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**Datasheet for the decision
of 6 September 2013**

Case Number: T 0852/09 - 3.3.04
Application Number: 00918362.5
Publication Number: 1171078
IPC: A61K 6/00, C12N 9/20
Language of the proceedings: EN

Title of invention:

Compositions and methods for effecting the levels of cholesterol

Applicant:

Aventis Pharmaceuticals Inc.
The Trustees of The University of Pennsylvania

Headword:

Enhancers/AVENTIS PHARMACEUTICALS INC. *et al.*

Relevant legal provisions:

EPC Art. 83

Keyword:

"Main request - sufficiency of disclosure (no)"

Decisions cited:

G 0010/93, T 0500/01, T 0061/03, T 1063/06, T 0155/08

Catchword:

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Case Number: T 0852/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 6 September 2013

Appellant: Aventis Pharmaceuticals Inc.
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Bridgewater, NJ 08807 (US)

Appellant: The Trustees of The University of Pennsylvania
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Representative: Adamson Jones
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 27 November 2008
refusing European patent application
No. 00918362.5 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
G. Alt

Summary of Facts and Submissions

- I. The appeal was lodged by the applicants (hereinafter "appellants") against the decision of the examining division to refuse European patent application 00918362.5 with the title "*Compositions and methods for effecting the levels of cholesterol*" which was published as international application WO 00/57837.
- II. The examining division decided that the subject-matter of claims 1 and 2 of the sole request before them, which was filed with a letter dated 20 January 2005 and comprised claims 1 to 5, was insufficiently disclosed (Articles 83 EPC) and lacked novelty (Article 54 EPC) and that these claims contravened the requirements of Article 84 EPC. Moreover the subject-matter of claims 1 to 5 was found to lack inventive step (Article 56 EPC).
- III. Independent claim 1 of the sole request before the examining division read:
- "1. Use of an enhancer which preferentially enhances the enzymatic reactions between LIPG polypeptide and LDL cholesterol relative to the enzymatic reactions between LIPG polypeptide and HDL cholesterol and apolipoprotein AI in the manufacture of a composition for lowering the level of LDL cholesterol in a patient."
- IV. In its decision the examining division stated *inter alia* that the application did not define compounds as recited in claim 1, i.e. enhancers of LIPG enzymatic activity for use in medical treatment. The subject-matter of claim 1 was therefore purely speculative and

the wording of the claim constituted a mere statement of the result to be achieved and did not allow the scope of the claim to be ascertained in any meaningful and clear technical sense (Article 84 EPC). The fact that large compound libraries could be screened for the desired activity did not provide the skilled person with immediate or testable knowledge as to which compound or compound family could fall within the scope of the claims. Enhancers of LIPG enzymatic activity could act at any of the numerous undefined levels of the extremely complex signalling pathways controlling the LIPG activity and had no structural or direct functional properties in common. It furthermore held that undue experimentation was required to screen large compound libraries randomly, contrary to the requirements of technical support (Article 84 EPC) and sufficiency of disclosure (Article 83 EPC).

- V. With the statement of the grounds of appeal dated 1 April 2009 the appellants requested the board to set aside the decision under appeal and to order the grant of a patent on the basis of the claims of the request subject to the appealed decision (see section III). The appellants furthermore filed arguments in relation to novelty (Article 54 EPC), inventive step (Article 56 EPC) and clarity (Article 84 EPC). In the context of the latter, the appellants filed two further documents.
- VI. When summoning the appellants to oral proceedings to take place on 25 September 2013, the board expressed in a communication pursuant to Article 15(1) RPBA its preliminary opinion that the appeal was likely to be dismissed. In the communication the board explicitly referred to decision T 1063/06 (OJ EPO 2009, 516) and

held that the application of the principles addressed and observations made in this decision applied *mutatis mutandis* to the subject-matter of *inter alia* claim 1 of the sole request on file.

VII. With a letter dated 19 August 2013, the appellants withdrew their request for oral proceedings and announced that they would not be represented at the oral proceedings. Accordingly, the board cancelled the appointed oral proceedings.

VIII. Although the appellants did not explicitly address issues under Article 83 EPC in their statement of grounds of appeal (see section V), the following arguments made in an other context and which are relevant for the present decision, can be summarised as follows:

- The application as originally filed described assay methods which might be used to identify enhancers and inhibitors (modulators) of LIPG activity as recited in the claimed compositions including e.g. a fluorescent assay, a scintillation proximity assay and a radiometric phospholipase A assay. Additionally, Example 17 described assays for the *in vivo* assessment of compounds.
- Given that enhancer and inhibitor molecules of the activity of various enzymes were known in the art and in view of the guidance provided by the application regarding the methods that could be used to screen for such modulators of enzyme activity, one skilled in the art would be able to

employ methods to identify inhibitors and/or enhancers of LIPG activity as claimed.”

