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Datasheet for the decision of 7 September 2010

Case Number: T 0902/07 - 3.3.04

Application Number: 96939218.2

Publication Number: 0858467

IPC: C07K 14/82

Language of the proceedings: EN

Title of invention:
Materials and methods relating to the identification and sequencing of the BRCA2 cancer susceptibility gene and uses thereof

Patentees:
Cancer Research Technology Limited, et al

Opponent:
Myriad Genetics, Inc.

Headword:
BRCA2/CANCER RESEARCH TECHNOLOGY

Relevant legal provisions:
EPC Art. 54, 87, 88, 89
RPBA Art. 15

Relevant legal provisions (EPC 1973):
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Keyword:
"Main request, auxiliary requests 1-5, priority - (no), novelty (no)"
"Change of date of oral proceedings - (yes)"

Decisions cited:
G 0002/98, T 0073/88, T 0923/92, T 1213/05, T 0699/06

Catchword:
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Case Number: T 0902/07 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 7 September 2010

Appellants I: (Patent Proprietors)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 3 April 2007 concerning maintenance of European patent No. 0858467 in amended form.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: M. Wieser
R. Gramaglia

Summary of Facts and Submissions

I. Appeals were lodged by the Patent Proprietors (Appellants I) and by the Opponent (Appellant II) against the interlocutory decision of the Opposition Division according to which the European patent No. 858 467 could be maintained in amended form (Article 102(3) EPC 1973). The patent claims priority from GB 9523959; 23 November 1995 (P1), GB 9525555; 14 December 1995 (P2) and GB 9617961; 28 August 1996 (P3).

II. The Opposition Division decided that the subject-matter of claim 15 of the main request before it did not involve an inventive step contrary to the requirements of Article 56 EPC. However, it decided that the claims of the first auxiliary request met all requirements of the EPC.

In arriving at this decision the Opposition Division took several decisions concerning the entitlement of the claims to claim priority from the first or second priority document of the patent. These decisions were necessary as a number of relevant prior art documents has been published after the second but before the third priority document. The Opposition Division decided that priority for claims referring to the full length BRCA2 sequence could validly be claimed from the first and second priority documents.

III. Appellants I requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with their letter dated 21 December 2007 (being identical to the main request

before the Opposition Division). As first auxiliary request they requested that the appeal of Appellant II be dismissed (Appellants I's first auxiliary request filed with their letter dated 21 December 2007 being identical to the auxiliary request maintained by the Opposition Division). Moreover, they requested that the decision under appeal be set aside and the patent be maintained on the basis of the second to fifth auxiliary requests all filed with their letter dated 21 December 2007.

Appellant II requested that the decision under appeal be set aside and the patent be revoked.

Oral proceedings were requested by both parties should the Board not allow their requests.

IV. Claim 2 of Appellants I's main request read as follows:

"2. An isolated nucleic acid molecule consisting of the full length coding sequence or complete BRCA2 gene as obtainable by:

(a) using the nucleic acid sequences shown in figures 1,2 or 4 to construct probes for screening cDNA or genomic libraries, sequencing the positive clones obtained, and repeating this process to assemble the full length BRCA2 sequence from the sequences thus obtained;
(b) using the sequences shown in figures 1,2 or 4 to obtain oligonucleotides for priming BRCA2 nucleic acid fragments, these oligonucleotides being used in conjunction with oligonucleotides designed to prime from a cloning vector, to amplify by PCR nucleic acid

fragments in a library that contains fragments of the BRCA2 sequence, sequencing the amplified fragments to obtain the BRCA2 sequence between known parts of the sequence and the cloning vector, and repeating this process to assemble the full length BRCA2 sequence from the sequences thus obtained; and/or,
(c) using rapid amplification of cDNA ends (RACE), by synthesizing cDNAs from a number of different RNAs, the cDNAs being ligated to an oligonucleotide linker, and amplifying by PCR the BRCA2 cDNAs using one primer that primes from the BRCA2 cDNA sequence of figures 1 or 4 and a second primer that primes from the oligonucleotide linker, sequencing the amplified nucleic acid and repeating this process to assemble the full length BRCA2 sequence from the sequences thus obtained."

The identical claim is contained in each of Appellants I's auxiliary requests (claim 2 in the first and second auxiliary requests, claim 1 in the third, fourth and fifth auxiliary requests).

V. The Board expressed its preliminary opinion in a communication dated 15 January 2010 which was annexed to the summons to oral proceedings.

VI. In a letter dated 2 February 2010 Appellant II's representative requested the Board to postpone the oral proceedings appointed for 4 May 2010. The reason given for making the request was that the representative had a pre-arranged business trip to attend and speak at an international convention from 1 to 8 May 2010.

