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**Datasheet for the decision  
of 6 August 2009**

**Case Number:** T 0952/06 - 3.3.02

**Application Number:** 97903127.5

**Publication Number:** 0883403

**IPC:** A61K 31/54

**Language of the proceedings:** EN

**Title of invention:**

Method for treating sexual dysfunctions

**Applicant:**

The Regents of The University of California

**Opponent:**

-

**Headword:**

Compounds for use in treatment of sexual dysfunctions/THE  
REGENTS OF THE UNIVERSITY OF CALIFORNIA

**Relevant legal provisions:**

EPC Art. 123(2), 83, 111(1)

**Relevant legal provisions (EPC 1973):**

-

**Keyword:**

"Main request fails for lack of sufficiency of disclosure of  
the compounds claimed"

"First auxiliary request fails for lack of sufficiency of  
disclosure of the purpose claimed; and second auxiliary  
request meets the requirements of sufficiency of disclosure"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0952/06 - 3.3.02

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.02**  
**of 6 August 2009**

**Appellant:** The Regents of The University of California  
(Applicant) 300 Lakeside Drive  
22nd Floor  
Oakland  
California 94612-3550 (US)

**Representative:** Bradley, Adrian  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted 24 January 2006  
refusing European application No. 97903127.5  
pursuant to Article 97(1) EPC 1973.**

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** M. C. Ortega Plaza  
J. Van Moer

## Summary of Facts and Submissions

I. European patent application No. 97 903 127.5, based on international application WO 97/26884 was filed with 33 claims. Claim 1 read as follows:

"1. A method for treating a sexual dysfunction in a subject, said method comprising administering an effective amount of a compound that enhances the stimulation of  $\alpha$ -amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors in said subject, said enhancement being sufficient to diminish the symptoms of sexual dysfunction."

II. The following document *inter alia* has been cited during the examination and appeal proceedings:

(5) WO 94/02475

III. The appeal lies from the decision of the examining division refusing the patent application under Article 97(1) EPC 1973, pursuant to the requirements of sufficiency of disclosure (Article 83 EPC) and inventive step (Article 56 EPC).

IV. Claim 1 filed with the letter of 23 January 2003, serving as basis for the examining division's decision, read as follows:

"1. Use of a compound that is capable of upmodulating the response of  $\alpha$ -amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors to natural ligand binding, in the manufacture of a medicament for the treatment of sexual dysfunction."

As regards the "invention" claimed in claim 1 filed with the letter of 23 January 2003, the examining division considered that the requirements of Article 83 EPC were not met, since the application did not teach how to select the actually effective compounds which could treat all sexual dysfunctions encompassed by said claim.

Moreover, the examining division considered that the problem underlying the application was the provision of a compound for the treatment of sexual dysfunction and the solution defined in claim 1 concerned the use of a compound that is capable of "upmodulating" the response of AMPA receptors to natural ligand binding. The examining division argued that the only evidence provided for the alleged effect was that an unidentified compound ("the drug") was administered in the animal models ("Administration of AMPA-kines to rats"). However, there was no evidence provided to establish a causal link between the "AMPA-kine" of claim 1 and the treatment of sexual dysfunction. Thus, in the examining division's opinion, it was not credible that all the compounds encompassed by the definitions in the claims would solve the stated problem. On the contrary, the examining division pointed out that the application as filed acknowledged that "not all sexual dysfunctions are treated with the compounds used herein". Therefore, the examining division was of the opinion that the requirements of Article 56 EPC were not met.

- V. The applicant (appellant) lodged an appeal against this decision and filed an amended set of claims (claims 1

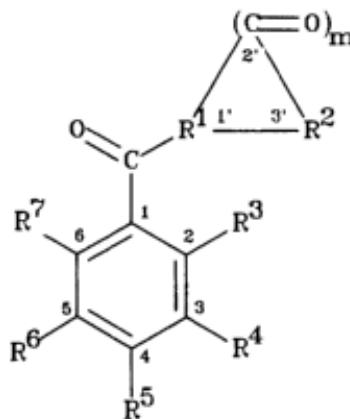
to 32) and some amended pages of the description. It also cited four post-published US patents.

VI. The board sent a communication as an annex to the summons for oral proceedings in which the board's preliminary opinion in relation to Articles 123(2), 84, 83 and 56 EPC was expressed. The board cited in said communication the pre-published document (5).

