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Datasheet for the decision of 2 February 2016

Case Number: T 1169/13 - 3.3.07

Application Number: 04782768.8

Publication Number: 1699434

IPC: A61K9/14, A61K9/16, A61K9/72, A61K31/58, A61K31/167, A61K31/137

Language of the proceedings: EN

Title of invention:
PROCESS FOR PREPARING A MEDICAMENT

Patent Proprietor:
NORTON HEALTHCARE LIMITED

Opponents:
AstraZeneca AB
Vectura Limited
AstraZeneca Pharma Poland Sp. z.o.o.

Relevant legal provisions:
EPC Art. 56, 111(1), 123(2)
RPBA Art. 13

Keyword:

Appeal decision -
remittal to the department of first instance (no)
Inventive step - main request (no)
Late-filed auxiliary requests - admitted (no)
Amendments - auxiliary requests - allowable (no)

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Case Number: T 1169/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 2 February 2016

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 March 2013 concerning maintenance of the European Patent No. 1699434 in amended form.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
D. Keeling

Summary of Facts and Submissions

I. Two notices of opposition were filed against European Patent No. 1 699 434 in which revocation of the patent in its entirety was requested.

II. The decision of the opposition division concerning maintenance of the patent in amended form was announced at the oral proceedings on 7 February 2013 and was based on two sets of claims filed respectively as main request with letter of 21 June 2012 and as auxiliary request 1 during said oral proceedings.

Claim 1 of auxiliary request 1 read as follows:

"1. A process for preparing an inhalable medicament comprising the steps of:
(a) combining a pharmaceutically active ingredient in the form of an agglomerate of primary particles having an agglomerate particle size such that the agglomerate is capable of passing through a sieve having a mesh of 50-3000 µm with a pharmaceutically acceptable particulate carrier which is lactose, wherein prior to step (a) the pharmaceutically active ingredient is passed through a sieve having a mesh of 50-3000 µm, and
(b) mixing the resultant material in a mixer to break up the agglomerate into primary particles dispersed in a pharmaceutically acceptable particulate carrier such that 90% or more of the pharmaceutically active ingredient exists as primary particles having a particle size of 50 µm or less."

and differed from claim 1 of the main request only in that it specified that the pharmaceutically acceptable particulate carrier "is lactose".

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

D1: Ikegami et al, Advanced Powder Technology, volume 11(3), 2000, pages 323-332
D2: Ikegami et al, Powder Technology, volume 130, 2003, pages 290-297
D8: de Villiers, International Journal of Pharmaceutics, volume 151, 1997, pages 1-6

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

a) While the subject-matter of claim 1 of the main request lacked novelty over document D8, the process of claim 1 of auxiliary request 1 was novel over D8 in view of the limitation to lactose as a carrier and over D2, as disintegration of particles was performed only upon inhalation in the corresponding device.

b) The process of claim 1 of auxiliary request 1 was inventive over document D1, which was the closest prior art and disclosed a similar process including spherical agglomeration instead of agglomeration by sieving. The problem was the provision of an improved process for preparing an inhalable medicament which was simpler and less time consuming without compromising the blend homogeneity and the respirable fraction. The solution was not obvious, as it was nowhere suggested to replace the spherical agglomeration method with a simple sieving step.

V. Opponent 1 and opponent 2 (appellants) lodged an appeal against that decision. In their statements of grounds appellant-opponent 1 supported the view that "the claims are not limited to achieving agglomeration by sieving" (point 2.2.2, second paragraph) and appellant-opponent 2 stated that contrary to the findings of the opposition division "sieving does not need to cause agglomeration according to the application as filed" (page 2, second paragraph).

VI. With the reply to the statements setting out the grounds of appeal the patent proprietor (respondent) filed two sets of claims as first and second auxiliary requests.

VII. With letter of 2 April 2015 a third party filed an intervention in the opposition proceedings, which included several additional documents (D20, D20A-D20E, D21-D26).

