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**Datasheet for the decision
of 19 November 2008**

Case Number: T 0080/05 - 3.3.04

Application Number: 95305602.5

Publication Number: 0699754

IPC: C07K 14/82

Language of the proceedings: EN

Title of invention:

Method for diagnosing a predisposition for breast and ovarian cancer

Patentee:

The University of Utah Research Foundation, et al.

Opponent:

Institut Curie
Assistance Publique-Hôpitaux de Paris
Institut Gustave Roussy - IGR
Belgian Society of Human Genetics et al.
Associazione Angelaserra per la Ricerca sul Cancro

Headword:

Method of diagnosis/UNIVERSITY OF UTAH

Relevant legal provisions:

EPC Art. 52(2), 53(a)(c), 54, 56, 57, 83, 84, 88, 89,
112(1)(a), 114(2), 123(2)(3)
EPC R. 29(1)

Relevant legal provisions (EPC 1973):

EPC Art. 87

Keyword:

"Admission of late-filed document into the procedure (no)"
"Main request -
Clarity and support by the description (yes);
Added subject-matter (no);
Extension of scope of protection (no);
Priority (yes);
Referral of questions to the Enlarged Board of Appeal (no);
Novelty (yes);
Inventive step (yes);
Sufficiency of disclosure (yes);
Patentable invention (yes);
Exception to patentability (no);
Industrial applicability (yes)"

Decisions cited:

G 0002/98, G 0001/04, T 0081/87, T 0118/89, T 0082/93,
T 0272/95, T 0633/97, T 1213/05

Catchword:

-



Case Number: T 0080/05 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 19 November 2008

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 3 November 2004
revoking European patent No. 0699754 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Kinkeldey
Members: M. Wieser
D. S. Rogers
G. Alt
R. Moufang

Summary of Facts and Submissions

- I. An appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division dated 3 November 2004 according to which European patent No. 0 699 754 was revoked (Articles 102(1) EPC 1973). The patent has the title "Method for diagnosing a predisposition for breast and ovarian cancer" and claims priority from eight US applications, P1 to P8, of which the second P2 and the fifth P5 were filed on 2 September 1994 and 24 March 1995, respectively.
- II. Six oppositions (Opponents 01 to 06) were filed against the patent covering the grounds of Article 100(a) EPC in combination with Articles 52(2), 52(4), 53(a), 54, 56 and 57 EPC 1973 and Rule 23e(1) EPC 1973, and Article 100(b) in combination with Article 83 and 100(c) in combination with Article 123(2) EPC 1973.

It is to be noted that the oppositions were filed before the entry into force of the EPC 2000 and therefore in the original notices of opposition all references to the Articles of the EPC were to the Articles of the EPC 1973. Taking into account the relevant transitional provisions, in this decision, instead of referring to articles 52(2), 52(4), 53(a), 54, 56, 57, 83 and 123 EPC 1973 and Rule 23e(1) EPC 1973, reference will be made to the corresponding Articles and Rules of the EPC 2000 that is Articles 52(2), 53(c), 53(a), 54, 56, 57, 83 and 123 EPC 2000 and Rule 29(1) EPC, unless otherwise stated. Throughout this decision the EPC 2000 will be referred to as the EPC.

The opposition of Opponent 05 was deemed not to have been filed, due to non-payment of the opposition fee (Article 99(1) EPC).

III. The Opposition Division decided that the main request before it did not meet the requirements of Article 123(2) EPC. Further it decided that the claims of auxiliary requests II and III did not comply with Articles 123(3) and 84 EPC. The Opposition Division, by exercising its discretion under Article 114(2) EPC, did not admit Patent Proprietor's auxiliary requests IIIa, IVa, IVb and VIa into the procedure, which were all filed at the oral proceedings before it. Moreover, it did not allow the re-introduction of auxiliary request I into the procedure, which had previously been withdrawn during the oral proceedings. Finally, the Opposition Division decided that the claims of auxiliary request VIIa lacked an inventive step under Article 56 EPC.

IV. The Board dispatched a communication dated 21 January 2008, wherein the parties were asked whether they maintained their actual requests in the light of decision T 1213/05, of 27 September 2007, posted on 12 December 2007.

V. Oral proceedings before the Board took place on 18 and 19 November 2008.

The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 7 of the main request submitted at the oral proceedings on 19 November 2008.

The Respondents I to IV (Opponents 01 to 04) requested that the appeal be dismissed and that questions (1) to (3) submitted at the oral proceedings on 18 November 2008 be referred to the Enlarged Board of Appeal.

No request was submitted by Opponent 06.

VI. Claim 1, 2, 6 and 7 of the main request read as follows:

"1. 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 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2, said alteration being indicative of a predisposition to said cancer.

2. 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 for SEQ ID NO: 2, said alteration being indicative of neoplasia.

6. A method for diagnosing a predisposition for breast and ovarian cancer in a human subject which comprises determining whether there is germline alteration 5385insC in the BRCA1 gene in a tissue sample of said subject, said alteration indicating a predisposition to said cancer.

7. A method for diagnosing a breast or ovarian lesion of a human subject for neoplasia associated with the BRCA1 gene locus which comprises determining whether there is mutation 5385insC in the BRCA1 gene in a sample from said lesion."

Dependent claims 3 to 5 refer to preferred embodiments of the methods of claim 1 and 2.

VII. The following documents are mentioned in the present decision:

- D1: Friedman et al., Nature Genetics (Dec. 1994)
8: 399-403
- D2: Miki et al., Science (Oct. 1994) 266: 66-71
- D3: Futreal et al., Science (Oct. 1994)
266: 120-122
- D4: Castilla et al., Nature Genetics (Dec. 1994)
8: 387-391
- D6: Simard et al., Nature Genetics (Dec. 1994)
8: 392-398
- D16: Albertsen et al., Nature Genetics
(Aug. 1994) 7: 472-479
- D49: Watson et al., Recombinant DNA, Scientific
American Books, Chapters 25, 29 and 30,
2nd Ed. 1994
- D77: Ioannou et al., Nature Genetics (Jan. 1994)

6: 84-89

- D78: Extract from the Genome Database on D17S1141
- D80: Shizuya et al., Proc. Natl. Acad. Sci. USA
(1992) 89: 8794-8797
- D81: Monaco and Larin, Trends Biotechnol.,
(July 1994) 12: 280-286
- D122: GenBank Sequence Revision History for U14680
- D124: Statement of Dr Mazoyer, 8 November 2004
- D125: Lewin B., Genes V, Oxford University Press,
1994, pages 1242, 1248 and 1250
- D126: Primers cited in D2
- D132: National Human Genome Research Institute;
Human Genome Sequence Quality Standards,
<http://www.genome.gov/10000923>
- D139: Declaration Dr Critchfield, 14 October 2008

VIII. The submissions made by the Appellant can be summarized as follows:

Amendments (Article 123(2) and (3) EPC)

The methods referred to in the claims were described as preferred embodiments of the invention in the application as filed. Restricting the claims as originally filed, which generally referred to

diagnostic methods determining any kind of germline alteration in a gene of interest, to a method wherein a specific preferred class of mutations, namely frameshift mutations were determined, did not result in a violation of the requirements of Article 123(2) and (3) EPC.

Clarity (Article 84 EPC)

The term "a germline alteration that is a frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide" was clear and would be understood by any person skilled in the art. By referring to "the open reading frame **for** SEQ ID NO:2" (emphasis added by the Board) it became clear that the reading frame was a feature of the nucleic acid coding for the amino acid sequence of SEQ ID NO:2.

Priority Right (Article 87 EPC 1973 and Articles 88 and 89 EPC)

The methods of the present invention relied on the detection of germline alterations shifting the open reading frame for SEQ ID NO: 2. The same invention was disclosed in priority document P2 and in claims 1 to 7, which therefore were entitled to claim priority from priority document P2. A nucleic acid sequence disclosed information concerning several different parameters such as size, sequence, coding region and open reading frame. The actual sequences which were disclosed in SEQ ID NOs: 1 and 2, and which slightly deviated between priority document P2 and the application as filed, were not a feature of the claimed subject-matter. SEQ ID NO: 2 and the nucleic acid sequence coding for it were only

a reference for the definition of the frame used by the diagnostic methods claimed.

Novelty (article 54 EPC) and inventive step (Article 56 EPC)

As the claims were entitled to claim priority from priority document P2, there was no relevant prior art on file for the assessment of novelty and inventive step. The requirements of Articles 54 and 56 EPC were thus met.

Sufficiency (Article 83 EPC)

The patent, by way of several examples, disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person (Article 83 EPC).

The objections raised under Articles 52(2), 53(a), 53(c), 57 EPC and Rule 29(1) EPC lacked substantiation and should be rejected by the Board.

IX. The submissions made by the Respondents can be summarized as follows:

Amendments (Article 123(2) and (3) EPC)

The application as filed did not concentrate on the determination of frameshift mutations, a term which was mentioned only twice in the application as filed. The selection of this specific subclass of mutations in the claims of Appellant's request, by which all other forms of mutations originally disclosed were disclaimed, had

therefore to be considered to contravene the requirements of Article 123(2) EPC.

Table 11 of the application as originally filed referred to two frameshift mutations only. The claims referred to each and every frameshift mutation in the sequence of the BRCA1 gene and were therefore considered to contain an unallowable intermediate generalisation.

Contrary to the claims as granted, which referred to mutations in the coding region of the BRCA1 gene only, the claims of the Appellant's request also referred to mutations in the non-coding region, and therefore contravened the requirements of Article 123(3) EPC.

Clarity (Article 84 EPC)

The essential features of the claimed methods ("germline alteration", "frameshift mutation" and "open reading frame") had been arbitrarily selected from different parts of the description. The claims, which were the result of a mosaic-like combination of features, were not supported by the description and lacked clarity.

SEQ ID NO: 2 showed the amino acid sequence of a BRCA1 polypeptide. As a polypeptide did not have an "open reading frame", the term "the open reading frame for SEQ ID NO:2" was not clear.

Right to priority (Article 87 EPC 1973 and Articles 88 and 89 EPC)

The claims could only enjoy priority right from priority document P5, being the earliest of the eight priority documents disclosing SEQ ID NOs: 1 and 2 corresponding exactly to SEQ ID NOs: 1 and 2 as disclosed in the application as filed.

Deciding differently would not only contradict the earlier decision T 1213/05 (*supra*) but also the gist of decision G 2/98 of the Enlarged Board of Appeal (OJ EPO 2001, 413). Accordingly, in this case, questions would have to be submitted to the Enlarged Board of Appeal in order to resolve this contradictory case law.

Inventive step (Article 56 EPC)

The claims did not solve a technical problem. Screening a patient for only one kind of mutation, namely frame shift mutations, when in fact other types of mutations were likely to be equally detrimental to the functioning of the gene and occurred with similar frequency, did not provide a solution to any problem. This had also to be considered when examining the requirements of Article 83 EPC.

The closest prior art was represented by document D16 and the technical problem to be solved was the further identification of BRCA1 for use in diagnostic methods.

Starting from document D16, the skilled person would have had a high expectation of success that the BRCA1 gene could be identified and isolated merely by the

application of conventional positional cloning techniques. Arriving at the claimed subject-matter was obvious from document D16 in combination with common general knowledge, or alternatively in combination with either of documents D77, D78, D80 or D81.

The inventors had carried out the necessary experimentation faster than others, but this did not justify the recognition of an inventive step. Suitable kindreds were also available to other scientific groups, and sooner or later one of these groups would have been successful as well. Any problems that might have been encountered in the course of the project would have been overcome by the skilled person using conventional means.

The patent and the invention it referred to moreover violated the requirements of Articles 52(2)(a) and (c), 53(a) and (c) and 57 EPC and Rule 29(1) EPC.

Reasons for the Decision

1. The appeal is admissible.

Late-filed documents (Article 114(2) EPC)

2. During the oral proceedings, Respondent IV filed a document of seven pages entitled "Lack of knowledge on intronic sequences", containing drawings and explanations, in support of its submissions as to why the second priority date could not be validly claimed. The Appellant requested that this document should not be admitted into the procedure.

3. When a Board decides whether or not to take into account late-filed evidence, the right to be heard of all parties has to be safeguarded (Article 113(1) EPC).

In decision T 633/97 of 19 July 2000, the Board found that the complexity of the examination necessitated by the late filed material was a criterion for considering it. New submissions should normally be disregarded if the complexity of the technical or legal issues raised was such that neither the Board nor the other party could be clearly expected to deal with them without adjournment of the oral proceedings. Once oral proceedings have been arranged in appeal cases, the decision to admit new evidence into the procedure should be governed primarily by a general interest in the appeal proceedings being conducted in an effective manner, i.e. dealing with all issues raised by the parties, while still being brought to a close within a reasonable time. Complex fresh subject-matter filed at short notice before or during oral proceedings ran the risk of not being admitted to the proceedings without any consideration of its relevance or allowability (see point (2) of the reasons).

4. In the present case, the information presented in the document filed by Respondent IV at the oral proceedings consists of a large amount of data collected from different sources presented in a rather complex format. In order to give the Appellant fair treatment and to respect his right to be heard, the admission into the procedure of the document in question would have required an adjournment of the oral proceedings to a later date. The Board therefore decides not to admit

this document into the procedure pursuant to Article 114(2) EPC.

Main request

Clarity (Article 84 EPC)

5. The claims of the main request differ from the claims as granted and it must thus be assessed whether they fulfil the requirements of Article 84 EPC in so far as the amendments are concerned.

6. The Respondents have argued that the expression "frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2" used in claims 1 and 2 (but not in the claims as granted) lacked clarity, contrary to Article 84 EPC, firstly because SEQ ID NO: 2 defined an amino acid sequence, whereas an open reading frame was always linked to a nucleic acid, not to a protein, and secondly because it was not clear whether "altering the open reading frame" in the context of the claims referred to an alteration of the DNA or of the reading frame.

7. According to common general knowledge, as represented for instance by the textbook of which document (125) is an excerpt, "[f]rameshift mutations arise by deletions or insertions that are not a multiple of 3 bp; they change the frame in which triplets are translated into protein" (page 1242, column 2, lines 11 to 13).

8. In view of this common general knowledge, the Board takes the position that a person skilled in the art

would understand the expression "frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2" as referring to a frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide, which frameshift mutation changes the frame in which triplets are translated into protein (i.e. the open reading frame) such that the frame is no longer the one that would result in the protein product with the amino acid sequence of SEQ ID NO: 2.

The Board thus considers that said expression defining the frameshift mutations in claims 1 and 2 would be clearly understood by a skilled person without any ambiguity.

9. The Respondents have furthermore argued that by defining the type of mutations rather than steps of the claimed method, the claims defined a result to be achieved and therefore lacked clarity and were not supported by the description, contrary to Article 84 EPC. Moreover, the broad scope of the claims was not justified by the actual technical disclosure of the patent, thereby resulting in a lack of support by the description (Article 84 EPC).

10. The Board cannot concur with this line of argument. Firstly, the Board is convinced that the skilled person would understand on the basis of the teaching of the description of the patent in suit and his/her common general knowledge how to perform the claimed methods. Secondly, the Board cannot see that the scope of the claims is unduly broad with regard to the technical disclosure of the patent in suit, since it is the

determination of a frameshift mutation as such that gives rise to the diagnosis of a predisposition to breast and ovarian cancer, irrespective of the exact methodology used for this determination.

11. Therefore, the requirements of Article 84 EPC are met.

Added matter (Article 123(2) EPC)

12. Claim 1 relates to 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 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2, said alteration being indicative of a predisposition to said cancer".

13. Article 123(2) EPC requires that a European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. In accordance with the established case law of the Boards of Appeal, the content of an application comprises the disclosure that is directly and unambiguously derivable from this application.

14. Claim 1 of the application as filed relates to a "method for diagnosing a predisposition for breast and ovarian cancer in a human subject which comprises determining whether there is a germline alteration in the sequence of the BRCA1 gene or a BRCA1 gene regulatory sequence in a tissue sample of said subject,

said alteration being indicative of a predisposition to said cancer".

Claim 1 of the main request thus differs from claim 1 of the application as filed in that the germline alteration that is to be determined in the claimed method cannot be any alteration, but is a "frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2".

It thus needs to be examined whether this feature introduced into claim 1 is directly and unambiguously derivable from the application as filed.

15. On page 9, lines 10 to 27 of the description of the application as filed (published version) of the patent in suit, it is stated under the heading "Testing the cDNA for Candidacy" that, in order to prove that a cDNA is the BRCA1 locus, "the key is to find mutations which are serious enough to cause obvious disruption to the normal function of the gene product. These mutations can take a number of forms. The most severe forms would be frame shift mutations or large deletions which would cause the gene to code for an abnormal protein or one which would significantly alter protein expression".

In the following paragraph, in lines 28 to 33 of the same page, it is stated that "[a]ccording to the diagnostic and prognostic method of the present invention, alteration of the wild-type BRCA1 locus is detected. In addition, the method can be performed by detecting the wild-type BRCA1 locus and confirming the lack of a predisposition to cancer at the BRCA1 locus.

"Alteration of a wild-type gene" encompasses all forms of mutations including deletions, insertions and point mutations in the coding and non-coding regions. Deletions may be of the entire gene or of only a portion of the gene. Point mutations may result in stop codons, frameshift mutations or amino acid substitutions".

