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**Datasheet for the decision
of 3 March 2011**

Case Number: T 0931/07 - 3.3.02

Application Number: 01974367.3

Publication Number: 1322300

IPC: A61K 9/72

Language of the proceedings: EN

Title of invention:

Inhalation particles incorporating a combination of two or more active ingredients

Patentee:

Orion Corporation

Opponent:

Glaxo Group Ltd.

Headword:

Inhalation particles containing two active ingredients/ORION

Relevant legal provisions:

EPC Art. 123(2), 114(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Amendments - added subject matter (yes) - necessary features not represented in claims"

Decisions cited:

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Catchword:

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Case Number: T 0931/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 3 March 2011

Appellant: Glaxo Group Ltd.
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Appellant: Orion Corporation
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
13 April 2007 concerning maintenance of the
European patent No. 1322300 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
L. Bühler

Summary of Facts and Submissions

- I. European patent No. 1 322 300, based on international application PCT/FI2001/000863, published as WO 2002/028377 and having application No. 01 974 367.3 in the EPO, was granted with 20 claims.

Claim 1 as granted read as follows:

"Inhalation particles incorporating, in an unagglomerated individual particle, a combination of two or more different active ingredients, wherein said particles are spherical and at least one of the active ingredients is in crystalline form."

- II. Opposition was filed against the granted patent under Article 100(a) EPC, novelty and inventive step, and Article 100(b) EPC, sufficiency of disclosure.

The opposition division held that the contested patent as amended according to the third auxiliary request met the requirements of the Convention. This statement explicitly included the assessment under Article 123(2) EPC.

- III. Both, the opponent and the patentee filed appeals against the decision of the opposition division.
- IV. With its statement of grounds of appeal, the appellant-patentee submitted three sets of claims as main request and first and second auxiliary request.
- V. On 18 November 2010, a communication was despatched, expressing the board's concern with respect to

Article 123(2) EPC, in particular, as far as claim 1 of the auxiliary requests contained amendments that related to features being disclosed in the application as originally filed in context with "unagglomerated individual particles".

VI. As an answer to the communication, the appellant-patentee, with letter dated 28 January 2011, submitted five sets of claims as main request and first to fourth auxiliary request replacing the requests as submitted together with the statement of grounds of appeal.

The wording of claim 1 of the appellant-patentee's main request reads (additions with respect to claim 1 as granted in bold):

"Inhalation particles incorporating, in an unagglomerated individual particle, a combination of two or more different active ingredients, wherein said particles are spherical and at least one of the active ingredients is in crystalline form, **wherein the active ingredients constitute at least 90 wt% of the total weight of the particles.**"

In claim 1 of the first auxiliary request the following text is added at the end of claim 1 of the main request:

"and wherein at least 90 wt% of the total weight of the particles is in crystalline form".

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the "two or more different active ingredients" are defined specifically

as "an anti-inflammatory drug and a bronchodilator as active ingredients".

Claim 1 of the third auxiliary request combines the amendments of claims 1 of the aforementioned three requests together.

In claim 1 of the fourth auxiliary request, the particles as compared to claim 1 of the third auxiliary request are defined as being free from other materials than the active ingredients; the claim reads (additions with respect to claim 1 as granted in bold):

"Inhalation particles incorporating, in an unagglomerated individual particle, a combination of **an anti-inflammatory drug and a bronchodilator as** active ingredients, wherein said particles are spherical and at least one of the active ingredients is in crystalline form, **wherein the particles are free from other materials than the active ingredients, and wherein at least 90 wt% of the total weight of the particles is in crystalline form.**"

- VII. With letter of 16 February 2011, the appellant-patentee filed further auxiliary requests 5 and 6. It informed the board that it withdrew its request for oral proceedings and that it would not attend the oral proceedings scheduled for 10 March 2011.
- VIII. The appellant-opponent, in its written submissions, raised objections concerning novelty, inventive step and sufficient disclosure.

In response to the Board's observations in its communication, the appellant-patentee argued that the Board's arguments related to Article 123(2) EPC could not proceed because the expression "particles obtained" in the description as originally filed clearly referred to particles obtained by the method as described in the entire section starting from page 5, line 14 and ending at page 9, line 10, rather than merely to the preferred embodiment of the preceding paragraph. Moreover, the clarifying term "in an individual particle" appeared also in the first sentence of the "Summary of the Invention".

