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Datasheet for the decision of 3 February 2015

Case Number: T 0301/11 - 3.3.07

02735680.7 Application Number:

Publication Number: 1401404

IPC: A61K9/48, A61K9/50, A61K9/14,

A61K9/16

Language of the proceedings: ΕN

Title of invention:

METHOD OF ENCAPSULATING AN ACTIVE SUBSTANCE

Patent Proprietor:

CSIR

Opponent:

Critical Pharmaceuticals Limited

Relevant legal provisions:

EPC Art. 100(c), 123(2) RPBA Art. 12(4), 13

Keyword:

Amendments - added subject-matter (yes) Requests filed with the statement of grounds - admitted (no)

Decisions cited:

G 0010/91, T 0144/09, T 0023/10



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 0301/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 3 February 2015

Appellant: CSIR

(Patent Proprietor) Corporate Building,

Scientia

Pretoria 0002 (ZA)

Representative: Becker Kurig Straus

Bavariastrasse 7 80336 München (DE)

Respondent: Critical Pharmaceuticals Limited

(Opponent) Blocity, Nottingham

Pennyfoot Street Nottingham

NG1 1GF (GB)

Representative: Potter Clarkson LLP

The Belgrave Centre

Talbot Street

Nottingham, NG1 5GG (GB)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 9 December 2010 revoking European patent No. 1401404 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chair R. Hauss
Members: D. Semino

P. Schmitz

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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 19 October 2010 revoking European Patent 1 401 404. The patent was granted on the basis of 9 claims, claims 1 and 9 reading as follows:
 - "1. A method of encapsulating an active substance in a polymeric encapsulating material to make an encapsulated product in particulate form by forming a mixture of a supercritical fluid, a polymeric encapsulating material and an active substance, causing or allowing the encapsulating material to encapsulate the active substance to form an encapsulated product,

separating the encapsulated product from the supercritical fluid, and

if necessary, subjecting the encapsulated product to size reduction to obtain encapsulated product particles in which the active substance is encapsulated by the encapsulating material,

the method being characterized in that, the forming of the mixture is of the supercritical fluid, the active substance and a polymeric encapsulating material in the form of an interpolymer complex comprising at least two different complementary polymers,

so that the encapsulated product comprises particles of the active substance encapsulated by the interpolymer complex,

wherein the supercritical fluid is carbon dioxide, wherein the forming of the mixture comprises the step of dissolving the supercritical fluid in the

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interpolymer complex to liquefy or plasticize the interpolymer complex."

- "9. A method as claimed in any of the preceding claims, characterized in that it comprises selecting the polymers, which form the interpolymer complex from complementary members of the group consisting of poly(vinylacetate)-crotonic acid copolymer, poly(vinyl pyrrolidone), poly(ethyleneglycol), poly(vinyl pyrrolidone)-poly(vinyl acetate) copolymer and poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) tri-block copolymer."
- 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 of inventive step, of insufficiency of disclosure and of extension of the subject-matter beyond the content of the application as filed (Article 100(a), (b) and (c) EPC). As to extension of subject-matter the objection was that there was no explicit disclosure in the application as filed of the use of carbon dioxide as supercritical fluid (section 9 of the notice of opposition).
- III. In a communication sent in preparation of oral proceedings dated 4 March 2010 the opposition division expressed the preliminary opinion that the application as filed disclosed the use of carbon dioxide as the preferred supercritical fluid (point 2 on page 4), so that there was no extension of subject-matter, and the final date for making written submissions and/or amendments according to Rule 116 EPC was indicated to be 19 August 2010.
- IV. With letter dated 19 August 2010 the opponent submitted inter alia that claim 9 and paragraph [0010] of the

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patent as granted containing a list of polymers from which the complementary polymer might be selected extended beyond the application as filed (section 3 of that letter).

- V. With letter dated 19 August 2010 the patent proprietor submitted a single set of claims as main request.

