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Datasheet for the decision of 24 March 2015

Case Number: T 1109/12 - 3.3.07

Application Number: 01998327.9

Publication Number: 1337239

IPC: A61K9/14, A61K9/72

Language of the proceedings: EN

Title of invention:
PARTICLES FOR USE IN A PHARMACEUTICAL COMPOSITION

Patent Proprietor:
Vectura Limited

Opponents:
NORTON HEALTHCARE LIMITED
AstraZeneca AB

Relevant legal provisions:
EPC Art. 56, 84, 100(b), 123(2)

Keyword:
Amendments - added subject-matter (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Inventive step - (yes)

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Case Number: T 1109/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 March 2015

Appellant: (Patent Proprietor)	Vectura Limited 1 Prospect West Chippenham, Wiltshire SN14 6FH (GB)
Representative:	Clarke, Christopher John Vectura Limited Intellectual Property Department One Prospect West Chippenham Wiltshire SN14 6FH (GB)
Respondent: (Opponent 1)	NORTON HEALTHCARE LIMITED Regent House 5-7 Broadhurst Gardens Swiss Cottage London NW6 3RZ (GB)
Representative:	Gillard, Richard Edward Elkington and Fife LLP Thavies Inn House 3-4 Holborn Circus London EC1N 2HA (GB)
Respondent: (Opponent 2)	AstraZeneca AB 151 85 Södertälje (SE)
Representative:	Lowry, Rachel Maria AstraZeneca AB, Global Intellectual Property 151 85 Sodertalje (SE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 March 2012 revoking European patent No. 1337239 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Semino
	D. T. Keeling

Summary of Facts and Submissions

I. The appeal of the proprietor (appellant) lies from the decision of the opposition division announced at the oral proceedings on 2 February 2012 to revoke European Patent No. 1 337 239.

II. The granted patent comprised 24 claims, independent claim 1 reading as follows:

"1. A method of making a composition for inhalation, comprising reducing the size of particles of additive material to produce particles with an MMAD of not more than 2 µm and mixing the additive particles with active particles, wherein the additive material is suitable for promoting the dispersal of active particles upon aerosolisation of a dry powder in a dry powder inhaler, and wherein the additive material is soft, having an indentation hardness of not more than 100 MPa, the method comprising the step of pressing or fusing the particles of additive material to the surfaces of the active particles by compressing the mixture of active and additive particles."

Further independent claims were directed to a composition (claim 15), the use of a composition (claim 20), a dry powder inhaler (claim 21), a pressurised metered dose inhaler (claim 22), the use of particles of an additive material for the manufacture of a composition (claim 23), and particles of an additive material (claim 24).

III. Two notices of opposition were filed in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and of inventive step, insufficiency of disclosure, and extension of

subject-matter beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

IV. During opposition proceedings, the following documents *inter alia* were cited:

D1: WO-A-00/33811
D2: X.-M. Zeng et al., "Particulate Interactions in Dry Powder Formulations for Inhalation", Taylor & Francis, 2001, pages 165-167
D12: WO-A-96/23485

V. The decision was based on the final set of claims 1-20 filed during oral proceedings on 2 February 2012 as sole request.

Claim 1 of said request read as follows (deletions and additions with respect to claim 1 of the patent as granted are indicated by strike through and underlining respectively):

"1. A method of making a composition for inhalation, comprising reducing the size of particles of additive material to produce particles with an MMAD of not more than 2 µm and mixing the additive particles with active particles, wherein the additive material is suitable for promoting the dispersal of active particles upon aerosolisation of a dry powder in a dry powder inhaler, and wherein the additive material is soft, having an indentation hardness of not more than 100 MPa, the method comprising the step of pressing ~~or fusing~~ the particles of additive material to the surfaces of the active particles by a milling step involving compressing the mixture of active and additive particles in a gap or nip of fixed predetermined width, wherein the additive is magnesium stearate."

Corresponding amendments were incorporated into subsequent independent claims.

