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Title of invention:
BIMODAL DRY POWDER FORMULATION FOR INHALATION

Patent Proprietor:
Innovata Biomed Limited

Opponent:
NORTON HEALTHCARE LIMITED

Headword:

Relevant legal provisions:
EPC Art. 111(1), 123(2), 123(3)

Keyword:
Amendments - added subject-matter (yes) - main request
Amendments - added subject-matter (no) - extension of the protection conferred (no) - first auxiliary request
Appeal decision - remittal to the department of first instance (yes)

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1664/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 January 2014

Appellant: (Patent Proprietor)	Innovata Biomed Limited 37 Queen Street Edinburgh EH2 1JX (GB)
Representative:	Adamson Jones BioCity Nottingham Pennyfoot Street Nottingham Nottinghamshire NG1 1GF (GB)
Respondent: (Opponent)	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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 June 2010 revoking European patent No. 1359902 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 29 April 2010 to revoke European Patent 1 359 902. The patent was granted on the basis of 48 claims, claim 1 reading as follows:

"1. A bimodal pharmaceutical composition comprising effective amounts of (i) a particulate coarse active ingredient and (ii) a particulate fine active ingredient, characterised in that the coarse ingredient possesses a greater mass median aerodynamic diameter (MMAD) than the fine ingredient, the MMAD of the coarse active ingredient being 4-20µm and the MMAD of the fine active ingredient being 1-4µm, and wherein the coarse ingredient comprises an agent which is active in the central/upper airways of a patient."

II. A notice of opposition was filed in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and extension of the subject-matter beyond the content of the application as filed (Article 100(c) EPC).

III. The decision was based on 6 sets of claims filed with letter of 29 March 2010 as main request and first to fifth auxiliary requests.

Claim 1 of the main request corresponded to granted claim 1 with the limitation of the range of the MMAD of the coarse active ingredient to "4-12µm". In claim 1 of the first auxiliary request the size ranges of "4-12µm"

and "1-4µm" were given for the "aerodynamic particle size" of the coarse and of the fine active ingredients instead of giving them for the MMAD of the ingredients. In claim 1 of the second auxiliary request the condition related to the sizes of the ingredients was reformulated as "wherein the aerodynamic particle size of 50% w/w of the particles of the coarse active ingredient is from 4-12µm and the aerodynamic particle size of 50% w/w of the particles of the fine active ingredient is from 1-4µm". Claim 1 of the third to fifth auxiliary requests corresponded to claim 1 of the main and of the first and second auxiliary requests respectively with the replacement of the condition "wherein the coarse ingredient comprises an agent which is active in the central/upper airways of a patient" with "wherein the coarse ingredient comprises a β2-agonist bronchodilator active in the central/upper airways of a patient and the fine ingredient is an anti-inflammatory corticosteroid".

IV. The decision under appeal can be summarised as follows:

a) The aerodynamic diameter and the mass median aerodynamic diameter (MMAD) were different ways of measuring the particle diameter and the ranges 4-12 µm and 1-4 µm of the aerodynamic diameter could not be equated to the same ranges for the MMAD. The ranges for the MMAD of claim 1 of the main request had therefore no basis in the original application, so that the requirements of Article 123(2) EPC were not met.

b) The ranges for the aerodynamic particle size of claim 1 of the first auxiliary request could be found in the original description; the requirements of Article 123(2) EPC were therefore

met. However, particles having an MMAD outside the ranges of granted claim 1 might have an aerodynamic particle size falling within the ranges of claim 1 of the first auxiliary request, so that the requirements of Article 123(3) EPC were not met.

c) The selection of the range 4-12 µm from the list of ranges for the aerodynamic particle size and of the discrete value 50% from the range of "at least 50%" in claim 1 of the second auxiliary request was a multiple selection within the original disclosure and contravened the requirements of Article 123(2) EPC.

d) Claim 1 of the third, fourth and fifth auxiliary requests contained the same amendments as the main request and the first and second auxiliary requests respectively, as far as the MMAD and the aerodynamic particle size were concerned, and did not meet the requirements of Article 123(2) or (3) EPC for the same reasons as outlined for the main request and the first and second auxiliary requests respectively.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted three sets of claims as main request and first and second auxiliary requests. Claim 1 of the main request corresponded to claim 1 of the main request on which the decision was based reading therefore as follows:

"1. A bimodal pharmaceutical composition comprising effective amounts of (i) a particulate coarse active ingredient and (ii) a particulate fine active

ingredient, characterised in that the coarse ingredient possesses a greater mass median aerodynamic diameter (MMAD) than the fine ingredient, the MMAD of the coarse active ingredient being 4-12µm and the MMAD of the fine active ingredient being 1-4µm, and wherein the coarse ingredient comprises an agent which is active in the central/upper airways of a patient."

