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**Datasheet for the decision
of 27 April 2015**

Case Number: T 0246/11 - 3.3.07

Application Number: 99915547.6

Publication Number: 1158958

IPC: A61K9/12

Language of the proceedings: EN

Title of invention:

IMPROVED POWDERY PHARMACEUTICAL COMPOSITIONS FOR INHALATION

Patent Proprietor:

CHIESI FARMACEUTICI S.p.A.

Opponents:

GLAXO GROUP LIMITED
NORTON HEALTHCARE LIMITED
SkyePharma AG

Relevant legal provisions:

EPC Art. 123(3), 100(b)

Keyword:

Amendments - extension of protection (yes)
Sufficiency of disclosure - auxiliary requests 1, 3, 4 (no)

Decisions cited:

T 1641/11



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Case Number: T 0246/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 27 April 2015

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 1 December 2010
revoking European patent No. 1158958 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: R. Hauss
 W. Ungler

Summary of Facts and Submissions

- I. European patent No. 1 158 958 was granted on the basis of eighteen claims. Independent claim 1 reads as follows:
- "1. A powder for use in a dry powder inhaler, the powder including an active ingredient and carrier particles consisting of one or more crystalline sugars, said carrier particles being mixed with 0.1-0.5 percent magnesium stearate by weight of the carrier, said magnesium stearate forming a coating of the surface of the carrier particles to an extent such that the coated particles have more than 15% of molecular surface coating."*
- II. Three notices of opposition were filed, opposing the patent under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was insufficiently disclosed and extended beyond the content of the application as filed.
- III. The present appeal lies from the decision of the opposition division, announced on 28 October 2010 and posted on 1 December 2010, revoking the patent.
- IV. The documents cited during the opposition proceedings included the following:
- D1: WO 96/23485 A1
- D4: Drug Development and Industrial Pharmacy, 6(6), 573-589 (1980)
- D5: Trans. Faraday Soc. 40, 546-551 (1944)
- D5a: Stein, J.: "Contact Angle",
www.uweb.engr.washington.edu/research/tutorials/contact.html

- D6: R. Brindos, G. Selvaduray: "Effect of Temperature on Wetting Angle", www.sjsu.edu/faculty/selvaduray/page/mate251/WettingAngle.doc
- D10: Lieberman et al.: Pharmaceutical Dosage Forms, Disperse Systems, Vol. 1, New York 1988, 22-25
- D13: Capillary Rise as an Alternative Contact Angle Measurement, www.firsttenangstroms.com; July 2000
- D14: Il Farmaco 10, 330-341 (1984)
- D26: Expert report of Professor Graham Buckton (2009)
- D29: Test report "Contact angle analysis of lactose/magnesium stearate mixtures by various methods" (28 August 2009)
- D31: Expert opinion of Professor Ruggero Bettini (13 September 2010)
- D33: US 6 528 096 B1
- D33a: Amended description pages 3, 6 and 7 showing corrected data (submitted with the patent proprietor's letter dated 21 September 2010)

V. In the decision under appeal the opposition division considered an amended main request and six auxiliary requests filed by the patent proprietor.

According to the definition of claim 1 of the main request, the carrier particles consisted of α -lactose monohydrate and the extent of surface coating was such that the coated particles had a water contact angle of more than 50°.

The opposition division held that it could not be derived from the patent specification or from common general knowledge how the parameter "water contact angle", which was a critical feature of the claims of the main request, was to be determined. The known methods which might be used would not yield the same result.

In the claims of the first auxiliary request, the requirement that the coated carrier particles have a water contact angle of more than 50° had been replaced by the requirement that the particles have more than 15% of molecular surface coating calculated according to document D5. Since the calculation of said parameter was to be based on the value of the water contact angle, and the calculation of a parameter "molecular surface coating" was not evident from document D5, the parameter was not properly disclosed.

The same reasoning applied to the claims of the second and third auxiliary requests, which specified more than 23% and more than 35% molecular surface coating, and to the claims of the fourth auxiliary request, which combined the parameters "water contact angle" and "molecular surface coating".

The fifth and sixth auxiliary requests differed from the main request and the first auxiliary request, respectively, by the addition of a feature defining a process by which the coated carrier particles could be obtained. The objection of insufficiency of disclosure with regard to the parameters "water contact angle" and "molecular surface coating" as explained in the context of the main request and first auxiliary request also applied to the fifth and sixth auxiliary requests.