 Claim 1 of the main request corresponded to claim 1 as granted with the exception of a reformulation of the definition of the polymeric encapsulating material in the forming step as "comprising at least two different complementary polymers that interact together by hydrogen bonding to form an interpolymer complex", while claim 9 remained unamended.
- VI. At the beginning of the oral proceedings before the opposition division on 19 October 2010 the patent proprietor declared that three auxiliary requests were ready to be filed (point 2 in the minutes). The opponent objected to claim 9 and paragraph [0010] of the contested patent under Article 123(2) EPC and to the amendment in claim 1 of the main request under Article 123(3) EPC, but stated that the objections no longer included lack of support for the feature concerning the use of carbon dioxide (point 3 in the minutes, first four paragraphs). Then the patent proprietor took position on the two objections of the opponent (point 3 in the minutes, last four paragraphs). After an interruption the chairman announced that "claims 1-9 as amended with the letter dated 19 August 2010 complied with the requirements of Article 123(3) EPC but did not comply with the requirements of Article 123(2) EPC" (see point 5 in the minutes). As the patent proprietor asked for time to file an auxiliary request, the proceedings were interrupted for half an hour (point 6 in the minutes).

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After the interruption the patent proprietor "announced his decision not to file any further request" (point 7 in the minutes). The chairman of the opposition division announced therefore the revocation of the patent on the ground of Article 100(c) EPC (point 8 in the minutes).

- VII. The decision under appeal, which was accordingly based on the main request filed with letter of 19 August 2010, can be summarised as follows:
 - a) Even though the term "interpolymer complexes" was omitted in one instance in claim 1 of the main request, it still appeared twice, so that the omission had no influence on the scope of the claims and the requirements of Article 123(3) EPC were met.
 - As to added subject-matter (Articles 123(2) and 100(c) EPC), the specific copolymers listed in claim 9 had no basis in the application as filed. The polymers mentioned in the examples of the original application were used only in specific combinations and were from specific suppliers, so that they could not provide a basis for the generalisation in the claims. The term "copolymers" in the description could not be taken as a basis for the specific copolymers, as they were the result of a two-fold or three-fold selection from all the possible polymers. In addition the tri-block copolymer in claim 9 was only disclosed in the original application as a polymer surfactant. Further, the application as filed did not contain any disclosure that the specific copolymers of claim 9 should interact together by hydrogen bonding. Similar objections

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applied to paragraph [0010] of the patent. For these reasons the subject-matter of claim 9 and of paragraph [0010] had no basis in the application as filed.

VIII. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant filed three sets of claims as main request, first auxiliary request and second auxiliary request together with amended description pages for the auxiliary requests.

The main request corresponded to the main request on which the decision under appeal was based.

In claim 9 of the first auxiliary request the list of polymers was replaced by "the group consisting of hydrophilic polymers, hydrophobic polymers, hydrophobically modified hydrophilic polymers and hydrophilically modified hydrophobic polymers, such as alginates, alkyl-and hydroxyalkylcelluloses, carboxymethyl cellulose and its salts, carrageenan, cellulose and its derivatives, gelatin, gellan, guar qum, qum arabic, maleic acid copolymers, methacrylic acid copolymers, methyl vinyl ether/maleic anhydride copolymers, pectins, polyacrylamide, poly(acrylic acid) and its salts, poly(ethylene glycol), poly(ethylene imine), poly(ethylene oxide), poly(propylene oxide) poly(methacrylic acid), sulphonated polystyrene, poly(vinyl acetate), poly(vinyl alcohol), poly(vinyl amine), poly(vinyl pyrrolidone), poly(vinyl sulphonic acid), starches and their derivatives, styrene maleic anhydride copolymers, crotonic acid copolymers, xanthan gum, and the derivatives and copolymers thereof". In the description paragraph [0010] was replaced by a

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paragraph containing the list of polymers of amended claim 9.

The second auxiliary request corresponded to the main request with the deletion of claim 9 and paragraph [0010].

- IX. The opponent (respondent) maintained in the reply to the statement of grounds the objection of extension beyond the application as filed against claim 9 and objected to the admittance of the auxiliary requests into the proceedings.
- X. In a communication sent in preparation of oral proceedings, the Board gave a preliminary opinion on the issues related to the amendments by stating the following (point 1.1):

"The Board shares the concerns of the respondent and of the opposition division regarding the amendments. Indeed the list on page 7 cannot provide support for the specific combinations of polymers in claim 9 and in paragraph [0010], nor can the examples, which disclose very specific embodiments, be generalised beyond what can be directly and unambiguously derived from them. Moreover, the disclosure of hydrogen bonding appears on page 4 of the original description among several alternatives of a list of possible interactions and not in connection to any specific polymer."