VIII. In a communication sent in preparation of oral proceedings, the Board made it clear that it was its intention "first to review the decision of the first instance, thereby considering the two appeals and the objections filed therein and then, in case none of the objections of the appellants were found to prejudice maintenance of the patent, to decide whether the case should be remitted for consideration of the intervention" (point 2). In addition it expressed the preliminary opinion that the wording of process claim 1 did "not define, as supported by the respondent, that agglomeration is performed through sieving" (point 4).

IX. In response to that communication the appellant filed with letter of 19 January 2016 four sets of claims as first to fourth auxiliary request, wherein the first and fourth auxiliary requests were newly filed and the

second and third auxiliary requests corresponded to the requests filed with the reply to the statements setting out the grounds of appeal.

Claim 1 of the first auxiliary request corresponded to claim 1 on which maintenance of the patent was based, wherein the process was defined as "consisting of the steps of" (as opposed to "comprising the steps of"). Claim 1 of the second auxiliary request corresponded to claim 1 on which maintenance of the patent was based, wherein the sieving step was reformulated as follows: "wherein prior to step (a) the formation of the agglomerates is achieved by passing the pharmaceutically active ingredient through a sieve having a mesh of 50-3000 µm". Claim 1 of the third auxiliary request corresponded to claim 1 of the second auxiliary request with the specification that the pharmaceutically active ingredient "is an anti-inflammatory steroid and/or a bronchodilator". Claim 1 of the fourth auxiliary request included the amendments of both the first and the second auxiliary request with the further specification that "the active ingredient comprises budesonide".

X. Oral proceedings were held on 2 February 2016. After hearing the parties and deliberating on the issue of remittal, the Chairman announced that the Board did not intend to remit the case, but would first hear arguments on the question of inventive step, starting from D1 as the closest prior art. The Chairman thereafter pointed out that the respondent would be free to refer to the documents submitted by the intervener in so far as it considered them relevant to the question of inventive step starting from D1. The parties were thereafter heard on the issues of inventive step starting from D1 for the request on which maintenance was based, admittance into the proceedings for the first and fourth auxiliary

requests and compliance with the requirements of Article 123(2) EPC for the second and third auxiliary requests, before the final deliberation took place.

XI. The arguments of the appellants and of the intervener, as far as relevant to the present decision, can be summarised as follows:

Remittal

a) There was no reason not to review the decision of the opposition division and to remit the case back to it without any examination in the substance. In this respect, there was no difficulty in considering the objections of the opponents on which the opposition division had taken a decision separate from the attacks of the intervener. On that basis, a remittal was not appropriate.

Request on which maintenance was based - inventive step

b) The process of claim 1 differed from the disclosure in document D1, taken as the closest prior art, in that it included a sieving step of the active ingredient before combination with a lactose carrier. However, the wording of the claim did not imply that agglomeration took place by sieving and an agglomeration step before sieving was not excluded. Not even the wording of paragraph [0022] mentioned agglomeration by sieving, because it referred to sieving of agglomerates. It could therefore not be acknowledged that the sieving step provided any simplification of the process of the prior art, all the more as the problem was not mentioned in the original application. As the addition of a sieving step did not provide any

advantage, the technical problem was the provision of an alternative and the solution was obvious, since sieving was a routine step in the field to provide uniformity, as shown by several prior art documents. There was no evidence that a sieving step, which could be accomplished without changing the properties of the agglomerates, could be detrimental in the process of D1. Moreover, document D2 did not teach away from the addition of a sieving step, as it disclosed two alternative and successful processes, one of which comprised sieving. The fact that in the second process disintegration took place in the inhaler did not make it unsuitable for the intended purpose and document D2 did not support therefore the presence of any prejudice against using a sieving step.

