EXHIBIT G

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Europäisches Patentamt	European Patent Office	Office européen des brevets
Beschwerdekammern	Boards of Appeal	Chambres de recours

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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
K2708OPP(EP)S3	95305601.7 - 2405 / 0705902

Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire
The University of Utah Research Foundation, et al

Appeal number: **T 1213 / 05 - 3304**

Please find enclosed a copy of the decision dated 27-09-2007.

PROC DISP

The Registrar - P. Cremona
Tel.: 089 / 2399 - 3341

Annex(es):
Registered letter with advice of delivery

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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
SP4/04 OPPO 01	95305601.7 - 2405 / 0705902
Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire	
The University of Utah Research Foundation, et al	

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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
GREENPEACEDE+AT OPPO 02	95305601.7 - 2405 / 0705902
Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire	
The University of Utah Research Foundation, et al	

Appeal number: **T 1213 / 05 - 3304**

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European Patent Office
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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
E18565 OPPO 03 (04 and 05)	95305601.7 - 2405 / 0705902

Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire
The University of Utah Research Foundation, et al

Appeal number: **T 1213 / 05 - 3304**

Please find enclosed a copy of the decision dated 27-09-2007.

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The Registrar - P. Cremona
Tel.: 089 / 2399 - 3341

Annex(es):
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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
K1874-EP OPPO 06	95305601.7 - 2405 / 0705902
Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire	
The University of Utah Research Foundation, et al	

Appeal number: **T 1213 / 05 - 3304**

Please find enclosed a copy of the decision dated 27-09-2007.

PROC DISP

The Registrar - P. Cremona
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Beschwerdekammern | Boards of Appeal | Chambres de recours

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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./ Brevet n°.
OPPO 07	95305601.7 - 2405 / 0705902

Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire
The University of Utah Research Foundation, et al

Appeal number: **T 1213 / 05 - 3304**

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Datum/Date
12. 12. 07

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./ Brevet n°.
BZ720EP OPPO 08	95305601.7 - 2405 / 0705902
Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire	
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Appeal number: **T 1213 / 05 - 3304**

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PROC DISP

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1213/05 - 3.3.04

DECISION
of the Technical Board of Appeal 3.3.04
of 27 September 2007

Appellant I: (Patent Proprietor)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 19 September 2005 concerning maintenance of European patent No. 0705902 in amended form.**

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
D. Rogers
B. Claes
G. Weiss

Summary of Facts and Submissions

I. Appeals were lodged by the Patent Proprietor (Appellant I) and Opponent 01 (Appellant II) against the interlocutory decision of the Opposition Division dated 19 September 2005 according to which European patent No. 0 705 902 could be maintained in amended form on the basis of claims 1 to 3 of the auxiliary request before it (Articles 102(3) and 106(3) EPC). The patent has the title "17q-Linked breast and ovarian cancer susceptibility gene" 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. Eight oppositions had been filed against the patent covering the grounds of Article 100(a) EPC in combination with Articles 52(2) and (4), 53(a), 54, 56 and 57 EPC, and Article 100(b) and (c) EPC.

III. The Opposition Division decided that the main request before it did not meet the requirements of Articles 123(2) and (3) and 84 EPC.

IV. The Board expressed its preliminary opinion in a communication dated 27 February 2007.

V. With letter dated 8 June 2007, the Board was informed that Opponent 7 had passed away.

VI. Oral proceedings before the Board took place from 24 to 27 September 2007.

Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of a main request (claims 1 - 29 filed with a letter dated 30 January 2006), or auxiliary request I (claims 1 - 14 filed with a letter dated 30 January 2006), or auxiliary request II (claims 1 - 32 filed on 25 September 2007 at the Oral Proceedings), or to dismiss the appeal of Appellant II (which corresponds to upholding the claims held allowable by the Opposition Division - hereafter referred to as "auxiliary request III"). Further, Appellant I requested to refer three questions to the Enlarged Board of Appeal.

Appellant II requested that the decision under appeal be set aside, that the patent in suit be revoked and to refer five questions to the Enlarged Board of Appeal.

Opponents 2 to 5, parties as of right, requested that the decision under appeal be set aside and that the patent be revoked.

Opponents 6 and 8, parties as of right, requested that the appeal of Appellant I be dismissed.

