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Datasheet for the decision of 23 June 2010

Case Number: T 0784/06 - 3.3.08

Application Number: 95906094.8

Publication Number: 0736107

IPC: C12Q 1/68

Language of the proceedings: EN

Title of invention:
Automatic genotype determination

Patentee:
Beckman Coulter, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:
Genotype determination/BECKMAN

Relevant legal provisions:
EPC Art. 52, 56

Relevant legal provisions (EPC 1973):
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Keyword:
"Main request: inventive step (no)"
"Auxiliary requests 1 to 11: inventive step (no)"
"Admission of auxiliary requests filed at the oral proceedings (no)"

Decisions cited:
G 0003/08, T 0208/84, T 0931/95, T 0767/99, T 0641/00, T 0914/02, T 0258/03, T 0531/03, T 0154/04

Catchword:
In the present case, the board could not establish for the claimed method an interaction between the technical activity of step A with the mental activities of steps B to E leading to a tangible technical result. Thus, in the assessment of inventive step, features B to E were ignored (see points 5 to 7 of the reasons) and an inventive contribution based on step A was denied (see points 8 to 11 of the reasons).

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Case Number: T 0784/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 23 June 2010

Appellant I: (Patent Proprietor)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 7 March 2006 concerning maintenance of the European patent No. 0736107 in amended form.**

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
J. Geschwind

Summary of Facts and Submissions

I. The patentee (appellant I) and the opponent (appellant II) each lodged an appeal against the interlocutory decision of the opposition division dated 7 March 2006, whereby the European patent N° 0 736 107, which had been granted on European application 95 906 094.8 (published as the international application WO 95/17524) with the title "*Automatic Genotype Determination*", was maintained on the basis of the sixth auxiliary request filed at the oral proceedings on 18 January 2006.

II. The main request (claims as granted), the first auxiliary request (claims 1 to 37) filed on 16 December 2005, the second auxiliary request (claims 1 to 32) filed on 16 December 2005 and the third auxiliary request (claims 1 to 36) filed on 18 January 2006 had been refused for lack of novelty over document D3 (Article 54 EPC). The fourth auxiliary request (claims 1 to 33) filed on 18 January 2006 had been refused for lack of inventive step over document D3 (Article 56 EPC). The fifth auxiliary request (claims 1 to 33) filed on 18 January 2006 had been refused because the opposition division had considered that it contained amendments which were inadmissible under Rule 57a EPC 1973.

III. The grounds for opposition were as set forth in Article 100(a) EPC that the invention was not new and did not involve an inventive step (Articles 54 and 56 EPC), in Article 100(b) EPC that the disclosure was insufficient (Article 83 EPC) and in Article 100(c) EPC that the subject-matter of the patent extended beyond

the content of the application as filed (Article 123(2) EPC).

IV. Appellant II filed its statement of grounds of appeal on 14 July 2006 in which it was argued that the sixth auxiliary request, as accepted by the opposition division, did not comply with the requirements of Articles 54, 56 and 123(2) EPC. Five new documents were attached to the statement of grounds.

V. Together with its statement of grounds of appeal dated 17 July 2006, appellant I filed nineteen auxiliary requests denoted 1B, 2, 2A, 2B, 3, 3A, 3B, 4, 4A, 4B, 5, 5A, 5B, 6, 6A, 6B, 7, 7A and 7B to replace the auxiliary requests then on file. Auxiliary requests 2, 6, 6A and 6B corresponded to the auxiliary requests 3, 4, 5 and 6 as considered by the opposition division in the decision under appeal. Six new documents were attached to the statement of grounds.

VI. In reply to the appellant II's statement of grounds of appeal, further submissions were filed by appellant I with a letter dated 29 November 2006, to which three new documents were attached.

VII. In its reply to the appellant I's statement of grounds, appellant II argued *inter alia* that auxiliary requests 2, 2A, 2B, 3, 3A and 3B lacked novelty, and that auxiliary requests 4, 4A and 4B lacked an inventive step. As regards auxiliary requests 5, 5A, 5B, 6 and 6A, appellant II relied on its submissions made in its statement of grounds with respect to the sixth auxiliary request on the basis of which the patent was maintained (present auxiliary request 6B). Furthermore,

it was argued that auxiliary requests 7, 7A and 7B did not comply with the requirements of Articles 56, 83 and 123(2) EPC.

VIII. A communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) presenting some preliminary, non-binding views of the board was sent to the parties on 23 March 2010.