The Board, in a communication dated 11 February 2010, noted that a request for postponement in the given circumstances amounted to a request to meet the convenience of one person (Appellant II's representative) at the expense of many others. As changing the date for oral proceedings might only be allowed "exceptionally" (Article 15(2) RPBA) under specific circumstances described in the Notice at the OJ EPO, 1/2008, Supplement, pages 61 to 62, Appellant II's request should be refused.

However, as the Board also noted that Appellants I's representative was reported by Appellant II's representative to "prefer a date for oral proceedings not being 4 May 2010", the oral proceedings were re-appointed for 27 April 2010.

VII. In a further letter dated 12 February 2010 Appellant II's representative again requested the Board to postpone the oral proceedings as he and at least two other biotech partners from his firm would be abroad from 16 to 27 April 2010 as part of a delegation of the firm with serious business commitments of importance for the firms business relations in the Asian market.

The Board noted in a further communication dated 1 March 2010 that this request as such should be refused for the same reasons as already indicated in the communication of 11 February 2010. However, its Registrar had established, by direct contact with Appellants I's representative, that, although himself available on 27 April 2010, he would prefer postponement to a later date. Accordingly the Board for a second time

reappointed oral proceedings which were finally held on 7 September 2010.

VIII. The following documents are referred to in this decision:

(1) GenBank entry U43746

(8) Nature Genetics, vol.12, March 1996, pages 333 to 337

(9) EP-A-0 785 216

(10) US 08/639,501

(P1) GB 9523959

(P2) GB 9525555

(P3) GB 9617961

IX. The submissions made by Appellants I, as far as they are relevant to the present decision, may be summarised as follows:

Claims referring to the full length BRCA2 sequence were entitled to claim priority from the first and second priority documents. The essence of the claimed invention was the identification of the BRCA2 gene by partial sequencing as disclosed in the first and second priority documents. Sequencing of the remaining part of the gene was a matter of routine work for a person skilled in the art.

X. The submissions made by Appellant II, as far as they are relevant to the present decision, may be summarised as follows:
A request for postponement of oral proceedings for business reasons cannot automatically be regarded as being of "work pressure nature". In specific cases a business trip had to be regarded as a serious reason for postponement of oral proceedings. Moreover, in cases interrelating with other important cases of the same client substitution of a representative who has dealt with the case for many years by another representative would be unacceptable to the client.

Claims relating to the full length BRCA2 sequence were not entitled to claim priority from any of the three priority documents. The first and second priority documents contained partial sequences of the BRCA2 gene only and did not therefore disclose the same invention as the patent which showed the complete BRCA2 coding sequence in figure 7.

Reasons for the Decision

Change of date of oral proceedings

1. This Board in a different composition has comprehensibly dealt with the issue of changing the date of oral proceedings in a recent decision (see decision T 699/06 of 29 June 2006). The argument of Appellant II for a postponement of oral proceedings were of a similar nature to those advanced, and not accepted by the Board, in that earlier decision the reasons of which apply here. The only difference is

that, in the present case, the representative of Appellants I was also in favour of a postponement (see T 699/06, point (16)).

Priority right (Articles 87 to 89 EPC)

2. Documents (1) and (8) are scientific publications dated 19 January 1996 and 12 March 1996, respectively. Document (9) is a European patent application published on 23 July 1997 claiming inter alia priority from US 08/639,501 (document (10)), filed on 29 April 1996.

Thus, the publication dates of documents (1) and (8) and the priority date of document (9) lie between the filing dates of the second priority document (P2) and the third priority document (P3) of the patent in suit.

It is undisputed that the disclosure in documents (1), (8) and (9), if it belonged to the state of the art under Article 54(2) or 54(3) EPC, would be detrimental to the novelty of the subject-matter of claim 2 of the main request (and all identically formulated claims in Appellants I's auxiliary requests).

Documents (1), (8) and (9) would not belong to the state of the art under Articles 54(2) and (54(3) EPC, if the claims were entitled to claim priority from (P1) or (P2), the first and second priority documents.

3. The complete BRCA2 coding sequence is not depicted in any of the three priority documents, but only in the application as filed (figure 7). It encodes 3418 amino acids.

(P1) and (P2), respectively, contain partial BRCA2 sequences while (P3) does not contain any coding sequence at all. The partial sequence of (P1) as depicted in figures 1 to 3 (corresponding to figures 1 to 3 of the patent) encodes 544 amino acids (about 16% of the complete sequence). The partial sequence of (P2) shown in figures 4 and 5 (corresponding to figures 4 and 5 of the patent) encodes 2329 amino acids (about 68% of the complete sequence).

4. The Enlarged Board of Appeal (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 giving rise to 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 ...".

5. In application of the Opinion G 2/98 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.

A summary of this case law of the Boards of Appeal is given in decision T 1213/05 of 27 September 2007 of this Board in a different composition (see points (22) to (25)).

6. Appellants I have argued that this case law of the Boards of Appeal did not apply in the present case since, contrary to the technical situation underlying those decisions, the claimed nucleotide sequence was not defined by sequence information but by a process for obtaining it. The essence of the present invention

was to be seen in the identification of the BRCA2 gene, whose identity had been confirmed by partial sequencing as disclosed in priority documents (P1) and (P2). Starting from this disclosure sequencing the rest of the gene (about 32% of the entire gene sequence not disclosed in document (P2)) was a matter of routine work that could have been done by a person skilled in the art without undue burden.

7. In fact the Appellants I seek to distinguish between technical features which are related to the function and effect of the invention (and which according to Appellants I are disclosed in (P1) and (P2)) and technical features which are not. This is exactly the approach which the EBA found to be inappropriate and prejudicial to a proper exercise of priority rights (point (9) of G 2/98).

Documents (P1) and (P2) disclose partial sequences of the BRCA2 gene only. They do not refer to "the same invention", in the sense of "the same subject-matter" referred to in Article 87(4) EPC, as the patent, which discloses in figure 7 the complete BRCA2 coding sequence (see Opinion of the EBA G 2/98, points (2) to (5)).

8. Yet further, the Board notes that claim 2 of Appellants I's main request is not directed to a method for identifying a gene, which according to Appellants I is the essence of the invention, but to "an isolated nucleic acid molecule consisting of the full length coding sequence or complete BRCA2 gene".

9. Appellants I referred to decision T 932/92 (OJ EPO 1996, 564) wherein, as they argued, it was decided that a claim to a DNA isolate defined by a process for its production was entitled to claim priority from a priority document containing sequencing errors.

10. In that earlier decision the Board decided that a claim referring to a process comprising the preparation of a protein which was defined by its function and by an amino acid sequence 1 to 527 as depicted in Figure 5, did not enjoy priority from the first and second priority documents which contained a Figure 5 that differed from Figure 5 of the patent in suit in respect of three amino acid positions 175, 178 and 191. It enjoyed priority only from the third priority document which disclosed the correct sequence (see points (3) to (17) of T 923/92).

However, in point (46), the Board decided that claim 1 of subsidiary request 3 was entitled to claim priority from the first priority document. This claim was formulated such that it referred to a DNA isolate obtainable by probing a cDNA library with one or more of three defined hybridisation probes, isolating strongly hybridising clones and using them to produce a DNA sequence having a restriction pattern shown in figure 4 "for the putative mature tissue plasminogen activator sequence" encoding a polypeptide of 527 amino acids. The claim defined the N-terminal and C-terminal amino acid of the protein and specified the human t-Pa activator function.

11. The first priority document disclosed the used starting material and hybridisation probes and it contained

figure 4 in identical form as the patent. The nucleotides corresponding to amino acid residues 30 to 67, which were responsible for binding of the hybridisation probes, were identical in figure 5 of (P1) and of the patent. Figure 5 of the first priority document and of the patent disclosed a polypeptide of 527 amino acids whose N-terminal and C-terminal amino acid were identical.

12. The claim which was found to be entitled to claim priority from the first priority document in decision T 923/92 was formulated differently than claim 2 of the main request in the present case, which is directed to "an isolated nucleic acid molecule consisting of the full length coding sequence or complete BRCA2 gene". Also the disclosure in the priority documents in that case was different than in the present case. Therefore, the passages of decision T 923/92 relied on by Appellants I do not apply in the present case.

13. The issue of entitlement to priority has been dealt with in the Opinion of the EBA G 2/98, five years after the publication of decision T 923/92. The case law of the Boards of Appeal with regard to the entitlement to priority of a claim referring to a nucleic acid sequence is uniform and definite. The arguments presented by Appellants I, therefore, have not persuaded the Board that there is anything in the present case which could justify a deviation from this case law. Accordingly, the Board arrives at the decision that the subject-matter of claim 2 of Appellants I's main request is not entitled to claim priority from (P1) or (P2).

The same applies to claim 2 of the first and second auxiliary requests and claim 1 of the third, fourth and fifth auxiliary requests.

Novelty - Article 54 EPC

14. As a consequence of the above decision on the right to priority, documents (1) and (8) belong to the state of the art under Article 54(2) EPC and document (9) belongs to the state of the art under Article 54(3) EPC.

15. Document (1) discloses the full length BRCA2 cDNA sequence. Document (8) refers on page 333, left column, lines 20 to 22 to document (1) and incorporates the full length BRCA2 cDNA sequence disclosed therein. Document (9) discloses the complete BRCA2 coding sequence as SEQ ID NO:1 on pages 49 to 65 (the identical sequence is disclosed in the priority document, document (10), on pages 90 to 106).

16. Accordingly, the subject-matter of claim 2 of the main request is not novel and does not meet the requirements of Article 54 EPC.

The same applies to claim 2 of the first and second auxiliary requests and claim 1 of the third, fourth and fifth auxiliary requests.

Order

For these reasons it is decided :

1. The decision under appeal is set aside.

2. The patent is revoked.

Registrar: Chairman:

V. Commare C. Rennie-Smith