First and fourth auxiliary requests - admittance

c) The preliminary opinion of the Board on the issue of sieving and agglomeration could not come as a surprise, as it followed arguments which had already been brought by the opponents in opposition and appeal proceedings. On that basis, the introduction of the wording "consisting of the steps of" in the first and fourth auxiliary requests was undoubtedly late filed. In addition, it had no basis in the original application and introduced a lack of clarity, as it was not clear which further process steps were excluded and which could be included. This was confirmed by the contradictory statements of the respondent. As they did not solve the outstanding issues, but introduced further problems, the first and fourth auxiliary requests should not be admitted into the proceedings.

Second and third auxiliary requests - amendments

d) The amendment specifying that the formation of the agglomerates was achieved by sieving had no basis in the original application. In paragraph [0022] it was specified that a loose agglomerate was sieved, which implied that it existed already before sieving. This clear reading could not be changed by the examples, all the more as not all of them related to agglomeration by sieving.

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

Remittal

a) According to the case law the Board had no discretion not to admit facts and evidence filed by the intervener. However, the objections of the intervener constituted a new opposition based on a significantly different factual framework, for which a remittal to the opposition division was appropriate. These objections were inextricably linked to those previously filed, as was the prior art, so that it was not possible to split the case in what had already been decided upon and what only came with the intervention. For example, the choice of the closest prior art might be different according to what was considered as available prior art and, even if the same document were chosen (e.g. D1), further documents might have an influence on its reading which could change the conclusion on inventive step. On that basis, the only reasonable solution was a remittal to the

opposition division for evaluation of the full case including the intervention.

Request on which maintenance was based - inventive step

b) The process of claim 1 differed from the disclosure in document D1, which was the closest prior art, in that sieving was used to prepare the agglomerates instead of spherical crystallisation. The fact that the agglomerates were formed by sieving was clear from the wording of the claim and from paragraph [0022], when reading the claim with a mind willing to understand. The technical problem was the provision of an improved process for preparing an inhalable medicament, which was simpler and less time-consuming, but still provided a homogeneous and dispersible medicament. The examples in the patent showed that the problem was solved. The solution was not obvious over the available prior art, since no document suggested that a sieving step could provide a simpler alternative to spherical agglomeration, which was an essential feature of D1. The fact that the solution seemed simple did not make it obvious. Moreover, a sieving step was completely unnecessary and undesirable in the process of D1, as it could be detrimental to the controlled agglomeration and disintegration performed therein. Moreover, document D2 taught away from the claimed invention, as in the embodiment including a sieving step mixing of the agglomerated with a lactose carrier took place without disintegration of the agglomerates, which was contrary to the purpose of D1 and the patent in suit, both of which required disintegration to take place. For these reasons, the solution was still

inventive, even if the technical problem was formulated as the provision of an alternative.

First and fourth auxiliary requests - admittance

c) As the opposition division had given a sound interpretation of the claim, it was reasonable to assume that it would be maintained by the Board, so that no amendments were necessary to clarify that agglomeration took place through sieving and that no other agglomeration steps could be included. Only after the communication of the Board it became clear that amendments were necessary to clarify the issue. On that basis, the amendments in the first and fourth auxiliary requests were a reaction to the preliminary opinion of the Board and the requests should be admitted into the proceedings. At the same time, the introduction of the wording "consisting of the steps of" made it clear that a further agglomeration step (e.g. by spherical agglomeration) was excluded, while necessary steps, such as synthesis and micronisation, were not excluded.

Second and third auxiliary requests - amendments

d) The amendment specifying that the formation of the agglomerates was achieved by sieving was based on paragraph [0022] of the original application. From that paragraph it was clear that the agglomerates were the final product and were not present before sieving. This was confirmed by example 1 and the further examples, which were not the basis for the amendment, but had a bearing on the reading of paragraph [0022].

