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Datasheet for the decision of 17 January 2012

Case Number: T 0453/08 - 3.3.02

Application Number: 99953858.0

Publication Number: 1128816

IPC: A61K 9/16

Language of the proceedings: EN

Title of invention:
Polyvinyl alcohol microspheres, and methods for making of the same

Patentee:
Biosphere Medical, S.A.

Opponent:
Biocompatibles UK Limited

Headword:
Cross linked polyvinyl alcohol microspheres/BIOSPHERE MEDICAL

Relevant legal provisions:
EPC Art. 54, 84, 111(1)
RPBA Art. 13

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility of the requests: main request (yes), auxiliary requests 2, 3, 8, 9 (yes), auxiliary requests 1, 4-7, 10, 11 (no)"
"Novelty, main request (no)"
"Clarity and support, auxiliary requests 2, 3, 8 (no)"
"Remittal to the first instance (auxiliary request 9)"

Decisions cited:
G 0009/91, G 0004/95, R 0016/09, T 0087/05

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0453/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 January 2012

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 27 December 2007 concerning maintenance of European patent No. 1128816 in amended form.**

Composition of the Board:

Chairman: M. C. Ortega Plaza
Members: D. Boulois
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 128 816, which was filed as application number 99953858.0, based on international application WO 00/23054, was granted on the basis of forty-nine claims.

Independent claims 1, 11, 22 and 32 as granted read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol and have a diameter ranging from about 10 µm to about 2,000 µm.

11. An injectable suspension suitable for embolization, which comprises crosslinked polyvinylalcohol microspheres, having a diameter ranging from about 10 µm to about 2,000 µm, and a suitable liquid carrier.

22. A method for the preparation of an injectable suspension comprising an effective amount of crosslinked polyvinylalcohol microspheres, having a diameter ranging from about 10 µm to about 2,000 µm, and a suitable liquid carrier for prophylactic or therapeutic embolization in a mammal.

32. A process for producing crosslinked polyvinylalcohol microspheres, having a diameter ranging from about 10 µm to about 2,000 µm, which comprises:
a) dissolving polyvinylalcohol in an acidic solution;
b) adding an aldehyde to said polyvinylalcohol containing solution, or vice verse, to form a

mixture;
c) adding said mixture, with agitation, to an oil containing from about 0.1% to about 10% of an emulsifier having HLB less than 5, or vice verse, to form an emulsion with droplets of polyvinylalcohol suspended in said oil;
d) heating said emulsion to condense said aldehyde on polyvinylalcohol chains and thereby forming spherical particles of crosslinked polyvinylalcohol;
e) removing said oil from said spherical particles of crosslinked polyvinylalcohol;
f) neutralizing said active aldehyde on said spherical particles of crosslinked polyvinylalcohol; and
g) washing said neutralized spherical particles of crosslinked polyvinylalcohol with a physiological aqueous buffer."

II. An opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC (lack of novelty and lack of inventive step).

III. The present appeal lies from an interlocutory decision of the opposition division maintaining the patent in amended form on the basis of the third auxiliary request filed at the oral proceedings before the opposition division (Articles 101(3)(a) EPC 2000).

IV. The documents cited during the opposition and appeal proceedings included:
(3) Thanoo, B.C. et al, J. App. Biomater., 1991, 2, 67-72
(5) US-A-4350773

(9) Tao, T. et al, Acta Pharmaceutica Sinica, 1988, 23(1), 55-60

(9.2) English translation of (9)

(17) Jiaqui, Y. et al, Nippon Acta Radiologica, 1996, 56, 19-24

(18) JP-A-06056676

(19) Extracts from a license agreement between Patentee and Hori S. /Hori T.

(20) Motohashi, et al, Sumitomo Chemistry 1985-I, 35-47

(20.2) English translation of (20)

(21.1) Kitamura, S. et al, Sumitomo Chemical Special Issue, 1980-I, 1-9

(21.2) English translation of (21)

(22.1) Hori, et al, Journal of International Radiology Vol. 11, No 3, 1996, 75-81

(22.2) English translation of (20)

(23) Experimental Report filed by appellant-opponent with its grounds of appeal (re-filed as CD-Model owing to the poor resolution of the scanned photographs of the paper copy)

(24) Kim, Ch., Pharmaceutical Research, Vol. 9, No. 1, 1992, pages 10-16

(25) Experimental Report filed by appellant-opponent on 27 June 2011

(26) "Google search" dated 6 December 2011

(27) Experimental Report filed by appellant-proprietor with letter dated 8 December 2011

V. The opposition division considered that the main request filed with the letter of 8 March 2007 met the requirements of Rule 57a EPC 1973 and Articles 123(2) and 84 EPC. However, the opposition division considered that the subject-matter of claim 1 of the main request lacked novelty vis-à-vis document (3).

The opposition division considered that the first auxiliary request filed with the letter of 10 October 2007 did not meet the requirements of novelty, since claim 1 was identical to claim 1 of the main request.

As regards the second auxiliary request filed with the letter of 10 October 2007, the opposition division considered that the subject-matter claimed in claim 1 lacked novelty vis-à-vis document (3) since the wording "essentially consists of" had to be interpreted as meaning "comprising" and thus had no limitative character.

As regards the third auxiliary request filed at the oral proceedings before the opposition division, the opposition division considered that it met the requirements of Article 123(2) EPC and that the feature "wherein the surface of the microspheres appears smooth under less then 1000-fold magnifications" was clear to the skilled person, and was not disclosed in any of the cited prior art, making the third auxiliary request novel.

The opposition division further considered that document (3) represented the closest prior art and that the problem to be solved was to provide improved microspheres useful for embolisation.

The opposition division was of the opinion that the subject-matter claimed in claim 1 of the third auxiliary request involved an inventive step (Article 56 EPC).

Furthermore, the opposition division did not admit the late-filed documents (17) to (19) into the proceedings.

VI. Both the patent proprietor (appellant) and the opponent (appellant) filed an appeal against said decision.

The appellant-proprietor filed with its grounds of appeal a fourth auxiliary request.

The appellant-opponent filed with its grounds of appeal an experimental report (23) and further documents (20) to (22). Moreover, it requested that documents (17), (18) and (20) to (22) be admitted into the appeal proceedings and gave reasons therefor. The appellant-opponent raised objections under Article 83 EPC against the feature "smooth" which appears in the auxiliary request serving as the basis for the maintenance of the patent in amended form.

VII. The opponent and the patent proprietor each filed counterarguments to the other party's appeal.

VIII. With a letter dated 21 April 2011, the appellant-opponent filed further arguments against the novelty of the third auxiliary request over document (3), and an additional document (24).

IX. A summons to oral proceedings was sent to the parties on 28 April 2011 and oral proceedings were scheduled to take place on 27 July 2011.

X. A communication expressing the preliminary opinion of the board within the meaning of Article 15(1) RPBA was sent to the parties on 11 May 2011.

In said communication the board expressed the preliminary opinion that the requests on file were not admissible and gave reasons therefor. In particular, the sets of claims containing new independent claims in the form of "product-for-use" claims (claims 19 to 21 of the main request, claims 20 to 22 of the first auxiliary request, claims 18 to 20 of the second auxiliary request and claims 19 to 21 of the third auxiliary request) were not admissible.

Moreover, the board pointed out that the opposition division's decision did not hold in relation to the assessment of Article 84 EPC for the amended claims. The term "essentially consists of crosslinked polyvinyl alcohol" in claim 1 of the second auxiliary request and the feature "and wherein the surface of the microspheres appears smooth under less than 100-fold magnifications" in claim 1 of the third auxiliary request were addressed in particular.

Furthermore, the board's communication drew the parties' attention to the fact that there was a lack of reasoning in the opposition division's decision to maintain the patent in amended form on the basis of the third auxiliary request, since said request contained an independent process claim, namely claim 22, which related to a process for producing microspheres which did not need to be those defined in claim 1.

XI. The appellant-opponent filed a letter dated 27 June 2011 as a reply to the board's communication dated 11 May 2011. The letter included additional experimental data as document (25).

XII. The parties were informed that the oral proceedings scheduled for 27 July 2011 had been cancelled.

XIII. The appellant-proprietor filed a letter dated 6 July 2011 as a reply to the board's communication of 11 May 2011. The letter included a new main request and eight auxiliary requests replacing the main and auxiliary requests previously on file. In it, the appellant-proprietor contested the introduction of the objections under Article 83 EPC into the procedure and cited the Enlarged Board of Appeal's decision G 9/91, EPO OJ 1993, 408.

The independent claims of the main request filed with letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm and are substantially spherical and sterile.

10. An injectable, sterile suspension suitable for embolization, which comprises crosslinked polyvinylalcohol microspheres, that are substantially spherical and have a diameter ranging from 10 µm to 2,000 µm, and a suitable liquid carrier.

19. A process for producing crosslinked polyvinylalcohol microspheres according to claim 1, which comprises:
a) dissolving polyvinylalcohol in an acidic solution;
b) adding an aldehyde to said polyvinylalcohol containing solution or vice verse, to form a

mixture;
c) adding said mixture, with agitation, to an oil containing from about 0.1% to about 10% of an emulsifier having HLB less than 5, or vice verse, to form an emulsion with droplets of polyvinylalcohol suspended in said oil,
d) heating said emulsion to condense said aldehyde on polyvinylalcohol and thereby forming spherical particles of crosslinked polyvinylalcohol;
e) removing said oil from said spherical particles of crosslinked polyvinylalcohol;
f) neutralizing said active aldehyde on said spherical particles of crosslinked polyvinylalcohol and
g) washing said neutralized spherical particles of crosslinked polyvinylalcohol with a physiological aqueous buffer, and
h) sterilizing said washed spherical particles of crosslinked polyvinylalcohol"

Claims 1 and 10 of auxiliary request 1 filed with the letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, and wherein the surface of the microspheres appear smooth under less than 1000-fold magnifications.

10. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol microspheres of claim 1, and a suitable liquid carrier."

Claims 1 and 10 of auxiliary request 2 filed with the letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol and have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, and wherein the surface of the microspheres, under microscopic examination, appear smooth under less than 1000-fold magnifications.

10. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol microspheres of claim 1, and a suitable liquid carrier."

Claims 1 and 10 of auxiliary request 3 filed with the letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, wherein the microspheres have a smooth surface such that no attrition occurs and no small-sized particles are generated from said microspheres.

10. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol of claim 1, and a suitable liquid carrier."

Claims 1 and 10 of auxiliary request 4 filed with the letter of 6 July 2011 read as follows:

"1. Use of microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile for the manufacture of a medicament for prophylactic and therapeutic embolization in a mammal.

10. The use of an injectable, sterile suspension suitable for embolization, which comprises crosslinked polyvinylalcohol microspheres that are substantially spherical and have a diameter ranging from 10 µm to 2,000 µm, and a suitable liquid carrier for the manufacture of a medicament for prophylactic and therapeutic embolization in a mammal."

Claims 1 and 10 of auxiliary request 5 filed with the letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, wherein the microspheres are in hydrogel form and comprise 0.5% to 20% by weight polyvinylalcohol.

10. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol of claim 1, and a suitable liquid carrier."

Claims 1 and 6 of auxiliary request 6 filed with the letter of 6 July 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, wherein the difference in diameter between the microspheres is from 0 µm to 150 µm, when the particles are in the form of an injectable suspension.

10. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol of claim 1, and a suitable liquid carrier."

Claim 1 of auxiliary request 7 filed with the letter of 6 July 2011 read as follows:

"1. An injectable, sterile suspension suitable for embolization, which comprises crosslinked polyvinylalcohol microspheres that are substantially spherical and have a diameter ranging from 10 µm to 2,000 µm, wherein the difference in diameter between the microspheres is from 0 µm to 150 µm, and a suitable liquid carrier."

Claim 1 of auxiliary request 8 filed with the letter of 6 July 2011 read as follows:

"1. A process for producing crosslinked polyvinylalcohol microspheres having a diameter ranging from about 10 µm to about 2,000 µm, which comprises:
a) dissolving polyvinylalcohol in an acidic solution;
b) adding an aldehyde to said polyvinylalcohol containing solution or vice verse, to form a mixture;

c) adding said mixture, with agitation, to an oil containing from about 0.1% to about 10% of an emulsifier having HLB less than 5, or vice verse, to form an emulsion with droplets of polyvinylalcohol suspended in said oil;
d) heating said emulsion to condense said aldehyde on polyvinylalcohol and thereby forming spherical particles of crosslinked polyvinylalcohol;
e) removing said oil from said spherical particles of crosslinked polyvinylalcohol;
f) neutralizing said active aldehyde on said spherical particles of crosslinked polyvinylalcohol and
g) washing said neutralized spherical particles of crosslinked polyvinylalcohol with a physiological aqueous buffer, and
h) sterilizing said washed spherical particles of crosslinked polyvinylalcohol."

XIV. A summons to oral proceedings was issued on 23 September 2011.

XV. With a letter dated 9 December 2011, the appellant-proprietor filed two additional auxiliary requests, the ninth and tenth. Furthermore, it also filed an experimental report numbered document (27). It also submitted a copy of a Google search as document (26).

Claim 1 of auxiliary request 9 filed with the letter of 9 December 2011 read as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are

substantially spherical and sterile, and wherein the surface of the microspheres, under microscopic examination, appear smooth under less than 1000-fold magnifications, obtainable by a process as defined in any one of claims 19 to 35."

Claims 19 to 21 are process claims.

Claim 1 of auxiliary request 10 filed with the letter of 9 December 2011 reads as follows:

"1. Microspheres useful for embolization wherein said microspheres comprise crosslinked polyvinylalcohol, have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile, obtainable by a process as defined in any of claims 19 to 35."