VII. Claim 1 of the main request read as follows:

"An isolated nucleic acid which comprises a coding sequence for the human BRCA1 polypeptide, wherein said polypeptide

- has 1863 amino acids,
- has a molecular weight of 208 kilodaltons, and
- comprises the amino acid sequence of SEQ ID NO: 82,

said coding sequence being comprised in a genomic DNA which is obtainable by:

(a) providing a human genomic library;
(b) screening the genomic library using a probe selected from the group consisting of:
(i) the following DNA sequence:

AG GAA AGT TCT GCT GTT TTT AGC AAA AGC GTC CAG
AAA GGA GAG CTT AGC AGG AGT CCT AGC CCT TTC ACC
CAT ACA CAT TTG GCT CAG GGT TAC CGA AGA GGG GCC
AAG AAA TTA GAG TCC TCA GAA GAG AAC TTA TCT AGT
GAG GAT GAA GAG CTT CCC TGC TTC CAA CAC TTG TTA
TTT GGT AAA GTA AAC AAT ATA CCT TCT CAG TCT ACT
AGG CAT AGC ACC GTT GCT ACC GAG TGT CTG TCT AAG
AAC ACA GAG GAG AAT TTA TTA TCA TTG AAG AAT AGC
TTA AAT GAC TCG A

and
(ii) the DNA sequence of any one of SEQ ID NOs: 35, 38, 41, 42, 47, 57, 62, 67, 72 and 81
and
(c) producing a genomic DNA comprising said coding sequence;

wherein said genomic DNA comprising said coding sequence is more than 100 kb in length;
and wherein the first exon within said genomic DNA immediately follows the nucleotide sequence corresponding to SEQ ID 35; or

said coding sequence being comprised in a cDNA which is obtainable by:
(aa) providing a cDNA library using human mRNA from

breast, thymus, testis or ovary;

(bb) screening the cDNA library using a probe having the following DNA sequence:

AG GAA AGT TCT GCT GTT TTT AGC AAA AGC GTC CAG
AAA GGA GAG CTT AGC AGG AGT CCT AGC CCT TTC ACC
CAT ACA CAT TTG GCT CAG GGT TAC CGA AGA GGG GCC
AAG AAA TTA GAG TCC TCA GAA GAG AAC TTA TCT AGT
GAG GAT GAA GAG CTT CCC TGC TTC CAA CAC TTG TTA
TTT GGT AAA GTA AAC AAT ATA CCT TCT CAG TCT ACT
AGG CAT AGC ACC GTT GCT ACC GAG TGT CTG TCT AAG
AAC ACA GAG GAG AAT TTA TTA TCA TTG AAG AAT AGC
TTA AAT GAC TCG A

and

(cc) producing a cDNA comprising said coding sequence;

wherein said coding sequence comprises the following nucleotides sequence:

AG GAA AGT TCT GCT GTT TTT AGC AAA AGC GTC CAG
AAA GGA GAG CTT AGC AGG AGT CCT AGC CCT TTC ACC
CAT ACA CAT TTG GCT CAG GGT TAC CGA AGA GGG GCC
AAG AAA TTA GAG TCC TCA GAA GAG AAC TTA TCT AGT
GAG GAT GAA GAG CTT CCC TGC TTC CAA CAC TTG TTA
TTT GGT AAA GTA AAC AAT ATA CCT TCT CAG TCT ACT
AGG CAT AGC ACC GTT GCT ACC GAG TGT CTG TCT AAG
AAC ACA GAG GAG AAT TTA TTA TCA TTG AAG AAT AGC
TTA AAT GAC TCG A

and

wherein upon hybridization of a Northern blot with a fragment of said cDNA a single transcript of 7.8 kb is identified in breast, thymus, testis and ovary tissue."

VIII. Claim 2 of auxiliary request I read as follows:

"A hybridization probe wherein the sequence of said probe comprises a portion of a coding sequence for a mutant BRCA1 polypeptide, which is

(i) a DNA sequence comprising the nucleotide sequence set forth in SEQ ID NO: 1 from nucleotide 120 to nucleotide 5708 or an allelic variant thereof having one of the following mutations defined with reference to SEQ ID NO: 1:
(a) T substituted for C at position 4056;
(b) an extra C at nucleotide position 5385; and
(c) G substituted for T at position 5443; or

(ii) a corresponding RNA,
said coding sequence portion including a mutation compared to the nucleotide sequence set forth in SEQ ID NO: 1 from nucleotide 120 to nucleotide 5708 as defined in any of (a) to (c),

with the proviso that said coding sequence portion does not comprise positions 1364, 1369, 1454, 1492, 1494, 1571, 1581, 2201, 2430, 2731, 3499, 4060, 4535, 4689 and 5609 of SEQ ID NO: 1."

IX. Claims 1 and 2 of auxiliary request II, which are identical to claims 1 and 2 as granted, read as follows:

"1. An isolated nucleic acid which comprises a coding sequence for the BRCA1 polypeptide defined by the amino acid sequence set forth in SEQ ID NO:2, or an amino acid sequence with at least 95% identity to the amino acid sequence of SEQ ID NO:2.

2. An isolated nucleic acid as claimed in claim 1 which is a DNA comprising the nucleotide sequence set forth in SEQ ID NO:1 from nucleotide 120 to nucleotide 5708 or a corresponding RNA."

