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Datasheet for the decision of 1 March 2018

Case Number: T 0712/13 - 3.3.01

Application Number: 06122165.1

Publication Number: 1780544

IPC: G01N33/53, C08G63/00

Language of the proceedings: EN

Title of invention:
Magnetic particles for diagnostics

Patent Proprietor:
JSR Corporation

Opponent:
Life Technologies Corporation

Relevant legal provisions:
EPC R. 76(2)(c), 76(2)(b)
EPC Art. 56, 123(2), 114(2), 104(1)
RPBA Art. 12(4), 13(1), 16

Keyword:

Admissibility of opposition (yes)
Inventive step - (no)
Amendments - added subject-matter (yes) - auxiliary requests 3 and 3a
Late-filed request - request clearly overcoming objection (no) - auxiliary request 3b
Different apportionment of costs - (no)

Decisions cited:

T 1059/98

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Case Number: T 0712/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 1 March 2018

Appellant: (Patent Proprietor)	JSR Corporation 6-10, Tsukiji 5-chome, Chuo-ku Tokyo 104-8410 (JP)
Representative:	TBK Bavariaring 4-6 80336 München (DE)
Respondent: (Opponent)	Life Technologies Corporation 5791 Van Allen Way Carlsbad, CA 92008 (US)
Representative:	HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 January 2013 revoking European patent No. 1780544 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	M. Blasi

Summary of Facts and Submissions

I. European patent No. 1 780 544 was granted with a set of nine claims, containing four independent claims. The granted claims are identical to claims 1 to 9 of the patent application as filed.

The four independent claims 1, 4, 5 and 7 read as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group.*

4. A probe-bound particles [sic] *comprising the organic polymer particles as defined in any one of claims 1 to 3 and a probe bound with the organic polymer particles.*

5. A process for producing organic polymer particles having a carboxyl group and 2,3-dihydroxypropyl group, the process comprising:

forming a polymer part by polymerizing a monomer part which contains a monomer (A) producing a carboxyl group by hydrolysis; and

hydrolyzing the polymer part.

7. A process for producing organic polymer particles having a carboxyl group and 2,3-dihydroxypropyl group, the process comprising:

forming a polymer part by polymerizing a monomer part which contains a monomer (B) producing a 2,3-dihydroxypropyl group by hydrolysis; and

hydrolyzing the polymer part."

II. The patent was opposed under Article 100(a) and (b) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step and was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

III. The documents cited in the opposition proceedings included the following:

D1: WO 2005/015 216 A1

D3: US 5,091,206 A

D11: JP 2005-232 237 A (2 September 2005)

D11B: English translation of D11

D15: "Measurement of the carboxyl groups of Examples 24 and 25 of WO 2005/015216 (D1)"

As for documents E0, E1 and D16 to D30 further mentioned in this decision, reference is made to point VII of the board's communication pursuant to Article 15(1) RPBA, dated 31 January 2018.

IV. In the course of the opposition proceedings, the patent proprietor requested that the opposition be rejected as inadmissible and, in case that request were to be refused, submitted claim requests, viz. an amended main request and seven auxiliary requests, all filed with a letter dated 5 October 2012.

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

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group, wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 1 to 300 µmol/g."*

Claims 1, 5 and 7 of **auxiliary request 3** read as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group, wherein the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group are obtained by a process comprising a step of producing an ester bond by reacting a hydroxyl group originating from a 2,3-dihydroxypropyl group in organic polymer particles having the 2,3-dihydroxypropyl group with a carboxylic anhydride.*

5. A process for producing organic polymer particles having a carboxyl group and 2,3-dihydroxypropyl group, wherein the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group are obtained by a process comprising a step of producing an ester bond by reacting a hydroxyl group originating from a 2,3-dihydroxypropyl group in organic polymer particles having the 2,3-dihydroxypropyl group with a carboxylic anhydride, the process comprising: forming a polymer part by polymerizing a monomer part which contains a monomer (A) producing a carboxyl group by hydrolysis; and hydrolyzing the polymer part.

7. A process for producing organic polymer particles having a carboxyl group and 2,3-dihydroxypropyl group, wherein the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group are obtained by a process comprising a step of producing an ester bond by reacting a hydroxyl group originating from a 2,3-dihydroxypropyl group in organic polymer particles having the 2,3-dihydroxypropyl group with a carboxylic anhydride,

the process comprising: forming a polymer part by polymerizing a monomer part which contains a monomer (B) producing a 2,3-dihydroxypropyl group by hydrolysis; and hydrolyzing the polymer part."

Claim 1 of **auxiliary request 7** reads as follows:

"1. An organic polymer particles [sic] *comprising:*

nuclear particles;

a magnetic material layer containing super-paramagnetic fine particles and provided in the outer layer of the nuclear particles; and

a polymer part having a carboxyl group and 2,3-dihydroxypropyl group and provided in the outer layer of the magnetic material layer,

wherein at least the surface of the organic polymer particles comprises a carboxyl group and a 2,3-dihydroxypropyl group."

V. Oral proceedings before the opposition division were held on 7 November 2012, during which the patent proprietor filed further claim requests as auxiliary requests 1a and 3a.

Claim 1 of **auxiliary request 3a** reads as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group, wherein the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group are obtained by a process comprising a step of producing an ester bond by reacting a hydroxyl group originating from a 2,3-dihydroxypropyl group in organic polymer particles having the 2,3-dihydroxypropyl group with a carboxylic anhydride,*

wherein the carboxylic anhydride is a polyvalent carboxylic anhydride and the step of producing an ester bond is a step of producing an ester bond and a carboxyl group."

VI. The decision under appeal is the decision of the opposition division, announced on 7 November 2012 and posted on 14 January 2013, revoking the patent.

VII. According to the decision under appeal:

- The opposition was admissible.

- The subject-matter of claim 1 of the main request and claim 1 of auxiliary request 1 lacked novelty over the disclosure of document D1.

- Auxiliary requests 1a and 3a were not admitted into the proceedings.

- The amendments in auxiliary requests 2, 3, 4 and 5 introduced subject-matter extending beyond the content of the application as filed.

- The subject-matter of claim 1 of auxiliary request 6 and claim 1 of auxiliary request 7, both relating to particles comprising a core, a magnetic material layer containing superparamagnetic fine particles and a polymer part having a carboxyl group and a 2,3-dihydroxypropyl group provided in the outer layer of the magnetic material layer, lacked an inventive step in view of the disclosure of document D3 in combination with document D11:

Document D3 disclosed organic polymer particles having a core-shell structure and containing superparamagnetic particles, useful for immunoassays and other diagnostic applications. The particles according to claim 1 of both auxiliary requests 6 and 7 differed from the

particles disclosed in example 7 of document D3 solely in that the polymer comprised 2,3-dihydroxypropyl groups. The technical problem to be solved was the provision of particles exhibiting low non-specific adsorption and high sensitivity. It was known from prior-art document D11 that the level of non-specific adsorption was low when 2,3-dihydroxypropyl groups were present on the surface of a polymer bead.

VIII. The patent proprietor (appellant) filed a notice of appeal against that decision.

IX. With the statement setting out the grounds of appeal dated 24 May 2013 the appellant maintained its highest-ranking request for rejection of the opposition as inadmissible, as well as the claim requests which had formed the subject of the decision under appeal (viz. the main request and auxiliary requests 1 to 7 filed with letter of 5 October 2012 and auxiliary requests 1a and 3a filed on 7 November 2012). The appellant also submitted two new sets of claims as auxiliary requests 1b and 1c and experimental data.

The experimental data were presented on pages 15 to 20 of the appellant's letter of 24 May 2013 (those pages will hereinafter be referred to as document **E0**).

Claims 1 and 4 of **auxiliary request 1b** read as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group, wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g.*

4. A probe-bound particles [sic] *comprising the organic polymer particles as defined in any one of claims 1*

to 3 and a probe bound with the organic polymer particles."

Claims 1 and 4 of **auxiliary request 1c** are identical to claims 1 and 4 of auxiliary request 1b, except for the requirement that the amount of the carboxyl group per the amount of solid components of the organic polymer particles must be within the range of 10 to 100 µmol/g.

X. With its reply to the appellant's statement of grounds the opponent (respondent) submitted *inter alia* a new objection, viz. that the subject-matter of claim 1 of the main request lacked novelty over the commercial product "Dynabeads® M-270 Carboxylic Acid".

The respondent also filed documents **D16 to D18, D18a** and **D19 to D23** in support of the alleged public prior use, and two further documents which were numbered **D24** and **D25**.

XI. With a letter dated 25 March 2014, the appellant filed claim requests designated as auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i and indicated that the following claim requests were being pursued: main request, auxiliary requests 1b, 1c, 1d, 1e, 1f, 1g, 1h, 1i, 3, 3a, 7, in that order.

Furthermore, the appellant submitted experimental data (hereinafter: document **E1**) and documents **D26 to D30** providing additional information with regard to the content of E1.

Claim 1 of **auxiliary request 1d** reads as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group,*

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein the amount of the 2,3-dihydroxypropyl group per the amount of solid components of said organic polymer particles is 10 µmol/g or more."

Claim 1 of **auxiliary request 1e** is identical to claim 1 of auxiliary request 1d, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

Claim 1 of **auxiliary request 1f** reads as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group,*

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein at least the surface of the organic polymer particles comprises a polymer part and at least the surface of the polymer part has a carboxyl group and a 2,3-dihydroxypropyl group."

Claim 1 of **auxiliary request 1g** is identical to claim 1 of auxiliary request 1f, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

Claim 1 of **auxiliary request 1h** reads as follows:

"1. An organic polymer particles [sic] *comprising a carboxyl group and 2,3-dihydroxypropyl group,*

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein the amount of the 2,3-dihydroxypropyl group per the amount of solid components of said organic polymer particles is 10 µmol/g or more,

wherein at least the surface of the organic polymer particles comprises a polymer part and at least the surface of the polymer part has a carboxyl group and a 2,3-dihydroxypropyl group."

Claim 1 of **auxiliary request 1i** is identical to claim 1 of auxiliary request 1h, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

XII. In a communication issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board observed, *inter alia*, that claim 1 of the main request was not restricted by any mandatory feature relating to the intended use of the particles or to their suitability for diagnostic methods. Thus it might be asked whether data relating to the performance of certain more specific particles in a specified diagnostic method (as provided in documents E0 and E1, if admitted) should be taken into account to formulate the objective technical problem which was to apply to the entire scope claimed. In view of these considerations, the objective technical problem might be defined as the provision of further organic polymer particles (see point 6.4 of the board's communication).

XIII. With a letter dated 23 February 2018, the appellant submitted further claim requests designated auxiliary requests 1b-A, 1c-A, 1d-A, 1e-A, 1f-A, 1g-A, 1h-A and 1i-A, each request consisting of a single claim.

The sole claim of **auxiliary request 1b-A** reads as follows:

"1. A probe-bound particles [sic] *for immunoassay comprising organic polymer particles and a primary probe bound with the organic polymer particles,*

the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group,

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g."

The sole claim of **auxiliary request 1c-A** is identical to that of auxiliary request 1b-A, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

The claim of **auxiliary request 1d-A** reads as follows:

"1. A probe-bound particles [sic] *for immunoassay comprising organic polymer particles and a primary probe bound with the organic polymer particles,*

the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group,

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein the amount of the 2,3-dihydroxypropyl group per the amount of solid components of said organic polymer particles is 10 µmol/g or more."

The claim of **auxiliary request 1e-A** is identical to that of auxiliary request 1d-A, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

The claim of **auxiliary request 1f-A** reads as follows:

"1. A probe-bound particles [sic] *for immunoassay comprising organic polymer particles and a primary probe bound with the organic polymer particles,*

the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group,

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein at least the surface of the organic polymer particles comprises a polymer part and at least the surface of the polymer part has a carboxyl group and a 2,3-dihydroxypropyl group."

The claim of **auxiliary request 1g-A** is identical to that of auxiliary request 1f-A, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

The claim of **auxiliary request 1h-A** reads as follows:

"1. A probe-bound particles [sic] *for immunoassay comprising organic polymer particles and a primary probe bound with the organic polymer particles,*

the organic polymer particles comprising a carboxyl group and 2,3-dihydroxypropyl group,

wherein the amount of the carboxyl group per the amount of solid components of said organic polymer particles is 5 to 100 µmol/g,

wherein the amount of the 2,3-dihydroxypropyl group per the amount of solid components of said organic polymer particles is 10 µmol/g or more,

wherein at least the surface of the organic polymer particles comprises a polymer part and at least the

surface of the polymer part has a carboxyl group and a 2,3-dihydroxypropyl group."

The claim of **auxiliary request 1i-A** is identical to that of auxiliary request 1h-A, except for the requirement that the carboxyl group content must be in the range 10 to 100 µmol/g.

XIV. Oral proceedings before the board were held on 1 March 2018. In the course of the oral proceedings, the appellant filed a further claim request as auxiliary request 3b, to be inserted in the hierarchy of its requests after auxiliary request 3 and before auxiliary request 3a.

The sole claim of **auxiliary request 3b** is identical to claim 1 of auxiliary request 3a (see point V above).

XV. The appellant's arguments may be summarised as follows:

Admissibility of the opposition

The opposition was inadmissible, since revocation of the opposed patent had not been requested. Instead, in point 8 of the notice of opposition, the appellant had requested revocation of EP 1 600 441. This was, however, not the patent which was the subject of the opposition and the present appeal proceedings.

Admission of evidence

During the proceedings at first instance, the discussion of the main request had focused on the issue of novelty rather than inventive step. The experimental data according to E0 had been submitted subsequently, in support of inventive step. Since it was not usual, or even possible, to include data relating to every conceivable fallback position in an application, it was

only fair that an applicant/patent proprietor should, as a rule, be permitted to rely on additional data in support of amended claims which contained further limitations.

Document E1 provided supplementary data in reaction to the respondent's formal objections to the content of E0, and to back up the appellant's arguments in support of the inventive step of auxiliary requests 1b to 1i.

Inventive step - main request

The particles defined in claim 1 of the main request differed from the magnetic polymer particles according to example 7 of document D3 firstly by having a 2,3-dihydroxypropyl group and secondly by having a carboxyl group content in the range of 1 to 300 µmol/g.

While not explicitly referring to the intended use of the organic particles, claim 1 should be read and understood in the general context of the patent, according to which it was clear that the particles were provided for diagnostic purposes.

The range for the carboxyl content was selected in order to minimise nonspecific adsorption when the particles were used in diagnostic methods for immobilising a probe, and to achieve a high signal intensity and high signal-to-noise ratio irrespective of any difference in sample preparation protocols. The presence of 2,3-hydroxypropyl groups was likewise associated with decreased non-specific adsorption.

These advantages were mentioned and supported in the patent in suit as well as in the application as filed, in particular in experimental examples 1 to 3 (paragraphs [0272] to [0289] of the patent in suit).

While it was conceded that the comparative tests described in the patent and the application as filed did not show a comparison between a carboxyl group content in the upper part of the range 1 to 300 µmol/g and a content higher than 300 µmol/g, the description contained an explicit statement of the inventors' knowledge that non-specific adsorption would increase at a carboxyl content higher than 300 µmol/g. This was further confirmed by the data provided in test reports E0 and E1.

Starting from the technical teaching of document D3, the objective technical problem to be solved was thus the provision of polymer particles achieving low non-specific adsorption and a good signal-to-noise ratio.

Document D3, teaching that a high content of carboxyl groups was desired, did not point the person skilled in the art towards lowering the content of carboxyl groups to be within the range defined in claim 1 of the main request. Furthermore, D3 did not disclose or suggest functionalisation with 2,3-dihydroxypropyl groups.

The person skilled in the art would not have combined the teaching of document D11 with that of document D3, since the chemical functionalisation taught in document D3 was designed for polystyrene particles, whereas document D11 related to polyether particles and, unlike D3, did not disclose magnetic particles.

Even if D11 were to be consulted, that document did not contain a clear technical teaching and did not suggest employing a 2,3-dihydroxypropyl group. Although D11 stated that hydrolysis of epoxy groups situated on the particle surface could reduce non-specific adsorption, the examples in D11 showed the exact opposite.

Under these circumstances, the cited prior-art documents could not lead the way to the particles defined in claim 1, even if the objective technical problem were to be defined as the provision of further polymer particles.

For these reasons, the subject-matter of claim 1 was not obvious having regard to the prior art.

