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**Datasheet for the decision
of 22 June 2015**

Case Number: T 0809/11 - 3.3.07

Application Number: 01971210.8

Publication Number: 1318785

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Language of the proceedings: EN

Title of invention:
PULMONARY DELIVERY OF L-DOPA

Applicant:
Civitas Therapeutics, Inc.

Relevant legal provisions:
EPC Art. 123(2), 83

Keyword:
Amendments - added subject-matter (yes) -
main request, first and second auxiliary request
Sufficiency of disclosure



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0809/11 - 3.3.07

**D E C I S I O N
of Technical Board of Appeal 3.3.07
of 22 June 2015**

Appellant: Civitas Therapeutics, Inc.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 3 August 2010
refusing European patent application No.
01971210.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman D. Semino
Members: R. Hauss
D. T. Keeling

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division, posted on 3 August 2010, refusing European patent application No. 01 971 210.8.

Independent claims 1 and 2 of the application as filed read as follows:

"1. A method for providing rescue therapy for a disorder of the central nervous system comprising administering to the respiratory tract of a patient in need of rescue therapy particles comprising an effective amount of a medicament, wherein the particles have a tap density less than about 0.4 g/cm^3 and are delivered to the alveoli region of the pulmonary system.

2. A method for providing rescue therapy for Parkinson's disease comprising administering to the respiratory tract of a patient in need of rescue therapy particles comprising an effective amount of an anti-Parkinson disease medicament, wherein the particles are delivered to the alveoli region of the pulmonary system."

The decision was based on a claim request filed with letter dated 8 January 2010 and, identically, with letter dated 8 July 2010. The independent claims of said request read as follows:

"1. An anti-Parkinson disease medicament for use in pulmonary delivery to provide rescue therapy.

4. The use of an anti-Parkinson disease agent in the manufacture of a medicament for delivery to the pulmonary system for use in providing rescue therapy."

In the decision under appeal the examining division referred to the reasoning provided in its earlier communication dated 10 March 2010. The examining division found *inter alia* that it was not clear whether claim 1 was intended to be in the format according to Article 54(5) EPC 2000. If that was however the case, the claim was not clear because, on the one hand, the term "rescue therapy" did not clearly identify a disease, and on the other hand, the term "anti-Parkinson disease medicament" was confusing because it covered very different classes of drugs. Especially drugs intended to treat the secondary symptoms of Parkinson's disease, e.g. antiepileptics or antipsychotics, could also be used in the treatment of situations unrelated to Parkinson's disease. Thus neither the drug nor the disease appeared to be sufficiently delimiting to define a clear therapeutic application. Since the wording of the claims failed to express the invention for which protection was sought in a clear and unambiguous way, the claimed subject-matter was furthermore considered not to comply with the requirements of Articles 83, 54 and 56 EPC.

- II. The appellant (applicant) lodged an appeal against the examining division's decision of refusal. With the statement setting out the grounds of appeal the appellant also submitted an amended main request and two auxiliary requests.

Claim 1 of the main request reads as follows:

"1. Use of an anti-Parkinson disease medicament in the manufacture of a medicament for pulmonary delivery to provide rescue therapy in a patient with Parkinson's disease."

Claim 1 of the first auxiliary request reads as follows:

"1. Use of levodopa, carbidopa, apomorphine, or any combination thereof, in the manufacture of a medicament for pulmonary delivery to provide rescue therapy in a patient with Parkinson's disease."

Claim 1 of the second auxiliary request reads as follows:

"1. Use of levodopa in the manufacture of a medicament for pulmonary delivery to provide rescue therapy in a patient with Parkinson's disease."

- III. In a communication issued in preparation for oral proceedings and advising the appellant of the board's preliminary opinion, the board mentioned i.a. the following objections under Articles 123(2) and 83 EPC:
- The appellant had not indicated the basis in the application as filed for the amendments effected in the claims of the current requests; in particular, the treatment addressed was not restricted any more to the delivery of particles.
 - It had not been shown or rendered credible that rapid onset treatment, i.e. "rescue therapy", could be achieved by pulmonary application of anti-Parkinson drugs other than levodopa.

- IV. With letter dated 11 June 2015 the appellant filed a new main request and five auxiliary requests.
- The main request and the first and second auxiliary requests were identical to the corresponding requests previously submitted with the statement setting out the grounds of appeal.

Claim 1 of the third auxiliary request reads as follows:

"1. Use of an anti-Parkinson disease medicament in the manufacture of a medicament for pulmonary delivery to

provide rescue therapy in a patient with Parkinson's disease, wherein the anti-Parkinson disease medicament is incorporated into particles having a tap density less than about 0.4 g/cm^3 and have [sic] a mass median aerodynamic diameter of less than about 5 microns."