X. The three claims of auxiliary request III read as follows:

"1. A nucleic acid probe wherein the nucleotide sequence of said probe comprises the following DNA sequence:

AG GAA AGT TCT GCT GTT TTT AGC AAA AGC GTC CAG
AAA GGA GAG CTT AGC AGG AGT CCT AGC CCT TTC ACC
CAT ACA CAT TTG GCT CAG GGT TAC CGA AGA GGG GCC
AAG AAA TTA GAG TCC TCA GAA GAG AAC TTA TCT AGT
GAG GAT GAA GAG CTT CCC TGC TTC CAA CAC TTG TTA
TTT GGT AAA GTA AAC AAT ATA CCT TCT CAG TCT ACT
AGG CAT AGC ACC GTT GCT ACC GAG TGT CTG TCT AAG
AAC ACA GAG GAG AAT TTA TTA TCA TTG AAG AAT AGC
TTA AAT GAC TCG A

or a DNA probe comprising a nucleotide sequence selected from the group consisting of SEQ ID NOs: 35, 38, 41, 42, 47, 57, 62, 66, 67, 72 and 81."

"2. A replicative cloning vector which comprises (a) an isolated DNA according to claim 1 and (b) a replicon operative in a host cell for said vector."

"3. Host cells in vitro transformed with a vector as claimed in claim 2."

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

D1: Miki et al., Science (Oct. 1994) 266: 66-71

D3: Friedman et al., Nature Genetics (Dec. 1994) 8: 399-404

D4: Castilla et al., Nature Genetics (Dec. 1994) 8: 387-391

D10: Kelsell et al., Hum. Mol. Genet. (1993) 2: 1823-1828

D11: Albertsen et al., Nature Genetics (Aug. 1994) 7: 472-479

D17: Simard et al., Nature Genetics (Dec. 1994) 8: 392-398

D22: Smith et al., Genes Chrom. Cancer (1994) 10: 71-76

D31: Clone Genbank Accession L18209 information

D52: Goldgar et al., Am. J. Hum. Genet. (1993) 52: 743-748

D88: Simard et al., Hum. Mol. Genet. (1993) 2: 1193-1199

D112: Feunton et al., Am. J. Hum. Genet. (1993) 52: 736-742

D120: Declaration Dr Shattuck

D122: Cropp et al., Cancer Res. (1994) 54: 2548-2551

D125: Positional Cloning of BRCA1

D128: Amplimer UM44_

D129: Couch et al., Genomics (1994) 24: 419-424

D136: Declaration Dr Matthijs

D154: Davies, K. and White, M.; Breakthrough - The race to find the Breast Cancer Gene, 1995, Ed. John Wiley & Sons, Inc., New York

D159: Personal Communication Couch

D160: Amplimer UM44_ History

D164: Documentation on "Human Genome Sequence Quality Standards", http://www.genome.gov/pfv.cfm?pageID=10000923

D165: Schmutz et al., Nature (2004) 429: 346-368

D166: Bermuda Standards, http://www.gene.ucl.ac.uk/hugo/bermuda2.htm

D172: Declaration Dr Critchfield

D173: Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, OJ EPO 2/1999, 101

D174: Judgment of the Court of Justice of the European Communities dated 9 October 2001; Case C-377/98

D175: Opinion of Advocate General Jacobs delivered on 14 June 2001, Case C-377/98

XII. The submissions by Appellant I, insofar as they are relevant to the present decision, can be summarized as follows:

Main request

Amendments (Article 123(2) EPC)

The subject-matter of claim 1 was directly and unambiguously derivable from the application as filed. The skilled person reading the application would realize that the probes specified in claim 1 could be used for the screening of genomic or cDNA libraries. In fact any part of the BRCA1 sequence would be useful for this purpose. Using the product-by-process format did not change the nature of the invention, as the product was still the same as in the application as filed. In view of the major technical contribution of the invention, allowing a product-by-process definition would be a fair solution in order to provide the entitlement to the second priority (P2).

Auxiliary request I

Amendments (Article 123(2) EPC)

The disclaimers in claims 2, 3, 6, 8, 12 and 13 were allowable under Article 123(2) EPC since they merely served to restore the second priority. The disclaimers had been drafted on the basis of a comparison between the second priority document and the European application, not on the basis of the prior art.
The list of situations in which disclaimers were held allowable in decisions G 1/03 and G 2/03 (OJ EPO 2004, 413) was not exhaustive, and was therefore not in contradiction to allowing the present disclaimers under Article 123(2) EPC. Furthermore, the disclaimers did not provide a technical contribution, since none of the sequence positions disclaimed were involved in causing breast cancer.

Auxiliary request II

The filing of a new request the claims of which were almost identical to the claims as granted had to be allowed even at a late stage of the proceedings.

As priority document (P2) disclosed the same invention as defined in the claims of auxiliary request II, the claims were entitled to claim priority from priority document (P2). Although priority document (P2) referred to SEQ ID NOs: 1 and 2 which deviated from SEQ ID NO's: 1 and 2 disclosed in the application as filed, it disclosed in an enabling form the same diagnostic target as defined in claim 1 of auxiliary request II.