Claims 19 to 21 are process claims.

XVI. The appellant-opponent filed a letter dated 16 December 2011 which included a request that Article 83 EPC be admitted into the proceedings. It also contested the admissibility of the oral submissions by an expert announced by the appellant-patentee with its letter dated 9 December 2011 to be made during the oral proceedings and cited Enlarged Board of Appeal decision G 4/95 EPO OJ 1996, 412.

XVII. With a letter dated 19 December 2011, the appellant-proprietor filed coloured copies of Figures 1 and 2 previously filed with the letter of 9 December 2011.

XVIII. With a letter dated 23 December 2011, the appellant-proprietor filed an amended auxiliary request 4, to replace the previous one.

The only difference between claim 1 of amended auxiliary request 4 and claim 1 of the request previously on file is that the word "and" was replaced by the word "or" in the expression "for prophylactic **or** therapeutic embolization in a mammal" (emphasis added).

XIX. Oral proceedings took place on 17 January 2012.

During the oral proceedings, the appellant-proprietor submitted a new first auxiliary request. The auxiliary requests filed with the letter of 6 July 2011 (first to third and fifth to eighth auxiliary requests), the letter of 9 December 2011 (ninth and tenth auxiliary requests) and the letter of 23 December 2011 (fourth auxiliary request) were maintained by the appellant-proprietor as the second to eleventh auxiliary requests.

Claim 1 of the first auxiliary request read as follows:

"1. An injectable, sterile suspension suitable for embolization, which comprises the crosslinked polyvinylalcohol microspheres that are substantially spherical and have a diameter ranging from 10 µm to 2,000 µm, and a suitable liquid carrier, wherein the crosslinked polyvinylalcohol microspheres in the injectable suspension are comprised of from about 0.5% to about 20% crosslinked polyvinylalcohol by weight in hydrogel form."

XX. The appellant-proprietor's arguments as far as relevant for the present decision may be summarised as follows (the requests are identified using the numbering as modified during the oral proceedings).

As regards the admission of the requests into the proceedings, the appellant-proprietor held that all requests were filed to overcome the reasons given in the opposition division's decision or either were in response to the appellant-opponent's objections or triggered by the board's communication. The main request and auxiliary requests 2 to 9 were filed six months before the oral proceedings, avoiding any surprise and unfair burden to the appellant-opponent.

In particular, the appellant-proprietor submitted that:

- The main and second auxiliary requests corresponded to requests serving as the basis for the opposition's division decision.
- Auxiliary request 3 was a direct reply to the board's communication, and specified the term "smooth".
- Auxiliary request 4 had been filed to overcome the board's objection against the term "smooth" and represented an alternative attempt to define the term "smooth" in a clearer way.
- Auxiliary request 5 was a remedy of an obvious error in the auxiliary request previously filed as auxiliary request 4.
- Auxiliary requests 6 and 7 were an attempt to replace the term "smooth" and to overcome the objections related to it.
- Auxiliary request 8 was restricted to the injectable composition and the process.

- Auxiliary request 9 contained process claims only.
- Auxiliary requests ten and eleven related to attempts to more clearly define the subject-matter claimed in a product-by-process form.

As regards the first auxiliary request submitted during the oral proceedings before the board of appeal, the appellant-proprietor justified its filing as being a direct response to the preceding novelty discussion for the main request. Moreover, the amendments introduced were of a simple nature since prior independent claim 10 had become claim 1 and the subject-matter of claim 13 had been incorporated into it. Thus, the appellant-opponent could not have been taken by surprise.

As regards the admission into the proceedings of the additional documents and experimental reports, the appellant-proprietor argued that document (27) should be admitted into the proceedings, as it was filed in response to the experimental report (25) filed with the letter dated 27 June 2011. Some time had been necessary to repeat the experimental process of document (3). Document (27) was submitted as evidence that microspheres according to the present invention cannot be produced according to the method of document (3).

The appellant-proprietor did not object to the admissibility of documents (23) or (25). However, it said that documents (17) to (22) and (24) should not be admitted as they had been filed late and they were *prima facie* not relevant. Documents (17) to (22) dealt with a copolymer of polyvinylalcohol and document (24) did not add anything to the existing documents.

As regards the main request, the appellant-proprietor argued that it met the requirements of Article 123(2) EPC, since it was clear from the description that the particles are spherical (pages 11 and 16 of the application as filed) and that the microspheres of the present invention are sterilized (page 16 of the application as filed).

As regards the novelty of the main request, the appellant-proprietor argued that the experiments produced by the appellant-opponent with document (23) showed that document (3) was not enabling and purely speculative, since the "dispersions were unstable at 2,000 rpm and produced many particles fragments" (document (23), page 3). Only when the stirring speed was decreased to 400 rpm, which was an arbitrary choice, were microspheres of PVA obtained. The pictures of the particles of document (23) did not provide any help in understanding how to prepare the microspheres. Thus, the skilled person must deviate from the teaching of document (3) in order to succeed in preparing microspheres. The appellant-proprietor further submitted that this was proven by the experiments in document (27), in which it was not possible to stir at a speed of 2,000 rpm in a 100 ml beaker and no microspheres could be obtained.

The appellant-proprietor argued that the polyvinylalcohol used in document (27) was a polymer of the type used in document (3), namely a PVA of type II, which did not have a high molecular weight. According to the appellant-proprietor, the experiments in document (25) were made by stirring at a speed of

2,000 rpm in a beaker of 100 ml, and that was not realistic.

Finally, the suitability of the microspheres of document (3) for embolization had neither be seriously contemplated nor supported by experimental data.

Document (9) was *per se* not enabling for making PVA microspheres. The skilled person does not know which catalyst, emulsion and dispersing agent is to be used. Of documents (5), (6), (11), (12), (13) cited by the opponent to support its arguments in favour of the enablement of the process in document (9), only documents (5) and (11) could be used in view of the publication dates of the documents compared with the relevant date of document (9).

The skilled person would therefore be in a position to start a research program to repeat the teaching of document (9).

As regards the clarity of the expressions "wherein the surface of the microspheres appear smooth under less than 1000-fold magnifications" and "wherein the surface of the microspheres, under microscopic examination, appear smooth under less than 1000-fold magnifications" in auxiliary requests 2 and 3, the appellant-proprietor submitted that they were clear to the skilled person. The person skilled in the art would simply investigate the microspheres under a magnification as close as possible to, but below 1,000 and examine whether they were smooth or not. The skilled person would also understand what "smooth" means, since it was a commonly used term, as for instance in document (24).

A definition for the term "smoothness" was given in the description on page 8, lines 11-13 of the application as filed.

Thus claim 1 of auxiliary requests 2 and 3 met the requirements of Article 84 EPC.

As regards the clarity of the expression "wherein the difference in diameter between the microspheres is from 0 µm to 150 µm" in claim 1 of auxiliary request 8, the skilled reader would be able to understand it too. The difference between the smallest and the biggest particle should not be more than 150 µm. Moreover, a dual distribution was also possible and it was encompassed by claim 1.

XXI. The appellant-opponent's arguments in so far as they are relevant for the present decision may be summarised as follows:

All the requests could be objected to as regards their admission into the proceedings. None of the requests on file was identical to any of the requests dealt with by the opposition division. They could not be seen as a response to objections raised during the appeal procedure or as meeting *prima facie* the criteria of clear allowability. No justification had been given for any of the requests as to why it would not have been possible to have filed it earlier. Moreover, most of the requests had been filed three weeks before the oral proceedings initially scheduled for July 2011, and, among them, some were filed less than one month before the present oral proceedings.

Additionally:

- In the main request and auxiliary requests 2 and 3, the fact that claim 19 contained a reference to claim 1 was not a response to any ground of opposition or objection raised (Rule 80 EPC).
- In auxiliary requests 4, 6 and 7 there was a change of dependency in claims 10 and 19.
- In auxiliary request 6, features were introduced which had been abandoned by the appellant-proprietor in its letter of 8 March 2007.
- Auxiliary request 5 had been filed very late with a change of dependency in claim 19.
- In auxiliary request 8, claim 10 now referred to claim 1.
- In both auxiliary requests ten and eleven, claims 1 and 19 had been amended in such a way as to render re-examination of the subject-matter necessary.

As regards the admission into the proceedings of new auxiliary request 1 filed during the oral proceedings, the appellant-opponent considered that this request was a very late request which presented a new claim and opened a new discussion. Documents (3) and (9) had been cited as novelty-destroying at the beginning of the procedure, and their relevance should not have constituted a surprise. Moreover, the subject-matter of claim 19 of auxiliary request 1 had also been amended, and this could not be seen as the result of the discussion on novelty.

As regards the admission of documents into the proceedings, the appellant-opponent considered that document (27) should not be admitted, since it had been

filed too late without justification, and it was not relevant, because it did not reproduce exactly the process of document (3).

On the other hand, documents (17) to (22) and (24) should be admitted into the proceedings, because of their relevance for the issue of novelty. Documents (17) to (22) had been filed in response to the opposition division's decision, in relation to the assessment of the features "smooth", "sterile" and "spherical". Document (26) was not relevant, since there was no date for the documents appearing as a result of the search, and should not be admitted.

As regards the main request, the appellant-opponent submitted that the subject-matter of claim 1 related to an unallowable combination of features and that it therefore infringed Article 123(2) EPC.

Documents (3) and (9) were novelty-destroying for claim 1 of the main request. In particular, the appellant-opponent submitted that the microspheres of document (3) were sterile and suitable for embolization. Concerning the issue of the enablement of document (3), the burden of proof was on the proprietor's side. Document (25) made it plausible that microspheres could be prepared according to the process of document (3). The experiments in document (27) had been performed under experimental conditions that were not reasonable. Thus, any discrepancy shown between the experiments in document (25) and document (27) did not prove that the process of document (3) was not enabling.

Document (3) taught how to make cross-linked PVA microspheres. It disclosed all the features of claims 1 and 10 of the main request.

In the experiments in document (27) the impeller is the same size as the beaker. The skilled person would have chosen another impeller, as a matter of common sense. The polyvinylalcohol employed in the experiments of document (27) has a high molecular weight, which necessitates a heating step for dissolution. In contrast, the experiments in documents (23) and (25) employed a low molecular weight polyvinylalcohol.

Additionally, document (9) was *prima facie* enabling, the burden of proof being on the proprietor to show the contrary. Document (9) disclosed the right particle size and the use of the particles for embolization. The process options were shown on page 3, and the choice of the specific reaction parameters could not be seen as an undue burden. Some documents, such as documents (5), (6), (11), (12) and (13), showed that the possible choices for the catalyst, emulsion and dispersing agent were known.

As regards auxiliary requests 2 and 3, the appellant-opponent submitted that the subject-matter of each claim 1 was unclear. The term "smooth" used in claim 1 of auxiliary requests 2 and 3 was a relative term. No method of measurement was given, yet the measurement was highly dependent on the method used, e.g. optical microscopy or electronic microscopy.

As regards auxiliary request 8, the expression "wherein the difference in diameter between the microspheres is

from 0 µm to 150 µm" in claim 1 was unclear. It was not clear how the difference in size was to be measured, and the subject-matter of the claim was inconsistent. Moreover, the subject-matter of auxiliary request 8 did not meet the requirements of Article 123(2) EPC.

The appellant-opponent objected to the remittal to the department of first instance for further prosecution on the basis of auxiliary request 9. It considered that the proprietor was not adversely affected by the opposition division's decision, as the request serving as the basis for the maintenance contained an independent process claim. The appellant-opponent further submitted that the request should be dealt with by the board in the interests of procedural economy.

XXII. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request filed with the letter dated 6 July 2011, or, alternatively, on the basis of one of the following auxiliary requests:

- the first auxiliary request received during oral proceedings;
- the second to fourth auxiliary requests, filed as the first to third auxiliary requests with the letter of 6 July 2011;
- the fifth auxiliary request, filed as the fourth auxiliary request with the letter of 23 December 2011;
- the sixth to ninth auxiliary requests, filed as the fifth to eighth auxiliary requests with the letter of 6 July 2011;

- the tenth and eleventh auxiliary requests, filed as the ninth and tenth auxiliary requests with the letter dated 9 December 2011.

Furthermore, it requested remittal to the department of first instance for further prosecution of the process claims.

The appellant (opponent) requested that the decision under appeal be set aside and that European patent No. 1128816 be revoked. It further requested that the board should make use of its power conferred by Article 111(1) EPC to proceed further with the case on substantive issues regarding the process claims.

Reasons for the Decision

1. *Admissibility*

1.1 The appeals are admissible.

1.2 Admission of the requests into the proceedings

1.2.1 The admission of changes to a party's submission after the filing of the statement of grounds of appeal and the reply thereto is, as specified by Article 13(1) RPBA, at the board's discretion and depends upon the circumstances of the case under consideration. According to Article 13(1) RPBA, the criteria to be considered when exercising this discretion are *inter alia* the complexity of the new subject-matter, the current state of the proceedings and the need for procedural economy. Account is taken of whether they

could have been filed earlier, and if so, the reasons why they were not (see R 16/09 of 19 May 2010, points 2.2.4 and 2.2.11). Moreover, the amendments should be of clear and simple nature and *prima facie* allowable (T 87/05 of 4 September 2007, point 2 of the reasons). A general principle is that the later the requests are filed, the less likely the requests will be held to be admissible.

1.2.2 The main request and auxiliary requests 2, 3, 8 and 9 were all filed with the letter dated 6 July 2001 at a late stage in the proceedings, as the main request and auxiliary requests 1, 2, 7 and 8 respectively.

1.2.2.1 The main request differs from the main request filed on 8 March 2007 in that the claims drafted as "product for use claims" (claims 19 to 21), which had been objected to in the board's communication dated 11 May 2011, have been deleted. This amendment constitutes a direct and clear response to an objection raised by the board of its own motion.

Moreover, process claim 19 has been amended by the introduction of a step h), namely a sterilizing step, and by the incorporation of a reference to the product of claim 1. These amendments represent a response to the board's communication, since the board had observed that the process claim was an independent claim and that the product obtained was not necessarily the product of claim 1. Furthermore, the amendments had been introduced to prevent further objections caused by the grounds for opposition. Thus, the amendments are *prima facie* a response to the grounds for opposition.

Consequently, the amendments to the main request are occasioned by developments during the appeal proceedings and *prima facie* address the issues raised by the board without giving rise to new ones and without adding complexity to the case under consideration. They constitute a direct, clear and fair attempt to respond to the board's communication. Therefore, although submitted after the filing of the statement of the grounds of appeal, the main request is admitted into the proceedings.

1.2.2.2 Auxiliary request 2 differs from auxiliary request 3 as upheld before the opposition division in an analogous manner to the way in which the main request differs from the previous main request (see point 1.2.2.1 above).

Consequently, auxiliary request 2 is admitted into the proceedings for analogous reasons to those stated above for the main request.

1.2.2.3 Auxiliary request 3 basically differs from auxiliary request 2 in that the expression "*under microscopic examination*" has been added to claim 1. The other amendments are analogous to the amendments made in auxiliary request 2.

Thus, the amendments introduced constitute a direct response to the board's communication.

Consequently, auxiliary request 3 is admitted into the proceedings.

1.2.2.4 Auxiliary request 8 differs from the main request as filed on 8 March 2007 in that all the product claims relating to the microspheres *per se* (previous claims 1 to 9) have been deleted.

Additionally, new claim 1 differs from independent claim 10 of the main request in that it incorporates the feature "*wherein the difference in diameter between the microspheres is from 0 µm to 150 µm*". This latter amendment in claim 1 represents a direct response to the board's observations in relation to the broad range of diameter size in the claims.

Furthermore, as for the main request, process claim 10 comprises a reference to the microspheres as "*defined in claim 1*" and the "product for use claims" have been deleted (claims 19 to 21). Therefore, the reasons given above for the main request apply *mutatis mutandis* to auxiliary request 8.

Consequently, auxiliary request 8 is admitted into the proceedings.

1.2.2.5 Auxiliary request 9 differs from the main request filed on 8 March 2007 in that all the product claims have been deleted.

The deletion of the product claims is seen as a direct response to the objections to them raised by the board. As already mentioned, the set of claims as granted contained an independent process claim.

The introduction of a step h), namely a sterilization step, in process claim 1 is a clear and simple response to the board's communication.

Consequently, auxiliary request 9 is admitted into the proceedings.

1.2.3 Auxiliary request 1 was submitted during the oral proceedings before the board, after the discussion on the novelty of the main request had taken place. This request was therefore submitted at a terminally late stage of the procedure.

Auxiliary request 1 basically differs from the main request in that claims 1-9 relating to the microspheres *per se* have been deleted. Moreover, the new claim 1, which corresponds to the previous independent claim 10, has been amended by the incorporation of the feature of dependent claim 13.

Additionally, independent process claim 9 has been amended by introducing the following feature: *"useful for embolization, which have a diameter ranging from 10 µm to 2,000 µm, and are substantially spherical and sterile*".

The discussion during the oral proceedings before the board of the novelty of the main request vis-à-vis documents (3) and (9) did not justify the filing of a new request. The novelty of the main request had been contested during the opposition proceedings and in the written proceedings in appeal. The assessment of the novelty of the subject-matter claimed in any requests vis-à-vis documents (3) and (9) could not have taken

the appellant-proprietor by surprise, since both documents had been on file since the beginning of the procedure, and no new issues were introduced during the oral proceedings before the board in this respect.

Furthermore, the re-drafting of the new claims which originate from a combination of prior claims 10 and 13 constitutes a shifting of the invention at a very late stage of the proceedings. The introduced amendments would have occasioned a new discussion on novelty and raised, *prima facie*, new issues in relation to the clarity (Article 84 EPC) of the terms in the new context of the claim.

Admitting new auxiliary request 1 during the oral proceedings would have put into question the basic principles governing fair *inter parte* proceedings. *Inter parte* appeal proceedings cannot be seen as a means for re-examining the application, nor does the patent proprietor have the absolute right to file sequential auxiliary requests in the course of the discussions before the board of appeal.

The appellant-proprietor should have been prepared to respond earlier to the objections of lack of novelty by filing an adequate set of auxiliary requests.

Accordingly, auxiliary request 1 is not admitted into the proceedings.

1.2.4 Auxiliary request 4 was filed as auxiliary request 3 with the letter dated 6 July 2011, i.e. at a late stage in the proceedings.

Claim 1 of auxiliary request 4 differs basically from claim 1 of the main request filed on 3 March 2007 in that the feature "*wherein the microspheres have a smooth surface such that no attrition occurs and no small-sized particles are generated from said microspheres*" has been included at the end of the claim.

The feature "*wherein the microspheres have a smooth surface such that no attrition occurs and no small-sized particles are generated from said microspheres*" originates from the description and was not present originally in any of the granted claims. This amendment raises new issues which would necessitate a complex assessment of the content of the description and is considered to be *prima facie* not allowable under Article 84 EPC.

Accordingly, auxiliary request 4 is not admitted into the proceedings.

1.2.5 Auxiliary request 5 was filed with the letter dated 23 December 2011, i.e. at a very late stage in the proceedings.

Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 4 filed with the letter of 6 July 2011 in that the word "*and*" has been replaced by the word "*or*" in the expression "*for prophylactic and therapeutic embolization*". This particular amendment can be seen as remedying an obvious error.

Auxiliary request 5 does not contain claims of the product category, since claims 1-18 have been reworded as use claims in the "Swiss-type" form.

The justification given by the appellant-proprietor was that the rewording of the product claims as use claims represents a fair attempt to overcome the appellant-opponent's objections of lack of novelty regarding the product claims.

However, as mentioned in point 1.2.3. above, the objection of lack of novelty raised against the product claims was long known to the appellant-proprietor, and was already present in the opposition proceedings and pursued again by the appellant-opponent in its grounds of appeal.

As a matter of fact, it was clear from the beginning that the assessment of novelty would be a major issue in the present case. Thus, it was the appellant-proprietor's duty to provide as early as possible, for a complete defence, all possible fallback positions, *inter alia* a rewording of the product claims as use claims. This was not the case with auxiliary request 5, which was filed at a late stage in the proceedings.

Nor, moreover, can the filing of said request be seen as a last chance attempt, since the issue of novelty had not been decided prior to the oral proceedings before the board and had not yet been assessed by the board at the time of filing.

In *inter partes* appeal proceedings the principle of fairness and equity must apply to all parties. Thus, in

the absence of any good reasons for its late filing, i.e. exceptional circumstances that justify the late filing, auxiliary request 5 is not admitted into the proceedings.