Claim 1 of the fourth auxiliary request reads as follows:

"1. Use of levodopa, carbidopa, apomorphine, or any combination thereof in the manufacture of a medicament for pulmonary delivery to provide rescue therapy in a patient with Parkinson's disease, wherein the levodopa, carbidopa, apomorphine, or any combination is incorporated into particles having a tap density less than about 0.4 g/cm^3 and have [sic] a mass median aerodynamic diameter of less than about 5 microns."

Claim 1 of the fifth auxiliary request reads as follows:

"1. Use of levodopa in the manufacture of a medicament for pulmonary delivery to provide rescue therapy in a patient with Parkinson's disease, wherein the levodopa is incorporated into particles having a tap density less than about 0.4 g/cm^3 and have [sic] a mass median aerodynamic diameter of less than about 5 microns."

Apart from claim 1, each of the requests also contains four dependent claims.

- V. Oral proceedings took place on 22 June 2015. During oral proceedings, the appellant filed an amended version of the fifth auxiliary request which differs from the previous fifth auxiliary request only by deletion of the word "have" in claim 1.

VI. The appellant's arguments may be summarised as follows:

Added subject-matter

The application as filed was not restricted to the delivery of the drug in the form of particles. The "summary of the invention" as presented in the description (in particular the passage on page 5, line 10 to page 6, line 7) did not mention particles as a mandatory essential feature. The application of particles was described as one possible way of carrying out the invention, but the person skilled in the art would be aware that the drug could also be applied as moist droplets or mist.

Sufficiency of disclosure

The invention was based on the fact that pulmonary administration was a route of delivery which provided rapid delivery to the central nervous system (page 8, lines 6 to 10 of the description). In that context the nature of the drug was not relevant. It was therefore credible that the effect of rapid delivery, and thus rapid onset treatment, could not only be achieved with levodopa, but also with other anti-Parkinson drugs.

VII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or of one of the first to fourth auxiliary requests, as filed by letter of 11 June 2015, or on the basis of the claims of the fifth auxiliary request as filed during the oral proceedings before the board of appeal.

Reasons for the Decision

1. Amendments (Article 123(2) EPC)
 - 1.1 Main request, first and second auxiliary requests
 - 1.1.1 The treatment addressed in claim 1 of the main request, the first auxiliary request and the second auxiliary request is not restricted to the delivery of particles.
 - 1.1.2 Claim 1 of the application as filed, relating generally to rescue therapy for a disorder of the central nervous system, as well as the claims which relate more specifically to rescue therapy for Parkinson's disease by administering an anti-Parkinson disease medicament (i.e., independent claim 2 and dependent claims 2 to 30 and 41 to 43) all require without exception that particles comprising the medicament are to be delivered to the pulmonary system.
 - 1.1.3 The subject-matter of the application is correspondingly summarised starting on page 5, lines 11 to 15, of the description: "The invention relates to methods of treating disorders of the central nervous system (CNS). More specifically the invention relates to methods of delivering a drug suitable in treating a disorder of the CNS to the pulmonary system and include *[sic]* administering to the respiratory tract of a patient in need of treatment particles comprising an effective amount of a medicament."

Although the second sentence is grammatically incorrect ("the invention relates to methods ... and include...") and it is therefore uncertain what is the subject of the verb "include", the sentence will normally be understood by the reader to mean that the invention

involves, or possibly that said methods involve, the administration of (solid) drug particles.

In the appellant's opinion, the sentence means that the administration of the medicament in the form of solid particles is "included" in the invention in the sense of being only one among several possible options. That interpretation is however neither plausible in the immediate context nor in the context of the application as a whole, since no other options are mentioned in the sentence in question or envisaged in the remaining text of the application (see points 1.1.4 and 1.1.6 below), and the corresponding claims explicitly require particles (see point 1.1.2 above).

In any case, even considering the appellant's explanation as a potential meaning, the wording of the sentence on page 5, lines 12 to 15 cannot be said to constitute a direct and unambiguous disclosure of the option of administering the medicament in a non-particulate form.

- 1.1.4 On page 6, lines 1 to 5, the description goes on to state that "the invention is related to a method for treating Parkinson's disease includes [sic] administering to the respiratory tract of a patient in need of treatment or rescue therapy a drug for treating Parkinson's disease, e.g., L-Dopa", and that the drug is delivered to the pulmonary system.

Contrary to the appellant's view, the fact that particles are not mentioned in that passage does not necessarily indicate that other dosage forms are envisaged and intended to be part of the embodiment. Rather, the passage on page 6 describes a more specific embodiment of the general description of the invention given on page 5.

Again there is no direct and unambiguous disclosure of the option of administering the medicament in a non-particulate form.

