, but are a composition of matter. Therefore, any distinction on the basis of a product and a method of use is improper concerning these claims and the claims of Group I. Only claim 78 is a method of using a transgenic animal. Furthermore, it is believed that a search, especially a computer search, for a BRCA1 gene would also identify prior art with reference to the subject matter of claims 79-84. (This fact is also true for the subject matter of any of the claims discussed in this traversal of the Restriction Requirement.) Claim 78 and claims 79-84 are classified in Class 800, subclass 2 - a single subclass.

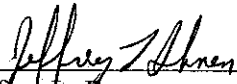
In addition to being sufficiently related to qualify as a single group and not imposing an undue burden on the Examiner for searching the claimed subject matter, the inclusion of the subject matter in proposed groups provides the basis for a more precise and rational examination of the subject matter of the present invention, which will lead to a more meaningful prosecution of the present application. In view of these factors, it is believed that the proposed groupings are more proper than the grouping set forth in the Restriction Requirement.

In view of this analysis, Applicants submit that a proper restriction of the claims is as set forth in Groups Ia - Group Va set forth above. Alternatively, Applicants believe that the BRCA1 gene claims and the transgenic animal claims should be examined as a single group for the reasons previously discussed. In this alternative grouping, Applicants submit that a proper restriction of the claims is as set forth in Groups Ib - Group VIIb set forth above.

In the event that the Examiner concurs with Applicants' analysis of the subject matter of this application, Applicants elect new Group Ia or Group Ib for examination. If the Examiner concludes that the claims should be grouped differently than set forth in the Restriction Requirement or proposed above, he is invited to telephone the undersigned to discuss the new grouping prior to the examination of the application. Finally, if the Examiner does not concur

with Applicants' analysis or proposals, Applicants provisionally elected Group I (claims 1-38, 44 and 45 as set forth in the Restriction Requirement) for examination.

Respectfully submitted,



Jeffrey L. Ihnen
Registration No. 28,957

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP
1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005
(202) 962-4810

Attorney Docket No.: 24884-109347-07
Dated: 05 February 1997
DC2/29139.01