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**Datasheet for the decision
of 12 March 2010**

Case Number: T 0827/08 - 3.3.02

Application Number: 02789515.0

Publication Number: 1441715

IPC: A61K 31/202

Language of the proceedings: EN

Title of invention:

Lipoxins and aspirin- triggered lipoxins and their stable analogs in the treatment of asthma and inflammatory airway diseases

Applicant:

THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

Opponent:

-

Headword:

Lipoxin analogs/THE BRIGHAM AND WOMEN'S HOSPITAL, INC.

Relevant legal provisions:

EPC Art. 54, 56, 123(2)

RPBA Art. 13

Relevant legal provisions (EPC 1973):

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Keyword:

"Main request: admissibility, allowability of amendments, novelty, inventive step - (yes): treatment of both airway inflammation and hyper-responsiveness not obvious"

Decisions cited:

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Catchword:

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Case Number: T 0827/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 12 March 2010

Appellant:

THE BRIGHAM AND WOMEN'S HOSPITAL, INC.
75 Francis Street
Boston
MA 02115 (US)

Representative:

Strehl Schübel-Hopf & Partner
Maximilianstrasse 54
D-80538 München (DE)

Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 23 November 2007
refusing European application No. 02789515.0
pursuant to Article 97(1) EPC 1973.

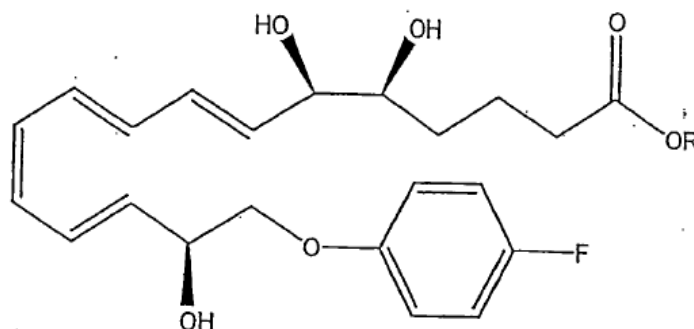
Composition of the Board:

Chairman: J. Riolo
Members: A. Lindner
C.-P. Brandt

Summary of Facts and Submissions

- I. European patent application No. 02 789 515.0 was refused by a decision of the examining division of 23 November 2007 on the basis of Article 97(1) EPC 1973 on the grounds that the subject-matter of claim 1 of the main and sole request lacked inventive step.
- II. The decision was based on claim 1 of the main request filed with letter of 22 September 2006, which reads as follows:

"1. Use of a lipoxin analog having the formula:



wherein R is a branched or unbranched alkyl, alkylene, or alkynyl group having 1 to 20 carbon atoms, a hydrogen atom, or a pharmaceutically acceptable salt, for the preparation of a medicament comprising a therapeutically effective amount of said lipoxin analog for the treatment or prevention of disorders of the respiratory tract or lung selected from the group consisting of bronchiectasis, eosinophilic lung diseases, allergic bronchopulmonary aspergillosis, Wegener's granulomatosis, sarcoidosis, hypersensitivity pneumonitis, lung injury associated with parasite

infection and chronic obstructive pulmonary disease (COPD)."

III. The documents cited during the examination and appeal proceedings included the following:

(1) US-B1-6 177 468

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

Document (1), which constituted the closest prior art, disclosed lipoxin A4 analogs for the treatment of inflammatory lung diseases. The subject-matter of present claim 1 differed from this disclosure by the selection of a specific lipoxin and by the selection of specific inflammatory lung diseases. Regarding the latter selection, document (1) concerned the treatment of columnar epithelial inflammations including inflammatory lung diseases characterised by migration of PMN (polymorphonuclear cells). The skilled person, trying to find further lung diseases characterised by PMN migration would inevitably identify them. He would understand from the teaching of document (1) that the claimed diseases could be treated with lipoxin analogs.

As regards the selection of the active agent, the specific lipoxin analogs of the presently claimed formula were generically disclosed by document (1). However, in the absence of any non-obvious effect, the selection of the specific compounds of present claim 1 did not involve an inventive step.

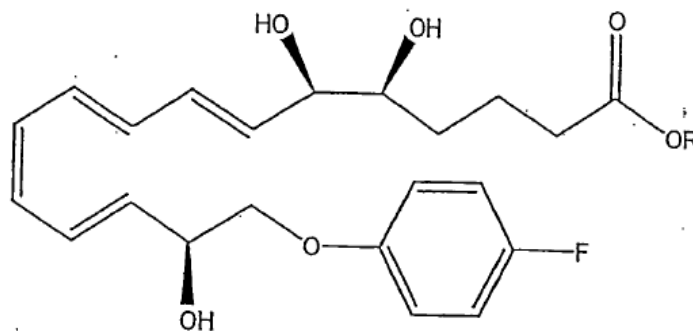
V. The appellant (applicant) lodged an appeal against this decision.