IX. In reply to the board's communication, appellant I filed on 21 May 2010 a new main request and eleven auxiliary requests (1 to 11) to replace all the previous requests. On the same date, appellant II filed additional submissions.

X. Oral proceedings took place on 23 June 2010 at which appellant I filed four further auxiliary requests (12 to 15).

XI. The **main request** consisted of claims directed to a method and claims directed to a device. Claims 1 and 22 thereof read as follows:

"1. A method of determining the genotype at a locus within genetic material obtained from a biological sample, the method comprising:
A. reacting the material at the locus to produce a first reaction value indicative of the presence of a given allele at the locus;
B. forming a data set including the first reaction value;
C. establishing a distribution set of probability distributions, including at least one distribution, associating hypothetical reaction values with

corresponding probabilities for each genotype of interest at the locus;
D. applying the first reaction value to each pertinent probability distribution to determine a measure of the conditional probability of each genotype of interest at the locus, and
E. determining the genotype based on the data obtained from step (D)."

"22. A device for determining the genotype at a locus within genetic material obtained from a subject, the device comprising:
(a) reaction value generation means for producing a first physical state, quantifiable as a first reaction value, indicative of the presence of a given allele at the locus, the value associated with reaction of the material at the locus;
(b) storage means for storing a data set including the first reaction value and other reaction values obtained under comparable conditions;
(c) distribution establishment means for establishing a set of probability distributions, including at least one distribution, associating hypothetical reaction values with corresponding probabilities for each genotype of interest at the locus;
(d) genotype calculation means for applying the first reaction value to each pertinent probability distribution to determine the conditional probability of each genotype of interest at the locus; and
(e) genotype determination means for determining the genotype based on data obtained from the genotype calculation means."

Each of auxiliary requests 1 to 3 and 6 to 9 consisted of claims directed to a method and claims directed to a device whereas auxiliary requests 4, 5, 10 and 11 consisted only of claims directed to a method.

Claim 1 of each of auxiliary requests 1 to 5 was identical to claim 1 of the main request which in turn was identical to claim 1 as granted. Claim 1 of each of auxiliary requests 6 to 11 differed from 1 of the main request in that the feature "*wherein each allele is a single specific nucleotide*" had been added at the end of the claim.

Claim 22 of auxiliary request 6 differed from claim 22 of the main request in that the feature "*wherein each allele is a single specific nucleotide*" had been added at the end of the claim.

Claim 22 of auxiliary request 8 differed from claim 22 of the main request in that the feature "*wherein the reaction value generation means includes an optical transducer; wherein each allele is a single specific nucleotide*" had been added at the end of the claim.

Auxiliary requests 12 to 15 consisted only of claims directed to a device.

XII. The following two documents are referred to in the present decision:

(D7): A-C. Syvänen et al., Genomics, Vol. 8, 1990, pages 684 t0 692

(D13): WO 92/15712

XIII. The submissions made by appellant I, insofar as they are relevant to the present decision, may be summarised as follows:

Main request and auxiliary requests 1 to 11 (inventive step)

The method according to claim 1 represented a technical solution to a technical problem, namely a way of finding out something real about physical, genetic material. Steps B to E of the method were technical steps. The data generated and collected in steps A and B were treated in steps C and D. The core of the invention was in those two latter steps. Step C allowed a probabilistic approach the results of which could be scored and manually or automatically (using a software) treated in an improved manner. This improved data treatment allowed by the probabilistic approach was the major contribution to the art of the invention, as compared to the deterministic approach of the prior art.

Decisions such as T 641/00 (OJ EPO 2003, 352), T 531/03 of 17 March 2005 and T 931/95 (OJ EPO 2001, 441) had analysed the method claims by disregarding certain features for inventive step purposes because they were considered to be non-technical, e.g. they related to economic concepts. However, this was not the case for the method of claim 1, where the genotype was a technical feature and steps B to E represented the way in which the genotype was determined based on probability distribution.

This issue arose under Article 56 EPC but was of course closely related to questions of exclusion from patentability under Article 52 EPC. In particular, Articles 52(2) and 52(3) EPC excluded from patentability mathematical methods, methods for doing business and programmes for computers, but only when a patent/application related to such methods or activities as such. In trying to develop ways to assess computer-implemented and business methods-related inventions, the boards of appeal had developed a case law that focused more on inventive step than on the exclusion from patentability *per se*, but which nevertheless arose from the need to assess the patentability of inventions in relation to which exclusion issues arose. No such issues arose in the present case.

