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**Datasheet for the decision
of 19 November 2013**

Case Number: T 2460/09 - 3.3.07

Application Number: 01966751.8

Publication Number: 1267866

IPC: A61K9/12, A61K9/14, A61K31/40,
A61P11/08

Language of the proceedings: EN

Title of invention:
THE TREATMENT OF RESPIRATORY DISEASES

Patent Proprietor:
Sosei R&D Ltd.

Opponent:
MEDA Pharma GmbH & Co. KG

Headword:
The treatment of respiratory diseases/Sosei R&D

Relevant legal provisions:
EPC Art. 123(2), 123(3), 111(1)
RPBA Art. 13

Keyword:
Main request, Auxiliary requests 1-9 - Article 123(2) (no)
Auxiliary request 10 - Admission into the proceedings
Auxiliary request 10 - Article 123(2) and (3) (yes)

Decisions cited:

Catchword:



**Beschwerdekammern
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Case Number: T 2460/09 - 3.3.07

**D E C I S I O N
of Technical Board of Appeal 3.3.07
of 19 November 2013**

Appellant: Sosei R&D Ltd.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 2 November 2009
revoking European patent No. 1267866 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: D. Boulois
D. T. Keeling

Summary of Facts and Submissions

- I. European patent No. 1 267 866 based on application No. 01 966 751.8 was granted on the basis of a set of 14 claims.
- II. An opposition was filed against the granted patent. The patent was opposed under Article 100 (a) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, and extended beyond the content of the application as filed.
- III. The appeal by the patent proprietor lies from the decision of the opposition division to revoke the patent. The decision was based on the set of claims as granted as main request and on four sets of claims filed with letter of 20 December 2007 as auxiliary requests 1 and 2 and with letter dated 8 August 2009 as auxiliary requests 3 and 4.
- IV. Independent claim 1 of the main request read as follows:

"1. A dry powder inhaler comprising a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles that have a mass median aerodynamic diameter of less than 30 μm and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder comprising up to 5 mg glycopyrrolate."
- V. According to the decision under appeal, the main request did not meet the requirements of Article 123(2)

EPC, because the features

- a) "glycopyrrolate in the form of microparticles",
- b) "mass median aerodynamic diameter of less than 30 μm " and
- c) "wherein the inhaler is capable of dispensing a unit dose of the powder comprising up to 5 mg glycopyrrolate"

present in claim 1 went beyond the scope of the originally filed application.

The opposition division considered also that the subject-matter of dependent claims 2, 4 and 6 of the main requests also did not comply with the requirements of Article 123(2) EPC.

Auxiliary requests 1-4 also did also not comply with the requirements of Article 123(2) EPC for the same reasons.

- VI. The patent proprietor (appellant) filed an appeal against the decision of the opposition division.

- VII. With the statement of grounds of appeal, the appellant filed nine auxiliary requests.
The subject-matter of the independent claims of the auxiliary requests read as follows, difference(s) compared with the main request shown in bold:

- a) Auxiliary request 1

"1. A dry powder inhaler comprising a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 μm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit

dose of the powder of the powder **comprising 5 mg glycopyrrolate.**"

b) Auxiliary request 2

The subject-matter of claim 1 of auxiliary request 2 differed from the subject-matter of claim 1 of auxiliary request 1 by the further addition of the feature **"wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles, and wherein the medicament permits the glycopyrrolate to exert its pharmacological effect over a period of greater than 12 hours"**.

c) Auxiliary request 3

"1. A dry powder inhaler comprising **a controlled release medicament formulation** suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles.**"

d) Auxiliary request 4

"1. A dry powder inhaler comprising a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, and

wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles**, and the dry powder medicament has a mass median aerodynamic diameter of less than 30 μm ".

e) Auxiliary request 5

"1. A dry powder inhaler comprising a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 μm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising less than 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles**".