XIII. The appellants and the intervener requested that the decision under appeal be set aside and the patent be revoked.

XIV. The respondent requested that the case be remitted to the opposition division for further prosecution or that the appeals be dismissed or, in the alternative, that the patent be maintained on the basis of the claims of the first, second, third or fourth auxiliary requests, as filed with letter of 19 January 2016.

Reasons for the Decision

Admissibility

1. Neither the admissibility of the appeals, nor the admissibility of the intervention were contested by the respondent. Also the Board has no reason to put the admissibility of the appeals and of the intervention into question with the consequence that the appeals and the intervention are admissible.

Remittal

2. The opposition division decided in the appealed decision *inter alia* on the question of inventive step for the request on which maintenance was based, which is still the first request to be decided upon in appeal proceedings. That decision was obviously based on the documents filed in opposition proceedings, in particular on document D1. Several further documents were filed with the intervention.

2.1 The Board does not see any reason why the case should be remitted to the opposition division, before reviewing the appealed decision, which is the main role of the

appeal proceedings. This includes in particular the review of the decision on inventive step for the request on which maintenance was based.

2.2 While it could be reasonable to consider remittal to the opposition division, if it were found that the objection of lack of inventive step starting from D1 as the closest prior art (and the further objections decided upon by the opposition division) did not hold, it is not appropriate to undertake this step before the review has taken place, as this would cause, in spite of the filing of an appeal, the proceedings before the opposition division to be reopened without any guidance as to whether and to what extent the first decision was correct.

2.3 The Board does not see any reason why any of the documents filed by the intervener could have any impact on the analysis of inventive step starting from document D1 as the closest prior art, as alleged by the respondent, who claimed that they could change the reading of document D1. However, in order to fully satisfy the right to be heard of the respondent, the Chairman during the oral proceedings and before hearing the parties on that issue pointed out that the respondent would be free to refer to the documents submitted by the intervener in so far as it considered them relevant to the question of inventive step starting from D1 (point X, above). The fact that none of these documents was cited by the respondent in its submissions is a confirmation that a review of the decision on inventive step is possible without taking into account the additional objections and the additional documents filed with the intervention.

2.4 On that basis, the Board finds it appropriate to exercise its discretion under Article 111(1) EPC by not remitting the case to the opposition division.

Request on which maintenance was based - inventive step

3. The parties agreed on the choice of document D1 as the closest prior art as well as on the identification of a missing feature with respect to the process of claim 1, namely the absence in the process disclosed in D1 of a sieving step (a passage through a sieve having a mesh of 50-3000 µm) of the pharmaceutically active ingredient before its combination with lactose as a carrier. In view of the disclosure in D1 (see in particular sections 2.1 on page 324 and 2.3 on page 325 for the steps of the process including agglomeration by spherical crystallisation and the result section on pages 326 to 331 with figures 2 and 3 for the particle size of the agglomerates and of the disintegrated particles), the Board has no reason to take a different approach.

3.1 The main issue of dispute, which also has a fundamental role in the formulation of the technical problem, concerns whether, as submitted by the respondent, the sieving step in the process of claim 1 implies that agglomeration is achieved by sieving, so that a previous agglomeration step (e.g. by spherical crystallisation) is excluded. In other words, it needs to be determined whether the difference between the process of claim 1 and the one disclosed in D1 is that agglomeration is carried out by sieving instead of spherical agglomeration (as alleged by the respondent) or simply that a sieving step is added to the process.

3.2 The Board, analysing the wording of process claim 1, comes to the conclusion that the view of the respondent

cannot be followed. Claim 1 defines a process comprising a sieving step of a pharmaceutically active ingredient, a combination step of the active ingredient in the form of an agglomerate with lactose as a carrier and a mixing step of the resultant material to break up the agglomerate, but does not specify when the active ingredient is brought into the form of an agglomerate, so that it does not imply that agglomeration is performed through sieving. While it is defined that the ingredient used in the combination step is in the form of an agglomerate, it is left open whether it is already so before sieving or only after it.