With letter dated 16 February 2011, the appellant-patentee requested admission of its late filed auxiliary requests 5 and 6 into the proceedings, because these requests were believed to address some of the issues which were raised on 10 February 2011, in the oral proceedings relating to a companion case, and which it expected the appellant-opponent to raise during oral proceedings in the current case.

The appellant-opponent requested that the decision under appeal be set aside and that the European patent be revoked.

- IX. The appellant-patentee requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of the first to fourth auxiliary requests, all filed with letter of 28 January 2011, or on the basis of auxiliary request 5 or 6, filed with letter of 16 February 2011.

Reasons for the Decision

1. The appeals are admissible.
2. *Admissibility of auxiliary requests 5 and 6*

These auxiliary requests were introduced as an answer to arguments which were discussed in a parallel case concerning an independent and self-consistent application.

These arguments, however, *de facto* are not introduced into the current case. Therefore, the admission of the corresponding requests has no basis. Being late filed and not representing a reaction to newly introduced issues, they cannot be admitted into the proceedings.

3. *Requirements of Article 123(2) EPC; all requests remaining in the proceedings (main request and first to fourth auxiliary request)*

- 3.1 Claims 1 of all these requests contain additional features with respect to claim 1 as granted. Adding these features puts all features of the granted claim into a new context which results in assessment of the whole claim as amended under Article 123(2) EPC.

- 3.2 Claims 1 of all requests concern inhalation particles incorporating, in an unagglomerated individual particle, a combination of two or more different active ingredients.

Original disclosure of the feature that an individual particle has to be understood to refer to an

unagglomerated individual particle is derived from page 9, lines 12 to 14. The corresponding paragraph starts with the statement "The particles obtained incorporate, in an individual particle ...".

In the preceding paragraph, preferred conditions of the process for preparation of particles are indicated. The following words "the particles obtained ..." must therefore be understood to refer to particles that are produced by this process and that at least exhibit all the properties resulting from this process.

The corresponding properties are described such that the particles are crystalline and spherical and that they have a narrow particle size distribution and rough surfaces. The particle size is further specified as "such that the mean mass aerodynamic diameter of said particles is between about 0.5 - 10 μm , ..." (see page 9, lines 1 to 6 of the description as originally filed).

However, the properties "crystalline" and "spherical" are represented in claims 1, but the other properties linked to them are missing. As a result, each of the current claims 1 of all requests represents *inter alia* subject-matter not exhibiting necessarily linked properties.

- 3.3 Therefore, each of claims 1 of all requests on file and admitted into the proceedings contains subject-matter which extends beyond the content of the application as originally filed and thus fails to comply with Article 123(2) EPC.

4. In addition to the arguments and conclusions set out under point 3 above and consequently and finally leading to the decision, for the sake of taking account of all arguments presented by the appellant-patentee, the following remarks are added:

4.1 The words "in an individual particle" are disclosed in another context than the particles obtained by a specific process and the feature "in an individual particle" doesn't appear in this claim instead of "unagglomerated individual particles". Moreover, there is no statement in the description as originally filed that these two expressions were to be understood synonymously.

Therefore, the conclusion on the features necessarily to be contained in the claim has to be maintained.

4.2 Even if the wording "particles obtained" in line 12 on page 9 of the description as originally filed would refer to the entire section starting from page 5, line 14 and ending at page 9, line 10, rather than merely to the preferred embodiment of the preceding paragraph, as the appellant-patentee stated, there still were particular properties necessarily linked to these particles that are not contained in current claims 1. On page 5, lines 14 to 16 it is set out that "the particles of the present invention are preferably prepared using a one-step continuous process, which can directly produce desirable particle size range". This range, on page 6, lines 9 to 10 is defined as "typically between about 1-5 μm ".

Thus, even if the arguments of the appellant-patentee would succeed in this respect, current claims 1 would miss an important feature which still results in their subject-matter extending beyond the content of the application as originally filed.

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:

N. Maslin

U. Oswald