VII. The appellant filed a letter dated 6 July 2009 in response to the board's communication. With this letter the appellant filed five auxiliary requests.

Claim 1 of the first auxiliary request read as follows:

"1. A compound of the formula



wherein

$R^1$  is a member selected from the group consisting of N and CH;

m is 0 or 1;

$R^2$  is a member selected from the group consisting of  $(CR^8)_m$  and  $C_{n-m}R^8_{(n-m)-2}$ , in which n is 4, 5, 6, or 7, the  $R^8$ 's in any single compound being the same or different, each  $R^8$  being a member selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub> alkyl, or one  $R^8$  being combined with either  $R^3$  or  $R^7$  to form a single bond linking the no. 3' ring vertex to either the no. 2 or the no. 6 ring vertices or a single divalent linking moiety linking the no. 3' ring vertex to either the no. 2 or the no. 6 ring vertices, the linking moiety being a member selected from the group consisting of CH<sub>2</sub>, CH<sub>2</sub>-CH<sub>2</sub>, CH=CH, O, NH, N(C<sub>1</sub>-C<sub>6</sub> alkyl), N=CH, N=C(C<sub>1</sub>-C<sub>6</sub> alkyl), C(O), O-C(O), C(O)-O, CH(OH), NH-C(O), and N(C<sub>1</sub>-C<sub>6</sub> alkyl)-C(O);

$R^3$ , when not combined with any  $R^8$ , is a member selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub> alkyl, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

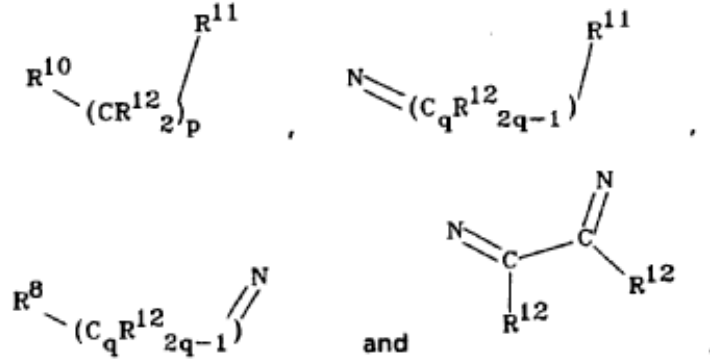
$R^4$  is either combined with  $R^5$  or is a member selected from the group consisting of H, OH, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

$R^5$  is either combined with  $R^4$  or is a member selected from the group consisting of H, OH, C<sub>1</sub>-C<sub>6</sub> alkoxy, amino, mono(C<sub>1</sub>-C<sub>6</sub> alkyl)amino, di(C<sub>1</sub>-C<sub>6</sub> alkyl)amino, and

CH<sub>2</sub>OR<sup>9</sup>, in which  $R^9$  is a member selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub> alkyl, an aromatic carbocyclic moiety selected from phenyl and naphthyl, an aromatic heterocyclic moiety selected from pyridyl, pyrazinyl, pyrimidinyl, quinazolyl, isoquinazolyl, benzofuryl, isobenzofuryl, benzothiofuryl, indolyl, and indolizinyll, an aromatic carbocyclic alkyl moiety selected from phenyl(C<sub>1</sub>-C<sub>6</sub>)alkyl and naphthyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, an aromatic heterocyclic alkyl moiety selected from pyridyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, pyrazinyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, pyrimidinyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, quinazolyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, isoquinazolyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, benzofuryl(C<sub>1</sub>-C<sub>6</sub>)alkyl, isobenzofuryl(C<sub>1</sub>-C<sub>6</sub>)alkyl, benzothiofuryl(C<sub>1</sub>-C<sub>6</sub>)alkyl, indolyl(C<sub>1</sub>-C<sub>6</sub>)alkyl, and indolizinyll(C<sub>1</sub>-C<sub>6</sub>)alkyl, and any such moiety substituted with one or more members selected from the group consisting of C<sub>1</sub>-C<sub>3</sub> alkyl, C<sub>1</sub>-C<sub>3</sub> alkoxy, hydroxy, halo, amino, (C<sub>1</sub>-C<sub>6</sub>)alkylamino, di(C<sub>1</sub>-C<sub>6</sub>)alkylamino, and methylenedioxy;

$R^6$  is either H or CH<sub>2</sub>OR<sup>9</sup>;