The patent was thus revoked on the ground that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (in respect of all requests).

VI. The appellant (patent proprietor) lodged an appeal against that decision.

With the statement setting out the grounds of appeal the appellant submitted a new main request and an auxiliary request.

Claim 1 of the **main request** reads as follows:

"1. A powder for use in a dry powder inhaler, the powder including a steroid as an active ingredient having a particle size of less than 10 μm and carrier particles consisting of α -lactose monohydrate, said carrier particles being mixed with 0.1-0.5 percent magnesium stearate by weight of the carrier, said magnesium stearate forming a coating of the surface of the carrier particles, said coated carrier particles being obtainable by mixing α -lactose monohydrate and magnesium stearate in a Turbula mixer that operates at a rotating speed of 16 r.p.m for at least 120 min."

Claim 1 of the auxiliary request, hereinafter **first auxiliary request**, reads as follows:

"1. A powder for use in a dry powder inhaler, the powder including a steroid as an active ingredient having a particle size of less than 10 μm and carrier particles consisting of α -lactose monohydrate, said carrier particles being mixed with 0.1-0.5 percent magnesium stearate by weight of the carrier, said magnesium stearate forming a coating of the surface of the carrier particles to an extent such that the coated particles have more than 15% of molecular surface coating, said coated carrier particles being obtainable by mixing α -lactose monohydrate and magnesium stearate in a Turbula mixer that operates at a rotating speed of 16 r.p.m for at least 120 min."

VII. In reply to the appellant's statement of grounds, respondent-opponent 1 and respondent-opponent 2 raised objections with regard *inter alia* to added subject-matter, extension of the scope of protection

and insufficiency of disclosure (Articles 123(2)-(3) and 100(b) EPC).

Respondent-opponent 2 submitted the following document:

D36: Test report "Contact angle analysis Lactose/
magnesium stearate powder mixtures" (August 2011)

VIII. Respondent-opponent 3 did not reply in substance to the statement setting out the grounds of appeal.

IX. With letter dated 27 March 2015, the appellant submitted two further sets of claims as second and third auxiliary requests.

Claim 1 of the **second auxiliary request** is identical to claim 1 of the main request except that it specifies a duration of mixing of α -lactose monohydrate and magnesium stearate of at least 180 minutes.

Claim 1 of the **third auxiliary request** is identical to claim 1 of the first auxiliary request except that it specifies a duration of mixing of α -lactose monohydrate and magnesium stearate of at least 180 minutes.

X. In a communication issued in preparation for oral proceedings, the board observed that the critical issues appeared to be, in particular, compliance of all requests with Article 123(2) EPC, compliance of the main request and second auxiliary request with Article 123(3) EPC, and sufficiency of disclosure especially with regard to the parameter "more than 15% of molecular surface coating" present in the first and third auxiliary requests (Article 100(b) EPC).

XI. With letter dated 23 April 2015 the appellant filed a fourth auxiliary request.

Claim 1 of the **fourth auxiliary request** is identical to claim 1 of the third auxiliary request.

XII. Oral proceedings were held on 27 April 2015 in the absence of respondent-opponents 1 and 3.

XIII. The appellant's arguments can be summarised as follows:

i) Extension of protection (Article 123(3) EPC)

The mixing conditions specified in claim 1 of the main request and in claim 1 of the second auxiliary request yielded particles with more than 15% of molecular surface coating, based on the corrected values for table 6 of the patent as presented in D33a (amended description pages filed during opposition) and the equivalent US patent D33.

In the case of the main request, although corrected table 6 (D33a) showed a value, obtained after 120 minutes' mixing, of only 14% of surface coating correlated to a water contact angle of 39°, that value was within the margin of error taking into account the results presented in table 7 of the patent specification for the contact angle found in three batches after 120 minutes' mixing (viz. 39°, 42° and 42°, with 42° corresponding to 16% or 17% of surface coating).

Thus the feature indicating the degree of surface coating was redundant and could be deleted without extending the scope of protection in comparison with claim 1 as granted.