Admission of auxiliary requests

Auxiliary requests 1b and 1c had been presented in reaction to the opponent's experimental data (D15) and the opposition division's finding that the subject-matter according to the main request lacked novelty. The opposition division's reasoning on that issue had been fully accessible only after receipt of the written decision. The requests could not have been filed during the proceedings at first instance, since the opposition division, at the oral proceedings of 7 November 2012, refused to accept further requests.

Auxiliary requests 1d to 1i and 1b-A to 1i-A had all been presented in reaction to arguments and objections raised by the respondent and the board. The requests were all based on the main request, amended to include certain straightforward limitations. Modifying existing requests in response to new and unforeseeable facts and arguments was a usual and justified way of defending a patent.

Auxiliary request 3a had been presented in the first-instance proceedings in reaction to an objection raised by the opposition division in its written preliminary opinion. The opposition division's decision not to admit auxiliary request 3a was not reasoned and was not based on a proper consideration of all the facts.

Auxiliary request 3b, which consisted of a sole claim identical to claim 1 of auxiliary request 3a, was presented in reaction to an objection which had been raised for the first time at the oral proceedings before the board, namely that claim 5 of auxiliary request 3a, for the same reasons as claim 7 of auxiliary request 3, did not meet the requirements of Article 123(2) EPC.

Inventive step - auxiliary requests 1b to 1i-A

The data provided in the patent in suit and in documents E0 and E1 particularly supported the narrower ranges defined for the carboxyl group content in auxiliary requests 1b and 1c; apart from that, the inventive-step assessment remained the same as set out for the main request.

Auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i each contained one or both of the explicit requirements that the 2,3-dihydroxypropyl content was at least 10 µmol/g and that the functional groups were located on the particle surface. This was to address the respondent's argument that the functional groups did not provide a technical effect across the entire scope claimed (since according to the respondent's interpretation, claim 1 of the higher-ranking requests covered embodiments wherein the functional groups were buried inside the particles or the 2,3-dihydroxypropyl content was too low to produce a noticeable technical effect).

The amendments carried out in auxiliary requests 1b-A, 1c-A, 1d-A, 1e-A, 1f-A, 1g-A, 1h-A and 1i-A, in comparison with auxiliary requests 1b, 1c, 1d, 1e, 1f, 1h and 1i, respectively, clearly established that the particles to be considered had to be suitable for use in immunoassays and capable of binding a probe, and

that this aspect therefore had to be taken into account in the inventive-step discussion. In that context, it was pointed out that document D3 did not disclose probe-bound particles in example 7, and document D11 taught that epoxy groups were intended for probe binding (rather than carboxyl groups taught in D3). The person skilled in the art would have had no incentive to combine two approaches which used different functional groups for probe binding.

Auxiliary request 3 - amendments

The amendments effected in claims 1, 5 and 7 of auxiliary request 3 found support on pages 39, 40, 42, 44, 45 and 46 of the application as filed. While the amendments were derived from the "third embodiment" of the invention, major parts of the scope of that embodiment fell within the scope of the claims as granted (i.e. the "first embodiment"). It was immediately evident to a skilled person reading the application that the first embodiment and the third embodiment overlapped to such an extent that the method of introducing a carboxyl group according to the third embodiment might be applied to the method of introducing a carboxyl group in the first embodiment as well. In any case, even the original disclosure of the third embodiment alone supported particles having both carboxyl groups and 2,3-dihydroxypropyl groups.

Auxiliary request 7 - inventive step

The arguments in favour of inventive step with regard to claim 1 of auxiliary request 7 were essentially the same as for claim 1 of the main request. That the particles according to auxiliary request 7 were magnetic was another reason for not combining the teaching of document D3 with that of D11, since D11

was not about magnetic particles. The claimed particles were inventive due to the unexpected technical benefit that the presence of 2,3-dihydroxypropyl groups decreased the undesirable nonspecific adsorption.

Different apportionment of costs

A different apportionment of costs should be ordered. In the proceedings before the opposition division, the respondent had filed a huge amount of paper without discussing the relevance thereof. This strategy, which caused confusion and additional work, continued at the appeal stage. Furthermore, the respondent had presented a new objection based on allegations of a public prior use in respect of which a series of documents had been filed.

XVI. The respondent's arguments may be summarised as follows:

Admissibility of the opposition

The patent number EP 1 600 441 was mentioned only once in the notice of opposition. This was a typographical error. The notice of opposition and EPO Form 2300E correctly identified the opposed patent and confirmed that the opposition was filed against the patent as a whole.

Admission of evidence

Test report E0, allegedly showing that the choice of a carboxyl concentration in conformity with the main request resulted in an improvement over the prior art, should have been filed during the proceedings at first instance, during which the appellant had pursued the same main request. Not only was E0 late-filed, but it also represented an impermissible attempt by the appellant to cure a fundamental deficiency in the

application as filed, namely a total lack of data. According to established EPO case law, post-filed data could not be used as the sole basis for establishing that a patent application (or the patent issued from it) solved the technical problem it purported to solve.

Since document E1 was intended to support the credibility of a technical effect in favour of auxiliary requests 1b and 1c, both submitted with the appellant's statement of grounds, it should have been filed at an earlier stage in the appeal proceedings.

Moreover, the data presented in E0 and E1 were in any case not conclusive.

Inventive step - main request

The particles defined in claim 1 of the main request differed from the disclosure of the magnetic particles according to example 7 in document D3 by the specified range of 1 to 300 µmol/g for the concentration of carboxyl groups and by the presence of 2,3-dihydroxy-propyl groups.

No specific technical effect had been shown in connection with the carboxyl group concentration. In particular, the data provided in the patent in suit did not relate to a direct comparison with particles according to D3. The data provided in test reports E0 and E1 were not conclusive, since it could not be verified whether any of the particles tested were in conformity with the present claims, and it could not be established that there was a link between any technical effect observed and a technical feature distinguishing the claimed particles from those of document D3. Hence, the specified range of 1 to 300 µmol/g carboxyl group content must be regarded as an arbitrary choice.

It was furthermore not credible that any proportion of 2,3-dihydroxypropyl groups would provide the alleged technical benefit of reducing non-specific adsorption, given that claim 1 covered embodiments with a low content of such groups, which might not even be located on the particle surface.

Moreover, the definition of claim 1 was not restricted to particles for diagnostic purposes.

The objective technical problem should accordingly be defined as the provision of further organic polymer particles.

The subject-matter of claim 1 would have appeared obvious to a skilled person seeking to solve that problem, since both carboxyl groups and epoxy groups were envisaged in document D3 as functional groups to be incorporated on the particle surface. The teaching of D3 did not exclude carboxyl group concentrations in the range of 1 to 300 µmol/g. Epoxy groups (introduced with glycidyl methacrylate monomers) would inevitably hydrolyse to yield 2,3-dihydroxypropyl groups.

Document D11, which like document D3 related to surface-functionalised organic polymer particles for use in bioassay applications, would also have been consulted. D11 explicitly taught that the non-specific protein adsorption of the particles could be reduced through hydrolysis of epoxy groups located on the particle surface (D11B: paragraph [0014]), thus providing a further incentive for the person skilled in the art to introduce 2,3-dihydroxypropyl groups.

Admission of auxiliary requests

Auxiliary requests 1b and 1c should have been presented during the proceedings at first instance at the same

time as the main request, since they related to further sub-ranges of the carboxyl content.

Auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i had been filed at an even later stage in the proceedings than auxiliary requests 1b and 1c. All of them incorporated additional limitations taken from the description which had no counterpart in the claims as granted. They also represented a divergent set of requests by randomly covering different subject-matter. Moreover, the subject-matter of those auxiliary requests was not *prima facie* clearly allowable.

Even if filed in reaction to a new issue raised in the board's written communication, auxiliary requests 1b-A, 1c-A, 1d-A, 1e-A, 1f-A, 1g-A, 1h-A and 1i-A had been presented at a very late stage in the proceedings and could not *prima facie* be regarded as allowable; consequently those requests should not be admitted.

Auxiliary request 3a had not been admitted in the proceedings at first instance and was *prima facie* not allowable, because it did not meet the requirements of Article 123(2) EPC for the same reasons as auxiliary request 3. The additional amendments in claims 1 and 5 of auxiliary request 3a were not suitable to overcome that objection. With an identical claim 1, late-filed auxiliary request 3b clearly did not overcome that deficiency of auxiliary request 3a.

Inventive step - auxiliary requests 1b to 1i-A

The reasons against inventive step as set out for the main request also applied to auxiliary requests 1b and 1c, since the narrower ranges defined for the carboxyl group content (with an upper limit of 100 µmol/g) did not change anything in the respondent's arguments.

The subject-matter of claims 1 of auxiliary requests 1b-A and 1c-A did not contain any further feature distinguishing the claimed subject-matter from the disclosure in document D3 (which likewise disclosed the bonding of biological material to the polymer particles, e.g. in examples 29 and 30 and in its general teaching), and therefore the amendments carried out in these requests could not provide a contribution in support of inventive step. The objective technical problem could be defined as the provision of alternative polymer particles for probe binding. Contrary to the appellant's allegation (made in support of the argument that the teaching of document D3 would not have been combined with that of D11), both D3 and D11 expressly taught the option of copolymerising monomers with different functional groups for modifying the particle surface.

As far as the technical features introduced in auxiliary requests 1d, 1d-A, 1e, 1e-A, 1f, 1f-A, 1g, 1g-A, 1h, 1h-A, 1i and 1i-A were concerned, the lower limit of 10 µmol/g for the content of 2,3-dihydroxy-propyl groups was arbitrary and not substantiated by any actual data. The requirement that the functional groups must be located on the surface of the particles was also met by the particles of the prior art, and therefore it could not make a difference for the assessment of inventive step.

Auxiliary request 3 - amendments

The amendments introduced in claims 1, 5 and 7 of auxiliary request 3 combined technical features from two separate embodiments of the application as filed and therefore contained added subject-matter, in contravention of Article 123(2) EPC.

Auxiliary request 7 - inventive step

Like the particles of auxiliary request 7, the particles according to document D3 were magnetic and had a core-shell structure. Since amended claim 1 did not specify a range for the content of carboxyl groups, the presence of 2,3-dihydroxypropyl groups remained as the only distinguishing feature. The same arguments applied as set out for the main request and in the decision under appeal.

Different apportionment of costs

A different apportionment of costs should be ordered. The appellant had submitted an excessive number of auxiliary requests. The large number of late-filed auxiliary requests had caused additional expense which would not have arisen if all requests had been filed in good time. Moreover, the respondent had been obliged to incur additional costs due to the need to conduct experiments to challenge the appellant's late-filed auxiliary requests, which contained subject-matter not present in the claims of the patent as granted.

XVII. The appellant requested that the decision under appeal be set aside and that the opposition be rejected as inadmissible or, in the alternative, that the decision under appeal be set aside and the patent be maintained in amended form on the basis of one of the following claim requests:

- main request filed with the letter dated 5 October 2012,
- auxiliary request 1b filed with the statement of grounds of appeal dated 24 May 2013,
- auxiliary request 1b-A filed with the letter dated 23 February 2018,

- auxiliary request 1c filed with the statement of grounds of appeal dated 24 May 2013,
- auxiliary request 1c-A filed with the letter dated 23 February 2018,
- auxiliary request 1d filed with the letter dated 25 March 2014,
- auxiliary request 1d-A filed with the letter dated 23 February 2018,
- auxiliary request 1e filed with the letter dated 25 March 2014,
- auxiliary request 1e-A filed with the letter dated 23 February 2018,
- auxiliary request 1f filed with the letter dated 25 March 2014,
- auxiliary request 1f-A filed with the letter dated 23 February 2018,
- auxiliary request 1g filed with the letter dated 25 March 2014,
- auxiliary request 1g-A filed with the letter dated 23 February 2018,
- auxiliary request 1h filed with the letter dated 25 March 2014,
- auxiliary request 1h-A filed with the letter dated 23 February 2018,
- auxiliary request 1i filed with the letter dated 25 March 2014,
- auxiliary request 1i-A filed with the letter dated 23 February 2018,
- auxiliary request 3 filed with the letter dated 5 October 2012,
- auxiliary request 3b filed at the oral proceedings on 1 March 2018,
- auxiliary request 3a filed on 7 November 2012,

- auxiliary request 7 filed with the letter dated 5 October 2012.

Furthermore, the appellant requested that documents D16 to D25 not be admitted into the proceedings.

The appellant also requested a different apportionment of costs.

XVIII. The respondent requested that the appeal be dismissed, and within the purview of that request, that auxiliary requests 1b, 1c, 1d, 1e, 1f, 1g, 1h, 1i, 1b-A, 1c-A, 1d-A, 1e-A, 1f-A, 1g-A, 1h-A, 1i-A, 3a and 3b not be admitted into the proceedings,

and furthermore that neither the appellant's experimental data (E0 and E1) nor documents D26 to D30 be admitted.

The respondent also requested a different apportionment of costs.

Reasons for the Decision

1. Admissibility of the opposition

1.1 The notice of opposition clearly and unambiguously identifies the opposed European patent No. 1 780 544 and the extent to which it is opposed (namely the patent as a whole; see the notice of opposition, page 1 and EPO Form 2300E, sections I and V, filed on 9 September 2010). Not only is the correct patent number mentioned in EPO Form 2300E and more than ten times in the notice of opposition, but also the content of the notice of opposition clearly relates to the patent in suit.

1.2 Hence the notice of opposition complies in those respects with Rule 76(2)(b) and (c) EPC, Rule 76 being the applicable implementing regulation in the present case in view of the applicability of Article 99 EPC in the version of 13 December 2007 (see Article 7(1) of the Revision Act of 29 November 2000 and Article 1 No. 2 of the Decision of the Administrative Council of 28 June 2001, see OJ EPO 2003, special edition No. 1, pages 201 ff.).

1.3 The patent number "EP 1 600 441", relating to a patent with the title "Crystal form of lercanidipine hydrochloride for use as an antihypertensitive agent" granted to a company different from the appellant, is mentioned only once on page 20 of the notice of opposition. Considering the whole content of the notice of opposition and the accompanying EPO Form 2300E, this is an obvious error, because it is clear that it should have been the number of the patent in suit and nothing else could have been intended. The error, being an

obvious one, cannot therefore be prejudicial to the admissibility of the opposition.

1.4 Accordingly, the board had no reason to hold the opposition inadmissible pursuant to Rule 76(2)(b) and (c) and Rule 77(1) EPC. This is also in line with the opposition division's finding (see point VII above).

2. Admission of evidence

2.1 Test report E0

2.1.1 Test report E0 was first submitted as part of the statement setting out the grounds of appeal (see point IX above). Pursuant to Article 12(1), 12(2) and 12(4), second half-sentence, RPBA, it is thus, in principle, to be taken into account in the proceedings.

2.1.2 Article 12(4), first half-sentence, RPBA, confers on the board the discretionary power to hold inadmissible evidence which could have been presented in the first-instance proceedings. This provision, in line with Article 114(2) EPC, is basically intended to forestall tactical abuse.

2.1.3 In the proceedings at first instance, the appellant argued with regard to the inventive step of the subject-matter of the main request (see the letter of 5 October 2012, page 3) that it was readily apparent to a skilled person that the technical effect of lessened non-specific absorption, mentioned in the application as filed (see page 12, lines 1 to 3), was plausibly achieved by keeping the carboxyl group content below 300 µmol/g. The subsequent discussion of the main request during the proceedings at first instance focused however on the issue of novelty relative to the disclosure of document D1 (see the opponent's letter

of 31 October 2012 and the decision under appeal, point 5.4 of the reasons). According to the appellant, test report E0 was submitted to provide supplementary data in support of inventive step by showing that the concentration of carboxyl groups as specified in the main request and in new auxiliary requests 1b and 1c (which defined narrower concentration ranges) resulted in improvements over the prior art.

2.1.4 Considering the development of the case, the board concluded that the late filing of test report E0 did not constitute tactical abuse but was a legitimate attempt by the appellant, who was the losing party in the proceedings at first instance, to improve its position by filling potential gaps in its argumentation on the issue of inventive step.

2.1.5 Hence the board saw no compelling reason for not taking test report E0 into account in the appeal proceedings.

2.2 Test report E1

2.2.1 According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion.

2.2.2 Test report E1 was submitted with the appellant's letter of 25 March 2014 (see page 10, point c)) in reply to the respondent's objections regarding deficiencies in the data presented in test report E0 (see the respondent's reply to the statement setting out the grounds of appeal, in particular point 9.3).

2.2.3 Hence the filing of E1 was occasioned by a procedural development. Furthermore, its content does not raise new issues that shift the focus of the discussion.

2.2.4 In these circumstances, the board found it appropriate to exercise its discretion under Article 13(1) RPBA to admit E1 into the proceedings.

2.3 Documents D16 to D18, D18a and D19 to D30

In the context of the discussions which were relevant for the outcome of the present decision, the parties did not ultimately rely on any of documents D16 to D18, D18a and D19 to D30. Hence a decision on their admission into the proceedings was not required.

3. Main request - inventive step

Patent in suit

3.1 The patent in suit seeks to provide polymer particles for diagnostic applications that involve immobilising substances to be analysed on particles. One possible reason for insufficient sensitivity of such methods is the non-specific adsorption of substances/impurities onto the particle surface (see paragraphs [0001] to [0004] of the description). Counter-measures for controlling and decreasing non-specific adsorption are therefore desired. According to the patent in suit (see paragraph [0010]), it is an object of the invention to provide

- organic polymer particles easily bound to a probe (a primary probe) for detecting proteins or nucleic acids, while exhibiting low non-specific adsorption,
- a process for producing such organic polymer particles, and
- probe-bound particles made from the organic polymer particles with a probe bonded thereto.

According to the patent in suit, the inventors found (see paragraphs [0014], [0015] and [0023]) that non-specific adsorption to polymer particles having two specific types of functional groups, namely carboxyl groups and 2,3-dihydroxypropyl groups, was low and that probe-bound particles exhibiting high sensitivity in the field of biochemical and medical products could be obtained by using the organic polymer particles according to the patent in suit.

Starting point in the prior art

3.2 The respondent considered that, *inter alia*, both documents D1 and D3 were suitable as the starting point in the prior art for the assessment of inventive step, while the appellant preferred document D1 but did not contest that document D3 was, in principle, also a suitable starting point.

3.3 Both documents relate to similar polymer particles intended for the same general technical purpose as those of the patent in suit. If, as in the present instance, the skilled person had a choice of several workable approaches that might suggest the invention (in terms of several possible starting points), the rationale of the problem-and-solution approach requires that the invention be assessed relative to all these possible approaches before any decision confirming inventive step is taken (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.D.2). Conversely, it is sufficient for denying inventive step if the claimed subject-matter lacks an inventive step in respect of one of the possible starting points. In view of the ultimately negative outcome of the board's assessment starting from the teaching of document D3, as set out hereinbelow, it is

not necessary to address an alternative approach starting from the teaching of any other document.

3.4 Document D3 discloses a process for producing magnetically responsive particles having a polymer core particle covered by a coating comprising metal oxide and a crosslinked polymer. Preferably, the metal oxide is either superparamagnetic or paramagnetic (see D3, column 2, lines 49 to 50). The process according to D3 involves polymerising a monomer in admixture with magnetic particles, to form a metal-oxide-containing polymer layer on the core particle (see D3, claims 1 and 3). If surface-functionalised particles are desired, functional monomers (such as, *inter alia*, glycidyl methacrylate or methacrylic acid) may be used, or the particles can be coated further with another layer of functionalised polymer, to provide functional groups such as carboxyl, amino or hydroxyl suitable for passive or covalent binding of biological materials (see D3, claims 2, 4 and column 1, lines 58 to 63; column 3, lines 8 to 15, column 4, lines 34 to 51). The particles are suitable for a variety of biomedical applications, e.g. as solid phase for immunoassays or affinity purification.

Example 7 of D3 discloses polystyrene microparticles coated with a polystyrene layer containing a magnetic metal oxide and with a further polymeric layer containing carboxyl groups (introduced by undecylenic acid monomers). The content of carboxyl groups is not disclosed.

Distinguishing technical features

3.5 It was common ground that the particles defined in claim 1 of the main request differed from the particles according to example 7 in document D3 by the specified

range of 1 to 300 µmol/g for the content of carboxyl groups and by the presence of 2,3-dihydroxypropyl groups.

Technical effects

3.6 The patent in suit contains the following statements about technical effects which may relate to those technical features:

3.6.1 "In the organic polymer particles of this embodiment, the amount of the carboxyl group per the amount of solid components of the particles is preferably from 1 to 300 µmol/g, more preferably from 5 to 200 µmol/g, and most preferably from 10 to 100 µmol/g. If the amount of the carboxyl group is less than 1 µmol/g, binding of a primary probe may be difficult; if more than 300 µmol/g, on the other hand, non-specific adsorption of proteins and nucleic acids may increase". (see paragraph [0063])

3.6.2 "In the organic polymer particles of this embodiment, the 2,3-dihydroxypropyl group is a factor for exhibiting low non-specific adsorption and high sensitivity. The amount of the 2,3-dihydroxypropyl group per the amount of solid components in the organic polymer particles is preferably 10 µmol/g or more, more preferably 50 µmol/g or more, and most preferably 100 µmol/g or more. If the amount of the 2,3-dihydroxypropyl group is less than 10 µmol/g, non-specific adsorption of proteins and nucleic acids may increase." (see paragraph [0064])

3.7 In line with these statements, the appellant essentially argued that both the mandatory presence of 2,3-dihydroxypropyl groups and the upper limit of 300 µmol/g for the content of carboxyl groups were

technical features which had the effect of keeping non-specific adsorption at a low level and achieving a high signal-to-noise ratio when the particles were used for immunoassay applications. In support of that argument, the appellant relied on experimental data of comparative tests provided in the patent in suit and in test reports E0 and E1.

3.8 If comparative tests are chosen to demonstrate inventive step on the basis of an improved effect, the nature of the comparison must be such that the alleged advantage or effect is convincingly shown to have its origin in a technical feature distinguishing the claimed subject-matter from the starting point in the prior art (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.D.10.9).

The following criteria are relevant in this context:

(a) The comparative sample must be adequately representative of the starting point in the prior art, and the "inventive" sample must be adequately representative of the claimed subject-matter.

(b) Since a technical effect cannot be convincingly linked to a particular feature if several features are varied in the comparison, only one technical feature should be varied.

(c) Furthermore, it must be credible that the effect is obtained over the entire scope claimed for it to be taken into account in determining the objective technical problem.

3.9 With regard to criterion (c), while claim 1 of the main request relates to particles as such and its scope is not actually restricted by any mandatory feature relating to the intended use of the particles or to

their suitability for diagnostic methods, the following considerations are based on the assumption, made in favour of the appellant, that the claimed particles must be suitable for diagnostic purposes, in particular immunoassay methods, and that therefore a technical effect which is of advantage in such methods has relevance for the entire scope claimed.

3.10 Data provided in the patent in suit

3.10.1 The comparative tests in the patent referred to by the appellant (see paragraphs [0272] to [0289]) relate to

(i) a comparison of particles comprising 2,3-dihydroxy-propyl groups and 12 µmol/g carboxyl groups with similar particles not comprising 2,3-dihydroxypropyl groups, and

(ii) a comparison of particles comprising both 2,3-dihydroxy-propyl groups and 24 µmol/g carboxyl groups with similar particles not containing carboxyl groups.

In a specific chemiluminescence enzyme immunoassay method using an anti-AFP (human α-fetoprotein) antibody as a primary probe, the samples which contained both functional groups, in conformity with claim 1 of the present main request, turned out to provide higher signal-to-noise ratios and in particular lower noise intensities than the comparative samples containing only one of the functional groups.

3.10.2 In this, the comparative sample not containing carboxyl groups (see point 3.10.1, No. (ii) above and paragraphs [0283], [0284] and [0289] of the patent) is not representative of the particles according to example 7 of document D3 (the starting point in the prior art), since the prior-art particles contained

carboxyl groups. Hence the comparison which was carried out is not a comparison with the starting point in the prior art, and the test result cannot prove that the claimed particles achieve any specific technical effect due to the content of carboxyl groups in comparison with the particles of D3; in particular, the test setup (comparing a carboxyl content of 24 µmol/g with a content of 0 µmol/g) is not suitable to demonstrate that the upper limit of 300 µmol/g provides any technical advantage.

3.10.3 The comparison according to point 3.10.1, No (i) above (see paragraphs [0272], [0273], [0281], [0282], [0285], and [0288] of the patent) appears to show a benefit with regard to the noise level and signal-to-noise ratio, linked to the presence of 2,3-dihydroxypropyl groups on the particle surface; see, however, point 3.13 below.

3.11 Test reports E0 and E1

3.11.1 Test report E0 relates to a comparison between different organic polymer particles of unspecified composition, obtained by synthesis or purchase, which are characterised exclusively by their carboxyl group contents. 2,3-dihydroxypropyl groups are not mentioned. On the basis of the available information, it cannot be verified whether any of the particles tested was actually in conformity with the definition of claim 1, or whether the particles which were tested differed only in the content of carboxyl groups or also with regard to any further potentially relevant parameters (see criteria (a) and (b) mentioned in point 3.8 above). Since the composition and constitution of the sample particles is not described, the information provided in E0 is not conclusive and cannot be relied

on for the definition of the objective technical problem in the assessment of inventive step.

3.11.2 Likewise, test report E1 remains silent about the technical features of the particles which were compared, except for the parameters carboxyl group content and particle size. It cannot therefore be verified whether the data provided in E1 are conclusive in linking any technical effect observed to a technical feature distinguishing the particles according to claim 1 from the prior-art particles according to D3. As a consequence, E1 cannot provide a meaningful contribution to the assessment of inventive step.

3.12 For these reasons (see in particular points 3.10.2, 3.11.1 and 3.11.2 above), the board concludes that the appellant failed to show that any specific technical effect is associated with the carboxyl group content.

3.13 As far as a technical effect associated with the presence of 2,3-dihydroxypropyl groups is concerned (see point 3.10.3 above), the respondent argued that the favourable result of the comparative test reported in the patent in suit could not be extrapolated to the entire scope claimed (see criterion (c) mentioned in point 3.8 above), since claim 1 did not indicate a minimum concentration of 2,3-dihydroxypropyl groups and it was not mandatory that the functional groups were present on the surface of the particles. Thus claim 1 covered embodiments which would not achieve the desired technical effect. The board finds this objection justified; hence this technical effect cannot be used in the definition of the objective technical problem for the assessment of claim 1 of the main request.

Objective technical problem and solution

3.14 With regard to claim 1 of the main request, and starting from the technical teaching of document D3 (in particular, example 7), the objective technical problem is thus the provision of alternative polymer particles.

3.15 The board is convinced that this problem is credibly solved by the particles defined in claim 1.

Obviousness of the solution

3.16 One obvious option for providing alternative particles to those of example 7 would be to modify the surface functionalisation. Document D3 itself provides some scope in that respect:

The general teaching of document D3 does not exclude embodiments with a carboxyl group content in the range of 1 to 300 µmol/g. Carboxyl functionalisation is a preferred option and can be introduced, for instance, by monomers like methacrylic acid, or undecylenic acid used in preparing the polymer coating of the particles described in example 7.

D3 teaches furthermore that the functionalised monomers may be selected from one monomer or a mixture of monomers listed in column 4, lines 34 to 51. The list of monomers includes methacrylic acid, undecylenic acid and glycidyl methacrylate, which latter contains a 2,3-epoxypropyl group.

According to the patent in suit (see paragraph [0082], glycidyl (meth)acrylate is a monomer which produces a 2,3-dihydroxypropyl group upon hydrolysis. While document D3, which also proposes hydroxyl functionalisation (see column 3, lines 11 to 15), does not suggest or discuss hydrolysis of the epoxy groups,

it is mentioned in the patent in suit (see paragraph [0085]) that a portion of the functional groups may be hydrolysed during polymerisation. Thus, arguably, particles made with glycidyl (meth)acrylate may inherently contain 2,3-dihydroxypropyl groups, although it has not been shown that this would be an inevitable structural feature.

In any case, however, particles which are functionalised with 1 to 300 µmol/g carboxyl groups and 2,3-epoxypropyl groups are well within the scope of the teaching of document D3.

The appellant's argument that the person skilled in the art would have had no incentive to combine monomers with carboxyl groups specifically with glycidyl methacrylate must fail, since in order to provide alternative particles, it would be obvious to make a combination with any of the monomers suggested in D3 (see column 4, lines 39 to 47).

3.17 Document D11 (see D11B, claim 1, paragraphs [0005] and [0011] to [0014]) is another prior-art document concerned with polymer particles suitable for diagnostic applications and discussing options for surface functionalisation. The particles according to D11 provide an alternative to core-shell particles and are obtained by copolymerising a cross-linkable monomer and a monomer chosen from glycidyl methacrylate and glycidyl acrylate (with crosslinking being employed to provide better mechanical strength). Further functional groups such as carboxyl groups may be introduced by co-polymerising suitable monomers (see D11B, paragraphs [0012], [0013] and example 6). As in the patent in suit and in document D3, the functional groups serve to bond bioactive materials to the particles. According to D11 it is also possible to

change an epoxy group into a glycol group through hydrolysis. It is, moreover, pointed out that through hydrolysis of the epoxy group to make it a glycol group, the non-specific protein adsorption of the particle containing an epoxy group can be reduced further (see D11B, paragraph [0014]). While mis-spelt in D11B as "absorption", the meaning of this term was not contested.

3.18 The appellant argued that the person skilled in the art would not have combined the teaching of document D11 with that of document D3 because D11 did not describe magnetic particles and the preferred polymeric material of the carrier particles was different. The board does not find these arguments convincing, for the following reasons:

- The magnetic properties of the particles of D3 are useful for separating the particles from other materials, but would not be of relevance to issues concerning the chemical composition of the particles including surface functionalisation.

- According to document D3, any polymer can be used for the core particles (see D3, column 3, lines 17 to 45). What matters for the present discussion is that the particles of D11, like those of D3, are surface-functionalised, and both documents provide a technical teaching about options for surface functionalisation.

Hence the board comes to the conclusion that the person skilled in the art would have had no reason to refrain from combining the teaching of document D11 with that of D3.

3.19 Since the person skilled in the art, in order to provide alternative particles, would have envisaged

both additional surface functionalisation with hydroxyl groups and/or the use of monomers having 2,3-epoxypropyl groups (both taught in document D3), and would have learned from D11 that hydrolysing the 2,3-epoxypropyl groups (to form 2,3-dihydroxypropyl groups) was also an option, they would have arrived at the particles according to claim 1 without the exercise of inventive skill. The expectation mentioned in D11 that hydrolysing the epoxy groups would reduce undesirable non-specific adsorption would even have provided a further incentive.

3.20 The same conclusions apply to the "probe-bound particles" according to claim 4 of the main request. The only additional mandatory feature in this claim, in comparison with claim 1, is the presence of a material coupled, or bonded, to the particles. That is not a technical feature distinguishing the claimed subject-matter from the disclosure of document D3: According to the general teaching of D3, the particles serve the same purpose as those according to the patent in suit, namely the passive or covalent coupling of biological material (see D3, column 1, lines 58 to 60), and examples 29 and 30 of document D3 relate to the coupling of biological materials to the particles according to example 7. Hence that technical feature cannot provide an inventive contribution, and the subject-matter of claim 4 is obvious having regard to the prior art for the same reasons as that of claim 1.

More ambitious technical problem and obviousness

3.21 Even if the objection mentioned in point 3.13 above was disregarded and the technical problem was defined as the provision of surface-functionalised particles for diagnostic applications with improved properties, or

indeed with low non-specific adsorption, the benefit of 2,3-dihydroxypropyl groups over 2,3-epoxypropyl groups was already known from document D11, which teaches in paragraph [0014] that "through hydrolysis of the epoxy group to make it a glycol group, the non-specific protein adsorption of the particle containing an epoxy group can be reduced even further."

3.22 The appellant argued that the person skilled in the art would not have had any expectation of success in following that teaching, since the examples presented in D11 showed the opposite. Particles (12) to (21) of Table 2 had been obtained by hydrolysis of particles based on an epoxy-group-containing monomer; and specifically, particles (12) and (17) were based on particles (1). According to Table 3, particles (1) had the lowest non-specific adsorption.

The board observes in this regard that the adsorption rate values relied on by the appellant appear to differ only insignificantly between samples (between 0.000 and 0.004 µg/cm^2). However, the informational value of Tables 2 and 3 is indeed doubtful for the following reasons: In paragraph [0014], document D11 highlights the instability of epoxy groups in solution and the possibility of gradually occurring ring-opening, which requires storage as a dry powder, as a precautionary measure. It appears that no such measures were undertaken in the examples describing the preparation of the particles, yielding as its final product an aqueous suspension with a pH of 6.2 (see example 1). No conclusion can therefore be drawn as to the degree of hydrolysis in particles 1 to 11 in Table 3 so that a comparison with particles 12 to 21 is meaningless. The results in Table 3 therefore do not discourage the skilled person from following the explicit teaching in

paragraph [0014] that it is desirable to hydrolyse the epoxy groups.

3.23 For these reasons, the board finds that the subject-matter of claims 1 and 4 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

4. Admission of auxiliary requests 1b and 1c

4.1 Auxiliary requests 1b and 1c were first filed by the appellant with the statement setting out the grounds of appeal, in accordance with the requirements of Article 12(1) and (2) RPBA.

4.2 In comparison with the main request, the claims of both auxiliary requests restrict the range given for the content of carboxyl groups, in reaction to the respondent's experimental data (D15, presented one week before the oral proceedings at first instance) and the opposition division's subsequent decision with regard to novelty, which was based on those data. The amendments are straightforward and do not raise complex new issues.

4.3 In view of these considerations, the board saw no reason for holding auxiliary requests 1b and 1c inadmissible pursuant to the provisions of Article 12(4) RPBA.

5. Admission of auxiliary requests 1b-A and 1c-A

5.1 Auxiliary requests 1b-A and 1c-A each consist of a sole claim relating to the same subject-matter as independent claims 4 of auxiliary requests 1b and 1c, respectively, except that the claims of auxiliary requests 1b-A and 1c-A additionally specify that the

probe-bound particles are "for immunoassay" (see points IX and XIII above).

5.2 These amended requests were presented in reaction to point 6.4 of the board's written communication (see point XII above), in which the board pointed out that the definition provided in claim 1 of the main request was by no means restricted to particles suitable for diagnostic methods, whereas the appellant relied in its inventive-step reasoning on the performance of more specific particles in a specified diagnostic method. This issue, which was relevant for the definition of the objective technical problem, had not been discussed previously.

5.3 Since auxiliary requests 1b-A and 1c-A were thus presented by the appellant in order to address a new issue raised by the board, the board found it appropriate to exercise its discretion under Article 13(1) RPBA to admit those requests into the proceedings.

6. Auxiliary requests 1b, 1b-A, 1c, 1c-A - inventive step

6.1 The narrowing of the concentration range defining the content of carboxyl groups (5 to 100 µmol/g or 10 to 100 µmol/g, respectively) in claim 1 of each of auxiliary requests 1b, 1b-A, 1c and 1c-A does not change anything in the board's reasoning on inventive step as presented in section 3 above in the context of the main request. Based on the available information, it can still not be acknowledged that a specific technical effect is obtained, in comparison with the particles of D3, due to the presence of the specified content of carboxyl groups.

6.2 As far as auxiliary requests 1b-A and 1c-A relating to "probe-bound particles for immunoassay" are concerned, inventive step was discussed in section 3 above under the assumption that the particles must be suitable for diagnostic purposes, in particular immunoassay methods (see point 3.9 above), and taking into account the presence of a material coupled or bonded to the particles (see point 3.20 above, discussing claim 4 of the main request).

6.3 As a consequence, the subject-matter of claim 1 in each of auxiliary requests 1b, 1b-A, 1c and 1c-A does not involve an inventive step within the meaning of Article 56 EPC.

7. Admission of auxiliary requests 1d to 1i-A

7.1 Auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i (see point XI above) were filed by the appellant in reaction to the respondent's letter of 26 September 2013 and were intended to address in particular the respondent's objection that it was not credible that the level of non-specific adsorption would be advantageously low across the entire scope claimed, in the absence of any limitation concerning the nature of the polymer, the concentration of 2,3-dihydroxypropyl groups and/or the location of the functional groups in the particles.

All present requests relate to organic polymer particles comprising carboxyl groups and 2,3-dihydroxy-propyl groups. The claims of auxiliary requests 1d to 1i define further restrictions as to the concentration and location of such functional groups in the particles. Thus the respondent's argument that the auxiliary requests should be considered as "divergent" from the main request is not convincing.

7.2 The relationship between auxiliary requests 1d-A, 1e-A, 1f-A, 1g-A, 1h-A and 1i-A (each relating to "a probe bound particles for immunoassay", see point XIII above) and the corresponding auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i is the same as that between auxiliary requests 1b-A and 1b, or 1c-A and 1c. Likewise, they were filed by the appellant in reaction to the board's preliminary opinion, for the same reason as set out in section 5 above.

7.3 In view of these considerations, the board found it appropriate to exercise its discretion pursuant to Article 13(1) RPBA to admit auxiliary requests 1d, 1d-A, 1e, 1e-A, 1f, 1f-A, 1g, 1g-A, 1h, 1h-A, 1i and 1i-A into the proceedings.

8. Auxiliary requests 1d to 1i-A - inventive step

8.1 Several limiting technical features were introduced in different combinations into the claims of auxiliary requests 1d, 1e, 1f, 1g, 1h and 1i, namely

(1) narrower concentration ranges defining the carboxyl group content (5 to 100 µmol/g in claim 1 of auxiliary requests 1d, 1f and 1h and 10 to 100 µmol/g in claim 1 of auxiliary requests 1e, 1g and 1i),

(2) a minimum content of 10 µmol/g 2,3-dihydroxypropyl groups per solid components in claim 1 of auxiliary requests 1d, 1e, 1h and 1i, and

(3) the requirement that carboxyl groups and 2,3-dihydroxypropyl groups are located on the surface of a polymer which is located on the particle surface, in claim 1 of auxiliary requests 1f, 1g, 1h and 1i.

8.1.1 As already mentioned (see point 6.1 above), the narrowing of the concentration range for the carboxyl

group content (feature (1)) does not change anything in the board's reasoning with regard to inventive step, as presented in section 3 above in the context of the main request.

8.1.2 Features (2) and (3) were introduced by the appellant in order to address the objection that the alleged technical effect of reduced non-specific adsorption due to the presence of 2,3-dihydroxypropyl groups was not achieved across the entire scope claimed (see point 3.13 above). This aspect is, however, addressed in the board's reasoning presented in section 3 above, when defining a more ambitious technical problem (see points 3.21 and 3.22 above). The board furthermore observes with regard to feature (3) that the location of the functional groups on the particle surface is not a feature distinguishing the claimed subject-matter from the prior art, since the functional groups are also on the particle surface according to the teaching of documents D3 and D11. Hence these amendments cannot change the board's conclusions with regard to inventive step.

8.2 As far as auxiliary requests 1d-A, 1e-A, 1f-A, 1g-A, 1h-A and 1i-A (additionally restricting the claimed subject-matter to "probe-bound particles for immunoassay") are concerned, inventive step was discussed in section 3 above under the general assumption that the claimed particles must be suitable for diagnostic purposes, in particular immunoassay methods (see point 3.9 above), and taking into account the presence of a material coupled or bonded to the particles (see point 3.20 above, discussing claim 4 of the main request).

8.3 As a consequence, the board has arrived at the conclusion that the subject-matter of claim 1 of each of auxiliary requests 1d, 1d-A, 1e, 1e-A, 1f, 1f-A, 1g, 1g-A, 1h, 1h-A, 1i and 1i-A does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as set out for the claims of the main request and auxiliary requests 1b, 1b-A, 1c and 1c-A (see sections 3 and 6 above).

9. Auxiliary request 3 - amendments

9.1 Claim 1 of auxiliary request 3 was amended to include the requirement that the organic polymer particles claimed are obtained by a process comprising a step of producing an ester bond by reacting

(i) a hydroxyl group originating from a 2,3-dihydroxy-propyl group in organic polymer particles having the 2,3-dihydroxypropyl group

with

(ii) a carboxylic anhydride.

The same process step is mandatory in independent process claims 5 and 7 (see point IV above).

Thus the resulting particles are characterised firstly by containing both carboxyl groups and 2,3-dihydroxy-propyl groups, and secondly by having ester bonds obtainable from a reaction of a carboxylic anhydride with a 2,3-dihydroxypropyl group.

9.2 The application as filed describes four separate embodiments (or "objects"), the first embodiment (described on pages 4, 5 and 11 to 29) relating to organic polymer particles comprising carboxyl groups in combination with mandatory 2,3-dihydroxypropyl groups, and the third embodiment (described on pages 7, 8

and 39 to 52) relating to carboxyl-group containing particles having ester bonds, but not necessarily comprising 2,3-dihydroxypropyl groups.

9.3 The claims of the patent as granted and of the present main request and auxiliary requests relate to the first embodiment, while the amendment concerning a step of producing an ester bond in the claims of auxiliary request 3 relates to the third embodiment. Accordingly, the passages indicated by the appellant in support of the amendment (in particular, page 7, line 14 to page 8, line 2; page 39, lines 23 to 27 and page 40, lines 4 to 6; page 45, lines 22 to 24; page 46, lines 12 to 20) are all located in the part of the description which relates to the third embodiment (see point 9.2 above).

9.4 While, according to the application as filed, it is a possible option within the scope of the third embodiment that the reaction partner of the carboxylic anhydride for forming the ester bond is a hydroxyl group, which may furthermore be selected to be part of a 2,3-dihydroxypropyl group (see page 40: lines 1 to 6), it is not a mandatory requirement that the polymer particles will still comprise unreacted hydroxyl groups, let alone 2,3-dihydroxypropyl groups, after the reaction forming the ester bonds has taken place (see page 45: lines 22 to 24, presenting this as a desirable, but nevertheless optional, feature).

9.5 Hence the board arrives at the conclusion that more than one selection within the third embodiment would be required to arrive at the subject-matter of claims 1, 5 or 7 of auxiliary request 3, all concerning polymer particles containing both carboxyl groups and 2,3-dihydroxypropyl groups or the

preparation of such particles. These selections are at least: (1) the selection of particles initially containing 2,3-dihydroxypropyl groups and (2) the further selection to conduct the ester forming reaction with the carboxylic anhydride in such a manner that not all of the 2,3-dihydroxypropyl groups are reacted and thereby modified, or alternatively, the addition of a step for the subsequent re-introduction of 2,3-dihydroxypropyl groups.

9.6 In the absence of a direct and unambiguous disclosure of the required combination of technical features, it is not sufficient for the purposes of Article 123(2) EPC to recognise that the two embodiments in question may conceivably have an overlap.

9.7 The board furthermore agrees with the additional finding of the opposition division that the process steps which are to be combined according to claim 5 (namely, the step of producing an ester bond and the step of producing a carboxyl group by hydrolysis) are not specifically disclosed in combination anywhere in the application as filed.

9.8 As a consequence, the board considers that independent claims 1, 5 and 7 of auxiliary request 3 contain subject-matter extending beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

10. Auxiliary requests 3b and 3a

10.1 The sole claim of auxiliary request 3b, which was filed during oral proceedings before the board, only differs from claim 1 of auxiliary request 3 in the additional requirements that the carboxylic anhydride is

polyvalent and that the step of producing an ester bond also produces a carboxyl group (see points IV, V and XIV above). This amendment merely introduces additional limitations; it does not overcome, or even address, the objections under Article 123(2) EPC set out in section 9 above with regard to claim 1 of auxiliary request 3.

Since the request was thus evidently in conflict with the requirements of Article 123(2) EPC, the board exercised its discretion under Article 13(1) RPBA by not admitting auxiliary request 3b into the proceedings.

10.2 Claim 1 of auxiliary request 3a, which was filed with the statement setting out the grounds of appeal, is identical to the sole claim of auxiliary request 3b (see points V and XIV above).

For the same reasons as set out in the context of auxiliary requests 3b and 3 (see section 9 and point 10.1 above) , the board comes to the conclusion that claim 1 of this request contains added subject-matter and that, therefore, the requirements of Article 123(2) EPC are not met.

11. Auxiliary request 7 - inventive step

11.1 The polymer particles according to claim 1 of auxiliary request 7 comprise carboxyl groups and 2,3-dihydroxypropyl groups at the surface of the particles. In addition, they are core-shell particles and contain a magnetic material layer (containing superparamagnetic fine particles) provided in the outer layer of the core ("nuclear") particles. The claim does not specify the content of the carboxyl groups or the 2,3-dihydroxypropyl groups.

11.2 Since the particles according to example 7 of document D3 are also core-shell particles containing a magnetic material layer (see D3, examples 1, 6 and 7; the core being polystyrene particles), these are not technical features distinguishing the claimed particles from the starting point in the prior art and thus they cannot be relied on in support of an inventive step.

11.3 Nor did the appellant rely on the superparamagnetic properties of the fine particles as a distinguishing feature in support of inventive step. Irrespective of whether the magnetic material in the particles according to example 7 of claim 3 is superparamagnetic, document D3 discloses the general concept (which was, moreover, previously known) of employing a magnetic material in making the particles, in order to facilitate their separation from other materials, and D3 specifies that the magnetic material is preferably superparamagnetic or paramagnetic (see D3, column 1, lines 10 to 18; column 2, lines 33 to 53). Thus the concept of magnetic separation (including the use of superparamagnetic materials), which furthermore does not interact with the concept of chemical surface functionalisation which is the issue of the present discussions, was well known and cannot provide a contribution to inventive step.

11.4 As a consequence, the only relevant technical feature distinguishing the particles defined in claim 1 of auxiliary request 7 from those of example 7 in document D3 is the presence of 2,3-dihydroxypropyl groups on the particle surface.

11.5 Hence, the inventive-step assessment provided in section 3 for claim 1 of the main request (in particular in points 3.9, 3.10 and 3.13 to 3.22)

equally applies (*mutatis mutandis*) to claim 1 of auxiliary request 7.

11.6 As a consequence, the subject-matter of claim 1 of auxiliary request 7 does not involve an inventive step within the meaning of Article 56 EPC.

12. Different apportionment of costs

12.1 In opposition appeal proceedings, each party must, as a rule, bear the costs it has incurred. A different apportionment of costs may be ordered by the board for reasons of equity, upon a party's request (see Article 104(1) EPC and Article 16(1) RPBA).

12.2 In the present instance, the parties' requests for a different apportionment of costs relate *inter alia* to costs allegedly incurred during the proceedings before the opposition division. However, the board considers that it would not be empowered to order a different apportionment for costs incurred during the proceedings at first instance, since no request in relation to such costs was filed before the opposition division, and consequently no decision on such a request was taken by the opposition division (see also T 1059/98 of 19 February 2002, reasons, point 2.2).

12.3 Insofar as the parties' requests relate to costs incurred at the appeal stage due to the filing of additional claim requests or documents, or their allegedly late submission, the board observes that the excessive or late filing of requests or documents without any justification may in fact represent circumstances in which a different apportionment of costs might be ordered. However, in the present instance, the board does not see any inappropriate procedural behaviour or procedural acts going beyond

what would reasonably be expected of a party seeking to defend its rights. The increasing complexity is, in the board's view, the consequence of a normal development typically seen in cases where, in a chain reaction, one party's submissions prompt further submissions by the other party, and vice versa.

12.3.1 As far as the respondent's request for apportionment of costs is concerned, the board does not regard the number of auxiliary requests submitted by the appellant as excessive. In particular, a number of those requests merely represent permutations of certain limiting technical features intended to address specific objections raised in the course of the proceedings (see points 4.2, 5.2, 7.1 and 7.2 above). As to costs incurred due to the alleged late filing of auxiliary requests, the board, in the absence of further explanation by the respondent, has been unable to identify any additional costs attributable to the point in time of the filing of a request that would not have arisen had the request been filed at the outset of the appeal proceedings. Finally, while expenses for experiments in relation to subject-matter not present in the claims as granted may have arisen as a consequence of the appellant's filing of auxiliary requests directed to such subject-matter, said expenses equally resulted from the respondent's choice of objections and arguments to be brought forward in relation to those new requests.

12.3.2 As far as the appellant's request for apportionment of costs is concerned, the board does not share the appellant's view that an unreasonable number of new documents was submitted at the appeal stage. Furthermore, the submission of a new objection of lack of novelty based on allegations of a public prior use

is, as such, not considered by the board as malicious behaviour by the respondent, since it may be seen as a legitimate reaction to the appellant's filing of requests introducing further limitations late in the opposition proceedings and with the statement setting out the grounds of appeal. Documents D16 to D23 were all filed in support of the objection concerning public prior use, thus concerning the same issue, and D25 in support of common general knowledge in the context of an objection concerning lack of clarity in, *inter alia,* auxiliary requests 1b and 1c. The submission of the respondent's test report D24, intended to show that the appellant's test protocol was unsuitable, was occasioned by the submission of E0 (see point 9.3 of the respondent's reply to the statement of grounds).

12.4 In view of these considerations, the board sees no reason to deviate from the general principle outlined in Article 104(1) EPC, according to which each party to the proceedings must bear the costs it has incurred. Accordingly, the parties' requests for a different apportionment of costs are to be rejected.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The requests for a different apportionment of costs are rejected.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated