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D E C I S I O N
of 22 September 2005

Case Number: T 0213/04 - 3.3.02

Application Number: 96912935.2

Publication Number: 0831818

IPC: A61K 31/425

Language of the proceedings: EN

Title of invention:
Modulators of peroxisome proliferator activated receptor-gamma, and methods for the use thereof

Applicant:
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES
10010 North Torrey Pines Road
La Jolla California 92037 (US)

Opponent:
-

Headword:
PPAR-Gamma Modulator/SALK

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty (no) - process known in the state of the art"

Decisions cited:
-

Catchword:
-

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Case Number: T 0213/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 September 2005

Appellant: THE SALK INSTITUTE FOR BIOLOGICAL STUDIES
10010 North Torrey Pines Road
La Jolla California 92037 (US)

Representative: Polz, Leo, Dr., et al
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 25 September 2003 refusing European application No. 96912935.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

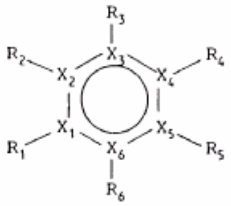
Chairman: U. Oswald
Members: H. Kellner
J. H. Willems

Summary of Facts and Submissions

I. European patent application No. 96 912 935.2 (publication No. WO 96/40128) was refused by a decision of the examining division on the basis of Article 97(1) EPC for lack of novelty under Article 54 EPC.

Claim 1 of the main request reads as follows:

"An in vitro method for modulating process(es) mediated by peroxisome proliferator activated receptor-gamma (PPAR-γ), said method comprising conducting said process(es) in the presence of at least one antagonist or partial-agonist of PPAR-γ, wherein said antagonist or partial-agonist of PPAR-γ has the structure I:



(I)

wherein:

each of X_1, X_2, X_3, X_4, X_5 and X_6 is independently selected from carbon, nitrogen, oxygen or sulfur, with the proviso that at least three of the atoms forming the ring are carbon,

R_1 is selected from alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, substituted aryl, alkylaryl, substituted alkylaryl, alkenylaryl, substituted alkenylaryl, alkynylaryl, substituted alkynylaryl, arylalkyl, substituted arylalkyl, arylalkenyl, substituted arylalkenyl, arylalkynyl, substituted arylalkynyl,

poly(alkylene oxide), substituted poly(alkylene oxide), poly(alkylene sulfide), substituted poly(alkylene sulfide), poly(alkylene amine), substituted poly(alkylene amine), -OR, -SR, -NR_2, wherein each R is independently selected from alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, substituted aryl, alkylaryl, substituted alkylaryl, arylalkyl, substituted arylalkyl, poly(alkylene oxide), substituted poly(alkylene oxide), poly(alkylene sulfide), substituted poly(alkylene sulfide), poly(alkylene amine) or substituted poly(alkylene amine);

R_2 is selected from hydrogen, alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, substituted aryl, alkylaryl, substituted alkylaryl, alkenylaryl, substituted alkenylaryl, alkynylaryl, substituted alkynylaryl, arylalkyl, substituted arylalkyl, arylalkenyl, substituted arylalkenyl, arylalkynyl, substituted arylalkynyl, oxyalkyl, poly(alkylene oxide) or substituted poly(alkylene oxide);

R_3 is selected from hydrogen, hydroxy, halogen, alkoxy, lower alkyl, substituted lower alkyl, alkenyl, substituted alkenyl, alkynyl or substituted alkynyl;

R_4 is selected from hydrogen, formyl, acyl, lower alkyl or substituted lower alkyl;

R_5 is selected from hydrogen, hydroxy, lower alkoxy, lower alkyl, substituted lower alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl or halogen; and

R_6 is selected from hydrogen, hydroxy, lower alkoxy, lower alkyl, substituted lower alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl or halogen,

wherein the term lower refers to straight or branched chain groups having in the range of about 1 to 4 carbon atoms."

II. The following document was cited inter alia during the proceedings before the examining division and before the board of appeal:

(1) LEHMANN J.M. ET AL: "An antidiabetic thiazolidinedione is a high affinity ligand for peroxisome proliferator-activated receptor γ (PPARγ)", XP002007689, The Journal of Biological Chemistry, Vol. 270, no. 22, June 1995, 12953-12956

III. The examining division considered that the subject-matter of claim 1 having regard to document (1) was not novel.

In this document an in vitro method was disclosed for modulating processes mediated by PPAR-γ, such as cell differentiation, to produce lipid accumulating cells, using a partial-agonist of this receptor, namely, pioglitazone, covered by structure I. Pioglitazone proved to be a partial-agonist because the experimental data reported in (1) show that the response induced by the compound flattens at a particular concentration and does not reach the activation level seen with BRL49653, a known agonist. This statement was in accord with the argumentation of the applicant in its letter dated

5 September 2002 with respect to the definition of a partial-agonist.

IV. The appellant lodged an appeal against the decision of the examining division.

V. Oral proceedings took place on 22 September 2005. The applicant had withdrawn its request for oral proceedings with its letter of 18 August 2005 and it was not represented in the proceedings.

The wording of claim 1 of the single request is the same as that of claim 1 before the examining division (see point I of this decision).

VI. The arguments of the appellant in the written procedure may be summarised as follows:

With respect to the assertion that the compound BRL49653 fell under the scope of claim 1, it was emphasized that BRL49653 was a known agonist and would therefore not be embraced by claim 1 and the claims were thereby novel over (1).

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 following points: the set of claims filed with the grounds of appeal dated 26 January 2004.

Reasons for the Decision

1. The appeal is admissible.

2. The claims of the single request are based on claims 1 and 2 together with page 13, lines 19 to 27, page 5, lines 20 to 37, and page 6, lines 6 to 8, of the application as originally filed.

The requirements of Article 123(2) EPC are consequently satisfied.

3. As far as novelty of the claimed subject-matter of the main request is concerned, the decision of the examining division contains well-founded arguments with respect to the compound pioglitazone disclosed in document (1) (see particularly figures 1 and 2) and anticipating novelty of the subject-matter of current claim 1.

The appellant did not submit any counter-arguments to these conclusions.

Pioglitazone is represented by formula I contained in claim 1 as requested, with X_1 to X_6 being C-atoms, R_2, R_3, R_5 and R_6 being hydrogen, R_1 being -OR wherein R is substituted alkyl and R_4 being substituted lower alkyl (see claim 1, formula I and definitions of the substituents R and atoms X below formula I). Further, the board is satisfied with the arguments of the examining division.

Consequently, the board has no reason to depart from the reasoning or the conclusion of the examining division in the impugned decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend U. Oswald