If a parameter which was used to define a substance in a claim was known to vary within margins of experimental errors, the occurrence of variation in such a parameter between a priority document and the corresponding later application did not necessarily abrogate entitlement to the claimed priority.

For further detailed submissions see "Reasons for the Decision" (points (19) and following).

Auxiliary request III

Articles 123(2)(3), 84, 52(2), 53(a), 57, 83 and 87 to 89 EPC

The amendments complied with Article 123(2) and (3) EPC, and the claims were clear under Article 84 EPC.

The objections raised by Opponents under Article 52(2) and Article 53(a) EPC lacked substantiation and should be rejected by the Board.

The probes according to claim 1 could be used as diagnostic tools which had to be considered as being an industrial application in the sense of Article 57 and Rule 23e(3) EPC.

The claimed subject-matter was disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person (Article 83 EPC).

The claimed subject-matter was furthermore directly and unambiguously derivable from the second priority document (Articles 87 to 89 EPC).

Novelty (Article 54 EPC)

Document D11 was not prejudicial to the novelty of the probe of claim 1. Firstly, it had not been sufficiently proven by document D136 that the first sequence mentioned in claim 1 was indeed present in YAC clone 22HE5, as correctly pointed out in the decision of the Opposition Division. Secondly, document D11 only disclosed a library of clones which could not destroy the novelty of the probe specified in claim 1.

Inventive step (Article 56 EPC)

In view of the uncertainties with respect to the chromosomal localisation of the BRCA1 gene at the second priority date, it was problematic to select a closest prior art document. The technical problem to be solved was the provision of probes for the BRCA1 gene to detect breast cancer. The positional cloning of the BRCA1 gene was very complex and involved many uncertainties, and there could not have been a reasonable expectation of success. During the cloning procedure, the inventors had to take a multitude of decisions many of which had the potential of leading to ultimate failure. Picking the right breast and ovarian cancer families (kindreds) was one of the crucial points that led to success. The solution to the technical problem as provided by the claimed subject-matter was thus not obvious over the prior art.

XIII. The submissions by Appellant II and by the parties as of right, Opponents 2 to 8, insofar as they are relevant to the present decision, can be summarized as follows:

Main request

Amendments (Article 123(2) EPC)

The product-by-process definition in claim 1 was not acceptable under Article 123(2) EPC, and the combination of features mentioned in claim 1 was not disclosed in the application as filed.

Auxiliary request I

Amendments (Article 123(2) EPC)

The disclaimers in claims 2, 3, 6, 8, 12 and 13 did not comply with Article 123(2) EPC since they provided a technical contribution to the claimed subject-matter. Furthermore, the reasons for which Appellant I attempted to restore the second priority by use of said undisclosed disclaimers were to overcome a non-accidental disclosure and/or an inventive step objection. This was not acceptable in view of decisions G 1/03 and G 2/03.

Auxiliary request II

The request, submitted at the oral proceedings before the Board, should not be admitted into the proceedings as being late filed. Should the Board admit the request the case had to be remitted to the department of first instance.

The claims of auxiliary request II could only enjoy priority right from priority document (P5), being the earliest of the eight priority documents disclosing SEQ

ID NO's: 1 and 2 corresponding exactly to SEQ ID NO's: 1 and 2 as disclosed in the application as filed.

Auxiliary request III

Amendments (Articles 123(2)(3) and 84 EPC)

Claim 1 did not comply with Article 123(2) EPC since the legend to Figure 7 on page 4, lines 30 to 32 of the application (published version), which referred to "a probe consisting of nucleotide positions 3631 to 3930 of BRCA1", did not indicate that the positions of the numbering of SEQ ID NO: 1 were meant.

Patentable inventions (Article 52(2)(a) EPC)

The claimed subject-matter was not patentable under Article 52(2)(a) EPC since the sequences of the probes according to claim 1 occurred in nature and were thus a discovery rather than an invention.

Exceptions to patentability (Article 53(a) EPC)

No proof had been provided by Appellant I showing that previous informed consent to the commercial exploitation of the invention by patents had been given by the donors of the cells critical for the invention, and that a benefit sharing agreement had been made. Therefore, the claimed invention was unethical and excluded from patentability in view of Article 53(a) EPC. Furthermore, the consequences of the patenting of the claimed invention had to be taken into account when examining the patentability under Article 53(a) EPC.

For further detailed submissions see "Reasons for the Decision" (points (46) and following).

Industrial applicability (Article 57 EPC)

The nucleotide probes according to claim 1 were useful for research purposes only which could not be considered as being an industrial application in the sense required by Article 57 and Rule 23e(3) EPC.

Sufficiency of disclosure (Article 83 EPC)

Since the patent did not disclose a technical application of the claimed subject-matter it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person as required by Article 83 EPC.