VI. The decision of the opposition division, as far as relevant to the present decision, can be summarised as follows:

a) The requirements of Article 123(2) EPC were fulfilled in respect of method claim 1 and the further independent claims in which analogous amendments had been undertaken. There was a general disclosure in the original application for the feature of claim 1 reading "pressing the particles of the additive material together with the active particles" which was not limited to the specific techniques listed in the description. Moreover, the specific combination of features defined by claim 1 was allowable, since it reflected the preferred embodiments and the examples of the patent as filed. In particular, magnesium stearate was the preferred additive and its indentation hardness was an intrinsic feature thereof.

b) The requirements of Article 84 EPC were fulfilled in respect of the feature "in a milling step in a gap or nip of fixed predetermined width", which had been introduced into the claims during the opposition proceedings, since the techniques in question were clear to the person skilled in the art.

c) The claims were sufficiently disclosed. Although a reference to the indentation hardness alone in a claim would cause undue burden with respect to its

measurement, the specification of the additive material as magnesium stearate alleviated said burden. With respect to the feature "MMAD lower than 2 µm", no convincing arguments or evidence had been put forward demonstrating that the skilled person would not be in a position to put the claimed invention into practice.

d) In view of the limitation of the additive material to magnesium stearate, novelty was not disputed.

e) The requirements of Article 56 EPC were not fulfilled. D1 was the closest prior art since it aimed at dry powders for inhalers with improved efficiency and delivery. The patent in suit differed from D1 in the MMAD of the additive particles being less than 2 µm, and in the choice of magnesium stearate as additive. The data provided in the application merely compared the respirability and dissolution properties of the composition in the presence and in the absence of magnesium stearate without providing comparative data with respect to the prior art. The problem to be solved was the provision of an alternative process for providing particles with good respirability. D1 taught that in order to achieve good respirability, the additive, preferably leucine, should have an MMAD of less than 10 µm, preferably less than 5 µm. As D1 did not indicate a lower limit for the particle size, the skilled person would have seriously contemplated working in the claimed particle size range of less than 2 µm. With respect to the choice of the additive, D1 acknowledged D12 which specifically referred to magnesium stearate as an alternative to amino acids among pharmaceutically acceptable additives.

Since D12 also concerned the field of dry powder inhalers, the person skilled in the art would replace the amino acid of D1 with magnesium stearate in order to solve the problem as posed.

VII. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal filed with letter of 23 July 2012, the appellant requested that the decision be set aside and the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1-3, all filed therewith. The main request was identical to the request on which the appealed decision was based.

VIII. With the reply to the statement of grounds, respondent-opponent 2 filed *inter alia* the following document:

DA6: Pharmaceutical Research, Plenum Press, Volume 14(11), November 1997: Abstract 1405, Staniforth et al., pages S-142 and S-143

IX. In a communication sent in preparation of oral proceedings, the Board summarised the points to be dealt with, and provided a preliminary view particularly concerning inventive step.

X. In response to that communication the appellant filed further arguments with letter of 3 March 2015, *inter alia* accepting that D1 represents the closest prior art and presenting a table summarising the results in D1 and in the patent. Amended description pages were also attached to that letter.

XI. Oral proceedings were held on 24 March 2015 in the absence of respondent-opponent 2 as announced with letter of 19 February 2015.

XII. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Sufficiency of Disclosure

a) The measured particle Volume Median Diameter (VMD) of 2.5 µm according to example 1 of the patent did not correspond to the actual size thereof due to agglomeration. When the agglomerates were broken up by ultrasonication, the particle size decreased to under 2 µm, as confirmed by table 1. Furthermore, the relation between VMD and Mass Median Aerodynamic Diameter (MMAD) was known, allowing the calculation of the latter from the former.

Inventive step

b) D1 could be considered as the closest prior art. The subject-matter of claim 1 differed from the disclosure in D1 not only in the replacement of leucine as additive by magnesium stearate, but also in the presence of process steps involving "reducing" the size of the additive particle (while according to D1, the desired size is achieved by creating the particles from vapour or solution), and compressing the mixture of active and additive particles "in a gap or nip of fixed predetermined width". In this respect, even the use of a food processor according to some of the examples of D1 did not unambiguously disclose a gap or nip of fixed predetermined width.

c) With reference to the comparative table filed with letter of 3 March 2015 (page 3), the fine particle

fraction (FPF) achieved by the compositions according to the patent was directly comparable with the FPF of the compositions of D1 because they employed the same measurement technique, were performed by the same company and had an inventor in common. These data demonstrated that the compositions prepared according to the patent had improved aerosol performance over those of D1, as evidenced by the increased FPF achieved. The objective technical problem was thus to provide a method for preparing a powder for inhalation comprising additive and active particles which had improved aerosol performance, in particular an increased FPF.

