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**Datasheet for the decision  
of 23 May 2014**

**Case Number:** T 1285/10 - 3.5.05

**Application Number:** 00957869.1

**Publication Number:** 1222602

**IPC:** G06F19/00

**Language of the proceedings:** EN

**Title of invention:**

ARTIFICIAL INTELLIGENCE SYSTEM FOR GENETIC ANALYSIS

**Applicant:**

Iris Biotechnologies Inc.

**Headword:**

Genetic analysis computing system/IRIS BIOTECHNOLOGIES

**Relevant legal provisions:**

EPC Art. 56, 84, 123(2)

**Keyword:**

Amendments - added subject-matter (no)  
Claims - clarity (yes)  
Remittal to the department of first instance

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
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Chambres de recours**

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Case Number: T 1285/10 - 3.5.05

**D E C I S I O N  
of Technical Board of Appeal 3.5.05  
of 23 May 2014**

**Appellant:** Iris Biotechnologies Inc.  
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**Representative:** Letzelter, Felix Phillip  
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 15 January 2010 refusing European patent application No. 00957869.1 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chair** A. Ritzka  
**Members:** P. Cretaine  
D. Prietzel-Funk

## Summary of Facts and Submissions

I. The appeal is against the decision of the examining division, posted 15 January 2010, to refuse European patent application No. 00 957 869.1. The decision was based on the grounds of added subject-matter (Article 123(2) EPC) and lack of clarity (Article 84 EPC) with respect to a main request and an auxiliary request, and further on the ground of insufficiency of disclosure (Article 83 EPC) with respect to the auxiliary request. In an obiter dictum appended to the decision, the examining division raised an inventive step objection (Article 56 EPC) against the claims of the main request, based on the disclosure of

D3: WO 97/20496

and the common knowledge of the skilled person as exemplified by the disclosure of

D6: M. Schena et al. "Quantitative monitoring of gene expression patterns with complementary DNA Microarray", Science, 20-10-1995,

D7: J. DeRisi et al. "Use of a cDNA microarray to analyse gene expression patterns in human cancer", Nature Genetics, 14-12-1996, or

D8: M. Schena et al. "Microarrays: biotechnology's discovery platform for functional genomics", Trends in Biotechnology, 07-1998.

II. Notice of appeal was received on 15 March 2010 and the appeal fee was paid on the same day. With the statement setting out the grounds of appeal, received on

21 May 2010, the appellant requested that the decision be set aside and that a patent be granted on the basis of a main request or an auxiliary request, both filed with the statement setting out the grounds of appeal. Oral proceedings were requested as a precautionary measure.

- III. A summons to oral proceedings scheduled for 23 May 2014 was issued on 24 February 2014. In an annex to this summons, the board gave its preliminary opinion on the appeal pursuant to Article 15(1) RPBA. In particular, objections were raised under Articles 123(2) and 56 EPC as regards the main request and under Articles 123(2), 83, 84 and 56 EPC as regards the auxiliary request.
- IV. With a letter of reply dated 22 April 2014, the appellant submitted amended sets of claims according to a main request and first and second auxiliary requests.
- V. At the oral proceedings, held as scheduled on 23 May 2014 the appellant withdrew the main request on file (submitted with the letter dated 22 April 2014) and requested that the decision under appeal be set aside and that a patent be granted according to the claims of a main request (submitted as first auxiliary request with the letter dated 22 April 2014) or of an auxiliary request (submitted as second auxiliary request with the letter dated 22 April 2014).
- VI. Independent claim 1 of the main request reads as follows:

"A method for diagnosing and recommending treatment for a physiological condition, comprising:

(i) collecting hybridization information of an array of oligonucleotides of a about 20 mer to about 25 mer or peptide nucleic acid probes comprising the steps of using chemical reagents to extract the DNA or RNA from a biological sample, applying the sample to the array of oligonucleotides or peptide nucleic acid probes, using an optical reader or scanner to image the hybridized chip and quantifying the gene expression levels for each spot,

