BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 13 March 2008

Case Number: T 0942/05 - 3.3.02

Application Number: 98962441.6

Publication Number: 1041971

IPC: A61K 9/14

Language of the proceedings: EN

Title of invention:
A method for making a pharmaceutical formulation

Applicant:
LEIRAS OY

Headword:
Method for making a powdered preparation/LEIRAS OY

Relevant legal provisions:
RPBA 2003: Art 11
RPBA 2007: Art 15
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility of late-filed request (no): not clearly allowable"
"The requirements of Article 123(2) are not met by the amended claims of the requests on file"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0942/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 13 March 2008

Appellant: LEIRAS OY
Pansiontie 45-47
FI-20210 Turku (FI)

Representative: LEITZINGER OY
Tammasaarenkatu 1
FI-00180 Helsinki (FI)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 7 February 2005 refusing European application No. 98962441.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 98 962 441.6 based on international patent application WO 99/34778 was filed with 14 claims. Claim 1 read as follows:

"1. A method for preparing a physically stable and homogeneous powdered preparation containing in particulated form an active agent and optionally conventional physiologically acceptable additives, such as a carrier, **characterized** in that the particles are suspended in a suspending agent, in which the particles are essentially insoluble in the suspending agent, and from the thus obtained suspension the suspending agent is evaporated."

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

(4) US-A-5 503 869
(5) US-A-4 044 126

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 Articles 54 and 56 EPC.

IV. The examining division considered that the set of claims filed with the letter of 24 March 2004 (only request before the examining division) met the requirements of Article 123(2) EPC.

As regards the requirements of novelty, the examining division was of the opinion that document (4)

anticipated the subject-matter of claims 1-3, 6 and 8-10 and document (5) anticipated the subject-matter of claims 1-3, 6 and 9-10.

Additionally, in the examining division's view, the subject-matter claimed in claims 1 to 10 lacked an inventive step.

V. The appellant lodged an appeal against this decision and filed with its grounds of appeal a main request and auxiliary requests I to III.

Claim 1 of auxiliary request I read as follows:

"1. A method for preparing a physically stable and homogeneous powdered preparation containing in particulated form an active agent and a carrier, wherein the particles are suspended in a suspending agent, in which the particles are essentially insoluble, and the thus obtained suspension is evaporated to remove the suspending agent."

Claim 1 of auxiliary request II read as follows:

"1. A method for preparing a physically stable and homogeneous powdered preparation for the powder reservoir or capsule of an inhaler, said product containing in particulated form an active agent and a particulated carrier, wherein the particles are suspended in a suspending agent, in which the particles are essentially insoluble, and the thus obtained suspension is evaporated to remove the suspending agent."

VI. The board sent a communication on 28 September 2007 conveying the board's preliminary opinion in relation to the requirements of Articles 123(2) and 84 EPC.

VII. The appellant filed a reply dated 9 November 2007 but did not file any further requests.

VIII. The board issued an invitation to attend oral proceedings on 29 November 2007 and sent, as an annex thereto, a communication in which it drew the appellant's attention to Article 11 of the Rules of Procedure of the Boards of Appeal (RPBA), EPO OJ 2003, 89.

IX. The appellant filed by fax on 6 March 2008 a letter dated 5 March 2008 with an additional set of claims enclosed, as auxiliary request IV.

Claim 1 of auxiliary request IV read as follows:

"1. A method for preparing a physically stable and homogeneous powdered preparation for the powder reservoir or capsule of an inhaler, characterized in that the method comprises:

forming a suspension of an active agent in particulate form and a particulated carrier in a suspending agent, the particulated carrier comprising lactose or glucose, the suspending agent comprising an alkane, wherein the active agent is essentially insoluble in the suspending agent; and

evaporating the suspending agent from the suspension."

The appellant confirmed with the said letter that it "will not attend to the hearing" but it did not withdraw the request for oral proceedings under Article 116 EPC, which had been filed with the grounds of appeal.

Moreover, as a consequence of the appellant's requests stated in the letter dated 5 March 2008, the sets of claims of the main request and auxiliary request III were withdrawn.

X. Oral proceedings took place on 13 March 2008 in the absence of the appellant.

XI. With its letter of 9 November 2007 the appellant submitted the following arguments in respect of Articles 123(2) and 84 EPC:

Although originally filed claim 1 defined the carrier as an optional feature, the carrier had to be (when present) a powder since the product obtained by the method claimed was "a physically stable and homogeneous powdered preparation". Furthermore, the originally filed claim's wording referred to the particles being suspended and this meant the particles of all components.

Lactose was mentioned on page 4 and example 2 of the application as filed as an appropriate carrier within the meaning of the invention.

The present invention related to a method for preparing a powdered preparation with improved properties over previously known products. As mentioned on page 1 of

the application as filed there were two types of inhalers, one with a powder stationary reservoir and one with a capsule containing premetered doses of powder. The aim of the invention was mentioned on page 3 of the application as filed as to overcome the drawbacks of the prior art to provide powder preparations more suitable for use in conventional inhalers.

With its letter dated 5 March 2008 the appellant submitted that the limitation introduced in claim 1 of auxiliary request IV concerning the definition of the carrier as being a particulated carrier comprising lactose and glucose was supported by the disclosure on page 1, line 25 of the application as filed.