The term "Turbula" had become a generic term for a specific type of tumbling blender, and its meaning was therefore clear to the skilled person. Thus, documents D1 (page 21, lines 1 to 4) and D4 (page 578, paragraph 2, line 2) could be cited as instances where

the term "Turbula" mixer was used without reference to a trademark.

ii) Sufficiency of disclosure (Article 100(b) EPC)

It was evident that the parameter "more than 15% of molecular surface coating", present in claims 1 of the first, third and fourth auxiliary requests, was to be determined by measuring the water contact angle of the coated carrier material and calculating the degree of molecular surface coating from the water contact angle, as mentioned in paragraph [0041] of the patent specification with reference to document D5. That the method of calculation was available to the person skilled in the art was corroborated by the fact that the respondents' experts had in any case been able to identify the correct equation, as could be seen in the expert statement D26 (point (14)) and test report D36.

The person skilled in the art would be aware that the water contact angle was a common parameter in the field of pharmaceutical powders, and that the sessile drop method was commonly used for its determination, as evidenced by documents D5a (page 1), D6 (page 6), D10 (page 22, paragraph 2), D13 (line 1) and D31 (page 1, bottom paragraph). That method was in fact employed to obtain the contact angle data presented in table 6 of the patent in suit. It was also clear that a compressed powder disc should be prepared to carry out the contact angle measurement in a powder (as was done for the respondents' tests described in D29 and D36). Even if it were uncertain which method was to be employed for the determination of the water contact angle, that would not be a problem of insufficient disclosure but of lack of clarity, at the utmost, which was not a ground of opposition according to Article 100 EPC.

As far as the calculation of the degree of molecular surface coating was concerned, while document D5 did not include the required equation applying to a two-component mixture, it did contain an equation for a single component, and it was straightforward to calculate a mixture contact angle by addition of values weighted according to the fractions of the components. The correct equation could also be found in document D14 (pages 338 to 339). As evident from documents D26 (pages 2 to 3) and D36, the respondents' experts had no difficulty in identifying the correct equation and in realising, on that basis, that table 6 of the patent specification did not show the correct values for "degree of coating".

XIV. The respondents' arguments can be summarised as follows:

i) Extension of protection (Article 123(3) EPC)

It had not been shown that the process steps describing the mixing conditions according to claim 1 of the main request or of the second auxiliary request resulted inevitably in more than 15% of molecular surface coating. Rather, the known facts and evidence pointed to a different conclusion:

- With regard to claim 1 of the main request, it was relevant that corrected table 6 (D33a) showed a value of only 14% molecular surface coating after 120 minutes' mixing.

- According to the test results reported in document D36, lubricant-coated lactose monohydrate particles obtainable according to claim 1 of the main request, whose water contact angle was determined using the appellant's preferred method (sessile drop), were found

to have a surface coverage of only 3%, well outside the scope of claim 1 as granted.

- The term "Turbula" was a trade mark designating a whole series of different products. It was not generally recognised as having a precise meaning. The mixer configuration was not precisely defined in claim 1, since the term "Turbula" could designate any model, not only the type "Turbula T 100" which had been used according to the examples of the patent. As the shear applied was therefore not defined, the efficiency of the mixing process could not be evaluated. It was not certain that all Turbula models were as efficient as the Turbula T 100.

ii) Sufficiency of disclosure (Article 100(b) EPC)

The parameter "molecular surface coating" was neither defined in the patent in suit nor did it have a recognised meaning in the art (as evidenced by the expert statement D26 in point (10)).

According to the patent in suit, a correlation existed between the degree of molecular surface coating and the water contact angle of the coated carrier. The person skilled in the art did not however receive sufficient guidance from the patent in suit with regard to the measurement of the water contact angle and the required calculation of the degree of molecular surface coating from the water contact angle.

Various methods were known for measuring a water contact angle, but it had not been shown that any method in particular was usual in the art for coated powders such as described in the patent in suit. A method using a compressed powder disc was not necessarily suitable, since magnesium stearate was a lubricant, expected to migrate under compression to the tablet surface and thus alter the sample. As shown in

test report D29, a considerable variation in results was obtained by changing the method and operating variables. The mention of reference values for the water contact angles of magnesium stearate and of lactose monohydrate in the patent in suit (page 6, lines 20 to 21) could not remedy the insufficiency, since no indication was given as to how the reference values should be obtained. This placed an undue burden on the skilled person, who would be obliged to test the reference samples with every possible technique and with different variables to see which combinations gave the reference values.