16. A reference to frameshift mutations in general is thus explicitly made only in the context of mutations useful to prove that a cDNA is the BRCA1 locus, whereas the paragraph describing the diagnostic and prognostic method of the invention only mentions those frameshift mutations that are the result of point mutations. However, the Board takes the position that a skilled person reading said passages of the application as filed would understand that the most severe forms of disruptive mutations, such as frameshift mutations, would also be among the preferred mutations to be tested for in diagnostic and prognostic methods, even if this is not explicitly mentioned. Making a distinction between mutations to be used when looking for proof that a cDNA is the BRCA1 locus and mutations that should be looked for in diagnostic and prognostic methods would not make any sense to the skilled person reading the above cited passages, and would therefore not reflect his/her understanding of the teaching of the application as filed. Therefore, the Board considers that the above cited passages of the description implicitly disclose that frameshift mutations in general are among those mutations to be determined in the diagnostic and prognostic methods according to the invention.

This is further supported by the disclosure of page 44, line 56 to page 46, line 37 of the application as filed (published version), which is part of Example 8 and relates to "Germline BRCA1 mutations in 17q-linked kindreds". Table 11 on page 46 shows that two frameshift mutations were identified as predisposing mutations, one resulting from an extra C and one resulting from an 11 bp deletion. Lines 21 and 22 of the same page state that the "frameshift and nonsense mutations are likely disruptive to the function of the BRCA1 product". The Board is convinced that a skilled person would understand from this disclosure that the identification of these specific mutations is not only a strong indication that the BRCA1 gene has indeed been found, but that the detection of any of these specific mutations in an individual would be indicative for a predisposition to breast and ovarian cancer.

17. Page 12, line 1 of the application as filed (published version) refers to the "sequence of the BRCA1 open reading frame shown in SEQ ID NO: 1", and page 42, lines 10 to 11 of the application as filed (published version) states that "[c]onceptual translation of the cDNA revealed a single long open reading frame of 208 kilodaltons (amino acid sequence: SEQ ID NO: 2)". In view of these statements, the Board furthermore considers that the skilled person, taking into account his/her common general knowledge (see point ...7 above), would directly and unambiguously derive from the application as filed that frameshift mutations in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide would alter the open reading frame as disclosed in the application as filed, i.e. the open reading frame for SEQ ID NO: 2.

18. The Respondents have argued that added subject-matter had been created by selecting frameshift mutations as one particular type of mutations out of a number of disclosed types of mutations. By limiting the claims to frameshift mutations, the Appellant had first made a selection from mutations in the coding and non-coding region, and after selecting mutations in the coding region, the Appellant had selected from deletion, insertion and point mutations. Within the group of deletion and insertion mutations, only those mutations that result in a frameshift had then been selected. This arbitrary selection of a specific type of mutation had not been suggested in the application as filed.
19. The Board does not agree with this argument. As outlined in detail in points (15) and (16) above, frameshift mutations have been disclosed in the application as filed as one relevant type of mutation, and the limitation to this particular type of mutation does thus not result in subject-matter which extends beyond the application as filed.
20. The Board also cannot follow the Respondents' argument that the limitation of the claims to frameshift mutations was the result of an unallowable intermediate generalization between the disclosure of any kind of mutation and the disclosure of only two specific frameshift mutations in Table 11, because page 9, lines 21 to 22 of the application as filed (published version) makes explicit reference to frameshift mutations in general, as discussed in points (15) and (16) above.
21. Consequently, the Board finds that claim 1 fulfils the requirements of Article 123(2) EPC.

22. Accordingly, the subject-matter of claim 2 can be derived from claim 2 of the application as filed in combination with the passage on page 9, lines 10 to 33 of the published version of the application as filed. Claim 3 is considered to be based on claim 3 of the application as filed, and claims 4 and 5 are considered to be based on claims 22 and 24 as filed, respectively. Claims 6 and 7 relate to methods which comprise determining the mutation 5385insC, which is disclosed on page 46 in Table 11 of the application as filed. Consequently, claims 2 to 7 also comply with Article 123(2) EPC.

Extension of scope (Article 123(3) EPC)

23. Claims 1 and 2 of the main request relate to diagnostic methods which comprise determining whether there is a frameshift mutation in the sequence of the BRCA1 gene, whereas claims 1 and 2 as granted relate to diagnostic methods which comprise determining whether there is any kind of alteration in the sequence of the BRCA1 gene. The scope of protection has thus been restricted with regard to the claims as granted.

24. The Respondents have argued that there was an extension of scope of protection, contrary to Article 123(3) EPC, because the claims as granted only related to mutations in the coding region, whereas the claims now under consideration also related to mutations outside the coding region.

25. The Board cannot follow this line of argumentation since both in the claims as granted and in the present claims, the mutation is "in the sequence of the BRCA1

gene coding for a BRCA1 polypeptide". Thus, there can be no extension of scope of protection.

26. Consequently, the requirements of Article 123(3) EPC are fulfilled.

Priority right (Article 87 EPC 1973 and Articles 88 and 89 EPC 1973)

27. Document D2 is a scientific publication dated 7 October 1994, thus published between the filing dates of the third priority document P3 (US 308104; 16 September 1994) and the fourth priority document P4 (US 348824; 29 November 1994) of the patent in suit. It is undisputed that the disclosure in this document, if it belonged to the state of the art under Article 54(2) EPC, would be highly relevant for the issues of novelty (Article 54 EPC) and/or inventive step (Article 56 EPC) of the claimed subject-matter.

Document D2 would not belong to the state of the art under Article 54(2) EPC if the claims were entitled to claim priority from the third priority document P3 (*supra*), or from second priority document P2 (US 300266; 2 September 1994).