As far as admittance of the auxiliary requests into the proceedings was concerned, it stated *inter alia* that no reasons had been submitted by the appellant as to why no auxiliary requests had been filed before the first instance (point 2.1, last two sentences).

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- XI. With letter of 30 December 2014 the appellant filed three further sets of claims as third to fifth auxiliary requests and gave arguments with regard to admittance of all auxiliary requests. The newly filed requests corresponded to the three requests on file with the deletion of the wording "by hydrogen bonding" in claim 1.
- XII. The respondent countered those arguments with letters of 26 January 2015 and 29 January 2015 and filed with the latter a "Declaration of Steven M. Howdle" setting out his recollection of the oral proceedings held before the opposition division.
- XIII. Oral proceedings before the Board were held on 3 February 2015.
- XIV. The arguments of the appellant can be summarised as follows:

Main request - amendments

a) The application as originally filed disclosed in the first full paragraph of page 7 a group of substances which may form the interpolymer complex including poly(ethylene oxide), poly(propylene oxide), poly(vinyl acetate), poly(vinyl pyrrolidone), crotonic acid copolymers and copolymers thereof. The term crotonic acid copolymer, such as e.g. poly(vinyl acetate)-crotonic acid copolymer as used in the examples. The disclosure of the generic class and of the specific example provided a basis for the presence of the specific copolymer in claim 9 of the main request. The same considerations applied to the other copolymers in

the list of claim 9. In other words, since the application as filed mentioned a number of polymers and gave specific examples of polymers and copolymers falling under this group, a limitation of a broad claim to specific embodiments mentioned in the description did not extend beyond the content as originally disclosed, but rather limited the application. As to the examples, it was relevant that, while specific products from specific suppliers were mentioned therein, the headings of the examples referred to the polymers in general terms. An objection under Article 100(c) EPC with reference to Article 123(2) EPC was therefore not justified.

Auxiliary requests - admittance

During the oral proceedings before the opposition b) division after discussion on the issues under Article 123(2) and (3) EPC with respect to claims 1 and 9 it was announced that claims 1-9 did not comply with the requirements of Article 123(2) EPC. The appellant had to assume that not only claim 9, but also claim 1 was found to contravene Article 123(2) EPC. As the appellant did not know why claim 1 was problematic, he was not in a position to amend claim 1 in a way which did not foil the economic focus of the patent. He was of the strong opinion that claim 1 found sufficient support in the specification as filed and accordingly it was decided not to file any auxiliary request and have the case assessed in appeal. It was only after reading the decision that the appellant understood that the revocation was based on a violation of Article 123(2) EPC by claim 9 alone, so that it was legitimate to file

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auxiliary requests addressing this issue with the statement of grounds. Had the appellant known that this was the only issue, the corresponding requests would have been filed at the oral proceedings. That the appellant had no abusive intention to delay the proceedings was clear from the fact that three auxiliary requests had been prepared, as announced at the beginning of the oral proceedings. In any case the objection to claim 9 had been filed by the respondent at a late stage of the opposition proceedings and an immediate reaction could not have been expected. On that basis the first and second auxiliary requests should be admitted into the proceedings. The third to fifth auxiliary requests were filed in reaction to the communication of the Board in view of the objection to hydrogen bonding as recited in claim 1 of all previous requests and were on stronger reasons also to be admitted into the proceedings.

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

Main request - amendments

a) Both claim 9 and paragraph [0010] contravened Article 123(2) EPC on the grounds that they defined certain specific polymers which were not described anywhere in the application as filed as being "complementary" to one another (by any kind of bonding, let alone by hydrogen bonding as according to the claim). The general teaching on page 7 was too vague, as it included a vast number of possible combinations and left the definition of the copolymers completely open. The examples on

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the other side provided a very specific teaching, which could not be generalised to the list of complementary polymers of claim 9. In respect to the examples, the headings were nothing more than a brief reference to the content of the examples themselves.

