

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS ALBERTSEN, RAKESH ANAND,
MARY CARLSON, JOANNA GRODEN,
PHILIP J. HENDGE, GEOFF JOSLYN,
KENNETH KINZLER, ALEXANDER F. MARKHAM,
YUSUKE NAKAMURA, ANDREW THLIVERIS,
BERT VOGELSTEIN, and RAYMOND L. WHITE

Appeal No. 1998-1283
Application No. 08/449,731

HEARD: March 8, 2001

Before WINTERS, ROBINSON, and MILLS, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 19, 20, 52, 53, and 64, which are all of the claims pending in the application.

Claims 19, 20, 52, 53, and 64 read as follows:

19. A method to aid in the diagnosis or prognosis of a neoplastic tissue of a human, comprising:

detecting somatic alteration of wild-type APC protein in a tumor tissue isolated from a human, said alteration indicating neoplasia of the tissue, wherein the alteration of wild-type APC protein is detected by immunoblotting.

20. A method to aid in the diagnosis or prognosis of a neoplastic tissue of a human, comprising:

detecting somatic alteration of wild-type APC protein in a tumor tissue isolated from a human, said alteration indicating neoplasia of the tissue, wherein the alteration of wild-type APC protein is detected by immunocytochemistry.

52. A method to aid in the detection of genetic predisposition to cancer, including familial adenomatous polyposis (FAP) and Gardner's Syndrome (GS), in a human comprising:

detecting a germline alteration of wild-type APC protein in a human sample selected from the group consisting of blood and fetal tissue, said alteration indicating predisposition to cancer, wherein the alteration of wild-type APC is detected by immunoblotting.

53. A method to aid in the detection of genetic predisposition to cancer, including familial adenomatous polyposis (FAP) and Gardner's Syndrome (GS), in a human, comprising:

detecting a germline alteration of wild-type APC protein in a human sample selected from the group consisting of blood and fetal tissue, said alteration indicating predisposition to cancer, wherein the alteration of wild-type APC protein is detected by immunocytochemistry.

64. A method to aid in the diagnosis or prognosis of a neoplastic tissue of a human, comprising:

detecting somatic alteration of wild-type APC protein in a tumor tissue isolated from a human, said alteration indicating neoplasia of the tissue.

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The examiner has relied on no references in rejecting the claims on appeal.

Grounds of Rejection

Claims 19, 20, 52, 53, and 64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which is not enabling for the subject claimed.

Claim 64 stands rejected¹ under 35 U.S.C. § 101 as claiming the same invention as claim 64 of copending Application No. 08/450,582.

Claims 19, 20, 52, and 53 are rejected¹ under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64 and 65 of copending Application No. 08/450,582.

We reverse the rejection under 35 U.S.C. § 112, first paragraph and dismiss the rejections under 35 U.S.C. § 101 and the judicially created doctrine of obviousness-type double patenting.

Discussion

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer of October 2, 1997 (Paper No. 17) for the examiner's reasoning in support of the rejections and to the appellants' Brief on Appeal filed May 19, 1997 (Paper No. 16) and Reply Brief filed December 2, 1997 (Paper No. 18) for the appellants' arguments thereagainst.

¹ Since the filing of this appeal, Application No. 08/450,582 has issued as U.S. Patent 6,114,124 on September 5, 2000. Therefore this rejection is no long "provisional" in nature.

Claim Interpretation

Claim 19 is directed to a method to aid in the diagnosis or prognosis of a neoplastic tissue of a human comprising detecting somatic alternations of the wild-type Adenomatous Polyposis Coli (APC) protein in a tumor tissue isolated from a human using immunoblotting. Claim 20 is directed to a similar method wherein the detection is by immunocytochemistry. Claim 52 is directed to a method of aiding in the detection of genetic predisposition to cancer in a human comprising detecting a germline alteration of wild-type APC protein in a human sample selected from blood and fetal tissue, wherein the alteration of the protein is detected by immunoblotting. Claim 53 is directed to a method similar to that of claim 52 except that the detection is by immunocytochemistry. Claim 64 is directed to a method to aid in the diagnosis or prognosis of a neoplastic tissue of a human comprising detecting somatic alteration of wild-type APC protein in a tumor tissue isolated from a human. We read the claims as being directed to a method which aids in the diagnosis and prognosis of a neoplastic condition or a predisposition to cancer and not, necessarily, to require that the data, resulting from the method, give a direct correlation or relationship to the underlying condition. Thus, any method involving the detection of somatic alterations of wild-type APC protein tissue which assists, in any way, in the diagnosis, prognosis, or detection of a predisposition to cancer would fall within the scope of the claims on appeal.