- 1.1.5 Apart from the passages on pages 5 and 6 of the description, the appellant did not cite any other passage in support of embodiments not employing particles.
- 1.1.6 Thus the board is not aware of any passage in the description as filed which unambiguously supports a general embodiment including the application of the medicament in non-particulate form, nor of any disclosure of a specific non-particulate embodiment, whereas several preferred embodiments with regard to the administration of particles are mentioned (see for instance page 6, line 21 to page 8, line 5 concerning inhalers, particle dosage, excipients and particle properties). Furthermore, particles are mandatory in the relevant claims (see point 1.1.2 above) and were employed in the examples (description: page 33 ff).
- 1.1.7 As a consequence, the board has come to the conclusion that the subject-matter of claim 1 of each of the main request, first auxiliary request and second auxiliary request, in that it is not restricted to the delivery of particles, contains subject-matter extending beyond the content of the application as filed, in contravention of Article 123(2) EPC.
- 1.2 Third to fifth auxiliary requests
 - 1.2.1 Claim 1 of each of the third to fifth auxiliary requests is restricted to embodiments in which the medicament is incorporated into particles; hence the objection under Article 123(2) EPC discussed in the context of the main request and the first and second

- auxiliary requests (see point 1.1 above) is no longer relevant.
- 1.2.2 The board sees no reason for other objections under Article 123(2) EPC in respect of the third to fifth auxiliary requests.
 2. Terminology
 - 2.1 In the light of page 5, lines 15 to 19 and page 11, lines 2-3 of the description, the board understands "rescue therapy" to be a treatment providing rapid delivery of a drug, and thereby rapid onset of therapeutic effects.
 3. Sufficiency of disclosure (Article 83 EPC) - third to fifth auxiliary requests
 - 3.1 Where a therapeutic application is claimed in a form approved for a further medical use, e.g. the use of a substance or composition in the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim. As a consequence, under Article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the therapeutic application (see the Case Law of the Boards of Appeal of the European Patent Office, 7th ed. 2013, II.C.6.2).
 - 3.2 In the present case, the application must therefore show the suitability of the drugs named in claim 1 for providing rescue therapy via pulmonary delivery in order to be in compliance with Article 83 EPC.
 - 3.3 In the present application, effects are shown only for levodopa (see examples 1, 3, 5 to 7) but not for any other anti-Parkinson drug. The appellant has not

provided further data concerning other anti-Parkinson drugs.

- 3.4 Thus it has not been shown or rendered credible that "rescue therapy", i.e. rapid onset treatment, may indeed be provided via pulmonary delivery over the entire claimed range of substances according to claim 1 of the third auxiliary request (relating to any anti-Parkinson disease medicament - a term which covers different classes of drugs with different structures and mechanisms of action) and of claim 1 of the fourth auxiliary request (relating to levodopa, carbidopa or apomorphine). In the absence of experimental evidence, it cannot be verified that the results obtained in the case of levodopa could be obtained with other anti-Parkinson drugs.
- 3.5 The appellant's sole argument was that the nature of the drug was actually irrelevant and that only the route of administration mattered for obtaining rapid delivery, the core of the invention being the choice of pulmonary delivery to provide rapid onset therapy. Since the desired technical effect of rapid delivery to the central nervous system had been shown for one drug, viz. levodopa, it was credible that it would also be obtained with other anti-Parkinson drugs, and in particular carbidopa and apomorphine.
- 3.6 Contrary to the appellant's view, it is however not self-evident that a variety of drugs characterised by different structural moieties and different mechanisms of action would be equally suitable for administration via the pulmonary route and would present an equally favourable pharmacokinetic behaviour suitable for providing rapid onset treatment. Different types of drugs are used in the treatment of Parkinson's disease, such as dopamine precursors, dopamine agonists,

inhibitors of various enzymes, and a variety of drugs used in the treatment of secondary symptoms, all having different chemical structures. In view of this, the appellant has provided neither experimental data nor arguments to render it credible that other anti-Parkinson medicaments apart from levidopa could be used to provide rapid onset treatment by pulmonary delivery. With regard to the fourth auxiliary request, the appellant has not provided any concrete explanation, e.g. based on the specific structure or activity of said drugs, why the conclusion should be reached that rapid onset treatment shown for levidopa would be achieved also in the case of carbidopa or apomorphine.

- 3.7 Based on the available information, the board has thus reached the conclusion that the subject-matter defined in claim 1 of the third auxiliary request and in claim 1 of the fourth auxiliary request is not disclosed in the application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in contravention of Article 83 EPC.
- 3.8 In view of the experimental data provided in the application, the subject-matter of claim 1 of the fifth auxiliary request is deemed to meet the requirements of Article 83 EPC.
4. The board has no other objections to the claims of the fifth auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent on the basis of the claims of the fifth auxiliary request as filed during the oral proceedings of 22 June 2015 and a description to be adapted.

The Registrar:

The Chairman:



N. Schneider

D. Semino

Decision electronically authenticated