d) The solution was not obvious in view of D1 in combination with either D12 or DA6, despite the fact that both documents disclosed magnesium stearate as a known additive for inhalation compositions, not least because said disclosures concerned ternary blends which necessarily included a carrier, the alleged beneficial effects thereof being related to reducing adhesion between the carrier and the active. Furthermore, according to D12 magnesium stearate was not preferred, since it caused premature segregation of the active particles from the carrier particles, an effect which was stated as being unacceptable. Additionally, even if the skilled person were to try to use magnesium stearate in place of leucine in the process according to D1, he would not have been able to produce the required magnesium stearate particles by either of the methods employed therein. There was thus no motivation for the skilled person faced with the objective technical problem to replace leucine with

magnesium stearate on the basis of the teachings of D12 or DA6, and the subject-matter of claim 1 consequently involved an inventive step.

XIII. The arguments of the respondents, insofar as relevant to the present decision, can be summarised as follows:

Amendments

a) Claim 1 was amended to include a pressing step, namely "pressing the particles of additive material to the surfaces of the active particles by a milling step involving compressing the mixture of active and additive particles in a gap or nip of fixed predetermined width". The limitation of pressing to the precise processing condition (the gap/nip) resulted in a combination of features which was not originally disclosed.

b) The application as filed discussed reducing the size of the additive material to an MMAD of "less than" 2 µm, while claim 1 recited "not more than" 2 µm. Since the former excluded 2 µm and the latter included it, subject-matter was added.

c) In view of the discussion on page 17, lines 4-6 of the application as filed, whereby the mixing of the active and additive particles might take place prior to or at the same time as the size reduction step, and the ensuing discussion of the pressing step, taking the embodiment whereby the additive size was reduced prior to mixing and combining it with the specific pressing step represented a previously unlinked combination.

d) It was not clear whether the wording of claim 1 provided a closed or an open definition of the additive, but, if it was a closed definition, it was a limitation to the nature of the additive not originally disclosed.

e) Claim 1 as a whole amounted to an arbitrary combination of features for which there was no disclosure in the specification as filed.

Clarity

f) Amended claim 1 according to the main request was not clear in view of the repetition of the wording "the method comprising". Moreover, the feature "the additive is magnesium stearate" did not make it clear whether is was an open or a closed definition of the additive and the feature "a gap or nip of fixed predetermined width" with reference to the compression of active and additive particles did not make it clear which techniques were covered.

Sufficiency of Disclosure

g) The disclosure did not enable the skilled person to prepare particles of additive having an MMAD of not more than 2 µm, either due to the specific techniques required not being identified in the specification, or due to the example describing particle sizes only by reference to the VMD thereof, stated as being 2.5 µm after the homogenisation step.

Inventive step

h) The only distinguishing feature of claim 1 over the disclosure of D1, taken as the closest prior art, was the choice of the additive, namely magnesium stearate. The appellant had failed to demonstrate the alleged improved FPF of the compositions of the patent in comparison to that measured for those according to D1. Consequently, the objective technical problem could only be formulated as the provision of an alternative method of making a composition for inhalation. Since DA6 taught that magnesium stearate was at least as good as, if not better than leucine in providing compositions having the desired FPF, the skilled person would have been duly motivated to replace leucine of D1 with magnesium stearate in order to solve the problem. Alternatively, motivation was provided by D12 which mentioned magnesium stearate as a possible additive. That according to D12 magnesium stearate was not preferred would not be a demotivation for the skilled person, since the patent itself did not pretend to overcome the disadvantages therein but rather ignored them. In this context, it was not inventive to take a known, albeit less beneficial, material from the prior art and simply tolerate its disadvantages.

i) The arguments of the appellant according to which neither DA6 and D12 are relevant due to the presence of a carrier, and that even if the skilled person were to try to replace leucine with magnesium stearate in the process according to D1, he would not have been able to produce magnesium stearate particles by either of the methods used

therein (vapour condensation or spray drying), were flawed. Firstly, the use of a carrier was also anticipated in the patent specification, and secondly, D1 taught that specific techniques were required to prepare the desired small particles only in respect of soft additives such as leucine, while milling remained the conventional method. Thus there was no prejudice preventing the skilled person from employing magnesium stearate in the process according to D1, as he would merely employ the conventional techniques disclosed therein in order to achieve the desired particle size.

j) Claim 1 therefore lacked inventive step in view of D1 in combination with D12 or DA6. Claim 11 also lacked inventive step as it was directed to the inevitable product of the method of claim 1.