Right to priority (Articles 87 to 89 EPC)

The subject-matter of claim 1 was not entitled to the second priority date, since there was no indication on page 6, lines 24 to 28 of the second priority document that by referring to "a probe consisting of nucleotide positions 3575 to 3874 of BRCA1", the positions of the numbering of SEQ ID NO: 1 were meant.

Novelty (Article 54 EPC)

The YAC clone 22HE5 mentioned in Figure 2 of document D11 was prejudicial to the novelty of claim 1. Evidence for this was provided in document D136. Claim 1 encompassed any nucleic acid probe comprising the mentioned sequence, and thus lacked novelty over any

isolated and individualized section of DNA comprising this sequence, such as YAC clone 22HE5.

Inventive step (Article 56 EPC)

The closest prior art was represented by document D11, and the technical problem to be solved was the identification and isolation of the BRCA1 gene.

Starting from document D11, 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 D11 in combination with common general knowledge, or, alternatively, from document D11 in combination with either document D128 or document D31.

The inventors had carried out the necessary experimentation faster than others merely because they had been able to put more money and manpower into the project, 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.

Reasons for the Decision

1. The appeals are admissible.

Main request

Amendments (Article 123(2) EPC)

2. Claim 1 is directed to a nucleic acid which comprises a coding sequence for the human BRCA1 polypeptide, whereby the claimed product is defined by features of the polypeptide as well as by features of a process of genomic DNA and cDNA library screening (product-by-process).

3. 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.

4. The Board considers that in the case of a product-by-process definition, the process defined in a claim also has to be directly and unambiguously derivable from the application as filed in order for the claim to comply with Article 123(2) EPC. This has not been contested by Appellant I.

4.1 As concerns the process steps of screening a genomic or cDNA library, page 14, lines 13 to 15 of the application (published version) of the patent in suit

states that "cDNA or genomic libraries of various types may be screened as natural sources of the nucleic acids of the present invention", and lines 17 to 18 mention that clones are "probed for the presence of desired sequences". Further, it is stated in lines 19 to 20 that the "DNA sequences used in this invention will usually comprise at least about five codons (15 nucleotides), more usually at least about 7-15 codons, and most preferably, at least about 35 codons".

4.2 On page 19 of the application as published, under the heading "Methods of Use: Nucleic Acid Diagnosis and Diagnostic Kits" it is stated that "in order to detect the presence of a BRCA1 allele predisposing an individual to cancer, a biological sample such as blood is prepared and analyzed for the presence or absence of susceptibility alleles of BRCA1" (lines 3 to 4). Further on the same page, PCR-based methods of target amplification and of detection of target sequences using nucleic acid probes are described. In lines 55 to 56 of the same page it is then stated that "[e]xamplary probes are provided in Table 9 of this patent application and additionally include the nucleic acid probe corresponding to nucleotide positions 3631 to 3930 of SEQ ID NO:1". The latter probe ("Northern probe") was also used for RNA hybridization (see page 4, lines 30 to 34 and Figure 7) and its sequence is the one stated in points (b)(i) and (bb) of claim 1. The probes in Table 9 represent intron borders and include the probes of SEQ ID NOs: 35, 38, 41, 42, 47, 57, 62, 67, 72 and 81 referred to in point (b)(ii) of claim 1. However, there is no disclosure on page 19 of the application as published of using these probes in the screening of genomic or cDNA libraries.

4.3 Claim 13 of the application as published is directed to a "nucleic acid probe suitable for a use as claimed in claim 11", wherein the nucleotide sequence of said probe may comprise the DNA sequence of the "Northern probe" or a sequence set forth in Table 9. As claim 11 is directed to an isolated DNA, not to a use, claim 13 should apparently refer to claim 12, the latter being directed to a "[u]se of an isolated nucleic acid (...) as a hybridization probe **to detect in a sample** (i) a DNA (...)" (emphasis added by the Board). Again, there is no suggestion of using the specified probes in the screening of genomic or cDNA libraries.

4.4 Appellant I has argued that it did not matter technically for which purpose the probes were disclosed, as any probe could be taken for the screening of a genomic or cDNA library. However, the Board considers that it is the actual teaching of the application as filed which is relevant, and that, therefore, the general disclosure of screening a genomic or cDNA library with a probe defined as comprising "at least about five codons" (see page 14, lines 13 to 20) cannot be combined with the more specific disclosure of using the "Northern probe" or a probe as set forth in Table 9 for **a different purpose**, namely the detection of DNA in a sample (page 19 and claim 13), without contravening Article 123(2) EPC.

4.5 Appellant I has further referred to Exhibits 1 to 20 as filed during the first instance proceedings with letter of 19 November 2004 as showing support for claim 1 of the main request in the application as filed. Exhibits 7, 8 and 15 relating to the steps of library screening as mentioned in points (b) and (bb) of claim 1

suggested that because the Northern blot probe sequence and the intron border DNA sequences fall into the definition given on page 14, lines 19 to 20 of the application as published (see point 4.1 above), this would provide a direct and unambiguous disclosure of these probes for screening a genomic or cDNA library. The Board cannot follow this reasoning since the specific probes mentioned in claim 1, steps (b) and (bb), have not been disclosed for use in screening a genomic or cDNA library.