(ii) transmitting said hybridization information into a central data processing facility, where the hybridization information transmission includes but is not limited to gene expression data,

(iii) analyzing said hybridization information to generate a hybridization profile, and comparing said hybridization profile to hybridization profiles stored in an updateable database having access to all input hybridization results and having access to patient family history information, having a set of rule linking stored hybridization profiles with associated diagnosed conditions and treatment options to provide analyzed data,

(iv) determining the most likely pathological or physiological conditions suggested by the comparative analysis of hybridization profiles, using artificial intelligence routines along with suggested methods of treatment for the conditions, to a user, and

(v) recommending methods of treatment based on the physiological condition, patient personal medical history, clinical observations, and updating the patient's file."

Claim 1 of the auxiliary request differs from claim 1 of the main request in that step (i) reads as follows:

"(i) collecting hybridization information of an array of peptide nucleic acid probes comprising the steps of using chemical reagents to extract the DNA or RNA from a biological sample, applying the sample to the array of peptide nucleic acid probes, using an optical reader or scanner to image the hybridized chip and quantifying the gene expression levels for each spot."

VII. At the end of the oral proceedings the board announced its decision.

### **Reasons for the Decision**

1. Admissibility of the appeal

The appeal complies with the provisions of Articles 106 to 108 EPC (cf. point II above) and is therefore admissible.

2. Admissibility of the requests

The claims of the main and auxiliary requests are based on those of the main request submitted with the statement setting out the grounds of appeal, which were themselves based on the claims of the main request on which the decision was based. These claims have been amended in order to overcome the objections under Articles 84 and 123(2) EPC which were the grounds for the refusal and in response to the Article 56 EPC objection raised by the board in the annex to the summons to oral proceedings.

Therefore the board decided to exercise its discretion under Articles 12(4) and 13(1) RPBA to admit the main and auxiliary requests into the proceedings.

3. Article 84 EPC

In the decision under appeal, the examining division objected to the expressions "updateable database", "hybridization profile", "all input hybridization results", "artificial intelligence routines" and "analysing information by ethnicity", still present in the claims of the main and auxiliary requests on file, as lacking clarity.

The board however judges that these expressions are sufficiently clear for the skilled person, in particular in the light of the description as a whole, for the following reasons.

The database which stores, inter alia, the hybridization profiles is part of the artificial intelligence system (see Figure 1). It is clear from the description as a whole (see in particular from page 15, line 21 to page 16, line 2) that this database may be updated, at least with the hybridization profiles of new patients or new hybridization profiles of existing patients. It is thus clear that this database is updatable.

It is also clear from the description as a whole that the term "hybridization profile" designates the information related to a patient, including the hybridization information collected from the patient and stored in the system database (see in particular from page 5, line 23 to page 6, line 9). No other

interpretation of the term "hybridization profile" could be envisaged by the skilled person.

Although the wording "all input hybridization results" is not used as such in the description, it is clear for the skilled person that it designates the hybridization information collected from the patients and stored in the database.

The expression "artificial intelligence routines" has a well-known meaning per se. The description gives two examples of such routines, namely a rule-based expert system and a neural network. Therefore, this expression is not broader than justified, contrary to what the division has argued in the decision.

The wording "analyzing information by ethnicity" is supported by the description (see page 4, line 25). Although a detailed analysis method is not disclosed, a simple classification of the profiles by ethnicity could be considered by the skilled person. This wording therefore does not lack clarity.

Therefore the board judges that the claims of the main and auxiliary requests meet the requirements of Article 84 EPC.

4. Article 123(2) EPC

- 4.1 The examining division found that the features "a database having access to patient family history", "recommending methods of treatment based on ...patient personal medical history, clinical observations", "updating the patient's file", "hybridization profile is generated by analysing information by ethnicity, region, occupation, age, sex" and "monitoring changes



in physiological conditions by integrating all pertinent genomic information, patient profiles and other information", which are still present in the claims of the main and auxiliary requests on file, were not supported by the application documents as originally filed.

The board however judges that these features are disclosed, at least implicitly, in the originally filed description, for the following reasons.

The description in page 29, line 12, mentions "family history" in the paragraph "User information". It is therefore clear for a skilled person that the wording "family history" relates to the history of the patient's family in terms of medical information.

Since medical treatment is based on diagnosis, and diagnosis is based, according to the description, on personal medical history and clinical observations, medical treatment is itself based on personal medical history and clinical observations.

The description mentions that the system repeatedly updates the existing information (see in particular page 15, lines 25 to 26). Among the information stored in the database are the files of the treated patients. It is thus implicit from the description as a whole that a patient's file is updated.

Since the description recites that the system analyses genetic information by ethnicity, region, etc., it is clear that these data play a role in the generation of a patient's profile.

The monitoring of conditions of a patient by integrating genomic information, patient profiles and other information is explicitly disclosed in page 4, lines 14 to 16. It is thus implicit that monitoring of changes of physiological conditions is also performed by integrating these different information.

- 4.2 Furthermore, the board is satisfied that the appellant has deleted from step (ii) of claim 1 according to the main request and from step (ii) of claim 1 according to the auxiliary request the feature that the hybridization information transmission includes other types of information such as patient information, statistical information, etc.

In that respect, the board agrees with the examining division that the transmission of the above-mentioned other types of information together within the transmission of the hybridization information was not disclosed in the originally filed documents.

The board is also satisfied that the appellant has deleted from step (iv) of claim 1 according to the main request and from step (iv) of claim 1 according to the auxiliary request the feature that "personal life dynamic information" has to be taken into account when determining the physiological condition of the patient. This wording is not present in the originally filed application documents. The term "life style" is to be found on page 24, line 23, albeit with reference to public information and not to patient information.

- 4.3 Claim 1 according to the main request has further been amended with respect to claim 1 of the main request on which the decision was based by specifying in step (i) that the nucleic acid array is an array of

oligonucleotides of about 20 mer to about 25 mer or peptide nucleic acid probes.

Claim 1 according to the auxiliary request has further been amended with respect to claim 1 of the main request on which the decision was based by specifying in step (i) that the nucleic acid array is an array of peptide nucleic acid probes.

The added features find support in page 8, lines 28 to 30 of the description.

4.4 In conclusion, the board judges that the main and auxiliary requests meet the requirements of Article 123(2) EPC.

5. Article 56 EPC

5.1 Prior art

D3 discloses a medical diagnostic analysis system and method wherein patient diagnostic data (e.g. blood test results) is compared in a database with predetermined ranges of specific indicators. The results of the comparison provide specific disease diagnosis and suggest treatments. It was common ground during the oral proceedings before the board that D3 represents the closest prior art to the subject-matter of the main and auxiliary requests.

D6, D7 and D8 disclose the use of hybridization information provided by complementary DNA (cDNA) microarrays as a basis for a medical diagnosis.

5.2 Main request and auxiliary request

Claim 1 of the main request differs from the method of D3 in that the patient-relevant data used for diagnosis is hybridisation information of DNA or RNA extracted from a patient's biological sample and collected in respect of an array of oligonucleotides of about 20 mer to about 25 mer or of an array of peptide nucleic acid probes.

Claim 1 of the auxiliary request differs from the method of D3 in that the patient relevant data used for diagnosis is hybridisation information of DNA or RNA extracted from a patient's biological sample and collected in respect of an array of peptide nucleic acid probes. Its subject-matter is thus included in that of claim 1 of the main request.

The appellant argued that the use of complementary DNA (cDNA) microarrays as a basis for medical diagnosis as taught by D6, D7 and D8 did not render obvious the use of an array of oligonucleotides of about 20 mer or an array of peptide nucleic acid probes as claimed, since the claimed arrays provided more precise information. The board agrees that D6, D7 and D8 disclose neither these kinds of arrays nor their advantages.

However, the board notes that the feature specifying the array as an array of oligonucleotides of about 20 mer to about 25 mer or as an array of peptide nucleic acid probes was not present in the originally filed claims or in the claims examined during the first-instance proceedings, and as such may not have been searched. Therefore the board is not in a position to examine the contribution of this feature to the inventive step of the subject-matter of claim 1 according to the main request, and *a fortiori* of

claim 1 according to the auxiliary request. It thus appears appropriate to remit the case to the examining division for further prosecution in that respect.

- 5.3 However, for the sake of completeness, the board makes the following observations as to the relevance of documents D3, D6, D7 and D8.

D6, D7 and D8 were published before the priority date of the present application. These documents teach that gene expression levels, extracted from hybridization information of nucleic acid arrays, might provide a basis for improved diagnosis and selection of the most appropriate treatment (see D6, page 469, right-hand column, last paragraph; D7, page 458, right-hand column, second paragraph; D8, page 305, right-hand column). It was thus at that time plausible for the skilled person that, due to the extremely high multiplicity of genes compared to the limited number of substance indicator levels used in D3, the use of gene expression data provided by the hybridization information from a DNA array would allow a much more accurate patient profiling.

The skilled person would thus have obviously recognised the advantages of using hybridization information from nucleic acid arrays for providing the relevant patient data, in order to improve the accuracy of the computerized diagnosis and treatment method of D3.

For these reasons, the board judges that a straightforward combination of document D3 with the teaching of one of documents D6, D7 or D8 would lead to the subject-matter of a claim comprising all the features of claim 1 of the main request with the

exception of the feature (see point 5.2 above) specifying the kind of nucleic acid array used.

The appellant argued in substance that none of documents D6 to D8 describes an actual diagnosis carried out on the basis of data generated by the utilization of DNA micro-array analysis. It also pointed out that the gene technology field was a completely new technical field at the publication dates of these documents and at the priority date of the present application. In that respect, the appellant stressed that the text passages of D6, D7 and D8 quoted by the board used expressions such as "might lead to characteristic changes in the patterns of gene expression" (see D6, p. 469 right column), "recognition of a partial genomic alterations in gene expression might provide a basis for improved diagnosis ..." (see D7, p. 458, right column), and "human genes may soon permit the expression analysis of the entire human genome" (see D8, abstract). According to the appellant, these passages at most suggested that data obtained from DNA micro-arrays might at some time in the future be used as a source of data for the diagnosis of diseases.

The board is not convinced by this argument, since documents D6 to D8 do not only describe speculative ideas but rather incite the skilled person to use hybridization data in clinical medicine. In particular, Figure 4 of D8 clearly shows that diagnosis and drug targets, i.e. treatment recommendations, can be based on gene expression data collected from DNA microarrays. Furthermore, complex genetic databases were already known at the priority date of the present application, as acknowledged by the description itself (see the

passage from page 2, line 16 to page 3, line 19, citing several published documents).

The appellant further argued that documents D6 to D8 do not contain any information as to how to use hybridization data in the diagnostic tools of D3. In particular, the appellant pointed to the "one-dimensional" character of the database used in D3, wherein each medical indicator is compared to a threshold.

Here again, the board is not convinced. The system of D3 does not simply compare indicators with thresholds but uses a correlation between a plurality of indicators and a plurality of diseases to provide a diagnosis, and relies on personal factors to provide a medical treatment (see for instance page 2, lines 5 to 33). Even if it can be assumed that a genetic database comprises a much larger number of parameters than the database of D3, the implementation of such a database in the system of D3 does not require any inventive skill for a computer specialist.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chair:



K. Götz

A. Ritzka

Decision electronically authenticated