XIV. The appellant requested that the decision under appeal be set aside and the patent maintained on the basis of the claims of the main request filed with the grounds of appeal on 23 July 2012 and the amended pages of the description filed by letter of 3 March 2015.

XV. The respondents requested that the appeal be dismissed.

Reasons for the Decision

Main request - amendments

1.1 Claim 1 of the main request was amended *inter alia* to include the feature of "pressing the particles of additive material to the surfaces of the active particles by a milling step involving compressing the mixture of active and additive particles in a gap or nip of fixed predetermined width". It is argued that

this feature comprises a combination not originally disclosed in the application as filed. However, the disputed feature is disclosed as a preferred embodiment on page 17, lines 10-15 and lines 31-34 of the application as originally filed. Here, various methods for pressing the particles of additive and active together are described, among which a milling step in a gap or nip of fixed predetermined width is a preferred embodiment, examples of which are the Mechano-Fusion and Cyclomix methods described in detail on pages 18 and 19. Thus the added feature is composed of features which are both preferred and explicitly linked to each other in the application as filed, and consequently is not objectionable under Article 123(2) EPC.

1.2 It was furthermore alleged that the requirements of Article 123(2) EPC were not met due to the application as filed disclosing the reduction of the size of the additive material to an MMAD of "less than" 2 µm, while claim 1 of the main request recites "not more than" 2 µm in respect of the same. However, in the context of the additive particle size-reduction step according to the application as filed (page 13, line 33 - page 14, line 13), it is stated that "The invention also provides a method for making particles of additive material.. the particles having a MMAD of not more than 2 µm, the method comprising the step of providing large particles of additive material having an MMAD of greater than 2 µm and the step of reducing the size of those particles such that the MMAD of the resulting particles is less than 2 µm". Thus both terms are disclosed in the application as filed and are used interchangeably, and the feature concerned is directly and unambiguously derivable from the application as filed.

1.3 It was furthermore argued that, in view of the discussion on page 17, lines 4-6 of the application as filed, taking the embodiment whereby the additive size is reduced prior to mixing, and combining it with the specific pressing step represents a previously unlinked combination not originally disclosed. However, the Board notes that it is stated as preferable that the step of reducing the size of the particles of additive material is conducted in the absence of the active substance (page 16, lines 31-33). This preference is confirmed by the examples. The Board thus considers that the combination of these preferred embodiments (see also point 1.1, above) is disclosed unambiguously in the application as filed.

1.4 The same conclusion applies in respect of the allegation that claim 1 of the main request amounts to an arbitrary and undisclosed combination of features taken from the description, since the features in question either represent preferred embodiments of the disclosure, or concern a feature redundant in view of the limitation of the additive to magnesium stearate (the indentation hardness parameter).

1.5 As to whether the wording of claim 1 provides a closed or an open definition of the additive, the Board notes that claim 1 has been limited to a method in which the additive "is" magnesium stearate: thus mixtures comprising further additives are excluded. Magnesium stearate as additive is clearly disclosed in the application as filed and, in particular, it is the sole additive employed according to the examples. Thus also in this regard, claim 1 of the main request is not objectionable under Article 123(2) EPC.

1.6 In view of this, it is concluded that the main request meets the requirements of Article 123(2) EPC.

Main request - clarity

2. The respondents objected to claim 1 under clarity in view of the repetition of the wording "the method comprising", and of the features "the additive is magnesium stearate" and "a gap or nip of fixed predetermined width" with reference to the compression of active and additive particles.

2.1 With respect to the repetition of the term "method comprising" in claim 1, the use of the definite article "the" in the second occurrence of the term serves as a clear reference to the first occurrence thereof, so that there can be no doubt that the wording refers to one and the same method. As far the expression "the additive is magnesium stearate" is concerned, there is also no doubt that "is" in this context does not allow the inclusion of further additives. With respect to the final feature objected to, the Board finds no lack of clarity in the wording itself, while the description offers further explanations together with references to techniques which fall under the definition provided in the claim.

2.2 It follows the claim 1 of the main request fulfills the requirements of Article 84 EPC.

Main request - sufficiency of disclosure

3. The respondents have argued that claim 1 of the main request is not sufficiently disclosed based on the allegation that the disclosure does not enable the

skilled person to prepare particles of additive material having an MMAD of not more than 2 µm.

