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**Datasheet for the decision  
of 25 October 2007**

**Case Number:** T 1389/04 - 3.3.02

**Application Number:** 98960386.5

**Publication Number:** 1059925

**IPC:** A61K 31/557

**Language of the proceedings:** EN

**Title of invention:**

EP<sub>2</sub>-receptor agonists as neuroprotective agents for the eye

**Applicant:**

ALLERGAN, INC.

**Opponent:**

-

**Headword:**

Use of EP<sub>2</sub>-receptor agonists/ALLERGAN, INC.

**Relevant legal provisions:**

-

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

EPC Art. 111(1)

**Keyword:**

Substantive amendments"  
"Remittal (yes)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1389/04 - 3.3.02

**DECISION**  
of the Technical Board of Appeal 3.3.02  
of 25 October 2007

**Appellant:**

ALLERGAN, INC.  
2525 Dupont Drive  
Irvine  
CA 92612 (US)

**Representative:**

HOFFMANN EITLE  
Patent- und Rechtsanwälte  
Arabellastrasse 4  
D-81925 München (DE)

**Decision under appeal:**

Decision of the Examining Division of the  
European Patent Office posted 19 July 2004  
refusing European application No. 98960386.5  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** A. Lindner  
P. Mühlens

## Summary of Facts and Submissions

I. European patent application No. 98 960 386.5 was refused by a decision of the examining division pronounced at the oral proceedings on 17 June 2004 on the basis of Article 97(1) EPC on the grounds that the main request lacked novelty (Article 54 EPC) and that the auxiliary request contained subject-matter that extended beyond the content of the application as originally filed (Article 123(2) EPC).

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

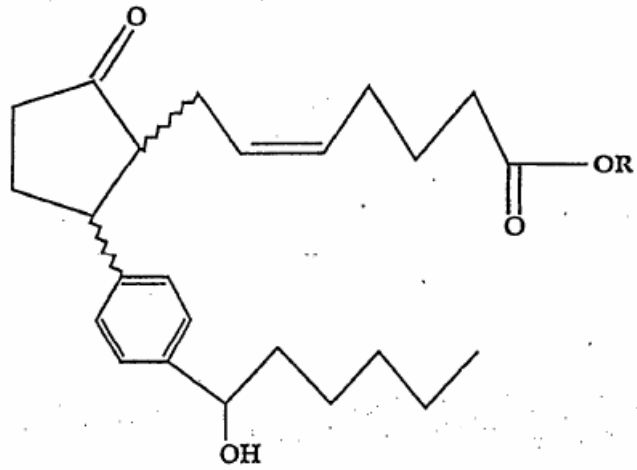
(2) D.F. Woodward et al.; J. Ocul. Pharmacol. Ther., 1995, 11(3); 447-454

(3) US-A-5 462 968

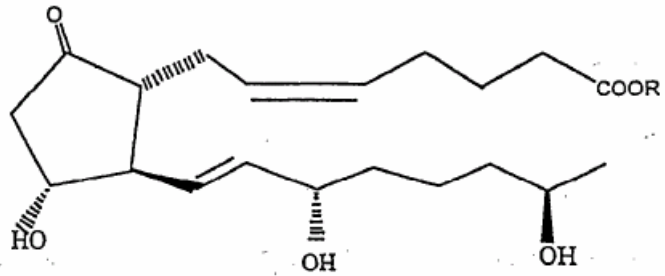
III. The decision was based on claims 1-11 of the main request filed on the entry into the regional phase before the EPO on 15 May 2000 and claims 1-11 of the auxiliary request based on the set of claims as filed with the letter dated 7 November 2002.