3.3 While the wording of claim 1 does not leave room for interpretation and there is no need to look at the description, paragraph [0022] of the patent, as cited by the respondent, cannot lead to a different reading of the claim, as it confirms that sieving is performed on an already formed agglomerate by mentioning the option of passing "the loose agglomerate through such a sieve", thereby clearly implying that the active ingredient is in the form of an agglomerate before sieving (see a full analysis of this paragraph in points 6.1 to 6.3, below). The fact that example 1 mentions "controlled agglomeration of budesonide by passing it through a sieve" (paragraph [0046], third sentence) has no bearing on the clear wording of claim 1.

3.4 The process of claim 1 therefore differs from the disclosure of document D1 in that an additional sieving step is included.

3.5 No evidence is available on file to show that the addition of a sieving step to the process of D1 results in an advantage or an improvement. Indeed, the addition of a step cannot result in a simplification

(independently of whether this aim is disclosed in the original application). Moreover, examples related to agglomeration by sieving for specific medicaments and under specific conditions (as e.g. example 1 in the patent) cannot support the presence of an effect for a process which does not specify that agglomeration is carried out through sieving.

3.6 In the absence of an effect or advantage related to the added feature, the problem to be solved is the provision of a further process for preparing an inhalable medicament, starting from the process of D1.

3.7 There is no doubt that a sieving step is a routine step in any process involving particulates and that the mesh size indicated in claim 1 is so broad as to include any size which could be of relevance for the agglomerates disclosed in D1. The addition of a routine step to a known process (which step may even be superfluous under the present circumstances) cannot, however, involve an inventive step.

3.8 In addition, the Board has no reason to consider a sieving step as detrimental to the process of document D1, as alleged by the respondent. The agglomerates prepared in the preliminary step of the process of D1 (section 2.1 on page 324) are subjected to routine steps after agglomeration (filtering, washing and drying, see last sentence of section 2.1), so that it cannot be concluded that another routine step in the field, such as sieving, would be considered by the skilled person detrimental to the process (so as to exclude carrying it out).

3.9 Finally, also the argument that document D2 would teach away from the addition of a sieving step cannot be

followed by the Board. While it is true that D2 discloses one embodiment with no sieving (which corresponds to the one in D1, see D2, sections 2.1 and 2.3 on page 291) and a second embodiment with sieving, but without disintegration of the agglomerates during mixing (sections 2.5 and 2.6 on page 292), no correlation is made in D2 between the presence of a sieving step and the occurrence of disintegration. Indeed, the two embodiments differ *inter alia* in the agglomerates which are produced (those of the second embodiment are defined by contrast as soft agglomerates, see section 2.5 on page 292) and in the mixers which are used (compare the blenders in sections 2.3 and 2.6), which differences may well be responsible of the fact that disintegration takes place in one case, but not in the other. In addition, neither of the embodiments is presented as dissatisfactory in the document (for the second embodiment the required disintegration takes place in the inhaler, see section 3.5 on page 295, last paragraph) and no indication is given that one of the techniques (or one specific step thereof) should not be used to obtain satisfactory powders. In summary, D2 does not support the presence of a prejudice against the addition of a sieving step in a process such as the one disclosed in D1.

3.10 On that basis, it is concluded that the process of claim 1 of the request on which maintenance was based does not involve an inventive step.

First and fourth auxiliary requests - admittance

4. The first and the fourth auxiliary requests were filed after the communication of the Board in preparation of oral proceedings. In claim 1 according to both requests the wording "consisting of the steps of" as opposed to

"comprising the steps of" is introduced to define the claimed process. The respondent supported the view that the amendment made it clear that a further agglomeration step (e.g. by spherical agglomeration) was excluded, so that agglomeration took place by sieving, and that it was a reaction to the preliminary opinion of the Board.

