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**Datasheet for the decision
of 4 July 2017**

Case Number: T 0758/12 - 3.3.08

Application Number: 07840663.4

Publication Number: 2046996

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:
METHODS FOR SELECTING MEDICATIONS

Applicant:
MAYO FOUNDATION FOR MEDICAL
EDUCATION AND RESEARCH

Headword:
Selecting psychotropic medications/MAYO FOUNDATION

Relevant legal provisions:
EPC Art. 52(2)(c), 84

Keyword:
Main and auxiliary request - patentable invention (no)
Main and auxiliary request - Article 84 EPC (no)

Decisions cited:
G 0010/93, T 0409/91

Catchword:



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Case Number: T 0758/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 4 July 2017

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 7 November 2011
refusing European patent application No.
07840663.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman P. Julià
Members: B. Stolz
J. Geschwind

Summary of Facts and Submissions

- I. The applicant/appellant filed an appeal against the decision of an examining division whereby European patent application No. 07 840 663.4 (published as International patent application WO 2008/017038) was refused. The examining division decided that the main request filed under cover of a letter dated 24 March 2010 lacked an inventive step (Article 56 EPC), and that the auxiliary request filed under cover of a letter dated 9 September 2011 contravened Article 123(2) EPC and lacked an inventive step (Article 56 EPC). In the statement setting out the grounds of appeal, the appellant maintained both, the main request and auxiliary request, underlying the decision under appeal.
- II. The appellant was summoned to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, the board introduced new documentary evidence and informed the appellant of the board's provisional, non-binding opinion on some of the issues of the appeal proceedings. The appellant was *inter alia* informed that the board considered it necessary to address certain issues in relation to Articles 52(2)(c) and 84 EPC.
- III. Under cover of a letter dated 28 June 2017, the appellant, without making further substantive submissions, informed the board that it would not attend the scheduled oral proceedings.
- IV. Oral proceedings were held on 4 July 2017 in the absence of the appellant.
- V. Claim 1 of the main request reads:

"1. A method for selecting a psychotropic medication for a patient, said method comprising

(a) providing said patient's genotype for a panel of genes, wherein said panel comprises a CYP2D6 gene, a CYP2C19 gene, a CYP1A2 gene, a serotonin transporter gene, and a serotonin receptor 2A gene; wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele; and

(b) selecting said psychotropic medication based on said genotype."

Dependent claims 2 to 13 refer to specific embodiments of the method of claim 1.

VI. Claim 1 of the auxiliary request reads:

"1. A method for selecting a psychotropic medication for a patient, said method comprising

(a) providing said patient's genotype for a panel of genes, wherein said panel comprises a CYP2D6 gene, a CYP2C19 gene, a CYP1A2 gene, a serotonin transporter gene, and a serotonin receptor 2A gene; wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele; and

(b) selecting said psychotropic medication based on said genotype,
wherein a patient having the CYP2D6*41 allele and a second, inactive CYP2D6 allele, is identified as a poor metabolizer."

Dependent claims 2 to 13 refer to specific embodiments of the method of claim 1.

- VII. The appellant requests in writing that the decision under appeal be set aside and a patent be granted on the basis of either the main request or the auxiliary request underlying the decision under appeal.

Reasons for the Decision

Extent of examination in appeal proceedings

1. In an appeal from a decision of an examining division, the board is not limited to examine issues on which the examining division decided adversely, in the present case issues under Articles 123(2) and 56 EPC. Rather, the board is empowered to examine whether or not the claims on file and the invention to which they relate fulfil all requirements of the EPC and, accordingly, raise new objections if it considers it necessary (see Order of decision G 10/93, OJ EPO 1995, 172). In the present case, the board considers that issues under Articles 52(2)(c) and 84 EPC must be addressed.

Article 113(1) EPC - right to be heard

2. As announced in writing, the appellant did not attend the oral proceedings. Nor did it file substantive arguments in reply to the board's communication pursuant to Article 15(1) RPBA (cf. point III, above). By neither replying to the board's communication in substance nor attending the oral proceedings, the appellant effectively chose not to avail itself of the opportunity to comment or present its observations on the board's provisional opinion (Article 113(1) EPC). As a consequence of appellant's course of action, there

are no submissions on file as regards the patentability of the claimed subject-matter (Article 52(2)(c) EPC) or the compliance with the requirements of Article 84 EPC, issues mentioned in points 6 to 10 of the board's communication pursuant to Article 15(1) RPBA and relating to the main and the auxiliary request.

Article 52(2)(c) EPC

3. As presently worded, claim 1 of the main and the auxiliary request encompasses subject-matter excluded from patentability. Claim 1 of both requests defines a method for selecting a psychotropic medication for a patient comprising the steps of (a) providing a patient's genotype, and (b) selecting said medication. Without further limitation, the term "*providing a patient's genotype*" includes the provision, i.e. the making available, of patient data, for instance, in the form of a print-out on a piece of paper when such data have been obtained in a step preceding the steps of the claimed method. Under these circumstances, the claimed method is reduced to a scheme, rule or method for performing a mental act or doing business with those data which as such is excluded from patentability (Article 52(2)(c) EPC).

Article 84 EPC

4. Step (a) of claim 1 of both requests is ambiguous and therefore unclear within the meaning of Article 84 EPC.

The step comprises the provision of a patient's genotype for a panel of genes which comprises the CYP2D6 gene and "*wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele*". This wording allows three possible interpretations:

(i) the feature "*wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele*" is interpreted as merely stating that the 2D6 alleles which can possibly be identified in said patient include or comprise the 2D6*41 allele, or

(ii) the feature "*wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele*" specifies that the patient carries said 2D6*41 allele. The claimed method is thus limited to selecting a psychotropic medication (step (b) of claim 1) for a patient who is already known to be a carrier of at least one 2D6*41 allele, or

(iii) the feature "*wherein said genotype for said CYP2D6 gene comprises the 2D6*41 allele*" is interpreted as requiring that "*providing said patient's genotype*" comprises determining experimentally if said patient comprises the 2D6*41 allele.

5. In view of this ambiguity, neither claim 1 of the main request nor claim 1 of the auxiliary request provide a clear definition of the claimed subject-matter.
6. Furthermore, claim 1 of both requests lacks essential technical features.

According to the established case law of the Boards of Appeal, Article 84 EPC has to be interpreted as meaning not only that a claim must be comprehensible from a technical point of view, but also that it must define the object of the invention clearly, that is to say indicate all the essential features thereof. All features which are necessary for solving the technical problem with which the application is concerned have to be regarded as essential features (see "Case Law of the

Boards of Appeal of the EPO", 8th edition 2016, II.A.3.2, page 272).

7. The goal of the method of claim 1 is the selection of a "*psychotropic medication for a patient*". The method comprises the determination of the patient's genotype for a panel of five genes (CYP2D6, CYP2C19, CYP1A2, a serotonin transporter gene (5-HTT), and a serotonin receptor 2A gene (HTR2A)) (step(a)), followed by the selection of said medication based on said genotype (step (b)). Step (b) does however not define any rules, criteria, parameters or properties for the selection of a psychotropic medication based on a patient's genotype of the five genes. The claim therefore lacks essential technical features.

8. Moreover, according to Article 84 EPC, the claims must not only be clear but also supported by the description. This requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified (see decision T 409/91, OJ EPO 1994, page 653, point 3.3 of the Reasons for the decision).

9. The patent application does not provide instructions how to select a psychotropic medication if a patient is a carrier of a 2D6*41 allele, either in combination with a second 2D6*41 allele or in combination with a different 2D6 allele, and particular alleles of the other genes mentioned in the claim.

Although the patent application discloses allelic variants of several cytochrome P450 genes (Table 1), there is no information on the activity level of any of

the mentioned alleles except for some CYP2D6 alleles (Table 10). Nor is there any information on the activity levels related to or associated with the polymorphisms of the serotonin transporter and the serotonin receptor 2A listed in Table 2.

The application contains also no information on the (exclusive) substrate and conditions to be used for determining the activity level of the CYP2D6 alleles. There is no reference to a "standard assay" (well known and generally accepted in the art) for measuring such activity levels, let alone to "standard assays" for measuring the activity of each and every allele of the other genes listed in the claims. Nor is there any information on the criteria (threshold) used for classifying a CYP2D6 allele as a poor, intermediate, extensive or ultra-rapid metabolizer.

10. Thus, claim 1 of the main and the auxiliary request, directed to a method for selecting a psychotropic medication, relates to subject-matter which, after reading the description, is not at the disposal of the person skilled in the art.
11. The subject matter of claim 1 of the main and the auxiliary request is neither clearly defined nor supported by the description (Article 84 EPC).

Conclusion

12. In the absence of an allowable request, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Wolinski

P. Julià

Decision electronically authenticated