R<sup>4</sup> and R<sup>5</sup> when combined form a member selected from the group consisting of



in which:

R<sup>10</sup> is a member selected from the group consisting of O, NH and N(C<sub>1</sub>-C<sub>6</sub> alkyl);

R<sup>11</sup> is a member selected from the group consisting of O, NH and N(C<sub>1</sub>-C<sub>6</sub> alkyl);

R<sup>12</sup> is a member selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub> alkyl, and when two or more R<sup>12</sup>'s are present in a single compound, such R<sup>12</sup>'s are the same or different;

p is 1, 2, or 3; and

q is 1 or 2; and

R<sup>7</sup>, when not combined with any R<sup>8</sup>, is a member selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub> alkyl, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

wherein said compound is capable of upmodulating the response of α-amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors to natural ligand binding,

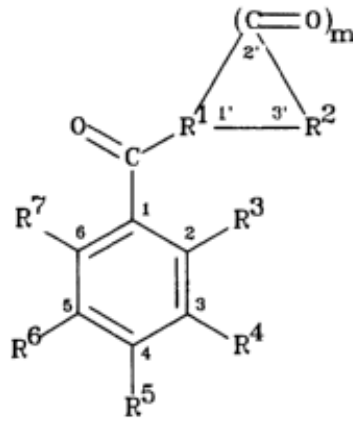
for use in the treatment of sexual dysfunction selected from decreased sexual desire, the inability to sustain a penile erection, inability to ejaculate and/or the inability to experience orgasm.

"

Claim 1 of the second auxiliary request read as follows:

"1. A compound of formula





wherein

$R^1$  is N or CH;

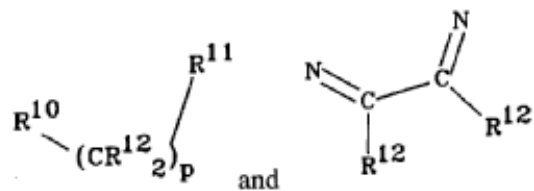
m is 0 or 1;

$R^2$  is  $(CR^8_2)_{n-m}$  or  $C_{n-m}R^8_{(n-m)-2}$ , in which n is 4, 5, 6, or 7, the  $R^8$ 's in any single compound being the same or different, each  $R^8$  being a member selected from the group consisting of H and  $C_1$ - $C_6$  alkyl;

$R^3$  is a member selected from the group consisting of H,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

$R^6$  is H;

$R^4$  and  $R^5$  are combined to form a member selected from the group consisting of



in which:

$R^{10}$  and  $R^{11}$  are O;

$R^{12}$  is a member selected from the group consisting of H and  $CH_3$ ;

p is 1 or 2; and

$R^7$  is a member selected from the group consisting of H,  $C_1$ - $C_6$  alkyl, and  $C_1$ - $C_6$  alkoxy;

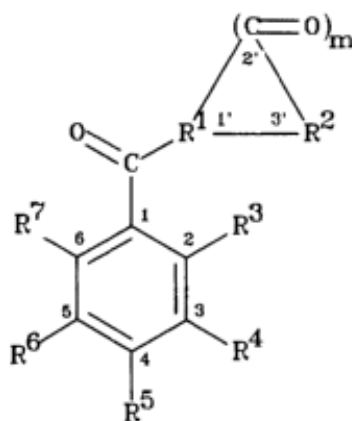
wherein said compound is capable of upmodulating the response of  $\alpha$ -amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors to natural ligand binding,

for use in the treatment of sexual dysfunction.

"

Claim 1 of the third auxiliary request read as follows:

"1. A compound of formula



wherein

$R^1$  is N or CH;

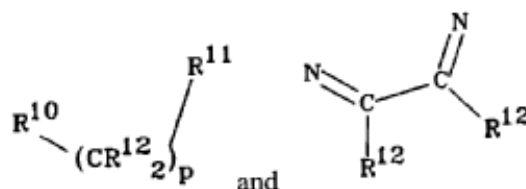
m is 0 or 1;

$R^2$  is  $(CR^8)_m$  or  $C_{n-m}R^8_{(n-m)-2}$ , in which n is 4, 5, 6, or 7, the  $R^8$ 's in any single compound being the same or different, each  $R^8$  being a member selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub> alkyl;

$R^3$  is a member selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub> alkyl, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

$R^6$  is H;

$R^4$  and  $R^5$  are combined to form a member selected from the group consisting of



in which:

$R^{10}$  and  $R^{11}$  are O;

$R^{12}$  is a member selected from the group consisting of H and CH<sub>3</sub>;

p is 1 or 2; and

$R^7$  is a member selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub> alkyl, and C<sub>1</sub>-C<sub>6</sub> alkoxy;

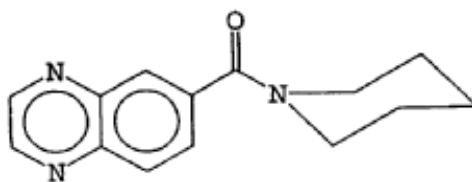
wherein said compound is capable of upmodulating the response of  $\alpha$ -amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors to natural ligand binding,

for use in the treatment of sexual dysfunction, wherein the sexual dysfunction is neurogenic, psychogenic or age-related.

"

Claim 1 of the fourth auxiliary request read as follows:

"1. A compound of formula

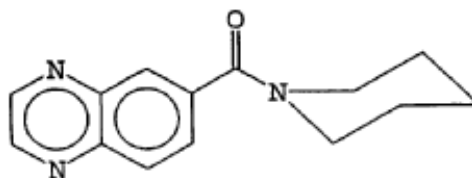


**for use in the treatment of sexual dysfunction.**

"

Claim 1 of the fifth auxiliary request read as follows:

"1. A compound of formula



**for use in the treatment of sexual dysfunction**

**wherein the sexual dysfunction is neurogenic, psychogenic or age-related.**

"

- VIII. The board sent a communication on 27 July 2009 in which the objections to the main request were maintained.
- IX. In a letter dated 30 July 2009 the appellant stated that it withdrew its main request filed with the grounds of appeal and that it maintained its request for oral proceedings.
- X. Oral proceedings took place on 6 August 2009.
- XI. During the oral proceedings the appellant renumbered the auxiliary requests 1 to 5, filed with the letter of 6 July 2009, as a new main request and auxiliary requests 1 to 4, respectively. Moreover, the appellant submitted during the oral proceedings amended first and

second auxiliary requests to replace the previous first and second auxiliary requests.

The difference between the first auxiliary request filed during the oral proceedings and the previous first auxiliary request (filed as second auxiliary request with the letter of 6 July 2009) was the amended definition of R<sup>2</sup> in claim 1 which now reads:

"R<sup>2</sup> is (CHR<sup>8</sup>)<sub>n-m</sub> or C<sub>n-m</sub>HR<sup>8</sup>(<sub>n-m</sub>)-<sub>3</sub> in which n is 4, 5, 6 or 7, the R<sup>8</sup>'s in any single compound being the same or different, each R<sup>8</sup> being a member selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub> alkyl;" (*emphasis added*)

The same amendment was introduced in claim 1 of the second auxiliary request (filed as third auxiliary request with the letter of 6 July 2009).

XII. The appellant's arguments can be summarised as follows:

The appellant stated that the main request now covered a finite number of compounds which were defined by standard meanings. Hence, the conditions set out in Article 84 EPC were fulfilled.

As regards the requirements of Article 83 EPC the appellant submitted that the skilled person was able to prepare these compounds in the light of the general information in the description of the application, making use of his general common knowledge and in view of the fact that some of the compounds were known from document (5). The application as filed also contained general information concerning the mode of application and a general dosage recommendation.

Furthermore, the appellant pointed to page 10 of the application as filed and argued that the description contained enough information to make it plausible that there was a causal link between the up-modulation of AMPA receptors to the natural ligand binding and the positive effects on sexual dysfunction. Moreover, one compound of formula I, namely 1-(quinoxalin-6-ylcarbonyl)piperidine, had been tested in the animal model for sexual dysfunction and had been shown to have positive effects in the treatment of reduced sexual drive and arousal or desire and aged-related decline in sexual performance (shown in Fig. 1 by means of the values for intromission latency and ejaculation latency).

The appellant further stated that, to the best of its knowledge, the tested compound only showed that activity was upmodulating the response of AMPA receptors to natural ligand binding. Thus, it was plausible that there was a causal link between this activity, expressed as a functional feature in the claim, and the positive physiological effects on the sexual intercourse in the animal model. Therefore, the scope claimed was sufficiently supported by the description.

Moreover, the application as filed taught on pages 30 to 32 about the assays on how to measure whether or not a compound fulfilled the function of upmodulating the response of AMPA receptors to natural ligand binding.

As regards the description on page 34 and the definition of the sexual dysfunction to be treated by

the compounds of formula I, the appellant submitted that it was natural that the indication corresponded to a valid generalisation and that this was common in the case of compounds for medical use. As an example the appellant cited that, in the case of compounds for use as anti-cancer agents, not every compound would be appropriate for every type of cancer and this would not invalidate the generic definition.

When asked by the board about the meaning of the alkyl definitions in the amended claims, the appellant stated that the claims now referred to the standard meaning, i.e. **unsubstituted** C<sub>1</sub>-C<sub>6</sub> alkyl. The appellant also stated that all the substituted alkyl options appearing on page 11 of the description as filed were no longer claimed in any of the requests and that the description would be adapted to the restricted claims.

As regards the first and second auxiliary requests the appellant submitted that the definitions of the compounds were the same and related to the preferred subclass defined at the end of page 9 (lines 22 to 24) together with the preferred definitions on page 20, line 9 to the end. This subgroup of compounds was directly and unambiguously derivable from pages 9 and 10 of the description and was covered by a majority of the examples of specific compounds of formula I on pages 23 and 24.

Moreover, the appellant also submitted that this subgroup of compounds defined in claim 1 of the first and second auxiliary requests was accessible to the skilled person starting from the disclosure of document (5) which disclosed compounds covering the structural

variations of amended claim 1 of the first and second auxiliary requests and the specific methods for their preparation. The claimed compound class was accessible to the skilled person in view of document (5), together with his common general knowledge and the teaching of the application as filed.

As regards the sufficiency of support in relation to the functional definition and the medical indication appearing in claim 1 of the first and second auxiliary requests, the appellant referred *mutatis mutandis* to the arguments and the passages of the description cited previously in relation to the main request.

Moreover, having regard to the chemical structure and pharmacological activity of the compound actually tested, the compounds now claimed in claim 1 of the first and second auxiliary requests represented a reasonable generalisation.

XIII. The appellant requested that the decision under appeal be set aside and the patent application be granted on the basis of the first auxiliary request filed with the letter dated 6 July 2009, now main request, or, in the alternative on the basis of the first or second auxiliary requests submitted during the oral proceedings or of the fourth or fifth auxiliary requests, now auxiliary requests third or fourth, filed with the letter dated 6 July 2009.

## **Reasons for the Decision**

### **1. Admissibility**



1.1 The appeal is admissible.

1.2 The sets of claims filed with the letter of 6 July 2009 were filed in a fair attempt to overcome the objections raised by the board in the communication sent as an annex to the summons to oral proceedings. Therefore they are admissible.

The two auxiliary sets of claims filed during the oral proceedings were filed as a direct response to an objection by the board during the oral proceedings in relation to Article 123(2) EPC. The amendments represented a clear and direct response to the objection. Hence, both sets of claims are admissible.

## 2. *Main request*

The wording of claim 1 of the main request, which relates to a compound for use in the treatment of sexual dysfunction selected from decreased sexual desire, the inability to sustain a penile erection, inability to ejaculate and/or the inability to experience orgasm, is within the meaning of a purpose-related product claim in accordance with Articles 53(c) and 54(5) EPC 2000.

The compounds claimed are defined structurally by means of a Markush formula together with broad but definite generic definitions. Additionally, the claim also contains a functional definition relating to the ability of the compounds to upmodulate AMPA receptors to natural ligand binding.

It has to be investigated first whether or not the requirements of sufficiency of disclosure are met for the claimed compounds.

The generic class of compounds (compounds of formula I according to the nomenclature of the application as filed) claimed in claim 1 of the main request is very broad and encompasses an extremely large number of possible variations and combinations for which the description is silent as to their origin (known or unknown compounds) and their specific preparation (required starting materials, intermediates, etc.). Pages 23 and 24 of the description of the application as filed show a list of 25 specific compounds of formula I. However, these 25 specific compounds do not represent a fair support for all the distinct subclasses and variations of compounds encompassed by claim 1 of the main request.

A thorough inspection of the generic disclosure (there is no specific preparative example, only generally disclosed preparative methods) on pages 27 to 29 under the heading "Preparation of Formula I compounds" shows that it conveys general information for the skilled person on how to prepare compounds showing the structural variations of the specific compounds on pages 23 and 24. However, this generic disclosure cannot be taken to represent a sufficient disclosure for each of the structurally distinct subclasses encompassed by formula I and defined in claim 1 of the main request. In fact, the skilled person is unable without a comprehensive search to find out for each of the structural variations claimed in the main request how to obtain the required starting materials and

intermediates and how to perform the required transformations. This lack of information in the description of the application as filed cannot be filled with the common general knowledge of the skilled person alone, since a full research programme is required to fill the gap. Therefore, the application as filed does not provide the skilled person with sufficient information to reduce the general instructions on pages 27 to 29 to practice without undue burden. Hence, the subject-matter of claim 1 of the main request is not sufficiently disclosed in the application as filed.

The appellant's arguments in relation to the main request do not hold for the following reasons:

Although it is a fact that some of the compounds encompassed by claim 1 are known from document (5) (not cited in the application as filed), this represents only a tiny subclass of compounds when compared with the broad definitions and structural variations encompassed by the generic Markush formula in claim 1 of the main request.

Moreover, even if the functional definition in the claim, which relates to the ability of upmodulating the response of AMPA receptors to natural ligand binding, is considered as serving to exclude those derivatives which do not have the defined pharmacological activity, this condition does not overcome the lack of sufficiency of disclosure in respect of the lack of accessibility of the compounds claimed.

Finally, as stated in point V of "Facts and submissions" above, the appellant referred in its grounds of appeal to several post-published US patents in order to show that the skilled person would be able to prepare an ample range of variations for compounds of formula I. However, as already stated in the communication sent as an annex to the summons for oral proceedings, this late reference to post-published US patents, unknown to the skilled person on the priority date of the application in suit, cannot serve to overcome a major problem of sufficiency of disclosure for the compounds claimed in the main request.

Consequently, the main request fails for lack of sufficiency of disclosure (Article 83 EPC).

3. *First auxiliary request*

- 3.1 Claim 1 of the first auxiliary request which relates to a compound for use in the treatment of sexual dysfunction is within the meaning of a purpose-related product claim in accordance with Articles 53(c) and 54(5) EPC 2000.

The compounds now claimed in claim 1 of the main request correspond to a preferred subclass defined in the application as filed.

In particular, the subject-matter of claim 1 of the first auxiliary request is directly and unambiguously derivable from the application as filed since the subclass now claimed corresponds to those derivatives of formula I wherein  $R^2$  is  $(CHR^8)_{n-m}$  or  $C_{n-m}HR^8(n-m)-3$  in which  $n$  is 4, 5, 6 or 7, and  $R^3$  is H,  $C_1$ - $C_6$  alkyl or

C<sub>1</sub>-C<sub>6</sub> alkoxy and the R<sup>8</sup>'s in any single compound being the same or different, each R<sup>8</sup> being a member selected from the group H and C<sub>1</sub>-C<sub>6</sub> alkyl, i.e. R<sup>8</sup> is not combined with the *ortho* residue R<sup>3</sup> or R<sup>7</sup> of the phenyl ring. This subclass of compounds in which R<sup>8</sup> is not combined with the *ortho* residue R<sup>3</sup> or R<sup>7</sup> of the phenyl ring is defined as a distinct subclass on page 19, lines 22 to 23 (separated from the subclass in which R<sup>8</sup> is combined with the *ortho* residue R<sup>3</sup> or R<sup>7</sup>, which is defined later on page 19, line 23 and on page 20, lines 1 to 8).

Moreover, the definitions for the residues R<sup>4</sup> and R<sup>5</sup> now in claim 1 of the first auxiliary request are specifically defined as preferred in the last paragraph on page 20.

Therefore, the subclass of compounds of amended claim 1 of the first auxiliary request is directly derivable from pages 19 and 20 of the description and is unambiguously covered by 12 of the 25 specific compounds listed on pages 23 and 24 of the application as filed.

Additionally, the deletion of the option CH<sub>2</sub>OR<sup>9</sup> for the residue R<sup>6</sup> is seen as a direct consequence of the specification of the definitions for R<sup>4</sup> and R<sup>5</sup> as given on page 20 (now introduced in claim 1 of the first auxiliary request) and is considered to be allowable since it does not single out any compound among the generic definitions already given in the application as filed.

Moreover, the definition of the medical condition as "sexual dysfunction" appears in claim 1 as originally filed and the basis for the functional definition in claim 1 of the first auxiliary request appears *inter alia* on page 15, lines 23-24 of the application as filed.

Consequently, claim 1 of the first auxiliary request meets the requirements of Article 123(2) EPC.

- 3.2 As already stated above, claim 1 of the first auxiliary request is a purpose-related compound claim in which the medical indication is defined as relating to the treatment of sexual dysfunction.

Therefore, it has to be investigated whether there is sufficiency of disclosure in relation to the medical condition to be treated by the compounds claimed.

The description clearly states that the compounds are "generally most useful to treat sexual dysfunctions in subjects having no demonstrable organic cause for the disorder" (page 34, second paragraph). The description also acknowledges that the compounds are "less likely to respond" in the case of sexual dysfunctions which originate from surgical interventions (such as prostata interventions) and of those diagnosed as vascular impotence (page 34, second paragraph). The description states that there has to be a psychogenic component in order that they may be addressed by the compounds of the application.

Moreover, under the heading "Administration to humans" of the application as filed (see page 39) it is stated

that: "As mentioned above, not all sexual dysfunctions are treated with the compounds herein. Thus, a first step in treating humans is generally determining which individuals have dysfunctions which are likely to respond (e.g. neurogenic, psychogenic or age-related sexual dysfunctions), and which will not".

Furthermore, in the first paragraph on page 40 it is clearly stated: "Although the psychosexual history of the subject may be the only criterion used to select candidates for treatment, it may be desirable to also rule out purely physical conditions that are not treatable with the compounds of the invention". In fact, the application as filed includes a chapter entitled "Diagnosis of dysfunctions that are substantially only neurogenic or psychogenic in origin" (see pages 40 to 43) in order to facilitate the exclusion of non-treatable subjects or sexual dysfunctions.

Thus, in the light of the description it is not plausible that any sexual dysfunction can be treated with the compounds claimed.

Moreover, having regard to the fact that the claim is a purpose-related compound claim there must be a plausible causal link between the compound claimed and the medical indication stated in the claim. However, this causal link is not plausible in the light of the description for any sexual dysfunction.

The application as filed discloses that: "The methods of the invention reduce intromission latency and ejaculatory latency and promote erections sufficient for vaginal penetration in male mammals suffering from

sexual dysfunctions that are predominantly psychogenic in nature" (page 8, lines 2 to 5). These sexual dysfunctions are the object of the test using an animal model. The appellant has stated that the drug tested in the animal model is compound 14 on page 23, which also appears as a particularly preferred compound at the top of page 27. This drug is representative for the scope of the compounds now defined in amended claim 1 of the first auxiliary request, but the test only corroborates the credibility of the treatment for certain sexual dysfunctions such as neurogenic, psychogenic or age-related ones where there is always an important neurogenic and/or psychogenic component). However, these specific sexual dysfunctions only cover a portion of all sexual dysfunctions and thus cannot be accepted in the light of the content of the whole description as sufficient support for the treatment of any sexual dysfunction.

Consequently, claim 1 of the first auxiliary request fails for lack of sufficiency of disclosure of the purpose for which the products are claimed (Article 83 EPC).

The appellant's arguments in favour of such a claim do not hold since although generalisations are in principle allowable (as for instance "for use in the treatment of cancer"), it is not plausible in the light of the content of the description that there is a causal link between the generally defined medical indication (sexual dysfunction) and the compounds in the purpose-related product claim.



4. *Second auxiliary request*

- 4.1 Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the purpose has been specified as "for use in the treatment of sexual dysfunction, wherein the sexual dysfunction is neurogenic, psychogenic or age-related".

Claim 1 of the second auxiliary request meets the requirements of Article 123(2) EPC in relation to the compounds claimed for analogous reasons to those given for claim 1 of the first auxiliary request.

Additionally, the specification of the medical indication finds support in the application as filed, *inter alia* page 39, line 15.

Consequently, amended claim 1 of the second auxiliary request meets the requirements of Article 123(2) EPC. As regards dependent claims 2 to 7 of the second auxiliary request, the board sees no reason to object to them under Article 123(2) EPC, since support for their wording can be found in the application as filed.

- 4.2 As already mentioned for the first auxiliary request, the subclass of compounds now claimed is covered by 12 of the 25 specific compounds listed on pages 23 and 24. Some of the compounds encompassed by amended claim 1 of the second auxiliary request are known compounds (see document (5)). Apart from that, the information given to the skilled person on pages 27 to 29 about the general methods for preparing this subclass of compounds can be considered as sufficient for the skilled person in the field.

Additionally, in contrast to claim 1 of the first auxiliary request, claim 1 of the second auxiliary request specifies the medical indications for which the tests on the animal model are valid evidence. Furthermore, the tested drug, compound 14 on page 23, illustrates the subclass of compounds now claimed and can be seen as representative of the compound's generalisation.

Consequently, there is sufficiency of disclosure in relation to the claimed subject-matter of the second auxiliary request since the purpose now specified for the subclass of compounds claimed is plausible in the light of the experimental data.

As regards the functional definition appearing in the claim "wherein said compound is capable of upmodulating the response of  $\alpha$ -amino-3-hydroxy-5-methyl-isoxazole-4-propionic acid ("AMPA") receptors to natural ligand binding", the following has been considered: this functional definition was included in the application as filed to define the generic compounds. Hence, its deletion could be questioned under Article 123(2) EPC since not every conceivable compound encompassed by the generic definitions in the claim will possibly have the mentioned activity.

Additionally, the description contains sufficient technical information about the tests to be performed by the skilled person in order to determine if the claimed compound fulfils the defined function (see, *inter alia*, pages 30 to 33). Furthermore, the functional definition appearing in the claim refers to a definite subclass of compounds whose structure is

also defined in the claim and of which the examples on pages 23-24 and in particular the tested drug (compound 14) are representative.

Consequently, the subject-matter claimed in the second auxiliary request is sufficiently disclosed (Article 83 EPC).

As regards the appellant's statement that, since the only biological activity of compound 14, which is the drug tested and shown to be useful for treating the specific sexual dysfunctions in the animal model, is upmodulating the response of AMPA receptors to natural ligand binding, there is a causal link between the medical indication and the functional definition, it has to be said that there is no evidence to the contrary. Moreover, as already said, it can be accepted that the tested drug is representative of the subclass of compounds now defined structurally in claim 1 of the second auxiliary request.

- 4.3 As regards the requirements of Article 84, the board notes the appellant's statement during the oral proceedings that the claim's wording now only concerns standard meanings and that the "substituted" alkyl options mentioned on originally filed page 11 are no longer meant (i.e. the description still has to be adapted to amended claim 1).

Under such circumstances the board sees *a priori* no reason to object to the definitions in claim 1 of the second auxiliary request within the meaning of Article 84 EPC.

5. *Remittal*

The decision of the examining division to refuse the application was based on a very broad claim 1 for which there was a lack of sufficiency of disclosure. The set of claims of the second auxiliary request now relates to a purpose-related product claim which meets the requirements of Article 83 EPC. Furthermore, as the facts on file stand, the reasons given by the examining division in relation to Article 56 EPC do not hold for the subject-matter of the second auxiliary request.

However, an inspection of the file by the board has shown that the supplementary European search report was partial owing to two facts: a lack of unity of invention (a second search fee was never paid for the compounds of formula II, which are no longer claimed) and the very broad definitions in claims 1 to 20 as originally filed, which encompassed an "extremely large number of possible compounds" (sheet C of the supplementary partial search report).

The following can be also read in sheet C of the supplementary partial European search report under the heading "Incomplete search report": "Claims 28-33 searched completely (*claim 28 as originally filed was directed to a single compound, namely compound 14*) and claims 1-20 searched incompletely".

The compounds claimed have now been restricted to an acceptable generic subclass of compounds defined by definite structural features. However, since the board does not have the information whether or not the European search was complete for the currently claimed

subclass, it is not possible to draw any conclusion on essential issues such as novelty or inventive step.

The fact that document (5) was found in the supplementary partial European search report can be seen as a result of the fact that the specific compound of originally filed claim 28 (claim searched completely) corresponds to one of the specific examples of document (5).

Therefore, under the circumstances described above, the board makes use of its discretionary power (Article 111(1) EPC) to remit the case to the department of first instance for investigation of the novelty and inventive step of the subject-matter claimed in the second auxiliary request filed during the oral proceedings before the board, once it has been established that said subject-matter has been searched completely.

**Order**

**For these reasons it is decided that:**

The decision under appeal is set aside.

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

The Registrar

The Chairman

N. Maslin

U. Oswald