Claim 1 of the first auxiliary request read as follows:

"1. A bimodal pharmaceutical composition comprising effective amounts of (i) a particulate coarse active ingredient and (ii) a particulate fine active ingredient, characterised in that the coarse ingredient possesses a greater mass median aerodynamic diameter (MMAD) than the fine ingredient, where the aerodynamic particle size of at least 50% w/w of the particles of the coarse active ingredient is from 4 to 12µm and the aerodynamic particle size of at least 50% w/w of the particles of the fine active ingredient is from 1 to 4µm, and wherein the coarse ingredient comprises an agent which is active in the central/upper airways of a patient."

VI. The opponent (respondent) replied to the statement of grounds of appeal with letter of 25 February 2011.

VII. In a communication sent in preparation of oral proceedings, the Board emphasised *inter alia* that with regard to claim 1 of the first auxiliary request it "has difficulties in following the arguments of the respondent under Article 123(3) EPC, as a distribution with 50% w/w of the particles in the range 4-12 µm cannot possibly have a mass median value outside of the range (while a mean value could well be out of it)" (paragraph 2.1).

VIII. Oral proceedings were held on 10 January 2014.

IX. The arguments of the appellant can be summarised as follows:

Main request - Article 123(2) EPC

a) The original description specified that any reference to particle sizes should be construed as meaning MMAD unless otherwise defined. As other terminology was used, but no other definition was given, the term "aerodynamic particle size" meant MMAD and the ranges and values given for the aerodynamic particle size applied to MMAD. In addition for the values of 6 µm for the aerodynamic particle size of the coarse ingredient and of 1 µm for the aerodynamic particle size of the fine ingredient it was specified that indicating these values meant that at least 50% by weight of the particles had an aerodynamic particle size of 6 µm and 1 µm respectively, which matched the definition of MMAD and was a further confirmation that all disclosed ranges and values referred to MMAD. In view of that the ranges 4-12 µm for the MMAD of the coarse active ingredient and of 1-4 µm for the MMAD of the fine active ingredient had a basis in the original application.

b) With regard to the combination of features added with respect to original claim 1, the range of dimensions of the coarse ingredient was the preferred one out of the two disclosed ranges, the range of dimensions of the fine ingredient was the only disclosed one, the definition of the coarse

ingredient referred to the preferred use indicated in the application and the restriction to particulate ingredients included three out of four disclosed possibilities.

First auxiliary request - Article 123(2) and (3) EPC

c) The disclosure in the original claims combined with the one on page 2 gave a clear basis for the amended definition of the particle size. For the rest the arguments outlined for the main request equally applied. As to the requirements of Article 123(3) EPC an extension of the protection could not result from the replacement of MMAD with its definition. While the distribution could well be trimodal, the examples given by the respondent to show extension of the protection did not apply, as in case three separate modes were present, they had to be considered as three separate ingredients, so that the exemplified distribution depicted a case in which a fine ingredient was present which fell both under the definition given in claim 1 as granted and the one of claim 1 of the first auxiliary request.

Remittal

d) After establishing that the requirements of Article 123 EPC were met the case had to be remitted to the opposition division. Firstly, even if an absolute right to two instances was not foreseen, it was generally desirable to have two instances deciding on the substantive issues of a case. Secondly, in case of an adverse decision, no other means of redress was available to the

patentee. Finally, the patent was still not close to its expiry date.