f) Auxiliary request 6

The subject-matter of claim 1 of auxiliary request 6 differed from the subject-matter of claim 1 of auxiliary request 5 by the further addition of the feature **"and wherein the medicament permits the glycopyrrolate to exert its pharmacological effect over a period of greater than 12 hours"**.

g) Auxiliary request 7

"1. A dry powder inhaler comprising a **controlled release medicament formulation** suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising

glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising less than 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles"**.

h) Auxiliary request 8

"1. A dry powder inhaler comprising a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising less than 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles**, and the dry powder medicament has a mass median aerodynamic diameter of less than 30 µm".

i) Auxiliary request 9

"1. **Use** of glycopyrrolate for the manufacture of a medicament suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate **in the form of microparticles that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, **wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles, by dispensing a unit dose of the medicament of 0.0-5 2 mg glycopyrrolate from a dry powder inhaler"**.

VIII. In the reply to the statement of grounds of appeal, the opponent (respondent) submitted arguments.

IX. With letter dated 26 October 2010, the appellant filed auxiliary request 10.

The subject-matter of independent claim 1 of the auxiliary requests read 10 as follows, difference(s) compared with the main request shown in bold:

"1. A dry powder inhaler comprising a **controlled release medicament** suitable for inhalation, for the treatment of a disease of the airways, wherein the medicament is a dry powder comprising glycopyrrolate in the form of microparticles **that have a diameter of from 0.1 to 10 µm** and the powder also comprises large carrier particles, and wherein the inhaler is capable of dispensing a unit dose of the powder of the powder **comprising less than 5 mg glycopyrrolate, wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles, and wherein the medicament permits the glycopyrrolate to exert its pharmacological effect over a period greater than 12 hours**".

X. In a communication sent in preparation of oral proceedings dated 18 October 2013, the board gave its preliminary non-binding opinion. At this stage, the board noted that none of the submitted requests appeared to fulfill the requirements of Article 100(c) EPC.

XI. With letter dated 29 October 2013, the appellant filed auxiliary request 11.

XII. With letter dated 13 November 2013, the appellant filed auxiliary request 12, and submitted technical arguments regarding the diameter and the aerodynamic diameter of micro-particles.

XIII. Oral proceedings took place on 19 November 2013.

XIV. The arguments of the appellant (patent proprietor), as far as relevant for the present decision, may be summarised as follows:

As regards the omission of the feature "*controlled release form that permitted the agent to exert its pharmacological effect over a period greater than 12 hours*" in claim 1 of the main request, the application as filed did not specify this feature to be essential (see page 2, lines 13-18). The type of release and the duration of the pharmacological effect were the direct consequence of the presence of micro-particles, and these features could thus be omitted from the subject-matter of claim 1.

The same argument was valid for all auxiliary requests 1-9.

As regards the parameters of diameter and aerodynamic diameter, it was common general knowledge that the calculation of the aerodynamic diameter was defined by the equivalent diameter. The replacement of the parameter of mass median aerodynamic diameter simply by the diameter was thus possible, in view of their relationship. There was no infringement of Article 123(2) or (3) EPC.

XV. The arguments of the respondent (opponent), as far as relevant for the present decision, may be summarised as follows:

The subject-matter of claim 1 the main request did not meet the requirements of Article 123(2) EPC because of

the omission of the essential characteristic that glycopyrrolate was in a controlled release form that permitted the agent to exert its pharmacological effect over a period greater than 12 hours. This feature appeared to be essential in view of the teaching of the description, where it was repeatedly mentioned. Other features of claim 1 that infringed the requirements of Article 123(2) EPC were the feature "*glycopyrrolate in the form of microparticles*", the feature "*mass median aerodynamic diameter of less than 30 μm* ", "*wherein the inhaler is capable of dispensing a unit dose of the powder comprising up to 5 mg glycopyrrolate*" and "*large particles*".

Moreover, the subject-matter of dependent claims 2, 4, 5, 6, 8, and 9 also went beyond the content of the earlier application as filed.