28. The right to priority is governed by Article 87 EPC 1973, which requires that the European patent (application) and the application whose priority is claimed relate to the same invention. Article 88(3) EPC further specifies that, if one or more priorities are claimed in respect of a European patent application, the right of priority shall cover only those elements

of the application which are included in the respective priority application(s).

29. According to the Opinion G 2/98 of the Enlarged Board of Appeal (OJ EPO 2001, 413), the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC 1973, means that the priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.
30. The second priority document P2 discloses methods for diagnosing a predisposition to breast and ovarian cancer in a human subject which comprise determining in a tissue sample of said subject whether there is a germline alteration in the BRCA1 gene, said alteration being indicative of a predisposition to said cancer (see page 1, lines 13 to 14, page 8, lines 12 to 13, page 16, lines 24 to 27, and claim 18). The second priority document P2 further contains on page 15, line 11, to page 16, line 7, a passage which correspond to that of page 9, lines 10 to 33 of the published version of the application as filed (discussed in the context of Article 123(2) EPC in points ...15 and 16 above), including the statement that the most severe forms of mutations causing obvious disruption to the normal function of the gene product are frameshift mutations or large deletions. Furthermore, the second priority document P2 refers to "the sequence of the BRCA1 open reading frame shown in SEQ ID NO: 1" (page 20, line 29) and states that "[c]onceptual

translation of the cDNA revealed a single long open reading frame of 208 kilodaltons (amino acid sequence: SEQ ID NO: 2)" (page 71, lines 18 to 19). The wording of claim 1 of the main request is thus directly and unambiguously derivable from the second priority document P2.

31. However, the nucleotide sequence of the cDNA coding for BRCA1 as disclosed in SEQ ID NO: 1 of the second priority document P2 deviates from the corresponding sequence disclosed in SEQ ID NO: 1 of the patent in suit by 15 nucleotide residues. These deviations in the BRCA1 coding sequence are listed in Table 1 submitted by the Appellant in his letter dated 25 June 2006 (see pages 3 and 5). Nine of these deviations lead to an amino acid change in the amino acid sequence of SEQ ID NO: 2, while six are "silent deviations" which do not result in amino acid changes. Thus, the 1863 amino acid long sequence of the BRCA1 protein shown in SEQ ID NO: 2 of the second priority document P2 deviates from the corresponding sequence disclosed in SEQ ID NO: 2 of the patent in suit in 9 amino acid positions. None of the 15 nucleotide changes is an insertion or a deletion or results in a stop codon.

The earliest priority document disclosing the nucleotide sequence coding for BRCA1 and the amino acid sequence of the encoded protein, which are identical to SEQ ID NOs: 1 and 2 disclosed in the patent in suit and in the application as filed, is the fifth priority document P5 (US 409305; 24 March 1995).

32. It has been argued by the Respondents that because of the above mentioned differences in the nucleotide and

amino acid sequences between the second priority document P2 and the patent in suit, only the fifth priority could be accorded to the claims of the main request.

33. In one line of argument, the Respondents submitted that the second priority date was not validly claimed because different results would be obtained with the claimed method depending on whether the nucleotide and amino acid sequences disclosed in the second priority document P2 or in the patent in suit were used as reference sequences.

33.1 According to the Respondents, one reason for such differing results was that the second priority document P2 contained insufficient information with respect to the sequences of the introns at the intron/exon boundaries of the BRCA1 gene. This was apparent from SEQ ID NO: 13 of the second priority document P2, in which little "v"s flanking for instance the sequences of exons 12 and 21 represented missing sequences. In the absence of a disclosure of the correct sequences of the intron/exon boundaries in the second priority document P2, a skilled person trying to design primers suitable to amplify the BRCA1 exon sequences concerned would have to select primers based on the exon sequences. When then trying to detect frameshift mutations in a patient's tissue sample, the skilled person would miss frameshift mutations arising from insertions or deletions in those parts of the exon nucleotide sequence that were used to design the primers. These frameshift mutations which would be missed when using the sequence information disclosed in the second priority document P2 would however be

detected when using the sequence information disclosed in the patent in suit or in the fifth priority document P5, which allowed the design of primers annealing to the intron sequences. Consequently, there would be differing results.

33.2 The Board acknowledges that the disclosure of the second priority document P2 with respect to the intron sequences of the BRCA1 gene is less complete than that of the patent in suit. However, the second priority document P2 on page 19, lines 16 to 18, in the context of testing for mutations, explicitly refers to the possibility of "sequencing messenger RNA after amplification, e.g. by PCR, thereby eliminating the necessity of determining the exon structure of the candidate gene". In view of this statement, the Board considers that the skilled person, being aware of missing intron sequence information for some of the intron/exon boundaries from SEQ ID NO: 13 of the second priority document P2, would have been able to rely on mRNA sequence information in order to identify also those frameshift mutations that could otherwise be potentially missed. It is important to note that only mutations occurring in the exons, and thus in the mRNA, would alter the open reading frame. For the reasons given above, the Board is not convinced that the missing sequence information for introns in the second priority document P2 would produce wrong results.

33.3 As a second reason why different results would be obtained by the claimed method depending on whether the nucleotide and amino acid sequences disclosed in the second priority document P2 or in the patent in suit were used as reference sequences, the Respondents

submitted that due to the large size of exon 11, one would have to design primers also in the middle of this exon in order to amplify it and determine whether it contains frameshift mutations. As the sequence of this exon as disclosed in the second priority document P2 contained a number of sequencing errors, the selection of primers from the areas which include these sequencing errors would result in a poor hybridization of the primers to the target. This would have the consequence that frameshift mutations occurring in these areas of exon 11 would not be identified when using the sequence information disclosed in the second priority document P2, but would only be identified when using the "correct" sequence information disclosed in the patent in suit and in the fifth priority document.

33.4 With respect to this line of argument, the Board can follow the Appellant's submission that when trying to identify mutations in the (yet unknown) sequence of a patient using primers, the skilled person would select experimental conditions under which the primers would anneal to the target sequence even if there was a single nucleotide difference between the primer and the target. It would not make sense to anneal the primers under highly stringent conditions because one would not know which sequence the patient's allele would have. The deviations in the sequences of the second priority document P2 when compared to the patent would therefore not affect the amplification and thus also not the identification of frameshift mutations.

33.5 In view of the above, the Board concludes that based on the evidence on file, the same results would be obtained by a skilled person performing the method of

claim 1 when using the sequence information of the second priority document P2 or when using the sequence information of the patent in suit.

34. The Respondents have also argued that because of the lack of sequence information for some of the introns of the BRCA1 gene, the second priority document P2 lacked enablement for methods of diagnosis using genomic DNA.
35. In this respect, the Board considers that since the knowledge of the intron sequences of the BRCA1 gene is not required to carry out the claimed invention (see point ...33.2 above), the lack of disclosure of certain intron sequences in the second priority document P2 has no bearing on the question whether or not the claimed subject-matter enjoys the second priority document P2.
36. In a further line of argument, the Respondents submitted that the claimed subject-matter did not enjoy the second priority date because by referring to SEQ ID NO: 2 of the patent in suit as a reference sequence, this sequence was a technical feature of the claim, which feature was however not directly and unambiguously derivable from the second priority document P2 in view of the sequence differences when compared to the patent in suit.
37. The Board cannot follow this line of argument. The invention claimed in claim 1 is a diagnostic method which comprises determining whether there is a germline alteration that is a frameshift mutation in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide altering the open reading frame for SEQ ID NO: 2. Frameshift mutations are commonly known to

"arise by deletions or insertions that are not a multiple of 3 bp; they change the frame in which triplets are translated into protein" (see point ...7 above). The "frame in which triplets are translated into protein", which may also be referred to as the reading frame, is however not changed by the deviations between SEQ ID NOs: 1 and 2 of the second priority document P2 and of the patent in suit, because none of the nucleotide changes is an insertion or a deletion.

In order to determine in the claimed method whether there is a frameshift mutation, it is not required to determine any kind of difference between the patient's nucleotide or amino acid sequence and a reference sequence. It is only required to determine whether there is a mutation which shifts the reference reading frame which is defined in the claim as the "open reading frame for SEQ ID NO: 2". This reference reading frame is the same in the second priority document P2, in the fifth priority document P5 and in the patent in suit.

Any mutation that qualifies as a frameshift mutation to be detected with the method of claim 1 when using the sequence information of the second priority document P2 would also qualify as a frameshift mutation to be detected with the method of claim 1 when using the sequence information of the fifth priority document P5 and of the patent in suit, and *vice versa*. The group of mutations to be detected with the method of claim 1 is thus exactly the same, irrespective of whether the sequence information disclosed in the second priority document P2, the fifth priority document P5 or the patent in suit is used as reference.

38. Therefore, the Board is convinced that the invention of claim 1 is directly and unambiguously derivable from the second priority document P2 and enjoys the second priority date.

39. With respect to the question of priority rights, the situation in the present case, as discussed above, differs from the one dealt with in decision T 1213/05 (supra) in the context of auxiliary request II then before that Board, which concerned product claims, and the amino acid sequence of SEQ ID NO: 2 as such was a technical feature of **the invention** (see points 19 to 34 of said decision).

In the present case, **the invention** is a diagnostic method in which the information conveyed by SEQ ID NO: 2 is a reference for the determination of frameshift mutations. In this respect there is no difference between the second priority document P2, the fifth priority document P5 and the patent in suit, for the reasons given above.

40. The Respondents have submitted that according to the decision T 81/87 (OJ EPO 1990, 250), there is no priority right if any essential element of the invention is missing, and have argued that in the present case, the correct nucleotide and amino acid sequences of BRCA1 represented such essential elements which were missing in the second priority document P2.

However, the Board is convinced that in the present case, no essential element of the claimed invention is missing in the second priority document P2, since the

sequence deviations between the second priority document P2 and the fifth priority document P5 and the patent in suit do not affect the determination of frameshift mutations according to the method of claim 1, as explained in detail in point (37) above.

41. In view of page 1, lines 14 to 18, page 8, lines 8 to 13, and claim 45 of the second priority document P2, the reasons given above as to why the subject-matter of claim 1 enjoys the second priority date apply analogously also for the subject-matter of claim 2. Additionally, the subject-matter of claims 3 to 5 is disclosed on page 16, lines 7 to 8 and page 20, lines 12 to 13, and claims 32 and 34 of the second priority document P2. Claims 6 and 7 relate to the determination of the specific alteration 5385insC, which is disclosed on page 76, lines 22 to 25 and Table 11 of the second priority document P2 as mutation 5329insC. The different numbers used for this mutation stem from the fact that SEQ ID NO: 1 of the patent in suit contains 56 additional, 5' non-coding nucleotides when compared to SEQ ID NO: 1 of the second priority document P2; the mutation itself is the same.
42. The Board concludes that the subject-matter of claims 1 to 7 of the main request enjoys the second priority date and that, consequently, document D2 does not constitute prior art under Article 54(2) EPC.

*Referral of questions to the Enlarged Board of Appeal
(Article 112(1)(a) EPC)*

43. Respondents I to IV requested to refer the following questions to the Enlarged Board of Appeal according to Article 112(1)(a) EPC:

"(1) With respect to errors in priority documents, does G 2/98 allow a difference in the assessment of relevance of errors between method claims and product claims?

(2) In a method claim should a technical feature such as a reference component (e.g. a probe or a DNA or AA sequence) be treated differently as far as errors are concerned than the same reference component when claimed as a product?

(3) Does the situation in (2) depend on whether the reference component is used directly or implicitly as a physical entity (e.g. a probe) or as a chemical formula (e.g. a DNA or AA sequence)?"

