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**Datasheet for the decision
of 4 August 2009**

Case Number: T 1008/06 - 3.3.02

Application Number: 00990641.3

Publication Number: 1239854

IPC: A61K 31/198

Language of the proceedings: EN

Title of invention:

Use of a hypoglycemic agent for treating impaired glucose metabolism

Applicant:

NOVARTIS AG, et al

Opponent:

-

Headword:

Hypoglycemic agent/NOVARTIS AG

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Inventive step - no: obvious to try"

Decisions cited:

-

Catchword:

-



Case Number: T 1008/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 August 2009

Appellant: NOVARTIS AG
Lichtstrasse 35
CH-4056 Basel (CH)

Representative: Gros, Florent
Novartis AG
CH-4002 Basel (CH)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 13 January 2006
refusing European patent application
No. 00990641.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

- I. European patent application No. 00 990 641.3 was refused by a decision of the Examining Division dated 13 December 2005 on the grounds of lack of inventive step.
- II. The decision was based on claims 1 to 9 of the main request received on 1 November 2004.

Independent claim 1 of this request reads as follows:

1. The use of nateglinide, or a pharmaceutically acceptable salt thereof for the manufacture of a medicament in subjects with IGM, especially IFG and/or IGT, for the prevention or delay of progression to overt diabetes mellitus type 2; for the prevention, reduction or delay in onset of a condition selected from the group consisting of increased microvascular complications; increased cardiovascular morbidity; excess cerebrovascular diseases; increased cardiovascular mortality and sudden death; higher incidences and mortality rates of malignant neoplasms; and other metabolic disturbances that are associated with IGM.

- III. The arguments in the decision may be summarised as follows:

The subject-matter of the set of claims filed with the appellant's letter dated 1 November 2004 was held to be not inventive vis-à-vis the closest prior-art document (9) (translation of "Preclinical studies of AY4166", The Japanese Journal of Clinical Studies ("Nippon

Rinsho"), vol. 55, suppl. 2, 1997, pages 159-163), which indicated the potential use of nateglinide for preventing progression from IGT (Impaired Glucose Metabolism) to NIDDM (Non-Insulin-Dependent Diabetes Mellitus), as well as its potential beneficial use in the treatment of NIDDM and the prevention of the onset and progression of diabetic complications in NIDDM.

IV. The appellant (applicant) lodged an appeal against the said decision.

With its grounds of appeal dated 12 May 2006, it filed a set of 7 claims as a new main request.

Claim 1 of this request reads:

1. The use of nateglinide, or a pharmaceutically acceptable salt thereof for the manufacture of a medicament in subjects with IGM, especially IFG and/or IGT for the prevention, reduction or delay in onset of a condition selected from the group consisting of increased cardiovascular mortality and increased cardiovascular mortality and sudden death.

V. Oral proceedings were held on 4 August 2009. The appellant did not attend.

VI. In its written submissions, the applicant considered that there was no teaching in the cited prior-art documents which suggested to the person skilled in the art to specifically use nateglinide for the manufacture of a medicament in subjects with IGM for the prevention, reduction or delay in onset of a condition selected from the group consisting of increased cardiovascular

morbidity and increased cardiovascular mortality and sudden death, so that the skilled person could not have a reasonable expectation that nateglinide would exhibit such an effect.

VII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the request filed with letter dated 12 May 2006.

Reasons for the Decision

1. The appeal is admissible.
2. Inventive step

The Board considers that document (9), which also discloses the use of nateglinide for preventing the progression from IGT to NIDDM, as well as its potential beneficial use in the treatment of NIDDM and the prevention of the onset and progression of diabetic complications in NIDDM, represents the closest prior-art document (page 7, last paragraph to page 8, first paragraph).

According to the description of the contested application as originally filed, the claimed nateglinide is useful inter alia for preventing progression from IGT to NIDDM, and it has a potential beneficial use in the treatment of NIDDM and in the prevention of the onset and progression of diabetic complications in NIDDM such as increased cardiovascular morbidity and increased cardiovascular mortality and

sudden death (page 8, last paragraph; page 14, third paragraph).

Accordingly, starting from document (9), the technical problem to be solved can be defined as the provision of a means for the manufacture of a medicament in subjects with IGM for the prevention, reduction or delay in onset of a condition selected from the group consisting of increased cardiovascular morbidity and increased cardiovascular mortality and sudden death.

The proposed solution is the subject-matter of independent claim 1, namely the use of a pharmaceutical composition comprising nateglinide.

The Board is satisfied that this problem is plausibly solved.

The question to be answered is thus whether the proposed solution, namely the use of a pharmaceutical composition comprising nateglinide, is obvious to the skilled person faced with the problem defined above in the light of the available prior-art documents.

In that respect, the application itself acknowledges that it is general knowledge that individuals with IGM are known to have a significant higher rate of progression to diabetes (NIDDM) than normoglycemic individuals and are known to be at high cardiovascular risk, i.e. a typical complication in NIDDM.

Moreover, document (9) teaches the potential use of nateglinide for preventing progression from IGT to NIDDM, as well as its potential beneficial use in the

treatment of NIDDM and the prevention of the onset and progression of diabetic complications in NIDDM (page 7, last paragraph to page 8, first paragraph; page 9, "closing remarks").

Accordingly, contrary to the appellant's statement in its grounds of appeal that the skilled person could not have a reasonable expectation that nateglinide would exhibit an effect on cardiovascular risks, it appears that the skilled person would arrive at the claimed use of nateglinide without inventive activity, by merely following the teaching of document (9) and on the basis of his general knowledge.

It follows that, contrary to the requirement of Article 56 EPC, the subject-matter of claim 1 lacks inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

N. Maslin

U. Oswald