The "Cassie & Baxter" equation which, according to the appellant, was needed to convert a water contact angle to a percentage value of molecular surface coating was shown neither in the patent in suit nor in the referenced paper D5, which furthermore did not relate to powder materials but to the far-removed technical field of textile fabrics, and did not mention the term "molecular surface coating". No evidence had been presented showing that the equation was common textbook knowledge easily accessible to a skilled person with experience of inhalation formulations (as opposed to a highly specialised expert in the field of powder surface science, like the expert of D26). Since, as conceded by the appellant (see D33a), the values for the degree of molecular surface coating given in paragraph [0019], table 6 and paragraph [0048] of the patent and in the corresponding passages of the application as filed were actually incorrect, they could not provide any indication to the reader with regard to the required calculation method. For all those reasons, it would not be readily apparent to the skilled reader which equation should be used.

XV. The parties' final requests were the following:

- The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or first auxiliary request, filed with the statement setting out the grounds of appeal, or on the basis of the second or third auxiliary requests filed with letter dated 27 March 2015, or on the basis of the fourth auxiliary request submitted with letter dated 23 April 2015.
- Respondent-opponent 1 requested in writing that the appeal be dismissed.
- Respondent-opponent 2 requested that the appeal be dismissed. It further requested that the case not be remitted to the department of first instance.
- Respondent-opponent 3 did not file any request.

Reasons for the Decision

1. Subject-matter of the patent in suit

1.1 The patent in suit relates to pharmaceutical formulations suitable for dry powder inhalers. In such formulations, a coarse carrier material (included to ensure powder flowability) is usually combined with fine inhalable drug particles which adhere to the surface of the carrier particles but are released from that surface during inhalation. The drug particles penetrate into the lower lungs, while the larger carrier particles are mostly deposited in the oropharyngeal cavity. The coating of carrier particles with a lubricant as an anti-adherent material had been proposed in the prior art to promote the separation of the drug particles from the carrier surface, with a

view to increasing the percentage of the respirable drug fraction. It was however known that certain amounts of lubricant may destabilise the particle mixture and cause segregation during handling and storage (see paragraphs [0005] to [0017] of the patent specification).

- 1.2 According to the teaching of the patent in suit, low amounts of magnesium stearate lubricant, by partially coating the carrier particles, are sufficient to augment the respirable fraction of drug particles without affecting the stability of the particle mixture. It is regarded as advantageous to attain a high degree of surface coating (see paragraph [0016]). In that context, the parameter "molecular surface coating" is mentioned, but not defined (see paragraph [0015] of the patent specification).
- 1.3 The degree of coating which can be obtained depends on the mixing time of carrier and lubricant (see paragraphs [0016] and [0043], example 4, table 6 of the patent specification). It is furthermore mentioned that there is a correlation between the parameter "water contact angle" and the degree of molecular surface coating and that the degree of molecular surface coating can be calculated according to document D5 (see paragraphs [0019], [0041], example 4: table 6, example 7 of the patent specification). It is mentioned in the text of the application as filed on page 6, lines 5 to 7, that the degree of molecular surface coating is determined by water contact angle measurement.
2. The parameter "molecular surface coating"
 - 2.1 The requirement that the coated carrier particles have more than 15% of molecular surface coating of magnesium

stearate is found in claim 1 as granted and in claims 1 of the first, third and fourth auxiliary requests. The feature is however absent from claims 1 of the main request and second auxiliary request.

- 2.2 As already mentioned, the patent in suit does not provide a definition of the parameter in question (see point 1.2 above). The information given in the patent in suit suggests that the degree of surface coating is to be calculated from an experimentally determined value of the water contact angle of the coated carrier particles, and that the formula for that calculation can be obtained from document D5 (see point 1.3 above).
- 2.3 According to the appellant, the parameter is to be determined by establishing the water contact angle on compressed powder discs using the "sessile drop" method, and by calculating the degree of molecular surface coating using the so-called Cassie & Baxter equation: $\cos\theta_{\text{mix}} = f_1\cos\theta_1 + f_2\cos\theta_2$, in which f_1 and f_2 relate to the fractions of a mixed component surface of two materials and $\cos\theta_1$, $\cos\theta_2$ relate to the contact angles formed by water on the pure components of the two materials, $\cos\theta_{\text{mix}}$ being the cosine of the contact angle formed on the mixture (see also document D26: points (13), (14)).
- 2.4 With regard to the issue of sufficiency of disclosure (first, third and fourth auxiliary requests) the question to be answered is thus whether this (or any other) method of determination is derivable from the information provided in the patent in suit (see point 1.3 above), taking into account common general knowledge, such that the person skilled in the art obtains unambiguous and complete instruction permitting the degree of molecular surface coating to be

determined without an undue burden of experimentation (see points 4 and 6 below).

2.5 With regard to the deletion of the parameter in question from the wording of claim 1 of the main request and second auxiliary request, it has to be established whether that deletion extends the protection claimed, in comparison with granted claim 1 (see points 3 and 5 below).

3. Main request - extension of protection

3.1 The feature present in granted claim 1, i.e. "to an extent such that the coated particles have more than 15% molecular surface coating", has been replaced in claim 1 of the main request by a "product-by-process"-type feature which specifies that the coated carrier particles are obtainable by mixing α -lactose monohydrate and magnesium stearate in a Turbula mixer that operates at a rotating speed of 16 r.p.m. for at least 120 minutes.

3.2 The question to be answered with regard to the requirement of Article 123(3) EPC (that amendments of the patent may not extend the protection conferred) is thus whether that process results inevitably in a value of more than 15% of molecular surface coating, in which case amended claim 1 covers only embodiments of granted claim 1.

3.3 With document D36, the respondents provided an experimental report indicating that carrier particles of α -lactose monohydrate and 0.1% by weight magnesium stearate were prepared using a Turbula[®] (Model T10B) mixer set at 16 r.p.m. for 120 minutes. Compressed powder discs were used for sessile drop contact angle analysis, giving a result of 21°. The corresponding

molecular surface coverage was calculated with the above-mentioned Cassie & Baxter equation (see point 2.3) to be 3%.

- 3.3.1 The component ratio and coating process according to D36 are in conformity with the definition of claim 1 of the main request.
- 3.3.2 Furthermore, the determination of the water contact angle and calculation of the degree of molecular surface coating were carried out by methods which the appellant regards as disclosed in the patent in suit and which were, in fact, used to obtain the data shown in the patent in suit (see points XIII.ii and 2.3 above). Thus it is not contested by the appellant that the degree of molecular surface coating can be determined by the methods employed according to D36.
- 3.4 The appellant did not present any argument as to why the data obtained according to D36 was not correct, but merely referred to its own data known from D33a, which showed a higher degree of molecular surface coating.
- 3.5 In these circumstances, since with D36, test results are on file which yielded a considerably lower value than 15% surface coating after 120 minutes' mixing, the board has to conclude that the process conditions such as specified in claim 1 of the main request will not inevitably result in particles having more than 15% of molecular surface coating.
- 3.6 As a consequence, claim 1 of the main request also includes embodiments with a lower degree of surface coating than 15% and thus extends the protection in comparison with claim 1 as granted, contrary to Article 123(3) EPC.

4. First auxiliary request - sufficiency of disclosure

4.1 According to claim 1 of the first auxiliary request, it is required that the coated carrier particles have more than 15% of molecular surface coating, which in the light of the above (see point 3) is to be regarded as a limiting feature in comparison with claim 1 of the main request.

4.2 As already mentioned, while the patent specification does not give a definition of the parameter "molecular surface coating", at least the following information can be derived from the patent in suit:

- that the carrier particles are coated to some extent with magnesium stearate,
- that the degree of coating is to be calculated from an experimentally determined value of the water contact angle of the coated carrier particles, and
- that the formula for that calculation can be obtained from document D5 (see points 1.3 and 2.2 above).

4.3 Determination of the parameter "water contact angle"

4.3.1 The patent in suit does not specify the method to be used for the measurement of the water contact angle.

4.3.2 Reference to document D5 is made in paragraph [0041] of the patent in suit as follows:

"At different mixing times samples were withdrawn and tested for uniformity of distribution of magnesium stearate, particle size, water contact angle and degree of molecular surface coating calculated according to Cassie *et al.* (Transactions of the Faraday Society 40; 546, 1944)".