44. Article 112(1)(a) EPC stipulates that the Board of Appeal, following a request from a party to the appeal, shall refer any question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law, or if an important point of law arises.

45. The questions as formulated by Respondents I to IV rely on the hypothesis that the "**reference component (e.g. a probe or a DNA or AA sequence)**" is a technical feature of the methods according to claims 1 to 7. Based on

this assumption it is asked whether a claim to a method using the reference component should be treated differently than a claim to the reference component per se, when it has to be decided if the claim is entitled to claim priority from a priority document, which compared to the application as filed contains deviations in the sequence of the reference product.

However, as discussed in points ..(36) to (39) above, the methods according to claims 1 to 7 rely only on that part of the information conveyed by SEQ ID NO: 2 which is necessary as a reference point for the determination of frameshift mutations, and this part of the information does not differ between the second priority document P2, the fifth priority document P5 and the patent in suit.

In order to determine in the claimed method whether there is a frameshift mutation, it is not required to determine any kind of difference between the patient's nucleotide or amino acid sequence and a reference sequence. It is only required to determine whether there is a mutation which shifts the reference reading frame which is defined in the claim as the "open reading frame for SEQ ID NO: 2". This reference reading frame is the same in the second priority document P2, in the fifth priority document P5 and in the patent in suit.

Thus, Respondent's I to IV questions, starting from the assumption that the "**reference component (e.g. a probe or a DNA or AA sequence)**" is a technical feature of the methods according to claims 1 to 7, are based on hypothetical considerations. Such questions are not

suitable for a referral (cf decision T 118/89 of 19 September 1990).

46. The Enlarged Board of Appeal in its Opinion G 2/98 (supra) has already decided that a narrow and strict interpretation of the concept of "the same invention" is to be applied, equating it with the concept of "the same subject-matter" referred to in Article 87(4) EPC. The Enlarged Board of Appeal in its Opinion did not provide any basis for the assumption that this narrow interpretation should be applied differently when the claim concerned is directed to a method or to a product.
47. No referral based on questions already decided by the EBA can be permitted (cf decision T 82/93, OJ EPO 1996, 274).

In view of the above, Respondent I to IV's request for referral of questions to the Enlarged Board of Appeal is refused.

Novelty (Article 54 EPC)

48. As a consequence of the above decision on right to priority, documents D1, D2, D3 and D4, which are the only documents the Respondents relied on in the written procedure when objecting to the novelty of the claimed subject-matter, do not belong to the state of the art under Article 54(2) EPC.
49. At the oral proceedings the Respondents did not further substantiate their arguments on this issue.

As the Board also has no objections in this respect the subject-matter of claims 1 to 7 is considered to be novel and to meet the requirements of Article 54 EPC.

Inventive step (Article 56 EPC)

50. It has been argued by the Respondents that, based on the teaching in document D16, the cloning of BRCA1 and its identification as the disease-causing gene could be achieved, and would have been achieved within a limited time period by one of the researchers in the field, who were to be regarded as the skilled person.

The problem, namely the further identification of BRCA1 for use in diagnostic methods, could then be solved either by combination of Document D16 with common general knowledge or with any of documents D77, D78, D80 or D81.

This Board in a different composition in decision T 1213/05 (*supra*) has already comprehensively dealt with the question whether, based on the disclosure in document D16 (which in decision T 1213/05 was document D11), the cloning of BRCA1 and its identification as the disease carrying gene involved an inventive step (see points (74) to (84) of decision T 1213/05). The Board arrived at the decision that, considering the uncertainties of the project, a person skilled in the art at the second priority date would not have reasonably expected to successfully arrive at the cloning of the BRCA1 gene within acceptable time limits merely by way of routine experimentation. The Board was convinced that achieving this goal was a major breakthrough which was not obvious to the skilled

person (point (80) of the reasons of decision T 1213/05).

51. The present Board has no reason to deviate from this decision. The Respondents' argument, which is based on the assumption that in the light of the disclosure in document D16 cloning of the BRCA1 gene did not involve an inventive step, is not convincing.

Neither a combination of document D16 with common general knowledge, nor with any of the documents D77, referring to a genomic library with PAC clones, D78, disclosing marker D17S1141 and corresponding to document D128 in the case underlying decision T 1213/05 (supra) or D80 and D81, both referring to BAC libraries and their use as an alternative to YACs, would lead the skilled person to the solution of the posed problem according to claims 1 to 7 in an obvious way.

52. The subject-matter of claims 1 to 7 involves therefore an inventive step and meets the requirements of Article 56 EPC.

Sufficiency of disclosure (Article 83 EPC)

53. The Respondents objected that the patent did not disclose the invention, namely a diagnostic method for determining a predisposition for breast and ovarian cancer, in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

They argued that screening a patient for only one kind of mutation, such as frameshift mutations, when other types of mutations are likely to be equally detrimental

to the functioning of the gene, did not provide a reliable diagnostic method. As there was no disclosure that frameshift mutations at all or any specific frameshift mutations, provided any particular type of linkage to breast and ovarian cancer it was irrelevant to the patient whether or not she had a frameshift mutation.

54. The patent discloses in paragraph [0059] that frameshift mutations are among the most severe mutations because they cause the gene to code for an abnormal protein and therefore lead to a loss of function. This teaching is in line with the common general knowledge of a person skilled in the art. As it is not disputed that at the date of the second priority document P2 it was known that the BRCA1 polypeptide played a decisive protective role in the genesis of breast and ovarian cancer, the Board is convinced that the detection of a mutation leading to a loss of function of this polypeptide does form a useful basis for a diagnostic test for determining a patient's predisposition to said cancer.