X. The arguments of the respondent can be summarised as follows:

Main request - Article 123(2) EPC

a) In the original application MMAD was one, but only one, method of measuring particle size, a numerical range relating to particle size should be read as being MMAD, unless otherwise defined, and "aerodynamic diameter" was given as an example of another possible definition. Aerodynamic particle size had to be seen as a synonym of aerodynamic diameter, which was different from MMAD, as confirmed by the claims. The indication that at least 50% by weight of the particles had a specific value or belonged to a specific range did not correspond to the definition of MMAD, which was instead a specific value which divided the mass distribution into two parts, each of which included 50% of the particles by mass. The disclosed ranges therefore did not refer to a mass median value, so that the specification of the ranges for the MMAD in claim 1 had no basis in the original application.

b) The indication of the two ingredients as being composed solely by the coarse, respectively fine fraction, their definition as "particulate", the specification of the ranges for the particle sizes of the two ingredients and the limitation to a coarse ingredient which was active in the central/ upper airways of a patient amounted to multiple selections from different embodiments of the

original disclosure taken as a reservoir of possible features and limited the patent to a specific undisclosed combination.

First auxiliary request - Article 123(2) and (3) EPC

c) The objection under Article 123(2) EPC concerning the multiple selections with respect to the original disclosure, which was raised for claim 1 of the main request, equally applied to claim 1 of the first auxiliary request. In particular, both original claim 2 and original claim 5 were directly dependent on claim 1 and related to two different embodiments. As to Article 123(3) EPC, a fine particle distribution with 50% by mass of the particles having a particle size 1-2 µm and 50% by mass with a particle size of 8-9 µm would fall under the definition in claim 1 of the first auxiliary request, but with a mass median of 5 µm would not fall under the scope of the patent as granted. That would be contrary to the requirements of Article 123(3) EPC. In this respect it was relevant to note that, as trimodal distributions were not excluded, a bimodal distribution for the fine fraction was covered by claim 1 and that the possibility of having a practicable embodiment which fell under amended claim 1, but not under the claimed patent was enough for the requirements of Article 123(3) EPC not to be fulfilled.

Remittal

d) A remittal was not appropriate in the present case, as an opposition had been filed in 2008, only eight years remained before the expiry of the

patent (reference was made to decision T 249/93 of 27 May 1998), all substantive issues had been addressed in writing by both parties and no new document had been filed in appeal. As no absolute right to have the issues decided on by two instances existed, the discretion of the Board had to be exercised in the present case by deciding on the substantive issues as well.

XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or of the first or second auxiliary request, all filed with the grounds of appeal.

XII. The respondent requested that the appeal be dismissed. In the event of the appeal being upheld, the respondent requested that the case not be remitted to the opposition division.

Reasons for the Decision

Main request - Article 123(2) EPC

1. Claim 1 of the main request includes a limitation for the ranges of the MMAD of the two ingredients ("the MMAD of the coarse active ingredient being 4-12µm and the MMAD of the fine active ingredient being 1-4µm") whose basis in the original application has been disputed. It needs to be analysed therefore whether the requirements of Article 123(2) are met in this respect.

1.1 Reference to MMAD can be found in the original application only in two instances, namely in original claim 1, which defines a composition "characterised in that the coarse fraction possesses a greater mass

median aerodynamic diameter (MMAD) than the fine fraction", and on original page 2, where first the wording of claim 1 is repeated (page 2, lines 4 to 8) and then a paragraph (page 2, lines 10 to 13) on MMAD is added whose first three sentences read:

"Particle size is commonly defined using mass median aerodynamic diameter (MMAD). Thus, hereinafter any reference to specific particle sizes should be construed as meaning MMAD unless otherwise defined as, for example, aerodynamic diameter. Although the sizes of the coarse and fine particles may vary, it should be understood that the coarse fraction possesses a greater MMAD than the fine fraction."

1.2 Values and ranges are instead given for the coarse fraction in original claim 2 and 3 with reference to the aerodynamic particle size ("the aerodynamic particle size of the substantially coarse fraction is from 4 to 20 µm", "at least 50% w/w of the coarse particles have an aerodynamic particle size of from 4 to 20 µm") and for the fine fraction in claims 5 and 6 using exactly the same terminology and a range "from 1 to 4 µm". A corresponding disclosure is to be found in the third full paragraph of page 2 (page 2, lines 18 to 23) which reads:

"Provided that the composition is bimodal as hereinbefore described, the aerodynamic particle size of the coarse fraction may be from 4 to 20 µm, preferably from 4 to 12 µm e.g. 6 µm. That is, at least 50% w/w of the particles have an aerodynamic particle diameter 6 µm. The aerodynamic particle size of the substantially fine fraction may be from 1 to 4 µm, e.g. 1 µm. That is, at least 50% w/w of the particles have an aerodynamic particle size of 1 µm."