3.1 The patent specification describes magnesium stearate as a soft additive material having an indentation hardness of 22 MPa and states that soft additive materials are not easily milled to a particle size of below 4 µm using conventional milling methods, often requiring the use of alternative methods such as homogenisation to achieve the desired diameter of 2 µm or less (paragraph [0028]). Said homogenisation process is further described in detail (paragraphs [0054] - [0056]) and exemplified (example 1, paragraphs [0087] - [0090]). This example provides magnesium stearate particles with a VMD of 2.5 µm, a size which is stated to result from the presence of agglomerates, subsequently broken up by ultrasound to produce particles having a VMD of below 2 µm (Table 1). The techniques required to produce the desired magnesium stearate particles are therefore adequately disclosed in the application and no evidence has been presented demonstrating that said techniques will not enable the skilled person to produce additive particles having the desired size.

3.2 Furthermore, although it is true that MMAD and VMD are not equivalent definitions of diameter, it must be emphasised that no evidence has been provided demonstrating that the skilled person would not be in a position to produce additive particles having the desired MMAD values. According to the evidence on file (see for example D2, section 5.5.7.1), the MMAD can easily be calculated from the VMD and the density of the particle. Notwithstanding this, the skilled person is aware of how to measure MMAD and there is no evidence that, as a matter of routine, he would not be

capable of adjusting process parameters (e.g. in respect of the homogenisation step) to provide the desired particle size, if not initially achieved.

3.3 It follows that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Main request - inventive step

4. *Closest prior art*

4.1 All parties agree that D1 represents the closest prior art, and the Board sees no reason to deviate from this choice. In particular, according to the process of D1 and in contrast to that of D12, the additive (the amino acid) is first mixed with the active material before mixing with the carrier, rendering said process structurally more similar to the claimed method despite not disclosing magnesium stearate as the additive.

4.2 Document D1 discloses a composition for a dry powder inhaler comprising an active material and low-density amino acid particles as additive (page 10, lines 7-9). Examples 3 and 4 disclose the method of producing the powder blends.

4.3 It is undisputed that the method of making a composition for inhalation according to claim 1 of the main request differs from that disclosed in D1 in the nature of the additive material. Thus while claim 1 is limited to magnesium stearate as additive material, the additive according to D1 is an amino acid, preferably leucine. In view of the conclusion reached by the Board, in what follows when considering this difference alone (see point 6.5, below), it is not relevant to

analyse whether there are further distinguishing features.

5. *Technical problem solved*

5.1 With letter of 3 March 2015 (point 5.3 on page 3 therein) the appellant provided a table comparing FPF results achieved with the compositions according to the examples of the patent with those achieved by some of the corresponding compositions according to examples 3 and 4 of D1. According to the appellant, direct comparison of said results is possible since the same measurement technique was used, the tests were performed by the same company within about 2 years of each other, and had an inventor in common. This was allegedly confirmed by the fact that almost identical results were obtained for the control sample (salbutamol without additive) in D1 and in the patent. Thus, it is alleged that the data demonstrate that the formulations prepared according to the patent had a high FPF (66%) while the formulations prepared according to the process of D1 comprising low density leucine were not as good (15 - 51%). On the basis of this effect, the appellant argues that the objective technical problem is to provide a method for preparing a powder for inhalation comprising additive and active particles which has improved aerosol performance, in particular an increased FPF.

5.2 The Board cannot agree with the position of the appellant in this regard, not least because none of the examples compared demonstrate a technical effect which can be linked to a single distinguishing feature, but also because D1 discloses further examples, not mentioned in the arguments of the appellant, having a higher FPF ("Mean respirable fraction" according to D1)

than the compositions according to the patent (see e.g. table 5 on page 35 of D1). While there are a plurality of further reasons as to why the Board arrives at this position, a detailed explanation is not necessary for reasons similar to those outlined in the analysis of the distinguishing feature (see point 4.3, above), i.e. in view of the conclusions presented below in respect of inventive step (see point 6.5, below).

5.3 Even if an improvement is not acknowledged with respect to D1, the Board considers that the examples of the patent provide sufficient evidence that the formulations disclosed therein (see in particular Table 2) display the effect of having a high FPF.

5.4 On the basis of this effect, the objective problem solved by the subject-matter of claim 1 of the main request with respect to the disclosure of D1 is the provision of a further method for preparing a powder for inhalation comprising mixed additive and active particles which has a high FPF.