In step A of claim 1, a physical sample material was reacted to produce a first reaction value indicative of the presence of a given allele at a locus. The data represented by the reaction value (for example at an intensity reading) reflected the allele present at the locus, i.e. which physical sequence of nucleotides was contained in a particular sample. In steps B to E, the data represented by the reaction values were processed to determine the genotype at the locus in the sample. This involved mathematical steps of establishing a distribution set of probability distributions and applying the reaction value to each pertinent probability distribution. However, this did not mean that steps B to E represented mathematical methods as such. Rather steps B to E represented the application of a mathematical method to the real-world, technical data obtained in step (a).

In each of decisions T 931/95 (see *supra*), T 641/00 (see *supra*), T 258/03 (OJ EPO 2004, 575), T 531/03 (see *supra*) and T 154/04 (OJ EPO 2008, 46), the application/patent failed under Article 56 EPC because the method that was being carried out related to fundamentally non-technical considerations.

In the present case, there was no doubt that the claimed subject-matter had technical character. Steps B to E of claim 1 related to the application of mathematical steps but the data to which they were applied did not represent economic or administrative or financial concepts as in the case of those decisions. Rather, the data reflected the physical character of a biological sample, i.e. what DNA sequences it possessed. The information that was extracted from the reaction value data generated a result, i.e. the genotype determination, which described this physical character. This was clearly technical in nature.

A better parallel could be made with the case of decision T 208/84 (OJ EPO 1987, 14) in which the invention was held patentable, notwithstanding the fact that it was based on a mathematical method, because - as in the present case - it was not claimed *per se* but as a tool for processing data representing a physical entity existing in the real world.

Similarly, in decision T 767/99 of 13 March 2002, which refers to T 208/94 (see *supra*), it was stated that the fact that a measure had been derived from or inspired by an insight originating in an activity which is *per se* excluded from protection did not imply that a claim

including the material expression or embodiment in its specific application in the solution to a technical problem was a claim to the excluded activity as such.

Finally, opinion G 3/98 of 12 May 2010 clearly stated that it was in fact a well-established principle that features which would, taken in isolation, belong to the matters excluded from patentability by Article 52(2) EPC could nonetheless contribute to the technical features of the claimed invention, and therefore could not be disregarded in the consideration of the inventive step.

Bearing in mind the above case law, all the steps of claim 1, including steps B to E contributed towards its technical character, i.e. determining the genotype, and should be taken into account in the evaluation of inventive step.

Auxiliary requests 12 to 15 (admission into the proceedings)

These requests could not take appellant II by surprise. In fact, each of them consisted of claims present in the main request, auxiliary request 6 or auxiliary request 8. They were submitted as a direct reaction to the much unexpected position taken by the board towards the main request and auxiliary requests 1 to 11. The device claims were no longer maintained in auxiliary requests 4, 5, 10 and 11 as a direct reaction to the decision of the opposition division.

XIV. The submissions made by appellant II, insofar as they are relevant to the present decision, may be summarised as follows:

Main request and auxiliary requests 1 to 11 (inventive step)

Steps B to E of claim 1 had to be regarded as non-technical. In accordance with the established case law of the EPO inventive step could not be based on non-technical features. Steps B to E related to statistic methods, i.e. mathematical methods which were not regarded as patentable according to Article 52(2)(a) EPC. These were used to determine the probability of a genotype, which was evidently of a non-technical nature. In accordance with paragraphs [0015] and [0016] and appendix A of the patent at issue computer-implementation was intended. As stated in G 3/08 (see *supra*) the fact that fundamentally the formulation of every computer program required technical considerations in the sense that the programmer had to construct a procedure that a machine could carry out, was not enough to guarantee that a computer program had a technical character.

As steps B to E of claim 1 were purely mathematical methods which did not require any further technical considerations and as they did not have any technical effect, they were non-technical and, therefore, had to be disregarded in the assessment of inventive step. Additionally, those mathematical methods were trivial and known to the skilled person. According to the case law of the technical boards of the EPO (see e.g. T 914/02 of 12 July 2005, T 531/03 (see *supra*) and

T 641/00 (see *supra*)) features relating to a non-invention within the meaning of Article 52(2)(a) EPC (so-called non-technical features) could not support the presence of inventive step.

In step A, the reaction value was determined by a general (e.g. biochemical) procedure and in steps B to E, a genotype was allocated to the reaction value based on a previously determined distribution using general statistical methods. Methods according to step A were known. Accordingly, any prior art document disclosing step A reacting the material at the locus to produce a first reaction value or reacting the material at the genetic locus to produce an input signal would have rendered the claimed subject-matter obvious, as the further general steps B to E were non-technical and contributed no further technical effect.

Auxiliary requests 12 to 15 (admission into the proceedings)

These requests were submitted at a very late stage of the procedure. They were not capable of overcoming the objections raised against the main request and auxiliary requests 1 to 11. In view of the summons, appellant I could not have been surprised by the position taken by the board towards the latter requests. The device of claim 1 was not inventive as it was directly linked to the method which itself was not inventive.

XV. Appellant I (patentee) requests that the decision under appeal be set aside and the patent be maintained on the basis of the main request or one of auxiliary

requests 1 to 11, all filed on 21 May 2010, or one of auxiliary requests 12 to 15 filed during the oral proceedings.

XVI. Appellant II (opponent) requests that the decision be set aside and the patent be revoked.

Reasons for the Decision

Main request

Preliminary remark

1. As agreed with the parties at the onset of the oral proceedings and despite other issues at stake, the debate focused on the issue of inventive step in view of the special situation created by the presence in claim 1, which is directed to an invention in the field of biotechnology, of a mix of technical and non-technical features.

Inventive step

2. Claim 1 is directed to a five-step method of determining the genotype at a locus within genetic material obtained from a biological sample. In step A the material is reacted to produce a first reaction value. In steps B to E each the following mental activities are performed based on the application of mathematical methods: (i) forming a data set (step B), (ii) establishing a distribution set of probability distributions (step C), (iii) applying the first reaction value to each pertinent probability

distribution (step D) and (iv) determining the genotype based on the data obtained from step D (step E). Thus, the claimed method is defined as a mix of technical and "non-technical" features, the latter, particularly steps C and D, being argued by the patentee to be core features of the invention.

3. Such a method is to be considered an invention within the meaning of Article 52(1) EPC (see decision T 641/00 (cf. *supra*), point 4 of the Reasons), which, to be patentable, should *inter alia* satisfy the requirement of inventive step, being reminded in this respect that Article 52(2) EPC does not exclude from patentability any subject-matter or activity having technical character, even if it is related to the items listed in this provision, including mathematic methods, since, according to Article 52(3) EPC), these items are only excluded "as such" (see decision T 154/04 (cf. *supra*), point 5(C) of the Reasons).

4. It is established case law that non-technical features, such as mental activities, are not to be ignored in assessing inventive step, insofar as they interact with the technical subject-matter of the claim for solving a technical problem and thereby contribute to the technical character of the claimed subject-matter. This principle was laid down in decision T 208/84 (see *supra*; cf. point 16 of the Reasons), re-affirmed in decision T 154/04 (see *supra*; cf. point 8(G) of the Reasons) and recently confirmed in opinion G 3/08 (see *supra*; cf. points 10.7.1, 10.13.2 (citing T 154/04), and 12.2.2. of the Reasons). It is in conformity with decisions T 931/95 (see *supra;* cf. point 8 of the Reasons, T 641/00 (see *supra*; cf. point 6 of the Reasons,

T 258/03 (see *supra*; cf. point 5.3 of the Reasons) and T 531/03 (see *supra*; cf. point 2.5 of the Reasons) which stipulate that for the assessment of inventive step account should be taken of only those features which contribute to the technical character of the claimed subject-matter.

5. Thus, for assessing inventive step of the method of claim 1, the first and fundamental question to be answered is whether, also in the light of the description (see pages 1 to 7 of the patent), the mental activities of steps B to E interact with the technical activity of step A so as to yield a tangible technical result. This question is answered positively by appellant I which sees in the data treatment the key for the determination of the genotype of the biological sample. Appellant II answers negatively as in its view the data treatment steps are too general to provide any technical contribution beyond a trivial one.

6. It is observed that steps B to C in claim 1 are indeed very generally formulated (cf. point 2 above). The description of the patent specification is in this respect no more generous than the claims in terms of information. In fact, the section entitled "*Summary of the Invention" on pages 2 and 3* is no more that a mere repetition of the claims and an outline of the flow of data treatment with no concrete details. As regards the description pages 4 to 7 with appendix A (see page 8) and the drawings, which are under the heading "*Detailed Description of Specific Embodiments*", they concern an unspecified embodiment wherein the data treatment is carried out using computer processing employing a computer software called "*GetGenos*". This section does

not provide a truly useful example of how to proceed within the framework of the outlined method. In fact, the mathematic reasoning starting from an actual experimental value determined according to step A and ending with the determination of a precise genotype according to step E is not described in detail. Moreover, it fails to supply a reasonably complete and sufficient description of the software "GetGenos" especially developed by the inventors to produce GBA data, some aspects of the processing of which are discussed on pages 4 to 7. This deficiency is remedied neither by the mathematic formulae referred to on page 5 nor by the mere code lines written in C language contained in Appendix A on page 8, which are said (see page 6, lines 56 to 58) to serve the purpose of generating probability distributions. No informational content can be attributed to the constants, variables and functions mentioned therein.

7. The above observations are seen as relevant here within the framework of the discussion on inventive step in that the stated deficiencies deprive the skilled reader of the information he/she needs to understand how to proceed from the first reaction value collected in step A through steps B, C and D to the determination on a probabilistic basis of the genotype of step E. Under these circumstances, no interaction can be established between the technical activity of step A with the mental activities of steps B to E leading to a tangible technical result, as required by the case law. The features of steps B to E, which pertain to a general manner of analysing the data, are thus to be ignored in assessing inventive step, which assessment can

therefore rely on a reasoning focusing only on the technical features of step A.

8. A method of determining the genotype at a locus within genetic material obtained from a biological sample as featured in step A of the method according to claim 1, i.e. comprising reacting the material at the locus to produce a first reaction value indicative of the presence of a given allele at the locus, is known from the prior art, as represented, for example, by documents D7 and D13 on file.

9. In document D7, a method for apo E genotyping is disclosed. Namely, the three-allelic polymorphism of the apolipoprotein E (apo E) gene in a population of six individuals is analysed by combining PCR amplification with a simple solid-phase step reaction to detect the variable nucleotides in two given loci of the apo E gene with radioactive labels. After completion of the detecting step reaction, the radioactivity resulting from the incorporated radioactive isotopes is measured, giving a reaction value indicative for each locus of the presence of a given allele.

10. In document D13, a method for determining the genotype of an organism at a given genetic locus is disclosed, which comprises obtaining from the organism a sample containing genomic DNA and carrying out assays using genetic bit analysis (GBA), i.e. the method especially referred to in the patent (see from line 24 on page 2 to line 6 on page 3, and lines 7 and 28 on page 7), to produce a colorimetric value that is indicative of the presence of a specific allele at a given locus.

Example 6 (see pages 45 to 47) describes the method in relation to genotyping at a given human or equine locus.

11. Thus, if the inventive step involved in the method of claim 1 has to be evaluated merely on the basis of the contribution offered by the general and broad wording of step A, the manifest conclusion is that there is no inventive step involved therein. Therefore, the main request does not satisfy the requirements of Article 56 EPC and, as such, cannot form the basis for the maintenance of the patent in an amended form.

Auxiliary requests 1 to 11

Inventive step

12. Claim 1 of each of auxiliary requests 1 to 5 and 7 to 11 is identical to claim 1 of the main request. Thus, the reasoning made above in relation to inventive step also applies and the conclusion is reached that also those auxiliary requests do not satisfy the requirements of Article 56 EPC. The same is true for auxiliary request 6 as the added feature "*wherein each allele is a single specific nucleotide*" which its claim 1 contains compared with claim 1 of the main request does not alter the reasoning. Thus, none of auxiliary requests 1 to 11 can form a basis for the maintenance of the patent in an amended form.

Auxiliary requests 12 to 15

Admission into the proceedings

13. During the written phase of the appeal proceedings appellant I had the opportunity to file a number of requests. A first main request (claims as granted) and nineteen auxiliary requests were filed together with the statement of grounds. Then, a further second main request and eleven new auxiliary requests were filed in reaction to the board's communication. This means a total of thirty two different requests which have been taken into consideration by the board until the filing of auxiliary requests 12 to 15. Ten of those requests did not comprise device claims (see auxiliary requests 1B, 2B, 3B, 4B, 5B, 6B and 7B of 5 March 2005, and auxiliary requests 4, 5, 10 and 11 of 21 may 2010).

14. Appellant I was aware that method claims were at risk of being refused by the board in view of the objections raised by the opposition division and appellant II. Therefore, it is not understandable why it did not file earlier auxiliary requests consisting only of device claims. In this respect, it has to be reminded that pursuant to Rule 12(2) RPBA, the statement of grounds and the reply should contain a party's complete case. Accordingly, the late filing of such requests during the oral proceeding is regarded by the board as an abuse of procedure. Therefore, using its discretion the board has decided not to admit auxiliary requests 12 to 15 into the proceedings.

Conclusion

15. As none of the requests on file, i.e. the main request and auxiliary requests 1 to 11, may form a basis for its maintenance in an amended form, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar The Chairman

A. Wolinski L. Galligani