5. The Board concludes that in claim 1, step (b), the screening of the genomic library using any one of the probes specified in points (i) and (ii), and step (bb), the screening of a cDNA library using a probe having the specified DNA sequence, are not directly and unambiguously derivable from the application as filed.

6. Consequently, the subject-matter of claim 1 of the main request does not comply with Article 123(2) EPC.

Auxiliary request I

Amendments (Article 123(2) EPC)

7. Claim 2 of auxiliary request I contains the disclaimer "with the proviso that said coding sequence portion does not comprise positions 1364, 1369, 1454, 1492, 1494, 1571, 1581, 2201, 2430, 2731, 3499, 4060, 4535, 4689 and 5609 of SEQ ID NO: 1". Claims 3, 6, 8, 12 and 13 contain similar disclaimers. Said disclaimers cannot be found in the application as filed.

8. Appellant I has submitted that the nucleotide and amino acid sequences disclosed in SEQ ID NOs: 1 and 2 of the second priority document have turned out to contain sequencing errors, and that the correct sequences as stated in the patent in suit are only disclosed in the fifth priority document (see grounds of appeal dated 30 January 2006, point 6.1.2.3). The disclaimers exclude those positions within SEQ ID NO: 1 by which this nucleotide sequence differs between the second priority document and the application as filed. The disclaimers have been incorporated into the claims in order to safeguard the second priority (see grounds of appeal, point 6.2.2.3).

9. Decisions G 1/03 and G 2/03 (OJ EPO 2004, 413) of the Enlarged Board of Appeal (EBA) provide criteria for allowing under Article 123(2) EPC a disclaimer which is not disclosed in the application as filed. According to these decisions, a disclaimer may be allowable in order to restore novelty by delimiting a claim against the state of the art under Article 54(3) and (4) EPC and against an accidental anticipation under Article 54(2) EPC, but not against a non-accidental anticipation under Article 54(2) EPC; an anticipation is said to be accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention. A disclaimer which is or becomes relevant for the assessment of inventive step or sufficiency of disclosure adds subject-matter contrary to Article 123(2) EPC.

10. Appellant I has submitted that the sole reason for introducing the disclaimers was to validly claim the

second priority, not to establish novelty and inventive step. The Board cannot follow this argumentation, since the issue of the right to priority cannot be seen in isolation from the effect it has on novelty and inventive step by virtue of Article 89 EPC, according to which the date of priority shall count as the date of filing of the European patent application for the purpose of Article 54(2) EPC. There is no provision in the EPC, that in order to obtain a patent, a priority has to be validly claimed. Therefore, the actual reason why Appellant I aims at claiming the second priority by the introduction of disclaimers has to be seen in prior art published between the second and fifth priority date, notably document D1. It is undisputed that document D1 is not an accidental disclosure and would become highly relevant for the evaluation of novelty and/or inventive step of the claimed subject-matter (see point (35) below). Hence, the Board considers that the disclaimers are in fact necessary to either restore novelty over a non-accidental disclosure or to establish an inventive step. These are, however, the areas excluded from the allowability under Article 123(2) EPC by the decisions of the EBA.

11. Consequently, the subject-matter of the claims of auxiliary request I does not comply with Article 123(2) EPC.

Auxiliary request II

Admission into the proceedings

12. Claims 1 and 2 of auxiliary request II are identical to claims 1 and 2 as granted (see section (IX) above).

13. Auxiliary request II, which was not before the Opposition Division, was filed by Appellant I on the second day of the oral proceedings. Appellant II and Opponents 2 to 6 and 8 objected to its late introduction into the proceedings. Furthermore, in the case the Board should allow auxiliary request II into the proceedings, they requested that the case be remitted to the department of first instance for further consideration according to Article 111(1) EPC.

14. According to the case law of the Boards of Appeal, a Patent Proprietor during opposition and opposition/appeal proceedings is entitled to amend a request already made; in particular he can reinstate the patent in the form in which it was granted, provided this does not constitute an abuse of the procedure. In requesting that the patent be maintained in a limited form the Patent Proprietor merely tries to delimit the patent to meet objections expressed by the EPO or the opponents. However, the Patent Proprietor does not, by virtue of such limitation, irrevocably abandon subject-matter covered by the patent as granted but not by the request as thus limited (cf decision T 123/85, OJ EPO 1989, 336).

15. Appellant I has filed auxiliary request II at the oral proceedings, after having been informed by the Board that the claims of his main request and of auxiliary request I contravened the requirements of Article 123(2) EPC. Reinstatement of the patent in a form which almost precisely corresponds to the form in which it was granted is considered to be a straightforward response

to the course of the oral proceedings and does not amount to an abuse of the procedure.

16. In general, to expedite the proceedings, parties to appeal proceedings are supposed to submit all facts, evidence and requests at the outset, or - if this is not possible - as soon as they can. They should not be filed piecemeal, this principle being enshrined in Articles 10a and 10b of the Rules of Procedure of the Boards of Appeal.

17. According to Article 114(2) EPC the European Patent Office may disregard facts or evidence which are not submitted in due time by the parties concerned. Thus, the Board may exercise its discretion when deciding on whether to admit late submissions.

The decision to admit a new request into the proceedings should take into account, amongst other factors, a general interest in the appeal proceedings being conducted in an effective manner while still being brought to a close within a reasonable time (cf decision T 633/97 of 19 July 2000, point (2) of the reasons for the decision).

The Board takes the view that the new auxiliary request II filed by Appellant I in response to the decisions announced by the Chair in the oral proceedings under Article 123(2) EPC with regard to his main request and auxiliary request I, whereby this auxiliary request II almost entirely corresponds to the claims as granted, does not raise additional technical or legal issues that neither the Board nor the other parties could have been expected to deal with. In fact, the question

whether or not the claims of auxiliary request II are entitled to a certain priority date, which is the core issue to be decided in the light of the disclosure in document D1 published between the third and fourth claimed priority dates of the patent in suit (see points (19) to (34) below), was known to the parties to be of outstanding importance during the opposition procedure and had already been extensively discussed by all parties involved in the context of the main request.

Therefore, in order to conduct the appeal proceedings in an effective and fair manner, the Board exercised its discretion and admitted Appellant I's auxiliary request II into the proceedings.

18. Remittal to the department of first instance lies within the discretion of the Board (cf decision T 249/93 of 27 May 1998, point (2) of the reasons for the decision). It is acknowledged that there is no absolute right for a party to have every aspect of a case examined in two instances (see for example decision T 133/87 of 23 June 1988). Other criteria, e.g. the general interest that proceedings are brought to a close within an appropriate period of time, have also to be taken into account.

Taking into consideration that the parties already had the opportunity to argue the issue of priority right (Articles 87 to 89 EPC) of the subject-matter of the claims of the patent as granted in the opposition procedure, the Board, using its discretion, decided not to remit the case to the department of first instance.

Priority right (Articles 87 to 89 EPC)

19. Document D1 is a scientific publication dated 7 October 1994, thus published between the filing date 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. Document D1 is authored by a group of 45 persons, among them the 10 inventors of the patent. 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 subject-matter of Appellant I's auxiliary request II.

Document D1 would not belong to the state of the art under Article 54(2) EPC, if the claims of auxiliary request II were entitled to claim priority from US 308104 (P3), the third priority document.

The third priority document (P3) discloses on pages 94 to 98 SEQ ID NO: 1 showing the nucleotide sequence coding for BRCA1 and on pages 98 to 103 SEQ ID NO: 2 showing the amino acid sequence of the protein. SEQ ID NOs: 1 and 2 are identically disclosed on pages 90 to 94 and 94 to 99 of the second priority document (P2), US 300266; 2 September 1994. Therefore, when comparing the disclosure in the application as originally filed underlying the patent in suit, with the disclosure in the documents from which priority is claimed, the Board will refer to the second priority document (P2), which is the earliest priority document from which these sequences can be derived.

20. The BRCA1 coding sequence disclosed in SEQ ID NO: 1 of priority document (P2) deviates from the BRCA1 coding sequence disclosed in the application as filed by 15 nucleotide residues. Nine of these deviations lead to an amino acid exchange in SEQ ID NO: 2 while six are so-called "silent deviations". The earliest priority document disclosing the nucleotide sequence coding for BRCA1 and the amino acid sequence of the protein which are exactly identical to SEQ ID NOs: 1 and 2 disclosed on pages 58 to 67 and pages 67 to 73 of the application as filed is the fifth priority document (P5) (see pages 114 to 123 and 123 to 129 of US 409305; 24 March 1995).

21. The EBA in the Opinion G 2/98 (OJ EPO 2001, 413) came to the conclusion that the requirement for claiming priority in respect of "the same invention", referred to in Article 87(1) EPC, means that 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.

When examining whether a narrow or strict interpretation of the concept of "the same invention" referred to in Article 87(1) EPC should be applied, the EBA considered that a narrow and strict interpretation of the concept of "the same invention", equating it with the concept of "the same subject-matter" referred to in Article 87(4) EPC, was entirely consistent with Articles 4F and 4H of the Paris Convention (points (2) to (5) of the reasons for the Opinion). This followed

from the very aim and object of the right of priority: the protection from novelty destroying disclosures during a period of twelve months from the date of filing of the first application is satisfied only in case of the filing of a subsequent application relating to the same invention.

