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**Datasheet for the decision  
of 5 August 2014**

**Case Number:** T 2507/10 - 3.3.01  
**Application Number:** 03794983.1  
**Publication Number:** 1539162  
**IPC:** A61K31/46  
**Language of the proceedings:** EN

**Title of invention:**

METHOD FOR IMPROVING THE ABILITY OF PATIENTS SUFFERING FROM  
LUNG DISEASES TO PARTICIPATE IN AND BENEFIT FROM PULMONARY  
REHABILITATION PROGRAMS

**Applicant:**

Boehringer Ingelheim Pharma GmbH & Co. KG  
Boehringer Ingelheim Pharmaceuticals, Inc.

**Headword:**

Use of tiotropium salts/BOEHRINGER

**Relevant legal provisions:**

EPC R. 115(2)  
RPBA Art. 15(3)  
EPC Art. 56

**Keyword:**

Inventive step (no) - obvious solution

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

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Case Number: T 2507/10 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 5 August 2014**

**Appellant:** Boehringer Ingelheim Pharma GmbH & Co. KG  
(Applicant 1) Binger Strasse 173  
55216 Ingelheim am Rhein (DE)

**Appellant:** Boehringer Ingelheim Pharmaceuticals, Inc.  
(Applicant 2) 900 Ridgebury Road  
Ridgefield  
Connecticut 06877 (US)

**Representative:** Weymann, Markus  
Boehringer Ingelheim GmbH,  
B Patente  
55216 Ingelheim am Rhein (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 10 June 2010  
refusing European patent application  
No. 03794983.1 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** A. Lindner  
**Members:** G. Seufert  
O. Loizou

## Summary of Facts and Submissions

I. The applicants lodged an appeal against the decision of the examining division refusing European patent application No. 03 794 983.1.

II. The present decision refers to the following documents:

- (1) W. Vincken *et al.*, European Respiratory Journal, Vol. 19, February 2002, pages 209 to 216
- (2) P. J. Rees, European Respiratory Journal, Vol. 19, February 2002, pages 205 to 206
- (3) F. P. V. Maesen *et al.*, European Respiratory Journal, Vol. 8, 1995, pages 1506 to 1513
- (4) WO 02/072095
- (5) R. Casaburi *et al.*, Chest, Vol. 127, 2005, pages 809 to 817
- (6) J. J. W. Liesker *et al.*, Chest, Vol. 121, February 2002, pages 597 to 608

III. The decision under appeal was based on the set of claims filed with letter of 24 April 2009. Claim 1 reads as follows:

"1. Use of a tiotropium salt for the preparation of a medicament for improving the ability of patients suffering from lung diseases to participate in and benefit from pulmonary rehabilitation programs, wherein the pulmonary rehabilitation programs the patients participate in and benefit from are to be understood as a multi-disciplinary approach, featuring the regular participation in sustained exercise for periods of at least 4 weeks."

The examining division held that the claimed subject-matter contravened Article 123(2) EPC since the feature "the patients participate in and benefit from" had no basis in the application as originally filed. In an *obiter dictum*, the examining division expressed its view that a claim without this feature would not be considered to be novel in view of any of the documents (1) to (4).

- IV. With the statement of grounds of appeal, the appellants challenged the examining division's decision regarding added matter.
  
- V. In a communication accompanying the summons to oral proceedings, the board expressed its preliminary opinion on the issues of added matter, clarity, novelty and inventive step. In particular, the board indicated that it did not share the appellants' understanding of claim 1. In the board's opinion, the wording of said claim did not exclude tiotropium salt therapy before starting a pulmonary rehabilitation program. Concerning inventive step, the board introduced document (6), which disclosed bronchodilator therapy, including anticholinergic agents, to improve exercise capacity in patients with chronic obstructive pulmonary disease (COPD).
  
- VI. With letter of 30 June 2014, the appellants informed the board that they would not be attending the oral proceedings scheduled for 5 August 2014 and requested a decision according to the state of the file. No observations or arguments with respect to the issues raised in the board's communication accompanying the summons were provided.

VII. The arguments of the appellants concerning added matter can be summarised as follows:

In view of the second paragraph on page 2 of the application as originally filed the skilled person would understand the teaching of the application as referring to the improvement of patients' ability to profit from programs they are actually participating in. The feature objected to was merely declaratory, and did not create subject-matter going beyond the content of the application as originally filed.