The independent claims of the main request before the examining division read as follows:

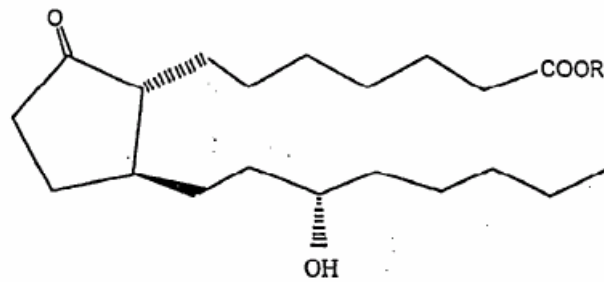
"1. Use of a compound of formula I, III, IV or V for the preparation of a medicament useful as a neuroprotective agent for the eye of a mammal



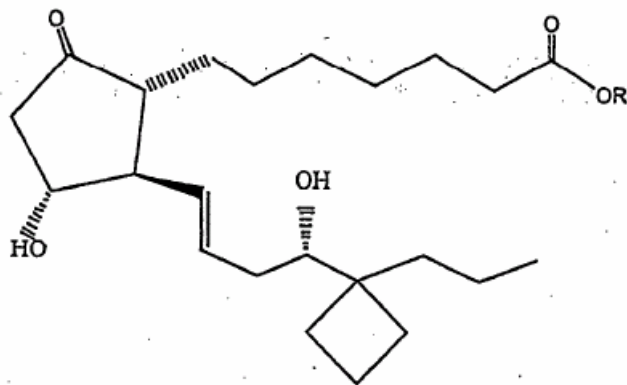
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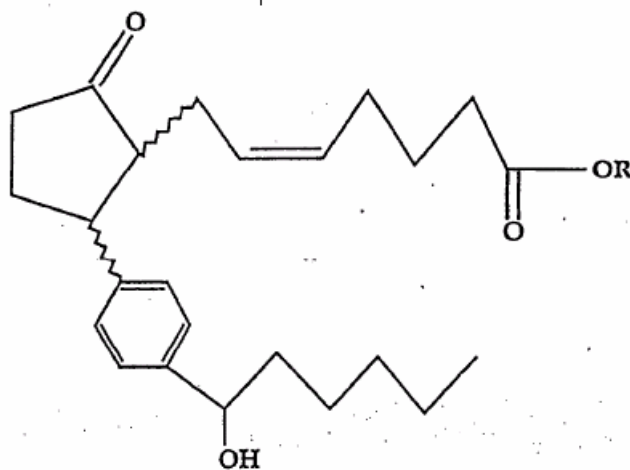


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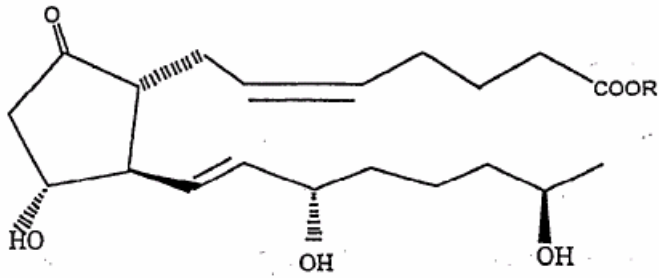
wherein the broken line attachment to the cyclopentane ring or the omega chain indicates the  $\alpha$  configuration and the solid line attachment to the cyclopentane ring or the omega chain indicates the  $\beta$  configuration, R is hydrogen or a saturated or unsaturated acyclic hydrocarbon group having from 1 to about 20 carbon atoms, or  $-(CH_2)_mR_1$  wherein m is 0-10, and  $R_1$  is an aliphatic ring having from about 3 to about 7 carbon atoms, or an aryl or heteroaryl ring having from about 4 to about 10 carbon atoms and wherein the heteroatom is selected from the group consisting of N, O and S.

7. Use of a compound having EP<sub>2</sub> receptor agonist activity for the preparation of a medicament useful as a neuroprotective agent for the eye of a mammal.

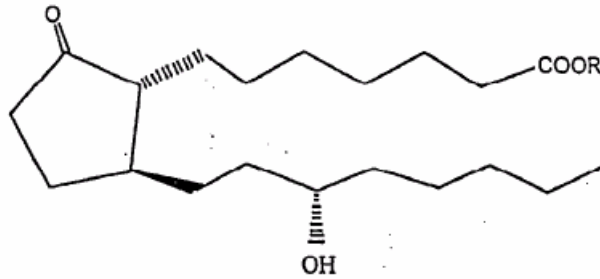
8. Use of a compound of formula I, III, IV or V for the preparation of a medicament useful for protecting the retinal or optic nerve cells in a mammal suffering a noxious action or at risk of experiencing a noxious action on said nerve cells



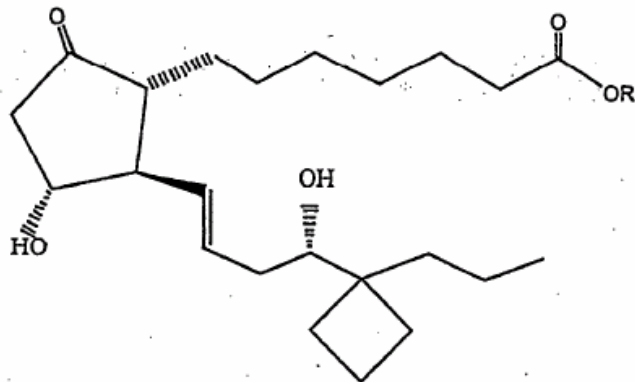
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wherein the broken line attachment to the cyclopentane ring or the omega chain indicates the  $\alpha$  configuration and the solid line attachment to the cyclopentane ring or the omega chain indicates the  $\beta$  configuration, R is hydrogen or a saturated or unsaturated acyclic hydrocarbon group having from 1 to about 20 carbon atoms, or  $-(CH_2)_mR_1$  wherein m is 0-10, and  $R_1$  is an aliphatic ring having from about 3 to about 7 carbon atoms, or an aryl or heteroaryl ring having from about

4 to about 10 carbon atoms and wherein the heteroatom is selected from the group consisting of N, O and S."

The independent claims of the auxiliary request are identical to those of the main request, except that the exclusion "wherein the mammal has no increased intraocular pressure" was added to independent claims 1, 7 and 8.

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

With regard to the novelty of the subject-matter as claimed in the main request, reference was made to documents (2) and (3) which related to the use of EP<sub>2</sub> agonists for lowering the intraocular pressure of patients suffering from glaucoma. Although these documents did not specifically mention neuroprotection, the damaging of the optic nerve was a well known consequence of glaucoma. It was acknowledged that the application under appeal taught a neuroprotective effect which was not related to the lowering of the intraocular pressure. However, this teaching would not make the person skilled in the art change his practice.

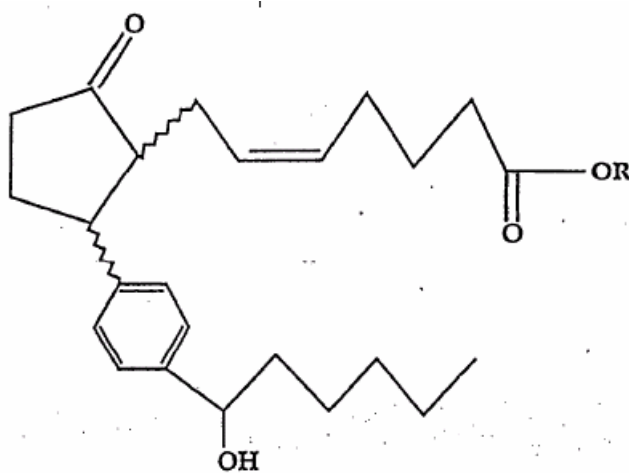
As for the auxiliary request, the examining division came to the conclusion that the exclusion "wherein the mammal has no increased intraocular pressure" had no basis in the application as originally filed.

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

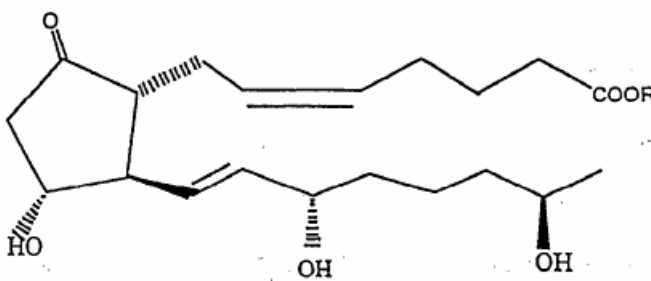
VI. Oral proceedings were held before the board on 25 October 2007.

VII. At the oral proceedings of 25 October 2007, the appellant filed a new main request. The sole independent claim reads as follows:

"1. Use of a compound of formula I, III, IV or V for the preparation of a medicament useful for protecting the retinal or optic nerve cells in a mammal suffering a noxious action or at risk of experiencing a noxious action on said nerve cells, to inhibit or prevent nerve cell injury or death

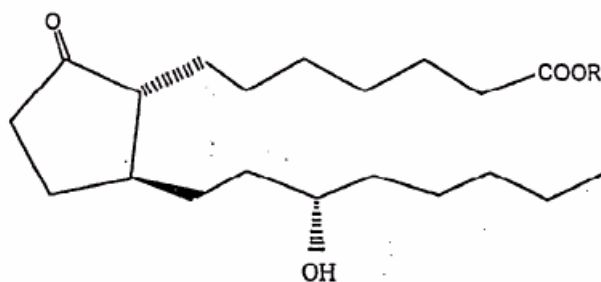


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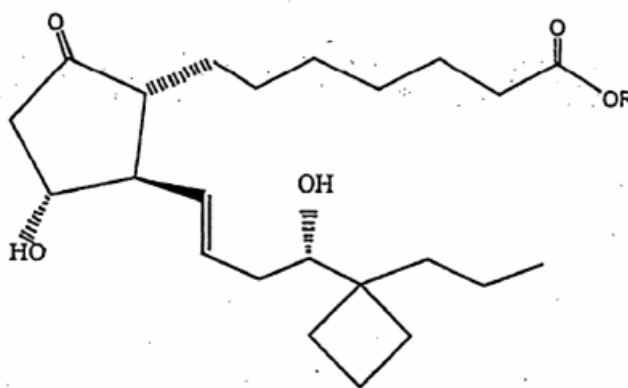


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wherein the broken line attachment to the cyclopentane ring or the omega chain indicates the  $\alpha$  configuration and the solid line attachment to the cyclopentane ring or the omega chain indicates the  $\beta$  configuration, R is hydrogen or a saturated or unsaturated acyclic hydrocarbon group having from 1 to about 20 carbon atoms, or  $-(CH_2)_mR_1$  wherein m is 0-10, and  $R_1$  is an aliphatic ring having from about 3 to about 7 carbon atoms, or an aryl or heteroaryl ring having from about 4 to about 10 carbon atoms and wherein the heteroatom is selected from the group consisting of N, O and S, wherein the noxious action is diabetic retinopathy, non-glaucomatous ischemia or wherein the noxious action is microangiopathic in nature and a symptom of the disease chosen from the group consisting of

polyarteritis nodosa, giant cell angitis, aortitis syndrome and systemic lupus erythematosus."

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the request filed in the oral proceedings.

### **Reasons for the decision**

1. The appeal is admissible.
2. By introducing the diseases as disclosed in original claims 11-13 into claim 1, the appellant made a serious attempt to overcome the grounds of refusal of the decision under appeal. The new main request is therefore admitted into the procedure.

3. Remittal:

In the present case, the amendments to the claims are substantial, insofar as the use of the compounds according to formulae I, III, IV and V for the preparation of a medicament for the protection of the optic nerve in connection with glaucomatous ocular hypertension, which was encompassed in the previous sets of claims, is now excluded by the introduction of specific diseases. Although, as was mentioned above in paragraph 2, these diseases were originally claimed in dependent claims 11-13, up to now they have not received any particular attention. As a consequence, the board is not in a position to conclude whether or not a further search is necessary for the amended claim,

possibly in combination with appropriate dependent claims yet to be filed.

Moreover, the substantial amendments made to the newly filed claim require substantial examination in relation to both the formal and the substantive requirements of the EPC, which should be carried out by the examining division as the first instance, so that the applicant's right to appeal to a second instance is maintained. As a consequence, the board has decided to remit the case to the first instance for further prosecution.

**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