6. *Obviousness*

6.1 The respondents have argued that the skilled person looking for an alternative to the method disclosed in D1 would have turned to the disclosures of D12 or DA6 in order to arrive at the solution proposed in claim 1 of the main request, since said disclosures identify magnesium stearate as a known alternative additive in inhalation formulations, and since DA6 in particular demonstrates that magnesium stearate is at least as good as, if not better, than leucine in providing a high FPF.

6.2 The Board does not dispute that magnesium stearate is a known additive in inhalation formulations. However, in the context of both D12 and DA6, it is used solely in ternary blends which necessarily include a carrier and in a completely different relationship to the active particles. While the method of claim 1 of the main request does not exclude the use of a carrier, the step of pressing the particles of additive material to the surfaces of the active particles by a particular milling step is an explicit feature thereof. The situation is similar in D1, where the active particles are blended to low-density leucine with specific mixing procedures (see in particular example 4, pages 34 to 36). In contrast to that, D12 seeks to provide carrier particles in which the problems of excessive adhesion between carrier particles and active particles are mitigated. This is achieved by the presence of additive particles which are attached to the surfaces of the carrier particles to promote the release of the active particles therefrom (page 4, line 9 - page 5, line 21). The proposed mechanism involves the preferential occupation of the high energy sites on the carrier particle by the additive particles, allowing the active particles to occupy the lower energy sites and thereby be more easily released (page 7, line 7 - page 8, line 6). Similarly, according to DA6 (see abstract), the addition of tertiary components (i.e. magnesium stearate or L-leucine) to the blends of the active and the carrier was shown to destabilise the powder blend as reflected by an increase in the FPF of the active, an effect which was attributed to the relative electrostatic attraction between the drug, the tertiary component (the additive) and the carrier material. Thus both D12 and DA6 provide the teaching that in an inhalation formulation *in which a carrier particle is used*, magnesium stearate can act to reduce adhesion

forces between the carrier particles and the active particles, with the effect of increasing the respirable fraction of the latter on inhalation.

6.3 In contrast, D1 discloses that in the case where the powder disclosed therein includes a diluent (such as a carrier), it is advantageous that the method of producing the powder includes the step of mixing the low-density amino acid with active material, followed by mixing with the diluent (page 20, lines 15-20). This preference is demonstrated in example 5 whereby a blend of active material and leucine was first prepared, followed by mixing with the carrier, lactose (page 36). Similarly, the method according to claim 1 of the main request comprises "the step of pressing the particles of additive material to the surfaces of the active particles". While the method of claim 1 is not limited to this step by virtue of the use of the term "comprising" and a carrier can be added thereafter, the specific step itself entails "pressing the particles of additive material to the surfaces of the active material", and no further components are foreseen during the pressing. In other words, although claim 1 does not exclude the presence of a carrier particle in the final composition prepared according to the method thereof, the claim cannot be interpreted as including within its scope the presence of carrier particles during said pressing step.

6.4 It follows from the above that the effect of achieving a high FPF demonstrated in the patent cannot be related to the mechanism described in D12 or DA6. The skilled person, looking to solve the above-mentioned problem starting from D1, would not find any motivation to look at the additives used in D12 nor DA6, as they describe the use of additives in association with a very

specific micro-environment which is totally different from that described in D1 and in claim 1 of the main request.

6.5 In the absence of a hint in the available prior art to use magnesium stearate as alternative additive in order to solve the posed problem starting from D1, it must be concluded that claim 1 of the main request involves an inventive step over the available prior art.

6.6 The same applies to independent claim 11, directed to a composition for inhalation comprising particles of an active substance and additive particles, the composition being obtainable by the method of claim 1, since the acknowledgement of the inventive step of method claim 1 was based upon the features and properties of the product thereof.

6.7 As there was no separate attack on any of the further independent claims of the main request, neither in the appealed decision not in the submissions of the respondents, the Board has nothing more to decide on the issue of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:

   - claims 1 to 20 of the main request filed with the grounds of appeal by letter of 23 July 2012;

   - description, pages 2, 3, 4, 7 and 8 of the main request filed by letter of 3 March 2015 and pages 5, 6, 9, 10 and 11 of the patent specification;

   - figures 1 to 6 of the patent specification.

The Registrar: The Chairman:

S. Fabiani A. Usuelli

Decision electronically authenticated