



SUBJECT: **EPO Decision T80/05**

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PURPOSE **For information**

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REFERENCE: **EXCO/US09/CET/1501**

MEETING:: **ExCo Washington D.C., US**

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TABLED TO : **All attendees**

1. INTRODUCTION

The Board of Appeal of the EPO has recently issued a decision (T80/05), according to which a patent should be granted for an invention referred to a method suitable for evaluating the predisposition of a patient for breast and ovarian cancer.

A very narrow interpretation of EPC has been given in this case, so that the field of patentable inventions seems to have been enlarged.

The patent is EP-0 699 754, filed by The University of Utah Research Foundation.

2. THE CLAIMS

Patent claim 1) according to the main request is: "A method for diagnosing a predisposition for breast and ovarian cancer in a human subject which comprises determining in a tissue sample of said subject whether there is a germline alteration that is a frameshift mutation in the sequence of the BRCA1 polypeptide altering the open reading frame of SEQ ID NO: 2, said alteration being indicative of a predisposition to said cancer".

Patent claim 2) is: "A method for diagnosing a lesion of a human subject for neoplasia associated with the BRCA1 gene locus which comprises determining in a sample from said lesion whether there is an alteration that is a frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame of SEQ ID NO: 2, said alteration being indicative of neoplasia".

Claims 3-7 depend on the first two claims.

3. PROBLEMS FACED

A number of problems were faced by the Board of Appeal. There were problems with clarity, priority right, novelty, inventive step, amendments and exceptions to the patentability.

Clarity was challenged on the basis that the frameshift mutation in the sequence of the BRCA1 gene altering the open reading frame for SEQ. ID No. 2 used in claims 1 and 2 of the main request defined an amino acid sequence whereas such open frame is always linked to a nucleic acid and not to a protein and it is not clear whether altering the open reading frame refers to an alteration of the DNA or of the reading frame.

A textbook is cited by the Board, in which it is stated that frameshift mutations arise by deletions or insertions and they change the frame in which triplets are translated into protein. It shows that the language of the claims is clear for a skilled person.

Referring to the amendments, the difference between the new and the old formulation of claim 1 lies in that the germline alteration that is to be determined in the claimed method cannot be any alteration, but it is the one explicitly set forth. Anyway, the particular alteration is briefly cited in the originally filed text of the specification, as the most severe forms of mutation. In particular, a reference to frameshift mutations in general is explicitly made only in the context of mutations useful to prove that a cDNA is the BRCA1 locus. It is



opinion of the Board that a skilled person reading that passage can understand that the most severe forms of disruptive mutations would also be among the preferred mutations to be tested for in diagnostic and prognostic methods. This is not considered as a selection of the possibilities given from the general broad scope of the filed application and not explicitly described, but the Board finds that frameshift mutations have been disclosed in the filed application as one of the relevant type of mutations.

Lack in inventive step was argued on the basis that one of the cited prior documents disclosed that the cloning of BRCA1 and its identification as the disease-causing gene could be achieved and would be achieved within a limited time period by one of the researchers in the field, who were to be regarded as the skilled persons.

In a previous case, the Board of Appeal stated that the cloning of BRCA1 and its identification as the disease carrying gene involved an inventive step; it was established that, due to the involved uncertainties, it could not be reasonably expected to successfully arrive at the cloning of the BRCA1 gene within acceptable time limits merely by way of routine experimentation.

Therefore, continuing this line, the Board set forth that the cited teachings in no way would lead the skilled person to the solution of the posed problem according to claims 1 to 7 in an obvious way.

One of the opposition grounds was that the methods claimed were based on the discovery of a mutation in the genome of a human, on the further discovery of a relationship that exists in nature between this mutation and a disease and on the purely mental act that a human exhibiting this mutation has a predisposition for the disease.

However, the Board set forth that the combining of Art. 52(2) (a) EPC with rule 29(2) EPC leads to conclude that an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention, which is here the case. Therefore, this method is

not a mere mental act, but it involves technical steps leading to an invention.

The assessment whether this invention belongs to the exceptions to the patentability is a very tricky point. The patent application, indeed, refers to a diagnostic method related to a human being. However, according to the interpretation of the Board of Appeal, the exception to the patentability arises only in case the diagnostic method is performed on the human or animal body. Since the diagnostic method is performed on a tissue sample taken away from a human body, the diagnostic method is not performed *stricto sensu* on a human body. Therefore, the invention, though referred to a diagnostic method in connection with a human being does not fall under the exceptions to the patentability set forth by the EPC.

3. A COMMENT

What makes this decision interesting (and a bit surprising) is the interpretation of the exceptions to patentability. In fact, according to this decision, such exceptions are interpreted in a very narrow way, which risks to become rather formal than substantial. If this kind of case law is followed in the future, it will become very important for people drawing up patent applications in this field to show how and in which extent the method is or can be performed out of the human body. In this way, such an exceptions will be applied very seldom and more due to errors in drawing up the application than for substantial problems.

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