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D E C I S I O N
of 28 November 1996

Case Number: T 0600/95 - 3.3.1

Application Number: 90306753.6

Publication Number: 0405834

IPC: C07D 01/06

Language of the proceedings: EN

Title of invention:
Tetrazole excitatory amino acid receptor antagonists

Applicant:
ELI LILLY AND COMPANY

Opponent:
-

Headword:
Enantiomer/ELI LILLY

Relevant legal provisions:
EPC Art. 54(1)

Keyword:
"Novelty (no)"
"Clear and unambiguous implicit disclosure"

Decisions cited:
T 0296/87, T 1048/92, T 0658/91, T 0181/82

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0600/95 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 28 November 1996

Appellant: ELI LILLY AND COMPANY
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Representative: Tapping, Kenneth George
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 February 1995 refusing European patent application No. 90 306 753.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: A. J. Nuss
Members: R. K. Spangenberg
S. C. Perryman

Summary of Facts of Submissions

I. The present appeal was filed on 11 April 1995. It lies against the decision of the Examining Division of 13 February 1995 refusing European patent application No. 90 306 753.6, filed on 20 June 1990 and published under No. 0 405 834.

II. The decision under appeal was based on the application documents as filed, including two sets of claims for different Contracting States. The first set of claims for all designated Contracting States except GR and ES contained four claims, the first of them reading as follows:

"Cis-(-)-4[(1(2)H-tetrazol-5-yl)methyl]-2-piperidinecarboxylic acid or a pharmaceutically acceptable salt thereof."

Claim 2 related to a pharmaceutical formulation comprising as an active ingredient the compound as claimed in Claim 1, Claim 3 to the compound claimed in Claim 1 for use as a pharmaceutical, and Claim 4 to a process for preparing the compound as claimed in Claim 1, starting from optically active precursors.

The sole ground of refusal was that the subject-matter of the above Claims 1 to 3 was not novel in the sense of Article 54, paragraphs (1), (3) and (4) for all designated Contracting States except DK with respect to the content of document

(1) EP-A-0 330 353.

The Examining Division held that this document implicitly disclosed the compound claimed or used according to the above claims, since this compound was

one of only two possible stereoisomers comprised by Claim 4 of document (1) and since it was expressly stated in the description of document (1) that "the compounds of the present invention include not only the (±) racemates, but also their respective optically active (+)- and (-)- isomers". It further held that these optically isomers could be prepared by a skilled person at the priority date of the application, so that the disclosure in document (1) was sufficient to make these compounds available to the public.

III. The Appellant (the Applicant) submitted that the objection raised under Article 54(1) EPC was based on a misinterpretation of the disclosure of document (1), since Claim 4 of that document related to a 50:50 - mixture of two enantiomers. He submitted that the attempt to add a claim concerning the (-) enantiomer to the statement of claim in document (1) would have given rise to an objection by the examiner in that application under Article 123(2) EPC, and that, therefore, document (1) did not constitute a specific disclosure of the present isomer, and that it does not provide an "individualised description" as required by the Appeal Board in T 296/87 (OJ EPO 1990, 195). The Appellant further referred to decision T 1048/92 (EPOR 1995, 207).

IV. In an Annex to the summons to attend oral proceedings the Board observed that the facts of the present case would seem to differ significantly from those relevant in decision T 1048/92 and referred to decision T 658/91 of 14 May 1993 (English translation of the original French text published in EPOR 1996, 25). In reply, the Appellant asked the Board to provide a preliminary view on the point whether it would have been allowable to add a claim to the present isomer to the claims of document (1). In addition, the Appellant indicated that he no longer wished to attend the oral proceedings.

V. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the sets of claims as filed and underlying the decision under appeal.

VI. Oral proceedings took place on 28 November 1996. The Appellant, although duly summoned, was not represented in accordance with his previous communication.

At the end of the oral proceedings the decision to dismiss the appeal was announced.

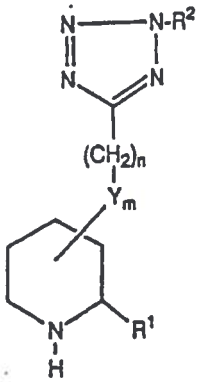
Reasons for the Decision

1. The appeal is admissible.

2. According to the consistent jurisprudence of the Boards of Appeal of the EPO (see e.g. the summary in IIC 1993, 696, in particular point 1.4, page 701) the interpretation of the technical disclosure contained in a given document does not normally depend on the purpose it serves, be it as representing state of the art (Article 54 EPC), as priority document (Article 87 EPC) or as the application as filed (Article 123(2) EPC). Nevertheless, the Board has no power to provide even a preliminary view on the point whether it would be allowable to add a claim to the present isomer to the claims of document (1), as requested by the Appellant. This question could only have been answered by the body competent for examining the patent application corresponding to document (1). In relation to the present case, the question whether such an amendment would have been allowable, is purely hypothetical and thus irrelevant.

3. The sole issue to be decided in these appeal proceedings is that of the novelty of the subject-matter of Claims 1 to 3 in respect of the disclosure in document (1).

3.1. This document, which is acknowledged as prior art in the description of the application in suit, relates to a generically defined class of tetrazole excitatory amino acid receptor antagonists of the following formula



in which the meanings of the substituents R^1, R^2 and Y as well as the meanings of "m" and "n" are not relevant to the present case.

In the description of this document it is stated that "the compounds of the present invention possess two asymmetric carbon atoms represented by the carbon atom of the piperidine ring which attaches to the tetrazole ring either directly or through one or more methylene groups, and the carbon atom of the piperidine ring which attaches R to the piperidine ring. As such, the compounds can exist as two diastereoisomers, their cis or trans isomers, and each of which can exist as the racemic mixture of such isomers or each individual optical isomer. **Accordingly, the compounds of the present invention will include not only the (±)-racemates, but also their respective optically active (+) and (-)-isomers**" (see page 5, lines 23 to

29; emphasis added by the Board.) The description then goes on to describe the method of obtaining the compounds of the above formula, followed by the following statement:

"The preceding description of the synthesis of the compounds of the present invention prepares a mixture of the cis- and trans-isomers, but predominantly as the cis-isomer. The diastereomers are easily separated from the mixture using standard chromatographic techniques, for example, employing silica gel or alumina adsorbents"(see page 9, lines 6 to 9).

On the bottom of page 9 it is said that the following examples further illustrate the compounds of the invention and their synthesis. Example 3 then describes the synthesis of cis-(±)-4[(1(2)H-tetrazol-5-yl)methyl]-2-piperidinecarboxylic acid.

3.2. In the present circumstances, the Board construes Claim 1 of the application in suit as concerning a substantially pure compound which is not contaminated by significant amounts of the other possible stereoisomers.

In accordance with the above-mentioned consistent jurisprudence of the Boards of Appeal, the novelty of such an individual chemical compound can only be denied if there is an unambiguous disclosure of this very compound in the form of a technical teaching (see in particular T 181/82, OJ EPO 1984, 401, No. 8 of the reasons, and T 296/87, OJ EPO 1990, 195, Nos. 6 and 7 of the reasons). It is thus not sufficient that the compound in question belongs conceptually to a disclosed class of possible compounds, without any pointer to the individual member. It is, however, not necessary that a detailed method for obtaining each and every individually disclosed compound must be

described, e.g. by way of a worked example, provided that the skilled person would still be able to synthesise or isolate that compound on the basis of the common general knowledge (see e.g. T 658/91-3.3.1 of 14 May 1993, cited in "Case Law of the Boards of Appeal of the EPO"(EPO 1996), Chapter I, sections C-2.5 and C-4.1).

3.3. It is true that the only reference to optically active compounds that can be found in document (1) is that on page 5, lines 27 to 29 (see point 3.1 above), according to which the invention described therein is to be construed as including the racemic mixtures as well as their optically active (+) and (-)- isomers. No method for obtaining these isomers from the racemates is mentioned in document (1). However, the compound according to the present Claim 1, which is the (-)-isomer contained in the racemic mixture obtained according to Example 3 of document (1) is an amino acid. The methods for separating racemic mixtures of amino acids into their respective optical isomers are well known to those skilled in the art, as stated in the decision under appeal. It is therefore not surprising that this finding was not disputed by the Appellant. It is thus immaterial that the decision under appeal in this context additionally relied upon document (1), page 9, lines 6 to 14, which relate solely to the separation of the cis and trans isomers, i.e. different chemical compounds and not optical isomers. Therefore, the disclosure of document (1) amounts to a technical teaching of any optical isomer of each individual racemic mixture disclosed in that document. In other words, in the Board's judgment the statement on page 5 of document (1) has the same effect as would have had an analogous statement added e.g. as an additional step H to Example 3 of document (1) (see also T 658/91-3.3.1 of 14 May 1993, cited above).

3.4. By contrast, in decision T 1048/92 the statements in the description, although quite similarly worded, were **not** construed by the Board as relating to an optical isomer of one particular example, because it held that in the circumstances of that case the disclosure of steric configurations in the relevant prior art document related solely to the penem ring system common to **all** compounds described in that document, whereas the compound in question was an optical isomer of a compound containing the penem ring system having the steric configuration indicated in the prior art document as the preferred one, and an **additional** centre of asymmetry in a side chain which was not present in other examples of the disclosed class of compounds. Thus the facts of that case were quite different from those of the present case, and the different conclusions drawn from these facts are in no way indicative of different concepts of assessing novelty.

4. For the above reasons Claim 1 of the set of claims for the Designated Contracting States other than GR and ES lacks novelty and the appeal must accordingly fail. Since the Appellant did not avail himself of the possibility to submit, e.g. by way of an auxiliary request, a text of the application not containing that claim, the Board need not consider whether the subject-matter of the remaining claims is novel.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

E. Görgmaier A. Nuss