Document D5 concerns porous surfaces (in particular, textile surfaces) and refers to several different water

contact angles: the advancing contact angle, the solid-water receding contact angle, the apparent receding contact angle, the apparent advancing contact angle and the apparent contact angle. Since the material examined is different in D5 and a different model system is used (coated wire gratings), it is not readily apparent from D5 which water contact angle is relevant to the powder materials of the patent in suit, nor how it should be measured.

- 4.3.3 Since the method of determination of the water contact angle is apparent neither from the patent in suit nor from the referenced paper D5, it remains to be examined whether any method would be evident based on common general knowledge.
- 4.3.4 While most of the the documents cited by the appellant (see point XIII.ii above; D5a, D6, D10, D13 and D31) mention that the "sessile drop method" is a commonly used or even the most commonly used technique, and confirm that in the case of pharmaceutical powders the measurement may be carried out on the surface of a disc obtained by compaction (see D10: page 22, D31: page 1), the information given in those documents does not necessarily lead to the conclusion that that would be the only method considered by the person skilled in the art with regard to the coated excipient particles of the patent in suit.
- 4.3.5 As can be derived from documents D26 and D29 submitted by the respondents, several methods are known (see D26, points (16) to (26)), such as "Liquid penetration", "Sessile drop on a flat surface", "Wilhelmy plate method") which could plausibly be carried out to measure a contact angle for a powdered system, using either a compressed disc or a powder bed as a sample. Since magnesium stearate is a tableting lubricant

which may migrate under compression to the sample surface, it is not certain that the person skilled in the art would necessarily favour a method using a compressed disc. Various methods in the art are known to produce significantly different results, depending not only on the technique used but also on variables chosen within that technique (see D26, also shown in test report D29 according to which the values for two samples of lactose and magnesium stearate varied from 38° to 99° and from 49° to 113°, depending on the methodology employed).

- 4.3.6 The reference values for α -lactose monohydrate and magnesium stearate indicated at the bottom of table 6 of the patent specification do not point to any specific method of determination, as further experimentation would be required to match those values to potential methods and measurement conditions.
- 4.3.7 In conclusion, taking into account the information given in the patent in suit combined with common general knowledge, different techniques giving different results would be considered feasible for the determination of the water contact angle.
- 4.4 Calculation of the degree of molecular surface coating
 - 4.4.1 While the patent in suit, in paragraph [0041], refers the reader to document D5 for the calculation of the degree of molecular surface coating (see point 4.3.2 above), said document does not, in fact, include the Cassie & Baxter equation which is (as is common ground between the parties) required to carry out said calculation. Nor does D5 at any point mention the parameter "molecular surface coating". As explained above, the document does not concern powder mixtures at all, since it relates to coated wire grating, or duck

feathers, as a model system for water-repellent porous textile surfaces.

4.4.2 In view of this, the board is at a loss to see how the required equation could be derived from the information given in document D5.

4.4.3 Since the values for molecular surface coating indicated in table 6 and in paragraphs [0019] and [0048] of the patent in suit were incorrect (as conceded by the appellant; see D33a), they could not have pointed the reader to the correct equation.

4.4.4 Nor has it been shown that the equation was part of the common general knowledge of the person skilled in the art:

- Document D14, not cited in the patent but identified by the appellant as reporting the required equation, is a scientific article rather than an extract from a general textbook. According to the established jurisprudence of the boards of appeal, common general knowledge is represented by basic handbooks and textbooks on the subject in question, but does not, as a rule, include patent literature and scientific articles (see, for instance, decision T 1641/11 of 3 May 2012, Reasons 3.6). The person skilled in the art could not be expected to be aware of the content of every scientific article on the properties of magnesium stearate, such as D14.

- The fact that Professor Buckton, the author of the expert report D26, could provide the correct equation does not demonstrate the skilled person's common general knowledge either, since said author is a specialist in powder wettability and surface science (D26: points (01), (03), (10)), and thus his specialised knowledge does not necessarily represent

the knowledge of the typical person skilled in the formulation of compositions for inhalation. The calculation in the respondents' test report D36 was carried out according to the information provided in D26 (see D36: point 4.3), so that the source of information was the same, i.e. the expert of D26.