VI. With the statement of the grounds of appeal dated 30 January 2008, the appellant filed auxiliary requests 1 and 2.

VII. In a telephone conversation on 8 March 2010, the board informed the appellant that the requirements for inventive step did not appear to be met as far as the main request was concerned. In connection with auxiliary request 1, the board raised objections under Article 123(2) EPC only.

VIII. With his letter of 11 March 2010, the appellant filed a new main request. The sole claim reads as follows:

"Use of a lipoxin analog having the formula:



wherein R is a branched or unbranched alkyl, alkylene, or alkynyl group having 1 to 20 carbon atoms, a hydrogen atom, or a pharmaceutically acceptable salt, for the preparation of a medicament comprising a therapeutically effective amount of said lipoxin analog for the treatment of both airway inflammation and

hyper-responsiveness in response to allergen sensitization and aerosol challenge."

IX. Oral proceedings were held on 12 March 2010, in the absence of the duly summoned appellant, in accordance with Rule 115 EPC and Article 15(3) RPBA.

X. The appellant's submissions can essentially be summarised as follows:

The available prior art documents concerned the treatment of acute pulmonary inflammation. They did not refer to the response of smooth muscle to lipoxin. As a consequence, the effectiveness of lipoxins in ameliorating both respiratory hyper-responsiveness and airway inflammation was not obvious.

XI. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter of 11 March 2010.

Reasons for the decision

1. The appeal is admissible.

2. Main request:

2.1. Admissibility:

The main request was filed at a late stage of the appeal proceedings, i.e. one day before the oral proceedings before the board. The admissibility of

these requests is therefore at the board's discretion and depends upon the overall circumstances of the case under consideration (see Article 13 RPBA). As the amendments were a reaction by the appellant to objections raised by the board in the telephone conversation of 8 March 2010, the board decided to admit the new main request into the proceedings (Article 13 RPBA).

2.2. Amendments:

The basis for the feature "for the treatment of both airway inflammation and hyper-responsiveness in response to allergen sensitization and aerosol challenge" can be found on page 2, lines 15-17 of the original application. The requirements of Article 123(2) EPC are therefore met.

2.3. Novelty:

None of the available documents of the prior art discloses the use of lipoxin analogs for the preparation of a medicament for the treatment of both airway inflammation and hyper-responsiveness. As a consequence, the claimed subject-matter is novel (Article 54 EPC).

2.4. Inventive step:

2.4.1. The present invention concerns the use of specific lipoxin analogs for the preparation of a medicament for the treatment of both airway inflammation and hyper-responsiveness (see page 2, lines 15-17, page 62, second formula and page 63, lines 7-9).

- 2.4.2. Document (1), which constitutes the closest prior art, discloses the use of lipoxin analogs for the treatment of inflammatory lung diseases involving migration of polymorphonuclear (PMN) cells across the columnar epithelium (see column 2, lines 1-14 and column 4, lines 4-8). The compounds defined by the formula of present claim 1 are generically but not specifically disclosed in document (1) (see column 7, line 46 - column 8, line 41).
- 2.4.3. In the light of this teaching, the problem to be solved can be seen in the selection of specific lipoxin analogs for the treatment of an alternative disease. This problem was solved by the subject-matter of present claim 1. In view of the disclosure in paragraphs [035], [036] and [141] of the original application, the board is satisfied that the above problem was plausibly solved.
- 2.4.4. The teaching of document (1) is limited to the treatment or prevention of inflammatory diseases caused or contributed to by the perturbation of columnar epithelia involving PMN migration (see column 1, line 59 to column 2, line 14). Starting from this teaching, the skilled person has no incentive to select the specific compounds corresponding to the formula of the present claim in order to treat a pathological condition including both an inflammatory (airway inflammation) and a non-inflammatory aspect (hyper-responsiveness). It is noted that the treatment of hyper-responsiveness directly effects responses of the airway smooth muscle to challenge and is thus not related to PMN migration (see page 18, lines 14-20 of

the original application). As a consequence, the subject-matter of the main request is not obvious in the light of document (1). The fact that hyper-responsiveness can be treated by the lipoxins defined in the present claim is not rendered obvious by any of the other available prior art documents either, which also relate to inflammatory diseases. The subject-matter claimed in the main request therefore meets the requirements of Article 56 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 with the order to grant a patent on the basis of the amended (sole) claim, filed with the letter dated 11 March 2010 and after any necessary consequential amendment of the description.

The Registrar:

The Chairman

N. Maslin

J. Riolo