55. The fact that frameshift mutations in the BRCA1 gene might not be the only mutations responsible for a patient's predisposition for breast and ovarian cancer, cannot be considered as proving that the subject-matter of claims 1 to 7 does not disclose the claimed invention in an enabling way. The possible existence of further diagnostic methods based on the determination of mutations different from frameshift mutations cannot have an influence on the answer to the question whether the patent in suit discloses the invention, namely a diagnostic method for determining a predisposition for

breast and ovarian cancer, in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

56. The requirements of Article 83 EPC are therefore met. *Patentable inventions (Articles 52(2)(a) and (c) and 53(c) EPC and Rule 29(1) EPC)*

57. In the notice of opposition, dated 10 October 2001, Respondent IV argued that the methods of the patent in suit 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 having this mutation has a predisposition for the disease. Therefore, the claims referred to subject-matter which was not patentable according to Article 52(2)(a) and (c) EPC.

Moreover it is argued that the requirements of Rule 23(e)(1) EPC 1973 (Rule 29(1) EPC) should be interpreted broadly and that the claims also violate the requirements of this Rule.

58. The methods of the patent in suit are performed on a tissue sample of a human subject and relate to a specific gene, namely the BRCA1 gene. The diagnostic methods make use of the knowledge of the open reading frame coding for the BRCA1 polypeptide, and identify frameshift mutations in the patient's sample.

In order to get the knowledge required to carry out the claimed diagnostic methods, it was necessary to isolate the gene of interest from the human body.

59. According to the case law of the Boards of Appeal (see decision T 272/95 of 23 October 2002), Article 52(2)(a) EPC is to be interpreted in accordance with the implementing Rule 23e(2) EPC 1973 (Rule 29(2) EPC) which states that an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention.

This finding applies to claims relating to products, here genes, and is a fortiori applicable to the method claims here at issue.

Accordingly, the subject-matter of claims 1 to 7 does not fall within the category of inventions which may not be patentable as being discoveries (Article 52(2)(a) EPC).

60. The diagnostic methods of the claims refer to the determination in a sample of a human subject whether there is a frameshift mutation. These features are considered as requiring working steps of technical nature which belong to the preceding steps which are constitutive for making a diagnosis as an intellectual exercise (see points (61) to (61) below).

Accordingly, the subject-matter of claims 1 to 7 does not fall within the category of inventions which may not be patentable as being methods performing mental acts (Article 52(2)(c) EPC).

61. Furthermore, Respondent IV argued that "a method for diagnosing a predisposition for breast and ovarian

cancer in a human subject" should not be regarded as a patentable invention according to Article 53(c) EPC.

62. Article 53(c) EPC (Article 52(4) EPC 1973) states that methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods **practised on the human or animal body** shall not be regarded as inventions which are susceptible of industrial application.

The Enlarged Board of Appeal in its Opinion G 1/04 (OJ 2006, 334) said that Article 52(4) EPC 1973 excludes diagnostic methods practised on the human or animal body only if the method steps of technical nature belonging to the preceding steps which are constitutive for making a diagnosis as an intellectual exercise are performed on a living human or animal body (see point (6) of the reasons).

63. According to present claims 1 to 7, all method steps of technical nature are performed on a tissue sample of a human subject. Respondent IV's argument therefore fails. The claims do not refer to subject-matter not patentable according to Article 53(c) EPC.

Exceptions to patentability (Article 53(a))

64. Respondent IV argued that the subject-matter of the claims contravened the requirements of Article 53(a) EPC. If the patent was granted, patients would no longer be able to have their genetic information read and interpreted by the organisation of their choice and it could not be guaranteed that criminal and medical gene databases were kept strictly separate, which was

an accepted ethical principle in the member states of the EPO.

65. This Board, in a different composition, already in decision T 1213/05 (supra) has dealt with the socio-economic and ethical consequences of the patenting of diagnostic methods involving the use of human genetic material.

The Board in the present composition follows decision T 1213/05 (supra, see especially points (52) and (53)) and, on this basis, rejects Respondent IV's objection under Article 53(a) EPC.

Industrial applicability (Article 57 EPC)

66. Respondents I to IV have objected that the claimed invention should not be considered as being industrially applicable contrary to the requirements of Article 57 EPC.

While Respondent IV argued that the claims referred to a diagnostic method which was not susceptible of industrial application as it fell within the subject-matter excluded from patentability by Article 52(4) EPC 1973 (see points (61) to (63) above), Respondents I to III argued that the patent contained no teaching which of the many possible mutations of the BRCA1 gene were in fact related to a patient's predisposition to breast and ovarian cancer. The claimed diagnostic methods therefore encompassed a large number of embodiments which did not solve any technical problem which resulted in the fact that the claimed invention was not industrially applicable as required by Article 57 EPC.

67. The diagnostic methods according to claims 1 to 7 are based on the determination of frameshift mutations altering the open reading frame for SEQ ID NO: 2. As already mentioned in points (53) to (55) above, referring to the requirements of sufficient disclosure (Article 83 EPC), the patent discloses in paragraph [0059] that frameshift mutations are among the most severe mutations because they cause the gene to code for an abnormal protein and therefore lead to a loss of function.

It is not disputed that, already, at the date of the second priority document P2 it was known that the BRCA1 polypeptide played a decisive protective role in the genesis of breast and ovarian cancer. Any mutation leading to a loss of function of this polypeptide has therefore to be considered to be indicative for a patient's predisposition to said cancer. A method aiming at the detection of such mutations is therefore considered to be a useful diagnostic test and thus industrially applicable.

68. The Board is not convinced by either of the Respondents' arguments. The requirements of Article 57 EPC are therefore met.

69. The description has been correctly adapted to the subject-matter of claims 1 to 7.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in the following version:

Description: Amended pages 3, 3a, 3b, 4 to 24 and 126 of the patent specification as granted, submitted at the oral proceedings on 19 November 2008; pages 25 to 125 of the patent specification as granted.

Claims: 1 to 7 of the main request, submitted at the oral proceedings on 19 November 2008.

Figures: 1 to 10 on pages 132 to 150 of the patent specification as granted.

The Registrar:

The Chair:

P. Cremona

U. Kinkeldey