1.3 It is undisputed that a mass median value of a distribution is the value which divides the mass distribution into two parts, one above the value and one below, each of which includes 50% of the particles by mass. That concept does not correspond to a condition of at least 50% by weight of the particles being at a specific value or within a specific limited range, but indicates that precisely 50% by weight of the particles are in the open, unlimited ranges above and below the median.

1.4 On that basis, the conditions indicating that at least 50% by weight of the particles lie within a range cannot be taken as a disclosure equivalent to the mass median value being within that range.

1.5 In addition, the application mentions aerodynamic diameter (which is a synonym of aerodynamic particle size) as an alternative definition of particle size to MMAD (see paragraph 1.1 above), so that the values given for the aerodynamic particle size cannot be taken as values disclosed for MMAD.

1.6 As no values are mentioned in relationship to MMAD in the original application and the values given for the aerodynamic diameter cannot be taken as a basis for the same values of MMAD, the specification of the ranges of MMAD for the coarse and the fine ingredient has no basis in the original application and claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

First auxiliary request - Article 123(2) and (3) EPC

2. In claim 1 of the first auxiliary request the quantitative condition concerning the particle size of the ingredients is redefined as "the aerodynamic particle size of at least 50% w/w of the particles of the coarse active ingredient is from 4-12µm and the aerodynamic particle size of at least 50% w/w of the particles of the fine active ingredient is from 1-4µm". It needs to be analysed whether by means of the amendment the objection under Article 123(2) EPC is overcome.

2.1 As detailed above (see paragraph 1.2), claims 2, 3, 5 and 6 and the third full paragraph on page 2 indicate two ranges for the particle size of the coarse ingredient (4 to 20 µm and 4 to 12 µm) and one range for the fine ingredient (1 to 4 µm) and relate these ranges to the aerodynamic particle size and more specifically to at least 50% by weight of the particles having an aerodynamic particle size within the ranges.

2.2 The cited claims and the cited passage of the description give therefore a direct and unambiguous basis for the particle size ranges as defined in claim 1 of the first auxiliary request. The amendment of the quantitative condition concerning the particle size of the ingredients therefore overcomes the objection under Article 123(2) EPC valid for claim 1 of the main request.

3. As to the combination of features in claim 1 of the first auxiliary request, it stems from original claim 1 with a reformulation of the definition of the active ingredients ("a first active ingredient which substantially comprises a coarse fraction" becomes a

"particulate coarse active ingredient" and "a second active ingredient which substantially comprises a fine fraction" becomes a "particulate fine active ingredient"), the addition of the ranges for the particle sizes of the ingredients (see paragraph 2 above) and the specification of the function of the active agent in the coarse ingredient ("active in the central/upper airways of a patient"). It needs to be analysed whether there is a basis for such a combination in the original application.

3.1 The reformulation of the definition of the active ingredients amounts only to a rewording with no change in meaning, as the coarse fraction (respectively the fine fraction) comprised in the first (respectively the second) active ingredient can be seen as a coarse (respectively a fine) active ingredient itself. Moreover, as particle sizes are defined for both ingredients, they are necessarily in the form of particles and therefore can be defined as "particulate".

3.2 As to the ranges for the particle sizes, original claim 1 gives only a relative condition (MMAD of the coarse fraction greater than MMAD of the fine fraction) and the only values to quantify that condition given in the original application (page 2, lines 18 to 23 and claims 2, 3, 5 and 6, see paragraph 1.2 above) are the ones added to claim 1 where for the coarse fraction the preferred range has been chosen out of the two disclosed and for the fine fraction the only disclosed range has been indicated.

3.3 As to the function of the active agent in the coarse ingredient, the only preferred function indicated at several instances in the original application (e.g. on

page 2, lines 28 and 29, page 3, lines 16 to 18, original claim 13) is the one specified in claim 1 of the first auxiliary request, namely the agent being "active in the central/upper airways of a patient". In the whole of the application only another possible class of agents is disclosed (though not as preferred) as being present alternatively, or in addition in the coarse fraction, namely a signalling agent (see e.g. page 4, lines 28 and 29 and original claim 9).

3.4 The combination of features of claim 1 of the first auxiliary request is not obtained by accomplishing multiple selections from different embodiments of the original disclosure taken as a reservoir of possible features as alleged by the respondent, but results from the combination of original claim 1 with the preferred particle sizes for the two ingredients (the particle sizes being a central feature of the invention already from the wording of original claim 1 itself) and the preferred active agent for the coarse ingredient. This combination, even if not explicitly mentioned in the original application, is on that basis directly and unambiguously disclosed therein.

3.5 In view of this the requirements of Article 123(2) EPC are met.

4. It needs finally to be analysed whether the amendments in claim 1 of the first auxiliary request extend the protection conferred with respect to the granted patent. This amounts to verifying whether there may be compositions which meet the requirements as to the particle sizes of claim 1 of the first auxiliary request, but not those of claim 1 as granted.

4.1 As to the fine ingredient, the question is to be answered whether the presence of a fine ingredient with at least 50% w/w of the particles with an aerodynamic particle size from 1-4 µm necessarily implies a MMAD for the fine ingredient within the range 1-4 µm or fine ingredients fulfilling the first condition exist with a MMAD outside the range.

4.1.1 As the MMAD indicates the median of the mass distribution of the aerodynamic particle size, namely the value for which 50% by mass of the distribution is above the value and 50% is below, if the condition in claim 1 of the first auxiliary request is strictly met (namely if more than 50% by weight of the particles are in the range 1-4 µm), there can be no doubt that it is mathematically not possible that the median lies outside of the range.

4.1.2 The limit case of exactly 50% by weight of the particle within the range needs to be considered with more care, as the respondent attempted to propose an example in which it is alleged that the implication does not hold, namely when the fine distribution is such that 50% by mass of the particles have a particle size 1-2 µm and 50% by mass a particle size of 8-9 µm.

4.1.3 However, such a case fulfills the requirement concerning the fine particles of claim 1 as granted for two reasons. Firstly, this distribution with two clearly distinct parts can be considered as a fine ingredient with particles in the range 1-2 µm (therefore falling under the condition in granted claim 1) and a further ingredient, which could well be the coarse one or even a third one, whose presence is not excluded (on the contrary it is contemplated, see paragraph [0027] of the granted patent and claim 9 of

the first auxiliary request). Secondly, even if the particles in the 1-2 µm range and those in the 8-9 µm range were considered as a single ingredient, the value of 2 µm would be a legitimate value of the median, as 50% of the particles by weight would be below it and 50% above. Indeed, this limit case would be the only one in which in strict mathematical terms the median would be undefined (any value between 2 and 8 µm would fulfill the condition), which shows that the respondent has artificially taken a technically not realistic condition (in practice there will always be one of the two fractions which is slightly above 50%). In this respect, the Board does not share the view of the respondent that an undefined value of the median between 2 and 8 µm would be sufficient for Article 123(3) EPC to be infringed, since, as explained, the skilled person would not consider the situation with an undefined median as a technically meaningful one.

4.1.4 Therefore for the fine fraction, it is always the case that if the condition as to particle size in claim 1 of the first auxiliary request applies, also the one of granted claim 1 is fulfilled. The same holds for the coarse fraction based on the same reasoning.

4.1.5 In view of this, there is no extension of the protection conferred by means of the amendments in claim 1 of the first auxiliary request and the requirements of Article 123(3) EPC are fulfilled.

Remittal

5. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings

of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

5.1 In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon a particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issue (Article 111(1) EPC).

5.2 The observations made above apply in full to the present case. The opposition division rejected all requests on file on the basis of Article 123 EPC, but did not decide on the grounds of lack of sufficiency of disclosure, novelty and inventive step. These issues, however, formed, *inter alia*, the basis for the request that the patent be revoked in its entirety and are clearly essential substantive issues of the case.

5.3 None of the specific reasons invoked by the respondent is considered by the Board strong enough to justify a deviation from these principles. In particular, the patent is not yet anywhere close to its expiry date and it is reasonable to expect that the opposition division will treat the case with some sort of priority. Moreover, the fact that both parties addressed the unresolved issues in their submissions and that no new

documents were filed on appeal has no bearing on the observations made above.

5.4 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the opposition division for the analysis of the remaining issues on the basis of the claims of the first auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

L. Fernández Gómez J. Riolo

Decision electronically authenticated