Auxiliary requests - admittance

b) During first instance proceedings the appellant was provided with a clear opportunity to file auxiliary requests that dealt with the objections to dependent claim 9 under Article 123(2) EPC. While the solution to the issue was clear and the filing of the requests would not have reduced in any way the rights on appeal, the appellant decided not to file any auxiliary request. The deliberate choice of the appellant prevented the opposition division from deciding on all the other grounds. The auxiliary requests filed with the statement of grounds could and should therefore have been submitted during the first instance proceedings and should not be admitted in appeal pursuant to Rule 12(4) of the Rules of Procedure of the Boards of Appeal. It was not credible that the appellant did not know on which objections under Article 123 EPC the main request was not allowed by the opposition division during oral proceedings. The minutes made it clear that only claim 9 had been discussed under Article 123(2) EPC and that the decision announced after deliberation referred to claim 1 only as far as Article 123(3) EPC was concerned. This was confirmed by the declaration of Mr Howdle. The situation was very similar to the one in T 23/10 of 18 January 2011 and the same conclusion should

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be reached, viz. that none of the auxiliary requests should be admitted into the proceedings.

- XVI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of one of the main request, the first auxiliary request and the second auxiliary request, all filed with the statement setting out the grounds of appeal, or on the basis of one of the third to fifth auxiliary requests filed with letter of 30 December 2014.
- XVII. The respondent requested that the appeal be dismissed. Furthermore, the respondent requested that none of the auxiliary requests be admitted into the proceedings. In the event that the requirements of Article 123 EPC were found to be met, the case should be remitted to the department of first instance.

Reasons for the Decision

Main request - amendments

1. Dependent claim 9 of the main request specifies that the polymers, which form the interpolymer complex, are selected "from complementary members of the group consisting of poly(vinylacetate)-crotonic acid copolymer, poly(vinyl pyrrolidone), poly(ethylene glycol), poly(vinyl pyrrolidone)-poly(vinyl acetate) copolymer and poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide) tri-block copolymer". Such a specification indicates therefore that out of the five listed polymers/copolymers couples or larger groups are chosen to form the interpolymer complex.

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1.1 The first full paragraph of page 7 of the application as filed reads as follows:

"The polymers which form the interpolymer complex by interpolymer complexation may be selected from complementary members of the group consisting of hydrophilic polymers, hydrophobic polymers, hydrophobically modified hydrophilic polymers and hydrophilically modified hydrophobic polymers, such as alginates, alkyl-and hydroxyalkylcelluloses, carboxymethyl cellulose and its salts, carrageenan, cellulose and its derivatives, gelatin, gellan, quar qum, qum arabic, maleic acid copolymers, methacrylic acid copolymers, methyl vinyl ether/maleic anhydride copolymers, pectins, polyacrylamide, poly(acrylic acid) and its salts, poly(ethylene glycol), poly(ethylene imine), poly(ethylene oxide), poly(propylene oxide) poly (methacrylic acid), polystyrene and sulphonated polystyrene, poly(vinyl acetate), poly(vinyl alcohol), poly (vinyl amine), poly(vinyl pyrrolidone), poly(vinyl sulphonic acid), starches and their derivatives, styrene maleic anhydride copolymers, crotonic acid copolymers, xanthan gum or the like, and the derivatives and copolymers thereof" (emphasis by the Board).

1.2 While poly(vinyl pyrrolidone) and poly(ethylene glycol) do appear in the list, none of the three copolymers of claim 9 is present in the list, which contains poly(ethylene oxide), poly(vinyl acetate) and poly(propylene oxide) as polymers and not as part of specific copolymers, a generic reference to crotonic acid copolymers with no indication of the further monomers present in it and an even more generic reference to copolymers at the end of the list.

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- 1.3 It it clear therefore that the specific copolymers in claim 9 of the main request are not directly and unambiguously derivable from the generic disclosure on page 7 of the application as filed. For even stronger reasons the specific combinations in claim 9 (complementary couples or larger groups of the five polymers/copolymers) cannot be derived therefrom.
- 1.4 In the examples of the application as originally filed specific couples or groups of three polymers are disclosed for the formation of an interpolymer complex, namely poly(vinylacetate)-crotonic acid copolymer in combination with poly(vinyl pyrrolidone) in examples 1, 2, 5, 6 and 7 (pages 16 to 18 and 20 to 22, also with poly(ethyleneglycol) as viscosity modifier in example 2 and with poly(ethylene oxide)-poly(propylene oxide)poly(ethylene oxide) tri-block copolymer as surfactant in example 7), poly(vinylacetate)-crotonic acid copolymer in combination with poly(vinyl pyrrolidone) poly(vinyl acetate) copolymer in example 3 (pages 18 and 19) and poly(vinylacetate)-crotonic acid copolymer in combination with poly(ethylene oxide)-poly(propylene oxide) -poly(ethylene oxide) tri-block copolymer in example 4 (page 19).
- 1.5 Apart form the fact that each of the examples discloses very specific polymers/copolymers and very specific conditions of formation of the interpolymer complex, the examples disclose in principle only three couples of polymers/copolymers for the formation of the interpolymer complex, all of them including poly(vinylacetate)-crotonic acid copolymer, and give no indication that the polymers/copolymers used therein could be used in different pairs or groups as covered by claim 9 of the main request. The specific combinations of claim 9 (couples or larger groups of

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the five polymers/copolymers) cannot therefore be directly and unambiguously derived from the disclosure in the examples of the application as originally filed.

1.6 On that basis the subject-matter of claim 9 of the main request is not directly and unambiguously derivable from any of the passages indicated by the appellant.

Claim 9 contains therefore subject-matter which extends beyond the content of the application as filed.

First and second auxiliary requests - admittance

- 2. The patent was revoked on added subject-matter with reference to Articles 123(2) and 100(c) EPC on the basis of the content of dependent claim 9 and of the corresponding paragraph [0010] in the description (see point VII, above). There was no other ground for the revocation of the patent. The appellant did not file any request to deal with this issue during the opposition proceedings, but filed two auxiliary requests addressing it with the grounds of appeal (the first auxiliary request in which the wording of dependent claim 9 was changed according to a paragraph of the original description and the second auxiliary request in which claim 9 was deleted).
- According to Article 12(1) and (4) RPBA, the notice of appeal and the statement of grounds of appeal form the basis of the appeal proceedings and shall be taken into account by the Board. However, Article 12(4) RPBA gives the Board discretion not to admit requests into the appeal proceedings which could have been presented in the first instance proceedings. When exercising its discretion the Board must take due account of the judicial nature of the appeal procedure and the interests of the parties concerned. The discretion

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given to the boards of appeal pursuant to Article 12(4) RPBA serves the purpose of ensuring fair and reliable conduct of judicial proceedings. By requiring all parties to complete their relevant submissions during opposition proceedings, the moment in time when the parties' case has to be complete is not determined by the procedural strategy chosen by the parties.

According to Article 12(4) RPBA, admission of auxiliary requests into proceedings hinges on the question whether a party to appeal proceedings was in a position to make its submission earlier, and whether it could have been expected to do so under the circumstances (T 23/10, supra, point 2.4).

- 2.2 The Board has no doubt that the fact that the patent was to be revoked on the single issue of added subject-matter in claim 9 and paragraph [0010] was made sufficiently clear at the oral proceedings before the opposition division. The minutes, whose correctness has not been contested by the parties, show that the only point which was disputed and discussed under Article 123(2) EPC concerned claim 9 and paragraph [0010], while the discussion on claim 1 related to Article 123(3) EPC (see point VI, above). The declaration of the opposition division that "claims 1-9 as amended with the letter dated 19 August 2010 complied with the requirements of Article 123(3) EPC but did not comply with the requirements of Article 123(2) EPC" could therefore only be understood as indicating that the objection to claim 1 under Article 123(3) EPC was not followed by the opposition division, while the one to claim 9 and paragraph [0010] under Article 123(2) held good.
- 2.3 On that basis the Board cannot accept the argument that the appellant had to assume that not only claim 9, but

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also claim 1 was found to contravene Article 123(2) EPC and that he did not known why claim 1 was problematic. Additionally, if there had been any doubt on the appellant's side, it would have been his duty to ask for clarification, all the more as he asked for time to file an auxiliary request.

- 2.4 A possible confusion on the appellant's side as to which objection under Article 123(2) EPC had been accepted by the opposition division can therefore not be seen as a reasonable justification for not filing a request addressing the issue for claim 9 and paragraph [0010] during opposition proceedings.
- 2.5 None of the further possible justifications indicated by the appellant can be accepted by the Board.
- 2.5.1 While it is true that the objection against claim 9 and paragraph [0010] was not present in the notice of opposition, it was raised two months before the oral proceedings and was fully discussed therein. Time was requested and given to the appellant to prepare an auxiliary request suited to address the issue.

 Moreover, the deletion of the dependent claim and of the corresponding paragraph was a possible solution to the issue which was straightforward and did not involve any limitation on the scope of the patent. Indeed, the objection regarding claim 9 did not involve any complex issue that justified the need to await the decision of the opposition division.
- 2.5.2 There was no loss of possible economic rights on the side of the appellant related to the filing of an auxiliary request solving the issue, as such a filing without withdrawing the higher ranking request would have preserved his right for a judicial review.

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- 2.5.3 The fact that it was announced at the beginning of the oral proceedings that three auxiliary requests were ready to be filed is also irrelevant, as those requests were never filed and their content is not known.
- In view of this, the fact that no auxiliary request was filed in opposition proceedings after time was requested and allotted to the appellant can only be seen as a deliberate choice not to have any further request decided upon by the opposition division on any other issue (see also T 144/09 of 4 May 2011, point 1.9). By means of this the appellant deliberately prevented a decision of the opposition division on the other grounds of opposition.
- 2.7 The appeal procedure is a judicial procedure, separate from the preceding purely administrative opposition procedure, in which an administrative decision of an opposition division is reviewed by a judicial authority. Its function is mainly to give the losing party an opportunity to challenge the administrative decision against it and to obtain a judicial ruling on whether this decision is correct (G 10/91, OJ EPO 1993, 420, Reasons point 18). Since the appeal board cannot be expected, as a review instance, to deal with all the outstanding issues after the amendment of the appellant's case, admission of the auxiliary requests into the proceedings would give the appellant the opportunity to compel the board to remit the case. This would be contrary to a reliable and fair conduct of proceedings (T 23/10, supra, point 2.8).
- 2.8 Under such circumstances the Board is of the opinion that the appellant not only could, but also should have filed auxiliary requests dealing with the critical

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issue at the latest at the oral proceedings before the opposition division, if he intended to have any further request admitted into the proceedings.

- 2.9 The filing of auxiliary requests dealing with the issue only during appeal is inconsistent with the previous conduct of the appellant, namely the deliberate choice not to file any request, thereby limiting the dispute before the opposition division and preventing it from deciding on other grounds. To admit the first and second auxiliary requests into the proceedings would allow the appellant to take advantage of this inconsistent conduct by unnecessarily prolonging the proceedings in a case where there was no justification for not filing the requests before the opposition division.
- 2.10 Under these circumstances the Board finds it appropriate to exercise its discretion under Article 12(4) RPBA by not admitting the first and second auxiliary requests into the proceedings.

Third to fifth auxiliary requests - admittance

- 3. As to the third to fifth auxiliary requests, they were allegedly filed in reaction to the communication of the Board in view of the objection to hydrogen bonding as recited in claim 1 of all previous requests.
- 3.1 The Board is of the opinion that the communication of the Board (see point X, above) did not contain any new and separate objection against claim 1 of the requests on file, but repeated the objection against claim 9 as dependent on claim 1 which was already present in the decision under appeal (see point VII b), above, fifth sentence).

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- 3.2 On that basis, there was no reason to file new requests at that stage. In any case, the main issue on claim 9 (see point 1, above) remains the same for claim 9 of the third auxiliary request, and the fourth and fifth auxiliary requests include the same amendments as the first and second auxiliary requests which resulted in those requests not being admitted into the proceedings.
- 3.3 In view of that the Board finds it appropriate to exercise its discretion under Article 13 RPBA by not admitting the third to fifth auxiliary requests into the proceedings.

Conclusion

4. As the only request admitted into the proceedings fails due to subject-matter which extends beyond the content of the application as filed, there is no need to decide on any other substantial point and the appeal is to be dismissed.

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Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



S. Fabiani R. Hauss

Decision electronically authenticated