XII. The appellant had requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of one of the auxiliary requests I, II, filed with the grounds of appeal, or IV, filed with letter of 5 March 2008.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of auxiliary request IV*

The admissibility of late-filed requests is at the board's discretion and depends upon the overall circumstances of the case under consideration, a

general principle being that the later the requests are filed, the less likely they are to be held admissible. Moreover, account has to be taken, *inter alia*, of whether they could have been filed earlier and if so the reason why they were not, and of whether they immediately appear to fulfil the formal criterion for allowability.

The board sent a detailed communication on 28 September 2007, dealing with the requests filed with the grounds of appeal.

Moreover, the communication sent as an annex to the summons to oral proceedings on 29 November 2007 expressly cited Article 11 of the Rules of Procedure of the Boards of Appeal (RPBA 2003). This Article corresponds to Article 15 of the RPBA (EPO OJ 2007, 536), which entered into force on 13 December 2007.

Hence, the board's communications were sent with the intention of allowing the board to come to a conclusion at the end of the oral proceedings, scheduled for 13 March 2008.

The appellant chose to file, six months later and only five working days before the date of the oral proceedings, a new set of claims as auxiliary request IV, announcing at the same time that it would not attend oral proceedings.

The appellant did not give in its letter dated 5 March 2008 any reasons for the late filing of auxiliary request IV. Moreover, the appellant's submissions contained a very brief comment about the basis to be

found in the originally filed application for one of the amendments introduced in redrafted claim 1 (see last paragraph of point XI above).

The amendments introduced in claim 1 of auxiliary request IV are *prima facie* not allowable under Article 123(2) EPC. This applies, in particular, to the specification that a "particulated carrier comprising lactose and glucose" is suspended in "an alkane" as suspending agent.

Apart from the fact that the passage on page 1 of the application as filed mentioned by the appellant appertains to the background art, the passage gives different information from that introduced in the redrafted claim, namely that: "Dry powders for inhalation are normally manufactured of micron size drug particles and a **coarser** carrier, e.g. lactose or glucose, by **mixing them in a dry homogenizer**". (page 1, lines 25 to 27) (emphasis added)

The nature of the carrier was not defined in the claims of the application as filed. Furthermore, in the description, glucose appears only in the paragraph under the heading "Further experiences and clarifications on the method", which refers to more specific features (nature of the drug, coarseness of the carrier and the fact that the alkane is an n-alkane) than those appearing in the amended claim: "Budesonide and three experimental drugs for inhalation have been formulated using the suspension mixing method. **Coarse** lactose or glucose was used as the carrier and the drug-carrier ratios varied between 1:200 and 50:100. **N-**alkane alone or mixed with a small amount of ethanol or

methanol was used as suspending agent." (page 9, lines 15 to 19) (emphasis added)

Hence, an unallowable generalisation has taken place when drafting claim 1 of auxiliary request IV (Article 123(2) EPC).

Finally, Article 15(3) RPBA 2007 makes clear that the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying on its written case.

Therefore, the late-filed auxiliary request IV is not admitted into the proceedings.

2. *Auxiliary requests I and II*

2.1 The method according to claim 1 of the application as filed did not require the presence of a carrier. The preparation concerned the suspension of an active agent in particulated form in a suspending agent in which the particles were essentially insoluble, followed by evaporation of the suspending agent.

This is confirmed by the content of the application as filed which discloses: "To overcome the drawbacks of the prior art the present invention provides a method for preparing a stable and homogeneous dry particulated product which method is characterised in that the particles are suspended in a suspending agent, and from the thus obtained suspension the suspending agent is evaporated. The other characteristics of the method of

this invention are revealed in the claims 2-13." (page 3, lines 22 to 29)

The optional additives mentioned in claim 1 of the application as filed are "conventional physiologically acceptable additives, such as a carrier". There is no clear requirement from the wording of originally filed claim 1 that the conventional physiologically acceptable additives be in particulated form, or that they necessarily be suspended in the suspending agent. Conventional physiological additives may indeed be in liquid form, such as ethanol (which is mentioned on page 9, line 18 of the application as filed), and the carrier, if present, may be dissolved before the evaporation step and not necessarily suspended.

However, the new claim 1's wording in auxiliary request I, **clearly** implies the carrier to be in particulated form ("containing in particulated form an active agent and a carrier") and that both particulated materials are suspended in the suspending agent prior to evaporation.

This way of reading the claim is confirmed by the appellant's submissions filed with the letter of 9 November 2007 in which it stated that according to claim 1 of auxiliary request I the carrier is necessarily in particulated form and all particles are to be suspended in the suspending agent (i.e. both the active drug and the carrier).

However, there is no basis in the application as originally filed for the subject-matter of the amended generic claim 1.

Moreover, the paragraphs appearing on page 4, which combined failed experiments with "surprisingly" successful experiences, are too specific in respect of several features of the method (nature of carrier, nature of suspending agent employed, sonic treatment) in order to serve as an allowable basis for the generic claim 1 of auxiliary request I.

The same applies to the content of the specific examples 2 to 4 (example 1 does not employ a carrier), which illustrate the specific preparation of specific formulations and cannot serve as a basis for the generic claims 1 without infringement of Article 123(2) EPC.

Therefore, claim 1 of auxiliary request I does not meet the requirements of Article 123(2) EPC.

2.2 The analysis made above for claim 1 of auxiliary request I applies *mutatis mutandis* to claim 1 of auxiliary request II, which explicitly specifies the carrier as a "particulated carrier".

2.3 Consequently the sets of claims of auxiliary requests I and II fail because they do not meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

N. Maslin U. Oswald