None of the auxiliary requests met the requirements of Article 123(2) EPC on reason of some or all of the deficiencies set forth for the main request.

Moreover, the replacement of the term "*mass median aerodynamic diameter of less than 30 μm* ", by the term "*diameter from 0.1 μm to 10 μm* " in auxiliary requests 1-7, 9, 10 violated the requirements of Article 123(2) and (3) EPC, since it led to a broadening of the subject-matter of claim 1 of these requests. Both parameters related to a different statistical measurement which could not be interchanged.

As regards auxiliary request 10, the combination of all features additionally could not find a basis in the original application.

XVI. The appellant (patent proprietor) requested that the decision under appeal be set aside or that the patent be maintained on the basis of the sets of claims submitted as auxiliary requests 1-9 filed by letter of 5 February 2010, auxiliary request 10 filed by letter of 26 October 2010, auxiliary request 11 filed by letter of 29 October 2013, or auxiliary request 12 filed by letter of 13 November 2013.

XVII. The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible
2. Main request - Article 123(2) EPC
 - 2.1 The subject-matter of claim 1 of the main request relates essentially to an inhaler comprising a medicament in dry powder form comprising glycopyrrolate in the form of microparticles and large carrier particles. There is no further feature in claim 1 relating to the type of release or the duration of the pharmacological effect.

Independent claim 1 of the application as filed related however to "*a composition for pulmonary delivery, comprising an antimuscarinic agent that exerts its pharmacological effect over a period less than 12 hours, in a controlled release formulation that permits the antimuscarinic agent to exert its pharmacological effect over a period greater than 12 hours*", the antimuscarinic agent being preferably glycopyrrolate (see original claim 2). The subject-matter of original

claim 1 was thus restricted by the specification of the type of release and the duration of the pharmacological effect of the active agent.

The question must be answered whether a person skilled in the art would derive the change of content of the claimed subject-matter -in the present case a generalisation- directly and unambiguously from the application as originally filed.

The particular kind of formulation as claimed in original claim 1 constitutes the sole subject of the application as filed which refers in the description consistently and repeatedly to "*a controlled release formulation that permits the agent to exert its pharmacological effect over a period greater than 12 hours*" (see page 2, lines 19-24; page 3, lines 4-15). The essence of the invention indeed resides in the formulation of an antimuscarinic agent, in particular glycopyrrolate, that normally exerts its pharmacological effect over a period less than 12 hours (see page 3, lines 25-28). By means of the controlled release formulation, the composition will have a duration of action greater than 12 hours. Both features, namely the "*controlled release formulation*" and the "*pharmacological effect over a period greater than 12 hours*" are thus indissociable and presented as essential in the original application. Hence, the original application does not contain any other disclosure regarding another type of formulation than a "*a controlled release formulation that permits the agent to exert its pharmacological effect over a period greater than 12 hours*".

The omission of this essential feature in claim 1 of the main request thus leads to a subject-matter

covering formulations providing any kind of release and duration of the pharmacological effect. This omission constitutes an undisclosed generalisation over the original application.

The amended subject-matter thus extends thus beyond the application as originally filed, leading to an infringement of Article 123(2) EPC.

In view of the conclusion reached above, it is not necessary to discuss the remaining objections raised by the appellant-opponent as regards the amendments.

2.2 Further arguments from the appellant

According to the appellant, the original application did not specify that a controlled release formulation was an essential feature, as disclosed on page 2, lines 13-18 and page 3, lines 7-11. Moreover the fact that the glycopyrrolate is embedded in micro-particles enables the feature of "controlled release" to be excluded from the subject-matter of claim 1, since this specific release is an inevitable consequence of the formulation.

The board however cannot follow this argumentation. The cited passages cannot be read in isolation from the general context of the description.

The first passage mentions that "*the pharmacokinetic effects of the drug will be controlled within a suitable formulation, to ensure that the product is able to produce its effect...*". The second passage mentions that "*the medicament being formulated so that one unit dose enables the agent to exert its pharmacological effect over a period greater than 12 hours*".