Reasons for the Decision

1. The appeal is admissible.

Procedural issue

2. In an appeal relating to a decision of an examining division refusing a European patent application, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC (Article 111(1) EPC). Hence the board can consider requirements that the examining division did not take into consideration in the examination proceedings or which it regarded as having been met (see decision G 10/93, OJ EPO 1995, 172, Headnote).
3. Therefore, also issues under Article 83 EPC, not specifically addressed during the examination phase, are dealt with by board in this decision.
4. The main thrust of the reasoning of the present decision was foreshadowed in the communication of the board pursuant to Article 15(1) RPBA (see section VI). Furthermore, since the appellants have not reacted substantively in response to the preliminary opinion of the board expressed in this communication and have merely withdrawn their request for oral proceedings, the board could come to this decision on the basis of the written proceedings before it.

Claim 1 - Sufficiency of disclosure (Article 83 EPC)

The decision in first instance

5. In its decision the examining division held that the application did not define any "enhancers" as recited in claim 1. The subject-matter of claim 1 was therefore purely speculative and defined as a mere statement of the result to be achieved. Although large compound libraries could be screened for the desired enhancer activity this did not provide the skilled person with immediate or testable knowledge of the compound or compound family which could fall within the ambit of the claim. In particular, enhancers of LIPG enzymatic activity could act at any of the numerous undefined levels of the extremely complex signalling pathways controlling the LIPG activity and have no structural or direct functional properties in common. Accordingly, undue experimentation was required to screen large compound libraries randomly, contrary to the requirements of disclosure (Article 83 EPC).

Claim construction

6. Claim 1 is directed to the use of an "enhancer" in the manufacture of a composition for lowering the level of LDL cholesterol in a patient. It is stated further that the enhancer "*preferentially* enhances the enzymatic reactions between LIPG polypeptide and LDL cholesterol relative to the enzymatic reactions between LIPG polypeptide and HDL cholesterol and apolipoprotein AI" (emphasis added by the board). For the purpose of claim construction, the latter feature therefore constitutes

merely an optional feature and has no bearing on the definition of the subject-matter and scope.

7. The application as originally filed defines an "enhancer" as "*a molecule which increases the expression of the LIPG polypeptide or which increases the enzymatic activity of the LIPG polypeptide*" (see page 29, lines 28 to 30). In line with established case law of the boards of appeal, a patent application, being a legal document, may be its own dictionary and may define technical terms and determine how a skilled person has to interpret a specific term when used in the description or claims (see e.g. decisions T 500/01 of 12 November 2003, point 6 of the reasons, and T 61/03 of 12 April 2005, point 4.2 of the reasons). The board therefore construes the meaning of the term "enhancer" of claim 1 to comply with the functional aspect of the definition contained in the description.
8. The board notes however, that the enhancer of claim 1 is not defined by any specific structural features, but merely by this functional feature and the capability to lower the level of LDL cholesterol in a patient. Consequently, claim 1 concerns all chemical compounds which increase the expression of the LIPG polypeptide or which increases the enzymatic activity of the LIPG polypeptide and can lower the level of LDL cholesterol in a patient without any restrictions to compound classes or chemical structure.
9. The board can concur with the appellants that the application describes a number of assay methods which can be used to identify enhancers and inhibitors (modulators) of LIPG activity as recited in the claimed

- composition. The appellants argued accordingly that the skilled person was able to employ these methods to identify inhibitors and/or enhancers of LIPG activity as claimed.
10. The board notes however, that the appellants have not denied the fact noted by the examining division that the application as originally filed does not concretely identify any enhancer having the functionality as required by the claim. Furthermore, although the application does contain theoretical examples how enhancers which increase the expression of the LIPG polypeptide or which increase the enzymatic activity of the LIPG polypeptide could be identified, the application as filed does not contain any guidance for the skilled person which would allow her/him an educated guess as to for example a particular chemical structural class to which the enhancers recited in claim 1 belong. In addition, the application does not teach any guidance how to effectively select such compounds which also comply with the functional feature of lowering the level of LDL cholesterol in a patient.
 11. Accordingly, in a search for enhancers recited in claim 1, the skilled person would have to test a virtually unlimited amount of chemical compounds of various chemical structures. The board judges therefore that the application as filed does not provide the skilled person at the relevant date of the application with any guidance enabling her/him, without undue experimentation, to identify the enhancers as defined in claim 1.

12. Therefore, similar to the findings and observations of the there competent board in decision T 1063/06 (OJ EPO 2009, 516, see points 5 to 6 of the reasons) the board in the present case judges that since the enhancers to be used are characterised in functional terms only and claim 1 merely represents for the skilled person an invitation to perform a research programme, it cannot carry out the invention within the entire scope claimed without undue burden (see also T 155/08 of 12 June 2012, point 6 of the reasons).
13. In view of the above considerations, the board comes to the same conclusion as the examining division, that the requirements of Article 83 EPC are not met with respect to claim 1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

P. Cremona

C. Rennie-Smith