VIII. The appellants requested in writing that the decision of the examining division be set aside and a patent be granted on the basis of the main request filed with letter of 24 April 2009.

IX. Oral proceedings took place as scheduled in the absence of the appellants. At the end, the decision of the board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Non-appearance of a party at oral proceedings before the board
  - 2.1 The appellants chose not to attend the oral proceedings before the board to which they had been duly summoned (see point VI above).
  - 2.2 According to Rule 115(2) EPC, oral proceedings may continue in the absence of a duly summoned party. Further, pursuant to Article 15(3) of the Rules of

Procedure of the Boards of Appeal (RPBA), the board is not obliged to delay any step in the proceedings, including its decision, by reasons only of the absence at the oral proceedings of any party duly summoned. Such party may then be treated as relying only on its written case. In deciding not to attend oral proceedings, the appellants chose not to avail themselves of the opportunity to present their observations and comments orally.

- 2.3 The appellants had been informed in the board's communication accompanying the summons to oral proceedings about the issues which the board would consider and decide on during the oral proceedings. They therefore had an opportunity to present their observations and comments on the grounds and evidence on which the board's decision is based. The board was, therefore, in a position to take a final decision at the oral proceedings despite the absence of the duly summoned appellants.

*Main and sole request*

3. Amendments

- 3.1 The examining division's decision that claim 1 of the sole request contravened Article 123(2) EPC is based on the understanding that the feature "the patients participate in and benefit from" reflects participation in a pulmonary rehabilitation program as mandatory for the claimed medical use. In other words, it reflects bronchodilator therapy with concomitant pulmonary rehabilitation programs, which according to the examining division did not have a basis in the application as originally filed.

- 3.2 The board disagrees with the examining division's understanding - shared by the appellants - and consequently with its conclusion. The wording of claim 1 does not exclude administration of tiotropium salts before starting a pulmonary rehabilitation program, thereby improving the mere ability of the treated patient to participate in and benefit from such a program.
- 3.3 The board is satisfied that the amendments made in claim 1 of the sole request are supported by the application as originally filed. In view of the negative outcome with respect to inventive step (see point 4 below), it is not necessary to go into further detail in this respect.
4. Inventive step
- 4.1 Claim 1 of the sole request is directed to the use of tiotropium salts (an anticholinergic bronchodilator) for the preparation of a medicament for the treatment of patients with lung diseases (e.g. COPD) enabling them to participate and benefit from pulmonary rehabilitation programs featuring regular participation in exercise.
- 4.2 The use of bronchodilators, including anticholinergic agents, in the treatment of patients with COPD in order to decrease airflow limitations in the airways and, as a consequence, improve dyspnea and exercise tolerance is already known from document (6) (abstract, page 599, left column, last paragraph to right column, second paragraph). Anticholinergic agents have been shown to have significant beneficial effects. Document (6) refers to studies with ipratropium, oxitropium and atropine.



Hence, the board considers document (6) as a suitable starting point for the assessment of inventive step.

- 4.3 In the light of the disclosure of document (6), the problem to be solved is the provision of a further method/medicament for the treatment of symptoms of pulmonary diseases in order to improve a patient's tolerance for exercise.

The solution proposed according to the present invention is the use of tiotropium salts.

- 4.4 The board has no doubt that this problem is solved.

- 4.5 It then remains to be decided whether the proposed solution is obvious for the skilled person.

Tiotropium salts are well-known and highly effective anticholinergic bronchodilators. They provide sustained improvements in lung function, dyspnea, COPD exacerbation and health-related quality of life as illustrated in any of the documents (1) to (3). The prior art therefore provides the skilled person with a clear indication about how to solve the underlying technical problem as defined in point 4.3 above, namely by selecting tiotropium salts as anticholinergic agent, thereby arriving at the presently claimed subject-matter without requiring any inventive ingenuity.

- 4.6 No arguments addressing this issue were provided by the appellants (see point VI above). During the first-instance proceedings, the appellants submitted document (5) in order to demonstrate the effectiveness of pulmonary rehabilitation under tiotropium therapy compared with the use of a placebo. However, since this

effectiveness is not an unexpected or surprising result, for the reasons set out above, document (5) cannot support an inventive step.

4.7 For the aforementioned reasons, the board concludes that the claimed subject-matter lacks the required inventive step (Article 56 EPC).

## Order

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

1. The appeal is dismissed.

The Registrar:

The Chairman:



R. Schumacher

A. Lindner

Decision electronically authenticated