Both passages thus refer explicitly not only to the formulation, but also to the effect linked therewith, which, according to the original description, can only be "*a controlled release formulation that permits the agent to exert its pharmacological effect over a period greater than 12 hours*".

As regards the term "*microparticle*", its meaning cannot be considered as synonymous with "*controlled release*", even less as meaning to provide "*a pharmacological effect over a period greater than 12 hours*", since these properties cannot be considered to be necessarily and intrinsically linked with the form of micro-particle. This is confirmed by the teaching of the original description, which envisages the addition of fast-acting micro-particles of glycopyrrolate to the claimed micro-particles with longer lasting effect (see description, page 6, lines 3-5).

3. Auxiliary request 1 - Article 123(2) EPC

As the subject-matter of claim 1 of auxiliary request 1 does not comprise any specification regarding the type of formulation and the duration of the pharmacological effect, the conclusions drawn for the main request also apply for this request, whose subject-matter goes beyond the content of the earlier application as filed, and does not meet the requirements of Article 123(2) EPC.

4. Auxiliary request 2 - Article 123(2) EPC

The subject-matter of claim 1 of auxiliary request 2 has been amended *inter alia* by the introduction of the term "*wherein the medicament permits the glycopyrrolate to exert its pharmacological effect over a period of greater than 12 hours*".

This term has been introduced independently of the type of formulation, i.e. a controlled release formulation. The dissociation of the duration of the pharmacological effect from the type of formulation presented as necessary in order to obtain said effect does not find a basis in the original application. A formulation different from a controlled release formulation providing such duration of the pharmacological effect is an information not present in the original application documents.

The subject-matter of claim 1 of auxiliary request 2 is therefore not derivable directly and unambiguously from the application as filed, contrary to the requirements of Article 123(2) EPC.

5. Auxiliary request 3 - Article 123(2) EPC

The subject-matter of claim 1 of auxiliary request 3 differs from claim 1 of the main request *inter alia* by the introduction of the term "*controlled release medicament formulation*" without specification of the duration of the pharmacological effect.

The subject-matter of claim 1 of auxiliary request 3 encompasses therefore controlled release formulations providing a pharmacological effect less than 12 hours, for which no teaching or disclosure is available in the original application.

The subject-matter of claim 1 of auxiliary request 3 is therefore not derivable directly and unambiguously from the application as filed, contrary to the requirements of Article 123(2) EPC.

6. Auxiliary request 4 - Article 123(2) EPC

The subject-matter of claim 1 of auxiliary request 4 does not comprise any term relating to the type of formulation and the duration of the pharmacological effect. The conclusions drawn for the main request thus apply *mutatis mutandis* for this request, which does not meet the requirements of Article 123(2) EPC.

7. Auxiliary request 5 - Article 123(2) EPC

Claim 1 of auxiliary request 5 does not comprise any feature regarding the type of release and duration of pharmacological effect, and for this reason auxiliary request 5 does not meet the requirements of Article 123(2) EPC.

8. Auxiliary request 6 - Article 123(2) EPC

Since the subject-matter of claim 1 of auxiliary request 6 does not refer to the type of formulation, auxiliary request 6 does not meet the requirements of Article 123(2) EPC.

9. Auxiliary request 7 - Article 123(2) EPC

The feature regarding the duration of the pharmacological effect is absent from the subject-matter of claim 1 of auxiliary request 7. Auxiliary request 7 does thus not meet the requirements of Article 123(2) EPC.

10. Auxiliary request 8 - Article 123(2) EPC

The subject-matter of claim 1 of auxiliary request 8 does not comprise any feature relating to the type of formulation and the duration of the pharmacological

effect. Auxiliary request 8 thus does not meet the requirements of Article 123(2) EPC.

11. Auxiliary request 9 - Article 123(2) EPC

In the absence of the features regarding the type of formulation and the duration of the pharmacological effect in claim 1 of auxiliary request 9, it must be concluded that auxiliary request 9 does not meet the requirements of Article 123(2) EPC.

12. Auxiliary request 10

12.1 Admission of auxiliary request 10 into the proceedings

Auxiliary request 10 was filed as a response to the respondent's objections under Article 123(2) and (3) EPC. Its admissibility had never been contested by the respondent before the oral proceedings, though it had had sufficient time to review the request.

The amendments made to the request are occasioned by objections raised during the appeal proceedings and *prima facie* address the issues raised by the board without giving rise to new ones and without adding complexity to the case under consideration. They constitute a direct, clear and fair attempt to respond to the respondent's objections. Therefore, auxiliary request 10 is admitted into the proceedings (Article 13(1) (3) RPBA).

12.2 Article 123(3) EPC

The replacement of the feature "*microparticles that have a mass median aerodynamic diameter of less than 30 µm*" by the feature "*microparticles that have a diameter*

of from 0.1 to 10 μm " has been objected to under Article 123(3) EPC by the respondent.

The appellant has shown the mathematic relationship between both parameters, wherein the aerodynamic diameter is determined by the diameter, and has demonstrated convincingly that particles having a mass median aerodynamic diameter of less than 30 μm always have a diameter of 10 μm or less, unless the micro-particles consist only of a material having a density higher than iron, which is not the case of the constituents of the micro-particles as claimed. The European patent has thus not been modified in such a way as to extend the protection it confers, according to Article 123(3) EPC.

12.3 Article 123(2) EPC

Even if some features were not disclosed *expressis verbis*, a basis could be found for all features of claim 1 of auxiliary request:

- (a) The term "*wherein the inhaler is capable of dispensing a unit dose of the powder comprising up to 5 mg glycopyrrolate*" could be derived from the subject-matter of original claims 23 combined with claims 14, 1 and 2. Claim 23 indeed relates to a dry powder inhaler comprising a unit dosage according to any of claims 1 to 15, while claim 2 specifies that the active ingredient is glycopyrrolate and claim 14 that it is present in an amount of less than 5 mg.
- (b) The term "*large carrier particles*" finds a direct basis in the original description (see page 5, line 18-20)

- (c) The feature "*microparticles that have a diameter of from 0.1 to 10 μ m*" is disclosed in original claim 5
- (d) The term "*wherein the glycopyrrolate is formulated with a hydrophobic material to form the microparticles*" is based on the passage "*the glycopyrrolate is formulated with a hydrophobic matrix material to form micro-particles suitable for inhalation*" (see page 5, lines 1-3).
- (e) As to the objection of the respondent that the combination of these features, in particular of the active agent, the particular micro-particle matrix and the particular size, the board notes that the features are not the result of a combination of multiple inventions, but a combination of preferred aspects of one single invention, which does not present new information to the skilled person.

As all subject-matter of the dependent claims objected to by the respondent has been deleted in auxiliary request 10, all subject-matter of said request finds a basis in the original application.

Auxiliary request 10 meets the requirements of Article 123(2) EPC.

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12.4 *Remittal to the first instance (Article 111(1) EPC)*

Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should, whenever possible, be given the opportunity to said consideration by two instances of the important elements of the case. The essential function of an appeal in *inter partes* proceedings is to

consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other essential issues outstanding. If the appeal on the particular issue is allowed, the case should normally be remitted to the first instance department for consideration of the undecided issues.

The observations and comments made above apply fully to the present case. The Opposition Division decided to revoke the patent on the ground that the claimed subject-matter extended beyond the content of the application as originally filed (Article 100(c) EPC), but left open the issues of novelty (Articles 52(1), 54 EPC) and inventive step (Articles 52(1), 56 EPC). These issues, however, form, *inter alia*, the basis for the requests of the respondent that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution on the basis of auxiliary request 10.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.

The Registrar:

The Chairman:



L. Fernández Gómez

J. Riolo

Decision electronically authenticated