4.1 While it is correct that the Board in the communication expressed the preliminary opinion that the wording of process claim 1 did "not define, as supported by the respondent, that agglomeration is performed through sieving" (point VIII, above), this corresponded to a reading of the claim which was already supported by both appellants in their statements of grounds of appeal (see point V, above).

4.2 The preliminary opinion therefore did not create a new situation which makes a reaction thereto legitimate and justifiable, as the argument was already present in the proceedings.

4.3 Moreover, it is highly questionable whether the amendment achieves the purpose for which it is inserted. Indeed, also the respondent accepted that, while the claimed process is limited to the listed steps, previous preparation steps (e.g. synthesis and micronisation) cannot be excluded, which then raises the question how the amendment may exclude an agglomeration step. On top of that, it is questionable whether a basis for the amendment may be found in the original application. In other words, the proposed amendment appears to introduce further problems without solving the issue for which it was meant.

4.4 In view of that the Board finds it appropriate to exercise its discretion under Article 13 RPBA by not

admitting the first and fourth auxiliary requests into the proceedings.

Second and third auxiliary requests - admittance and amendments

5. The second and third auxiliary requests were filed (even if with a different numbering) with the reply to the statements setting out the grounds of appeal (points VI and IX, above).

5.1 On that basis they form part of the appeal proceedings (Article 12(1) RPBA) and their admittance was not contested by the appellants or by the intervener. Also the Board does not see any reason to put their admittance into question.

6. In claim 1 of the second auxiliary request the sieving step is reformulated as "wherein prior to step (a) the formation of the agglomerates is achieved by passing the pharmaceutically active ingredient through a sieve having a mesh of 50-3000 µm".

6.1 Paragraph [0022] of the application as filed, which was the only basis indicated by the respondent, reads as follows:

"In order to provide a uniform dispersion of the active ingredient in the carrier, prior to mixing, the active ingredient (in the form of the loose agglomerate) has a particle size such that it is capable of passing through a sieve having a mesh of 50-3000 µm. One way of achieving such a particle size is to pass the loose agglomerate through such a sieve, although other methods of obtaining such particle sizes are known in the art, for example by granulation. Sieving the loose agglomerate is described."

6.2 The sentences concerning sieving are crystal clear and both refer to sieving of the loose agglomerate (or equivalently passing the loose agglomerate through a sieve), which makes it clear that the agglomerate has already been formed before sieving.

6.3 The meaning of this clear wording is further confirmed by the more detailed explanation which follows, where the beginning of paragraph [0024] reads:

"Sieving may be carried out on the dry loose agglomerate or, alternatively, a liquid carrier (or medium) may be used. A liquid carrier is particularly useful where the loose agglomerate is being passed through a sieve having a small mesh size."

6.4 The unequivocal reading of paragraph [0022] cannot be changed by the fact that in one of the examples the specific case of a "controlled agglomeration of budesonide by passing it through a sieve" (example 1, paragraph [0046], third sentence) is mentioned, all the more as this kind of agglomeration is not consistently present throughout the examples (see e.g. example 6, paragraph [0070], second sentence: "salbutamol sulphate agglomerates were sieved").

6.5 As the only passage of the application as filed cited by the respondent does not provide a basis for the amended feature concerning the reformulation of the sieving step in claim 1 of the second auxiliary request, it is concluded that this request does not meet the requirements of Article 123(2) EPC.

7. Claim 1 of the third auxiliary request contains the same wording concerning the reformulation of the sieving step

as claim 1 of the second auxiliary request. Therefore, the third auxiliary request does not meet the requirements of Article 123(2) EPC for the same reasons as given for the second auxiliary request (point 6, above).

Conclusion

8. As the requests which are on file and are admitted either do not involve an inventive step (request on which maintenance was based) or do not meet the requirements of Article 123(2) EPC (second and third auxiliary requests), the patent is to be revoked and there is no need for the Board to decide on any other issue.

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:

K. Boelicke J. Riolo

Decision electronically authenticated