1.2.6 Auxiliary request 6 was filed with the letter dated 6 July 2011 as auxiliary request 5.

It basically differs from the main request as filed on 8 March 2007 in that the feature "*and wherein the microspheres are in hydrogel form and comprise 0.5% to 20% by weight polyvinylalcohol*" has been added to claim 1. Claim 10 has been amended by the incorporation of a reference to claim 1, and the process claim has been amended as mentioned for the main request in point 1.2.2.1 above, i.e. the "product-for-use" independent claims submitted in the course of opposition proceedings (claims 19 to 21) have been deleted.

Even if it is considered that the amendment introduced in claim 1 was made in an attempt to overcome new objections raised in the board's communication, it represents a real shifting of the invention and opens up new issues, especially regarding the clarity of the claim (Article 84 EPC).

Consequently, the amendments introduced in claim 1 are not of a clear and simple nature, and are not *prima facie* clearly allowable. Auxiliary request 6 is not admitted into the proceedings.

1.2.7 Auxiliary request 7 was filed with the letter dated 6 July 2011 as auxiliary request 6.

It basically differs from the main request as filed on 8 March 2007 by the addition of the feature "*wherein the difference in diameter between the microspheres is from 0 µm to 150 µm, when the particles are in the form of an injectable suspension*" in claim 1.

The other modifications in product claim 10 and process claim 19, as well as the deletion of the "product for use" claims, are analogous to the modifications mentioned for auxiliary request 6 (point 1.2.6. above).

The feature introduced in claim 1 of auxiliary request 7 is merely an optional and conditional feature which does not clearly restrict the claim vis-à-vis claim 1 of the main request, since the claimed microspheres are not necessarily in the form of a suspension.

Consequently, auxiliary request 7 is not admitted into the proceedings.

1.2.8 Auxiliary requests 10 and 11 were submitted very late, with the letter dated 9 December 2011, as auxiliary requests 9 and 10.

The filing of these requests is not justified by exceptional circumstances, since they do not respond to any new argument by the board or submission by the appellant-opponent. No other reason for their late filing was given by the appellant-proprietor than that they were an attempt to more clearly define the subject-matter claimed. This is, however, not a justification for late filing, since there had been

opportunities to file such auxiliary requests far earlier.

Additionally, each claim 1 of these auxiliary requests has been newly reformulated as a "product by process" claim (obtainable by the process as defined in any of the process claims 19 to 35). On the other hand, process claim 19 of both requests relates to a process for making microspheres according to claim 1. Thus, the reformulation of the independent claims in the form of loop references raises *prima facie* new issues in relation to the requirement of clarity (Article 84 EPC).
Therefore, amended claim 1 of auxiliary requests 10 and 11 is *prima facie* not allowable.

Consequently, auxiliary requests 10 and 11 are not admitted into the proceedings.

2. *Admission of additional documents and experimental data*

2.1 The opposition division did not admit into the proceedings documents (17) to (19), which were filed on 10 October 2007 (Rule 71a EPC 1973). The division considered that these documents were not *prima facie* relevant for novelty and inventive step and that they were not more relevant than the documents already on file.

The board considers that the opposition division was correct in exercising its discretionary power not to admit these documents under Rule 71a EPC 1973 by taking into account the circumstances of the case and by giving precedence to the criteria of relevance. Indeed,

the board cannot discern any new issue which has not been discussed before the opposition division and which could justify the finding of a misuse in the opposition division's exercise of discretion.

Consequently, documents (17) to (19) are not admitted into the proceedings.

2.2 Document (26) was filed with the letter of 9 December 2011, i.e. at a late stage in the appeal proceedings. Said document is a print of a Google search on "smooth microspheres" performed in 2011. This Google search is neither pertinent nor relevant to the present appeal case and document (26) is therefore not admitted into the proceedings.

2.3 Document (22) was filed with the appellant-opponent's statement of the grounds of appeal and can be considered as a reaction to the arguments of the decision of the opposition division (Article 12 RPBA). Although document (22) may possibly not be relevant for the decision, it is pertinent and therefore is admitted into the proceedings.

2.4 Document (23) was filed with the appellant-opponent's grounds of appeal. The document is an experimental report concerning the preparation of microspheres of polyvinylalcohol according to document (3). It was filed in order to support the appellant-opponent's arguments in relation to the novelty assessment. Moreover, the admissibility of document (23) was not disputed by the appellant-proprietor. Consequently, document (23) is admitted into the proceedings.

2.5 Experimental report (25) was filed on 27 June 2011 by the appellant-opponent in response to the board's communication. Its content is *prima facie* relevant for the assessment of novelty vis-à-vis document (3) and the appellant-proprietor's arguments in relation to the non-enabling disclosure of document (3). Moreover, the appellant-proprietor has been able to assess its content and to reply to it.

Consequently, experimental report (25) is admitted into the appeal proceedings.

2.6 Experimental report (27) was filed on 9 December 2011 by the appellant-proprietor. It represents an attempt to respond to experimental report (25). Its content is *prima facie* relevant for the assessment of novelty vis-à-vis document (3). Consequently, experimental report (27) is admitted into the proceedings.

2.7 Document (24) was filed by the appellant-opponent with the letter of 21 April 2011 in an attempt to respond to the appellant-proprietor's arguments in appeal proceedings. This document discloses spherical cross-linked polyvinylalcohol beads (see Title; abstract; page 11 third paragraph). Document (24) is therefore *prima facie* relevant for the assessment of novelty and/or inventive step. Moreover, it was submitted well enough in advance of the oral proceedings before the board of appeal, which means that the appellant-proprietor had sufficient time to prepare his reply. Document (24) is admitted into the proceedings.

3. *Main request - novelty*

3.1 The main request was objected to by the appellant-opponent on the basis of Article 123(2) EPC and Rule 80 EPC in the course of the oral proceedings before the board of appeal. However, the board sees no need to conclude on these two issues for the main request, since the request fails for other reasons, as will become evident from the paragraphs below.

3.2 Document (3)

3.2.1 Document (3) discloses cross-linked polyvinylalcohol microspheres which are used as particulate emboli, and the method of preparation thereof. The microspheres have a size ranging from 100 to 1,500 µm (Abstract; Figures 1-4) and have as constituent cross-linked polyvinylalcohol of "low molecular weight" type (see page 68, Materials). Two types of microsphere are made, namely with and without barium sulphate (see page 68, Methods). The microspheres disclosed in document (3) have a substantially spherical shape, since the document states that "*this method led to the formation of nonaggregatory, predominantly spherical beads in less than one hour*" (page 69, left-hand column, end of first paragraph) and that "*Figure 3 shows the SEM of the PVA microsphere having a barium sulphate content of 40 wt%. The predominantly spherical shape of the microspheres could be ascertained from the photomicrograph*" (see page 69, right column).

The microspheres disclosed in document (3) are inevitably sterile, since document (3) states that "*it was observed that the barium sulphate was firmly*

trapped inside the microspheres as it did not leach out on prolonged standing in water, on sonication or on steam sterilization in 0.9% saline" and "*as in the case of barium sulphate, there was no migration of methyl iothalamate when the microspheres were subjected to sonication or steam sterilization*" (see pages 69, right-hand column, and 70, left-hand column, first and second paragraphs).

According to document (3), the microspheres are "*presumed to perform favourably in vascular occlusion*" (see page 72, conclusions). The formation of emboli on arteries using heparinized calf blood is explicitly mentioned on page 71 of document (3).

Consequently, document (3) anticipates all the features of the subject-matter claimed in claim 1 of the main request.

3.2.2 The relevance of document (3) was contested by the appellant-proprietor in relation to the "sterile" character of the microspheres and their "suitability for embolization". Moreover, the appellant-proprietor submitted that the content of document (3) concerned a non-enabling disclosure.

As stated above, document (3) studies the behaviour of the $BaSO_4$ or methyl iothalamate loaded microspheres on steam sterilization (see page 70). The explicit sterile character of the microspheres cannot therefore be denied.

As regards the term "useful for embolization" in claim 1 of the main request, it only reflects a

suitability of the claimed microspheres for embolization. Document (3) mentions the use of the microspheres as emboli several time (Abstract; pages 71 and 72). Furthermore, there is no reason to doubt the suitability for embolization of microspheres having the same size and shape as the microspheres of the present invention.

As regards the argument of lack of enablement of the disclosure of document (3), three documents were filed by the parties with experiments repeating the process of preparation of the microspheres disclosed in document (3), namely experimental reports (23), (25) and (27).

The appellant-proprietor filed in support of its argumentation of lack of enablement of the disclosure the experimental report in document (27) and based its argumentation of non-enablement mainly on the results of the experimental reports in documents (23) and (27).

The experiments in document (27) attempted to repeat the process of document (3) for making microspheres with $BaSO_4$ but did not manage to produce any microspheres. The result of the experiment was a mass of fibres which stuck to the impeller and which may not be regarded as microspheres. The content of document (27) is, however, not sufficient to show a lack of enablement of the disclosure of document (3).

The polyvinylalcohol used in document (27) has a molecular weight of 31 to 50 kDa, which cannot qualify as a low molecular weight PVA and is higher than the low molecular weight of the PVA used, for instance, in

the experiment in document (23). The board is therefore not convinced that the polyvinylalcohol used in document (27) is the same as that used in the experiments in documents (3) or (25) and that it can be considered a low molecular weight polyvinylalcohol. The presence of a heating step at 50°C, absent from the process in documents (3), (23) or (25), in order to dissolve the polyvinylalcohol, is an indication contrary to the appellant-proprietor's assertions.

Consequently, the technical information of document (27) does not disprove that the process of document (3) is enabling.

Additionally, the experiments in document (23) repeat the process of preparation of the microspheres of document (3) without $BaSO_4$. The microspheres obtained are shown to be smooth and spherical (see "Results" and "Conclusion"). The steering speed used during the process was lowered to 400 rpm, instead of 2,000 rpm as in document (3), since the "dispersions were unstable at 2,000 rpm and produced many particle fragments". The beaker was of the same size in both documents (3) and (23) and the stirrer was in document (3) a "half-moon stainless steel paddle stirrer" and in document (23) a PTFE stirrer (see "Comments on method" on page 3). The size of the stirrer in document (3) was not stated. Another difference consisted in the nature of the oil phase used in the process.

The differences in the processes cannot however serve to be regarded as evidence for a lack of enablement of the process in document (3). Document (3) is silent about the size of the stirrer, but it can be expected

to have an influence on the stirring speed which can be used. A lowering of the stirring speed down to 400 rpm is a self-evident adaptation between the stirrers available today and the size of the beaker.

On the other hand, document (23) shows explicitly that smooth and spherical microspheres had actually been obtained (Figure 1).

The experiments in document (25) repeat the process of making the microspheres comprising $BaSO_4$ of document (3). The successfully produced microspheres appear smooth and spherical under microscopic examination (Figure 1). Apart from the differences in the oil phase, the products and process conditions in the experiments of documents (3) and (25) are comparable. Thus, in view of the experimental results set forth in document (25), the board does not see any reason to question the enablement of the preparation process in document (3). As regards the argument concerning the feasibility of the stirring step in a beaker of 100 ml, document (25) shows that it appears possible to reach a speed of 2,000 rpm in a beaker of the chosen size with an appropriate stirrer.

3.2.3 Consequently, document (3) is novelty-destroying for the subject-matter of claim 1 of the main request.

3.3 Document (9)

3.3.1 Document (9) (understood to refer to the English translation submitted as document 9.2) discloses microspheres for embolization of the hepatic artery made from cross-linked polyvinylalcohol (see Abstract

and paragraph I.2., pages 2-3). The microspheres have a size of 150+/-30 µm (page 4, par. VI). Furthermore, the microspheres are "sphere-like particles under the optical microscope" (page 6). The microspheres are sterilized (page 4, paragraph IV, "Test of sterilization") and used for embolization (page 4, paragraph VI, "Test of embolization of the hepatic artery", and paragraph VII).

Consequently, document (9) anticipates all the features of the subject-matter claimed in claim 1 of the main request.

3.3.2 The relevance of document (9) was contested by the appellant-proprietor for lack of enablement of its disclosure.

According to the appellant-proprietor, document (9) gives only a general teaching regarding the manufacture of the microspheres of polyvinylalcohol. It submitted that the process used in document (9) concerns an emulsification polymerization, without giving any indication regarding the catalyst, the nature of the water in oil emulsion, or the dispersant.

However, document (9) is a scientific document which relates to the use of microspheres for embolization and to the comparison of different types of microsphere for said use. Thus, the main focus of interest of document (9) is the studies concerning the use of the microspheres in embolization and not the specific details of their manufacturing process. However, it is part of the general knowledge of the skilled person to know how to prepare PVA microspheres and which

catalysts to select for emulsion polymerization. Document (5) confirms that there are a number of catalysts, emulsions and emulsifying agents useful for the polymerization and cross-linking of polyvinylalcohol (see document (5) col. 3, line 58 to col. 4, line 24 and example 1).

The board is convinced that the skilled person would be able to reproduce the microspheres disclosed in document (9), as shown by the photographs on page 6, following the manufacturing process mentioned therein.

Consequently, document (9) is novelty-destroying for the subject-matter of claim 1 of the main request.

3.4 For the reasons given in points 3.2 and 3.3 above, the main request fails for lack of novelty of claim 1 (Articles 52(1) and 54 EPC).

4. *Auxiliary request 2 - Article 84 EPC*

4.1 Claim 1 of auxiliary request 2 has been amended to include the expression "*and wherein the surface of the microspheres appears smooth under less than 1,000-fold magnifications*" in order to overcome the lack of novelty of the main request.

4.2 Therefore, the question to be answered with respect to the clarity of the claim within the meaning of Article 84 EPC is whether it is possible to determine whether or not a particular embodiment falls within the claim.
Even if it is considered in favour of the appellant-proprietor that the skilled person would be able in

most cases to determine whether or not the surface of a microsphere is smooth, the condition of the appearance of smoothness is relative and subject to the observer and to the conditions under which it is observed. In order to establish a valid comparison between different microspheres having a certain degree of smoothness, a standard definition or a standard test would be required.

However, the claim does not even state the lowest magnification possible for observing the microspheres, nor does the description disclose any standard method. As a matter of fact, the description does not give any definition of the desired smoothness, nor do the examples illustrate that the microspheres are indeed smooth. There is indeed no observation reported on the microspheres prepared in the examples. Therefore, it is not possible to ascertain whether the surface of the claimed microspheres has to be perfectly smooth or if a certain number of surface irregularities may be tolerated.

In view of above, claim 1 of auxiliary request 2 does not fulfil the requirement of Article 84 EPC.

4.3 According to the appellant-proprietor, the term "smooth" is clear to the skilled person and serves to differentiate the claimed microspheres from those in the prior art.

It submitted that the definition of smoothness is common and was given in the description, as "*no attrition occurs and no small-sized particles are generated from said microspheres*" (page 8, lines 11-13 of the application as filed) and that the surface of

the microsphere should appear smooth at any magnification below the claimed magnification.

However, as explained in point 4.2 above, the subjective character and relativeness of the smoothness at any magnification below 1,000-fold cannot serve as a clear limitation of the claimed microspheres vis-à-vis the prior-art microspheres.

Moreover, the property presumably conferred as a result of the smooth surface of the microspheres, namely that "*no attrition occurs and no small-sized particles are generated from said microspheres*", renders the appreciation of the required smoothness even more unclear in the absence of explanations and experimental modalities in the form of a reproducible test in the application as filed.

The reference by the appellant-proprietor to the smooth beads shown in document (24) serves only to show that the term "smooth" is known, and is otherwise a further illustration of the subjectivity and relativeness of said term. This document shows pictures of "smooth" beads, but lacks any information on the magnification used for the photographs and does not provide any further definition of the term (page 11, right-hand column, "Preparation of PVAc and PVA beads; page 12, Fig. 2).

4.4 Consequently, auxiliary request 2 fails to meet the requirements of Article 84 EPC.

5. *Auxiliary request 3 - Article 84 EPC*

Claim 1 of auxiliary request 3 merely differs from auxiliary request 2 in that the term "*under microscopic examination*" has been added to claim 1.
Therefore, the reasons stated above for auxiliary request 2 apply *mutatis mutandis* to auxiliary request 3. The addition of the term "*under microscopic examination*" in claim 1 of auxiliary request 3 does not give any further indication as to a standard method for determining whether or not the particles are sufficiently smooth.
Thus, auxiliary request 3 fails, since claim 1 does not fulfil the requirements of Article 84 EPC.

6. *Auxiliary request 8 - Article 84 EPC*

6.1 Claim 1 of auxiliary request 8 relates to an injectable and sterile composition comprising cross-linked polyvinylalcohol microspheres. Additionally, claim 1 was amended by the introduction of the expression "*wherein the difference in diameter between the microspheres is from 0 µm to 150 µm*".
The appellant-opponent objected to auxiliary request 8 under Article 123(2) EPC. However, the board does not see any need to come to a decision on this point, in view of the fact that the request fails for other reasons.

6.2 The amendment to claim 1 introduces an inconsistency between the delimitation given in the claim for the size of the microspheres, i.e. a diameter ranging from 10 µm and 2,000 µm, therefore including microspheres with a diameter of less than 150 µm, and the fact that

the difference in diameter may be from 0 µm to 150 µm, which renders the subject-matter of the claim unclear. Moreover, the added feature introduces an unclear limitation to the size distribution of the microspheres, since the claim encompasses populations of microspheres having a uniform and narrow size, as well as populations having a multi-modal size. Therefore, claim 1 of auxiliary request 8 does not fulfil the requirements of Article 84 EPC.

6.3 The appellant-proprietor argued that the term was comprehensible to the reader willing to understand, since it was clear how to measure the difference in diameter. In other words, the difference between the smallest and biggest particles should not be more than 150 µm.
Even if it were to be considered that the skilled person would know how to measure the difference in diameters, claim 1 encompasses particles having a diameter smaller than 150 µm (10 µm is the specific lowest limit) and presenting simultaneously a difference in diameter of up to 150 µm. The appellant-proprietor's arguments do not overcome the objection of lack of consistency, in particular for microspheres having such smaller size.

6.4 Therefore, auxiliary request 8 fails for lack of clarity under Article 84 EPC.

7. *Remittal to the first instance (Article 111(1) EPC)*

7.1 Auxiliary request 9 contains only process claims relating to the process of preparing microspheres of

cross-linked polyvinylalcohol having a size ranging from 10 µm to 2,000 µm.

As a matter of fact, the set serving as a basis for the decision of the opposition division contained an independent process claim with no reference to the product of claim 1. In particular, the set of claims as granted contained an independent process claim 19.

The opposition division decided to maintain the patent in the amended form on the basis of the third auxiliary request as filed during the oral proceedings before the opposition division. This request comprised an independent process claim (claim 22) with no reference to the product claim.

The decision of the opposition division did not address the process claimed under Articles 54 and 56 EPC. Moreover, the minutes of the oral proceedings before the opposition division give no indication that the process claim had even been discussed during the oral proceedings before the department of first instance.

Consequently, the reasons for the maintenance of the process claim are neither stated in the decision nor are they implicitly apparent. Thus the process claimed in claim 1 of auxiliary request 9 has to be investigated on its own merits.

Consequently, the board uses its discretionary power under Article 111(1) EPC to remit the case to the department of first instance for further prosecution on the basis of a set of claims containing method claims only.

7.2 The appellant-opponent was not in favour of a remittal to the department of first instance since, in its opinion, the opposition division had tacitly maintained the process claim and the patentee had not been adversely affected by its decision. Moreover, it submitted that a remittal to the first instance would not be in the interests of procedural economy.

7.3 The board cannot follow the appellant-opponent's arguments against the remittal.

The appellant-proprietor does not know the reasons why the process claim was considered novel and inventive by the opposition division. To discuss the patentability of the process claims for the first time at the oral proceedings before the board of appeal would deprive the appellant-proprietor of the possibility to properly challenge the appellant-opponent's arguments.

In view of the fact that the decision of the opposition division has a fundamental deficiency, remittal to the first instance must be seen as a fair and equitable way of treating the parties. This aspect clearly outweighs the need for procedural economy.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the ninth auxiliary request submitted as auxiliary request 8 with letter of 6 July 2011.

The Registrar: The Chairman:

N. Maslin M. C. Ortega Plaza