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Datasheet for the decision of 22 May 2007

Case Number: T 0993/04 - 3.3.02

Application Number: 01982091.9

Publication Number: 1320369

IPC: A61K 31/519

Language of the proceedings: EN

Title of invention:
A method of analgesia

Applicant:
Wex Medical Limited

Opponent:
-

Headword:
Analgesia/WEX MEDICAL

Relevant legal provisions:
EPC Art. 111(1)

Keyword:
"Remittal to the first instance - shift of invention"

Decisions cited:
-

Catchword:
-

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Case Number: T 0993/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 May 2007

Appellant: Wex Medical Limited
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Representative: Vossius & Partner
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 12 February 2004 refusing European application No. 01982091.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent application No. 01 982 091.9, filed as WO 02/22129 based on international patent application PCT/CN01/01391, 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.

The wording of claim 1 of the main request before the examining division was:

"Use of a sodium channel blocking compound for the preparation of a pharmaceutical composition for the systemic administration for producing analgesia in a mammal experiencing pain, wherein said compound specifically binds to a site on an SS1 or an SS2 region of a sodium channel alpha subunit."

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

(2) CN 1 145 225 in its English translation provided by the applicant in its letter of 6 August 2003

(3) EP-A- 0 750 909

III. The examining division considered in its decision that the use of tetrodotoxin (TTX) for the preparation of a pharmaceutical composition for the systemic administration for producing analgesia in a mammal experiencing pain had already been disclosed in document (2).

IV. There were no arguments or conclusions in the Reasons for the Decision with respect to Articles 84, 83 and 123 EPC.

V. The applicant (appellant) lodged an appeal against the decision of the examining division and filed grounds of appeal together with five sets of claims as main and auxiliary requests. Additionally, it said it assumed that, because of the absence of objections with respect to Articles 84 and 123(2) EPC in the grounds for the decision of the examining division, the claims of its main request were considered to comply with the formal requirements set out in the EPC.

VI. In a communication dated 20 January 2006, the board particularly pointed out the well known principle that in the proceedings before the board the current requests would have to be examined in the light of all relevant articles of the EPC and not only Articles 54 and 56 EPC (Article 111(1) EPC).

The board further stated that, in addition to the objections raised by the examining division during the examination proceedings, there even seemed to be fundamental problems with regard to Articles 84, 83 and 123 EPC.

In fact, the examining division, in its communication of 9 October 2003 accompanying the summons to oral proceedings had pointed out *inter alia* that there were problems under Article 123(2) EPC, because the dependence of certain claims had been changed and therefore subject-matter had been introduced which

extended beyond the content of the application as originally filed.

VII. With its letter of 2 May 2006, the appellant filed a new set of claims as a main request replacing all previously filed requests. Additionally, it filed three sets of claims, named auxiliary requests I to III.

VIII. A first oral proceedings took place on 4 July 2006 in the presence of the representatives of the appellant.

During the oral proceedings, the requests submitted in writing were replaced by one set of claims as a main request and three single claims as auxiliary requests I to III.

After discussion of these requests, the board announced that the proceedings should be continued in writing on the basis of the IIIrd auxiliary request, and the next step would be a communication from the board.

IX. In this communication, dated 19 October 2006, concern was expressed about the teaching of auxiliary request III not being inventive with respect to the teaching of document (2) as a whole. This was stated without any prejudice to possible problems in regard to Articles 52 and 54 EPC.

X. With its letter of 26 April 2007 the applicant filed a new single claim as auxiliary request III replacing auxiliary request III as filed during the first oral proceedings.

The wording of this claim is:

"Use of tetrodotoxin in a suitable pharmaceutical vehicle for the preparation of a pharmaceutical composition for systemic administration so as to produce analgesia in late term cancer patients experiencing pain by repeated systemic administration, wherein a dose of 30 μg tetrodotoxin is administered by intramuscular injection twice a day (once every 12 hours) for three days."

XI. The arguments of the appellant, as set out in writing and during the second oral proceedings held on 22 May 2007, may be summarised as follows:

The subject-matter claimed in auxiliary request III was inventive *vis-à-vis* document (2) since

(i) in the light of the very good results set out in example 4 of (2), the skilled practitioner would not have had any incentive to modify or improve the regimen of document (2) for treating pain in cancer patients;

(ii) the skilled practitioner would not have applied any high TTX doses, as used for treating drug withdrawal symptoms in examples 3 and 5 of document (2), in the treatment of pain (example 4), because these indications were to be considered separately;

(iii) the skilled practitioner would not have dared to increase TTX doses for the treatment of chronic pain because of the extremely toxic nature of this substance and because even normal conclusions from the maximum dose of 2.0 μg/kg body weight used in document (2),

under normal conditions of conversion of animal data to data for use on humans, would lead to a maximum dose of 0.26 μg/kg (15.6 μg for a 60 kg person; according to the board's calculations). The degradation of TTX during heat treatment of its solutions, well known already at the priority date of the application in suit, was taken into account for this calculation.

(iv) the skilled practitioner would not have had any reason to believe that short treatment periods could result in long-term analgesia.

XII. As an answer to the board's question as to whether it was not possible that the dose of 2.0 μg/kg in the first part of example 3 of (2) was administered to non-addicted monkeys in order to explore a possible onset of addiction to TTX, the appellant expressed its view that this part of the example's text concerned only the description of the result of the experiment, as it was conducted in accordance with the text in its second part. There was no further discussion on this topic during the oral proceedings.

The question of what conclusions should be drawn from the fact that the current claim expressed dosing in an absolute value of 30 μg without any reference to body weight, was not answered during the proceedings.

Finally, the board drew the attention of the appellant to example 1 on page 8 as well as table 1 on page 12, in particular columns 2 and 3 concerning Groups A and B of the experiment in document (3), which could be of special interest with respect to the application in suit.

XIII. The appellant (applicant) requested that the decision under appeal be set aside and that a patent be granted on the basis of the claim of the main request (originally filed as auxiliary request III with letter of 26 April 2007) or, auxiliary, that the case be remitted to the first instance.

Reasons for the Decision

1. The appeal is admissible.

2. Subject-matter concerning a regimen of administration of TTX was not the subject of the decision of the examining division.

Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is well recognised that any party may be given an opportunity for two readings of the important elements of a case.

In the present case, the claim of the remaining request now relates to a regimen of administration. Thus, a new situation is created with respect to the new claim, which should now be examined on its own merit.

Therefore, the board exercises its discretion under Article 111 EPC and remits the case to the first instance for further prosecution in all formal and substantive aspects of the EPC, i.e. also taking into account Articles 123, 83, 84, Article 52(4) which in future will be Article 53(c), and Article 54 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution.

The Registrar: The Chairman:

A. Townend U. Oswald