The rejection under 35 U.S.C. § 112, first paragraph

Claims 19, 20, 52, 53, and 64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which does not enable one skilled in this art to practice the claimed invention without undue experimentation. The examiner explains the basis of the

rejection in the paragraph bridging pages 4-5 of the Examiner's Answer. The examiner urges that the "instant specification provides no direction, no working examples or guidance teaching the detection of alterations at the protein level or their predictable correlation to cancer." The examiner, further, urges that "the specification does not disclose that it is known or predictable that any alteration of the APC gene results in an immunologically altered protein distinguishable antigenically and detectable by immunological methods or by any other methods." The examiner contends that "it has not been demonstrated that detection of an altered protein is correlative with cancer, its prognosis, or the predisposition of a patient to developing cancer. Thus, the examiner concludes that (Answer, page 5):

[w]ithout further guidance with regard to the availability of antibodies or other means and their use in an assay detecting altered APC protein as well as predictable correlations between protein alteration and cancer, it would require undue experimentation by one of skill in the art to practice the instant invention.

Therefore, the issue is whether appellants' disclosure would have enabled one skilled in the art to make and use the claimed invention throughout its scope without undue experimentation. The Patent and Trademark Office (PTO) bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicants as to the scope of enablement. Only when the PTO meets this burden, does the burden shift to applicants to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

Factors appropriate for determining whether undue experimentation is required to practice the claimed invention throughout its full scope are listed in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include:

- (1) the quantity of experimentation necessary,
- (2) the amount of direction or guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the relative skill of those in the art,
- (7) the predictability or unpredictability of the art, and
- (8) the breadth of the claims.

On the record before us, we find that the examiner's reasoning has its own internal logic. However, we find that the examiner's statements, in support of this rejection, fall short of the requirement set forth above and fail to provide adequate evidence or reasons why one skilled in the art would doubt the statements and direction presented in the disclosure in support of the claimed invention. The examiner's conclusory statements relating to the Wands factors are not supported by facts or evidence which would provide a reasonable basis for the conclusions reached. We point out that the guidance provided by the specification is merely one of the factors which must be considered in determining whether the disclosure provided by applicants in support of a claimed invention is sufficient to permit those skilled in the art to which the invention relates to practice the invention without undue experimentation. That some experimentation may be necessary, does not equate to undue experimentation.

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Further, it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. In re Angstadt, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). A conclusion of lack of enablement means that, based on the evidence regarding the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

On this record, it does not appear that the examiner disputes that there are tumor suppressor genes that play a role in the tumorigenesis process (Specification, page 1). Appellants allege that they have discovered another gene on chromosome 5q which is named the Adenomatous Polyposis Coli (APC) gene. If this gene is responsible for expressing a protein which has tumor suppressing activity it follows that the absence of or modifications of the protein resulting from the expression of the gene could affect the tumorigenesis activity of the resulting protein. The examiner has not provided any evidence or pointed to any facts which would reasonably suggest that one skilled in this art could not readily distinguish between the presence of the complete protein and the absence of the complete protein in a tissue sample in the manner presently claimed. If we accept that the protein has the activity urged by the appellants, and the examiner has given us no reason to doubt appellants' proposition on this score, then the absence of the whole protein while possibly not absolutely predictable of cancer or the potential of cancer, is at the very least helpful information which would aid in the diagnosis and/or prognosis of cancer in a patient.

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That appellants have not established an absolute correlation to the presence of the complete protein or absence of the complete protein and the development of cancer is not determinative as to whether one could practice the presently claimed invention without undue experimentation. Therefore, the rejection of claims 19, 20, 52, 53, and 64 under 35 U.S.C. § 112, first paragraph, is reversed.

The double patenting rejections

Claim 64 stands rejected under 35 U.S.C. § 101 and claims 19, 20, 52, and 53 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 64 and 65 of Application No. 08/450,582, now U.S. Patent 6,114,124. At the oral hearing held March 8, 2001 appellants' representative indicated that both claims 64 and 65 were canceled in Application No. 08/450,582 prior to issuance of that application. Since the examiner only references claim 64 and 65 of that application and since we do not have the prosecution history from that application available for consideration, we can not readily determine whether the issue of double patenting or obviousness-type double patenting is still relevant to the claims presently on appeal. However the statement of the rejection by the examiner would suggest that the basis of this rejection at the time of this appeal, has changed in a manner which precludes meaningful review. Therefore, we dismiss both the rejection of claim 64 under 35 U.S.C. § 101 and the rejection of claims 19, 20, 52, and 53 under the judicially created doctrine of obviousness-type double patenting. Should further prosecution occur in this application we would urge the examiner to consider anew the claims of the

issued patent to determine whether double patenting issues relative to the presently pending claims are applicable. Should the examiner determine that there is proper basis for rejecting one or more of the claims of this application, the examiner should issue an appropriate Office action explaining the basis of the rejection and provide appellants with the appropriate opportunity to respond thereto.

Summary

The rejection of claims 19, 20, 52, 53, and 64 under 35 U.S.C. § 112, first paragraph is reversed. The rejection of claim 64 under 35 U.S.C. § 101 and the rejection of claims 19, 20, 52, and 53 under the judicially created doctrine of obviousness-type double patenting are dismissed.

REVERSED

SHERMAN D. WINTERS)
Administrative Patent Judge)
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) BOARD OF PATENT
DOUGLAS W. ROBINSON)) APPEALS AND
Administrative Patent Judge)
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DEMETRA J. MILLS)
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