In point (8.3) of the reasons the EBA considered an issue that had been raised in decision T 73/88 (OJ EPO 1992, 557), which, in order to assess whether a claim in a later European patent application was in respect of the same invention as the priority application pursuant to Article 87(1) EPC, made a distinction between technical features which are related to the function and effect of the invention and technical features which are not. This approach was said to be problematic because there are no suitable and clear, objective criteria for making such a distinction; it could thus give rise to arbitrariness. Different deciding bodies might thus arrive at different results when assessing these facts and circumstances. Furthermore, as pointed out in the referral of the President of the EPO underlying the Opinion, it had to be borne in mind that the assessment by these different deciding bodies of whether or not certain technical features were related to the function and effect of the claimed invention might completely change in the course of proceedings. This was the case, in particular, if new prior art was to be considered, with the possible consequence that the validity of a hitherto acknowledged right of priority could be put in jeopardy. Such dependence would, however, be at variance with the requirement of legal certainty.

Finally in point (9) of the reasons the EBA stated:

"... an extensive or broad interpretation of the concept of "the same invention" referred to in Article 87(1) EPC, making a distinction between technical features which are related to the function and effect of the invention and technical features which are not, with the possible consequence that a claimed invention is considered to remain the same even though a feature is modified or deleted, or a further feature is added (cf point 8.3 supra), is inappropriate and prejudicial to a proper exercise of priority rights. Rather, according to that analysis, a narrow or strict interpretation of the concept of "the same invention", equating it to the concept of "the same subject-matter" referred to in Article 87(4) EPC (cf point (2) supra), is necessary to ensure a proper exercise of priority rights ...".

22. In application of the Opinion G 2/98 (supra) of the EBA, the Boards of Appeal, in a number of decisions, have defined the concept of "the same invention" in the field of biotechnology and especially in connection with inventions referring to nucleotide sequences.

Decision T 351/01 of 2 July 2003 was concerned with a patent referring to a polynucleotide encoding a biologically active tissue factor protein (TFP). The polynucleotide was defined in claim 1 by a reference to Figure 2. The figure showed a polynucleotide comprising the coding sequence for TFP, which was about 900 nucleotides long (and the deduced TFP amino acid sequence) and in addition non-coding portions at both ends of the coding region.

The patent claimed priority from priority documents I and II which disclosed a polynucleotide having the same function, namely coding for TFP, but whose structure differed from that of the polynucleotide of claim 1 by five bases all found outside of the coding region. The Board concluded, that, in the light of the EBA's Opinion G 2/98 (supra), the Respondents' (Patent Proprietor's) arguments to the avail that the claimed invention was the TFP coding sequence which was the same in all the documents and that the differences observed in the non-coding portion were irrelevant, were not convincing. Claim 1 was directed to a polynucleotide as defined in Figure 2, i.e. to a polynucleotide which had the sequence from the first to the last nucleotide depicted in the figure. This sequence like the one reported in Figure 2 of the first and second priority documents encoded a TFP. However, it was structurally different. Thus, it could not be seen as the same subject-matter. For this reason, it was decided that claim 1 did not enjoy priority rights from the filing dates of either of priority documents I or II.

23. Decisions T 70/05 of 7 February 2006 and T 30/02 of 9 October 2006 both were concerned with the entitlement of a prior art document to the claimed priority date.

In decision T 70/05 (supra) the amino acid sequence of a death-domain-containing receptor disclosed in the priority document and in the application as filed differed at nine of 181 positions. In accordance with the "narrow or strict interpretation" laid down in Opinion G 2/98 (supra) the Board decided that claim 1

referring to the receptor defined by specific full-length sequence ("amino acid residues 1 to 181 of SEQ ID NO: 1") could not enjoy the claimed priority right. In point (20) of the reasons for the decision the Board stated:

"It is also the board's opinion that, based on a disclosure of a "wrong" nucleotide or amino acid sequence in the priority document - independently of the reasons for the possible mistakes, either arising from unintended sequencing or typing errors or else arising from a conscious choice to file an application at a very early stage and thus, comprising doubtful or incomplete data - it would not be fair to acquire a right over a broad area from which, only later on, the "correct" sequence might be selected and disclosed in a patent application. The possible advantages conferred by such a practice would only encourage and, in the long term, lead to a mischievous use of priority rights."

24. In decision T 30/02 a novelty attack was based on prior art document D16, which was only comprised in the state of the art if it enjoyed priority from document D15. Document D16 disclosed a recombinant DNA sequence encoding a xylanase characterised by a partial nucleotide sequence (SEQ ID NO: 13) which differed from SEQ ID NO: 7 of claim 1 of the patent in suit only in so far as it included two additional guanine residues at its 3' end. A DNA molecule comprising the sequence defined in SEQ ID NO. 13 of document D16 could be expected to hybridize to a DNA molecule comprising the sequence of SEQ ID NO: 7, thus rendered the patent in suit not novel.