4.4.5 Hence, taking into account the information given in the patent and common general knowledge, the person skilled in the art would not have been in a position to identify the correct equation required for the calculation of the degree of molecular surface coating.

4.5 This last point in particular gives rise to the conclusion that the claimed subject-matter as defined in claim 1 of the first auxiliary request is not disclosed in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art, with regard to the determination of the degree of molecular surface coating (Article 100 b) EPC).

While some doubt with regard to the method to be employed for measuring the water contact angle might in other circumstances and by itself be treated as a lack of clarity under Article 84 EPC, the potentially large variation in the results obtained only adds to the uncertainty when considering the issue of disclosure in the present case.

5. Second auxiliary request - extension of protection

5.1 Claim 1 of the second auxiliary request is identical to claim 1 of the main request except that it specifies a duration of mixing of α -lactose monohydrate and magnesium stearate of at least 180 minutes.

5.2 Only one experiment by the appellant is on file concerning particles prepared with a mixing time of

- 180 minutes. Those particles had a water contact angle of 46°, corresponding to 20% molecular surface coating (see D33a, corrected values of table 6 of the patent).
- 5.3 Various parameters may however affect the result obtained by the mixing process, such as the configuration of the mixer, in particular with regard to the shear forces applied during the mixing process, as well as the quality of the starting materials, e.g. with regard to particle size and surface properties.
- 5.4 In that context, the appellant cited documents D1 and D4 in support of the argument that the term "Turbula" has a generally accepted meaning.
- 5.4.1 Document D1 (page 21, lines 1 to 4) includes the remark "The particles may be mixed using a tumbling blender (for example a Turbula Mixer)." This remark contains no indication however that anything more was intended than to give an unspecific example of a tumbling blender, and does not permit the conclusion to be drawn that any specific mixer configuration was meant.
- 5.4.2 It is furthermore clear from the context in document D4 that the passage cited by the appellant: "mixtures of lactose and 0.5% magnesium stearate were prepared with the TURBULA mixer" (see D4: page 578, paragraph 2, line 2) actually refers to a specific Turbula model which was used in the experiments of D4; see page 575, lines 18 to 20: "Mixing operations were performed either in a TURBULA 2A mixer, which has a 2 liters capacity, or in a ERWEKA K8 15 VG cubic mixer,...".
- 5.4.3 Hence it has not been conclusively shown that the name "Turbula" had acquired a universally accepted meaning in the art, nor has it been specified, considering that differently configured "Turbula" models exist, what that meaning would be.

- 5.5 Document D36 provides evidence that, within the limitations of the process steps defined in claim 1 of the main request, particles can be prepared which present distinctly lower values for the contact angle and molecular surface coating than the particles produced with the same mixing duration of 120 minutes according to example 4 of the patent in suit (see point 3.3 above and table 6 in D33a).
- 5.6 While D36 does not include an experiment with 180 minutes' mixing time, it shows nevertheless that significant variations are possible while remaining within the same process requirements, which may be due to variations in the process conditions and starting materials as mentioned above (see point 5.3).
- 5.7 In these circumstances, one experiment is not sufficient to establish that the process according to claim 1 of the second auxiliary request results inevitably in a value of more than 15% of molecular surface coating. Further tests would have been required to assess the influence of various parameters such as the concentration of magnesium stearate, different types and particle sizes of lactose or different mixer configurations with varying shear conditions.
- 5.8 As a consequence, the board concludes that amended claim 1 of the second auxiliary request extends the protection in comparison with claim 1 as granted, contrary to Article 123(3) EPC.
6. Third and fourth auxiliary requests - sufficiency of disclosure
- 6.1 Like claim 1 of the auxiliary request, claim 1 of the third auxiliary request contains the feature that the coated particles have more than 15% of molecular

surface coating. Claim 1 of the fourth auxiliary request is identical to claim 1 of the third auxiliary request (see points IX and XI above).

6.2 Hence, the same objections apply in the case of the third and fourth auxiliary requests as those set out in the context of the first auxiliary request (see point 4 above).

6.3 As a consequence, the claimed subject-matter as defined in claim 1 of the third and fourth auxiliary requests is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated