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Datasheet for the decision of 29 March 2007

Case Number: T 0717/06 - 3.3.02

Application Number: 01103552.4

Publication Number: 1120113

IPC: A61K 31/00

Language of the proceedings: EN

Title of invention:
Use of selective ligands for treatment of disease states responsive to steroid or steroid-like hormone

Appellant:
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES, et al

Opponent:
-

Headword:
RAR selective ligands for the treatment of skin disorders/THE SALK INTITUTE FOR BIOLOGICAL STUDIES, ET AL.

Relevant legal provisions:
EPC Art. 76, 123(2)

Keyword:
"Main and first auxiliary requests (no): no basis for the feature RAR-β,γ selective ligand" in the application as filed"
"Second auxiliary request: admissibility (no): the request was filed late without a convincing explanation for the late filing"

Decisions cited:
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Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0717/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 29 March 2007

Appellant: THE SALK INSTITUTE FOR BIOLOGICAL STUDIES
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 November 2005 refusing European application No. 01103552.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: A. Lindner
J. Willems

Summary of facts and submissions

I. European patent application No. 01 103 552.4 was refused by a decision of the examining division dated 7 October 2005 on the basis of Article 97(1) EPC on the grounds that both the main and the auxiliary requests contain subject-matter that extends beyond the content of the parent application as filed and, in addition, lack novelty.

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

(7) EP-A-0 220 118

III. The decision was based on claims 1-6 of the main request and claims 1-5 of the first auxiliary request as filed with a letter of 7 September 2005.

Independent claim 1 and dependent claims 5 and 6 of the main request read as follows:

"1. Use of an effective amount of a RAR-ß,γ selective ligand for the preparation of a medicament for the treatment of a skin disorder.

5. Use according to Claims 1 to 4 wherein said ligand which selectively interacts with RAR-ß and/or RAR-γ is at least 5 times more active at 10^{-7} M than RAR-α.

6. Use according to Claims 1 to 4 wherein said ligand which selectively interacts with RAR-ß and/or RAR-γ is at least 25 times more active at 10^{-7} M than RAR-α."

Independent claim 1 and dependent claim 5 of the first auxiliary request read as follows:

"1. Use of an effective amount of a RAR-ß,γ selective ligand for the preparation of a medicament for the treatment of a skin disorder wherein said ligand which selectively interacts with RAR-ß and/or RAR-γ is at least 5 times more active at 10^{-7} M than RAR-α.

5. Use according to Claims 1 to 4 wherein said ligand which selectively interacts with RAR-ß and/or RAR-γ is at least 25 times more active at 10^{-7} M than RAR-α."

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

The subject-matter of claim 1 of both the main and the first auxiliary requests contained an unallowable generalisation of examples II and V of the parent application, as the parent application did not comprise a general disclosure of ligands with a selectivity for both RAR-ß and RAR-γ receptors.

Moreover, there was no basis in the parent application for the feature "ligand which selectively interacts with RAR-ß and/or RAR-γ and which is at least 5 or 25 times more active at 10^{-7} M than RAR-α" (claims 5 and 6 of the main request and claims 1 and 5 of the first auxiliary request).

In connection with novelty, the examining division held that document (7) contained the technical teaching that the compounds as disclosed therein were used for the

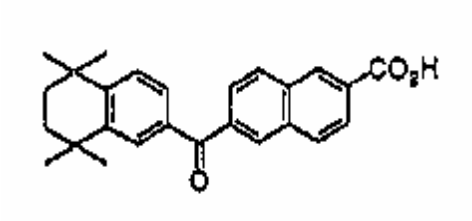
treatment of various skin disorders including acne and psoriasis. This teaching was fully applicable to the active agent as disclosed in example VII of document (7) and to the cream according to example 8 which contained the active agent of example VII. As the compound according to example VII of document (7) corresponded to compound IV of the application under appeal, the subject-matter of claim 1 of the main request was anticipated by document (7).

Moreover, example VII of document (7) was also detrimental to the novelty of claim 1 of the first auxiliary request. This also applied to the composition according to example 8.

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

VI. Oral proceedings were held before the board on 29 March 2007. During the oral proceedings, the appellant requested leave to file a second auxiliary request, claim 1 of which reads as follows:

"Use of an effective amount of Compound IV



which selectively interacts with RAR-ß and RAR-γ for the preparation of a medicament for the treatment of a skin disorder, wherein the compound is used at a concentration above $1x10^{-8}$ M."

VII. The appellant's submissions, both in the written procedure and at the oral proceedings can essentially be summarised as follows:

(a) As far as the basis for the feature "RAR-ß,γ selective ligand" in the parent application is concerned, it was held that selective ligands for steroid hormone receptors were described on page 6, lines 16-20. These compounds were further defined in lines 22-28 of the same page. In addition, the parent application disclosed two specific RAR-ß,γ selective ligands in the form of compounds I and IV in examples II and V. As the disclosure of these specific examples must be read in the light of the general disclosure and vice versa, there was a clear basis for the feature "RAR-ß,γ selective ligand" in the parent application as filed. The appellant emphasised that the general teaching of the parent application was not limited to the use of compounds which selectively interacted with a single subtype of the receptor, as in that case none of the specific examples would be encompassed by the said teaching.

(b) In connection with the late filing of the second auxiliary request, the appellant held that in the invitation to the oral proceedings the board had not given a preliminary opinion on the allowability of the amendments or on novelty.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, of the first auxiliary request, both

filed with letter of 7 September 2005 or, more alternatively, of the second auxiliary request filed during the oral proceedings.

Reasons for the decision

1. The appeal is admissible.

2. Main request:

2.1 Basis for the feature "RAR-ß,γ selective ligand":

2.1.1 The board agrees that compound I is a specific embodiment of an RAR-ß,γ selective ligand (cf. page 6, line 30 - page 7, line 3 of the parent and of the divisional applications as filed).

2.1.2 In connection with compound IV, the board notes that there is a contradiction between the disclosure of example V and the corresponding figure 5 on the one hand, where compound IV is described as a RAR-ß,γ specific ligand, and the passage on page 7, lines 25-34 on the other hand, where it is defined as a RAR-α,ß selective agent. As a consequence, the parent and the divisional applications as filed do not unambiguously disclose RAR-ß,γ specificity for compound IV.

2.1.3 When deciding whether or not the selective interaction with RAR-ß,γ can be generalised from compound I to any RAR-ß,γ specific ligand, it is necessary to examine the general teaching of the application under appeal: on page 1, lines 11-14 of the parent and divisional applications as filed it is stated that the present

invention relates to "the use of compounds which selectively or preferentially interact with a single subtype of a given steroid hormone or steroid-like hormone receptor class".

Similar statements can be found on page 2, lines 25-28: "...it would be desirable to have the ability to selectively treat subjects with compounds which selectively interact as ligands with the specific receptor subtype involved in the disease state."

and on page 5, lines 10-17:
"As employed herein, the phrase "ligand which selectively interacts with the receptor subtype associated with said steroid or steroid-like hormone responsive disease state to a significantly greater extent than with other subtypes of the same receptor class" refers to compounds which are preferentially selective for one receptor subtype in modulating the transcription activation properties thereof".

2.1.4 These passages show that the general teaching is concerned with ligands which are as selective as possible and preferentially interact with a single receptor subtype. In the light of this teaching, the parent and divisional applications as filed do not provide a basis which would allow the generalisation of the selective interaction with RAR-ß,γ from a single specific compound to any RAR-ß,γ ligand.

2.1.5 As a consequence, the subject-matter of the main request does not meet the requirements of Article 76 EPC (with regard to the parent application) and of

Article 123(2) EPC (with regard to the divisional application as filed).

2.2 Under these circumstances, there is no need to examine the remaining objections.

3. First auxiliary request:

As the feature "RAR-ß,γ selective ligand" is also present in claim 1 of the first auxiliary request, this request does not meet the requirements of Articles 76 and 123(2) EPC either.

4. Allowability of the second auxiliary request:

In accordance with Article 10b RPBA, any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the board's discretion. The discretion shall be exercised in view of *inter alia* the current state of the proceedings. In the present case, the appellant filed the second auxiliary request only at an advanced stage of the oral proceedings. As no new objections had been raised during the appeal procedure, the appellant must have been aware that the grounds for refusal of the decision under appeal would be dealt with at the oral proceedings. Moreover, the discussion of the main and first auxiliary requests at the oral proceedings did not involve any new facts or arguments which might have justified the filing of additional requests. As a consequence, the appellant could have filed the second auxiliary request much earlier. Therefore, and in view of the fact that the appellant did not put forward

convincing arguments for the late filing, the board decided not to admit the second auxiliary request.

It is additionally noted that there were also doubts as to the clear allowability of the claims, as there appeared to be *prima facie* problems with the novelty in connection with example 8 of document (7). Moreover, it was doubtful whether the feature "wherein the compound is used at a concentration above $1x10^{-8}$ M" had originally been disclosed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend J. Riolo