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Datasheet for the decision of 3 March 2022

Case Number: T 0387/19 - 3.3.07

Application Number: 10773176.2

Publication Number: 2480203

IPC: A61K9/00, A61K9/14, A61K31/167, A61K31/35, A61M15/00

Language of the proceedings: EN

Title of invention:
DRY POWDER FORMULATION OF TIOTROPIUM CARRIED IN BLISTER STRIP

Patent Proprietor:
Bilgic, Mahmut

Opponent:
Wuesthoff & Wuesthoff Patentanwälte PartG mbB

Headword:
Dry powder formulation of tiotropium/Bilgic Mahmut

Relevant legal provisions:
EPC Art. 54

Keyword:
Main request - Novelty (No)

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Case Number: T 0387/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 3 March 2022

Appellant: (Opponent)	Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstasse 2 81541 Munich (DE)
Representative:	Wibbelmann, Jobst Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 München (DE)
Respondent: (Patent Proprietor)	Bilgic, Mahmut Yildiz Teknik Universitesi Davutpasa Kampusu Teknoloji Gelistirme Bolgesi D Blok 34220 Esenler-Istanbul (TR)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 November 2018 rejecting the opposition filed against European patent No. 2480203 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	A. Jimenez

Summary of Facts and Submissions

I. European patent No. 2 480 203 was granted on the basis of a set of 12 claims.

Independent claims 1 and 10 as granted read as follows:

"1. A medicament formulation containing tiotropium or a pharmaceutically acceptable salt thereof for the treatment of respiratory disorders is wherein said medicament formulation is in dry powder form and is carried and stored in a peelable blister strip and is administered by dry powder inhaler characterized in that :
• each blister cavity is filled up to 70 to 100% of the total volume and is administered
• each blister has a cavity volume of 22 to 23 mm^3."

"10. Use of tiotropium or a pharmaceutically acceptable for the preparation of a medicament formulation in dry powder form according to any of the preceding claims."

II. An opposition was filed under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to reject the opposition.

IV. The documents cited during the opposition proceedings included the following:

D2: WO 2006/066908

V. According to the decision under appeal, the claims as granted met the requirements of Article 123(2) EPC and the claimed invention was sufficiently disclosed. None of the cited documents directly and unambiguously disclosed a combination of a dry powder comprising tiotropium and the blister as defined in claim 1; therefore, novelty was acknowledged.

With regard to inventive step, D2 was taken as closest prior art document. The claimed solution was not obvious over D2.

VI. The opponent (hereinafter the appellant) filed an appeal against said decision.

A communication from the Board, dated 29 November 2021, was sent to the parties. In it, the Board expressed its preliminary opinion that, *inter alia*, claim 10 appeared to lack novelty over D2.

VII. Oral proceedings took place by videoconference on 3 March 2022.

VIII. The arguments of the appellant may be summarised as follows:

Claim 10 referred to the use of tiotropium for the preparation of a medicament formulation of any of the preceding claims. Since D2 disclosed medicament formulations according to claim 2 of the opposed patent, wherein tiotropium has been used for preparing said medicament formulations, claim 10 lacked novelty.

IX. The patent proprietor (respondent) did not attend the oral proceedings, as announced by letter of 16 July 2021.

X. Requests

The appellant requests that the decision of the opposition division be set aside and the patent be revoked. It also requests to set aside the decision of the opposition division to admit document D11 and that documents D14 and D15 be admitted into the proceedings.

The respondent did not make any request or submission.

Reasons for the Decision

1. Patent as granted- Novelty

1.1 Claim 10 relates to the use of tiotropium for the preparation of a "medicament formulation" in dry powder form "according to any preceding claims". Said "medicament formulation" is characterized in its broadest definition in the preamble of claim 1 by the presence of tiotropium or a pharmaceutically acceptable salt thereof in a dry powder form.

The remaining features of claim 1, namely "is carried and stored in a peelable blister strip", and "is administered by dry powder inhaler", as well as the features characterizing the blister filling and volume, are not part of the "medicament formulation" of claim 1 and thus are not limiting for the subject-matter of claim 10.

1.2 D2 discloses the use of tiotropium for the preparation of a medicament in dry powder form (see D2, page 42, lines 25-28, page 43, line 21; page 47, line 20; page 49, lines 18 and 23). Said medicament formulation is released from an opened blister pocket to a mouthpiece of a aerosol dispenser for inhalation by a patient (see D2, page 1).

The above findings were not contested by the respondent, which did not file any substantive submission during the appeal procedure.

1.3 Consequently, the subject-matter of claim 10 lacks novelty over D2, and the patent as granted does not meet the requirements of Article 54 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated