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Datasheet for the decision of 28 September 2015

Case Number: T 0206/13 - 3.4.02

Application Number: 10183847.2

Publication Number: 2295954

IPC: G01N21/65, G01N33/543, G01N33/58, G01J3/44

Language of the proceedings: EN

Title of invention:
Surface-enhanced spectroscopy-active composite nanoparticles

Applicant:
Becton Dickinson and Company

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure (yes)

Decisions cited:
T 1011/01, T 2001/12

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Beschwerdekammern
Boards of Appeal
Chambres de recours

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

Case Number: T 0206/13 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 28 September 2015

Appellant: (Applicant)	Becton Dickinson and Company One Becton Drive Franklin Lakes, NJ 07417-1880 (US)
Representative:	Eder, Michael df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 14 September 2012 refusing European patent application No. 10183847.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	B. Müller
Members:	F. J. Narganes-Quijano
	A. Hornung

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application No. 10183847.2 (publication No. 2295954).

II. In its decision the examining division held that the claimed invention, and in particular the invention defined in claim 1, together with dependent claim 11 of the request then on file, was not sufficiently disclosed within the meaning of Article 83 EPC.

III. Among the evidence on file, the following documents are considered in the present decision:

D1: "Immunoassay readout method using extrinsic Raman labels adsorbed on immunogold colloids", J. Ni *et al.*; Analytical Chemistry, Vol. 71 (1999), pages 4903 to 4908

D2: "Synthesis of nanosized gold-silica core-shell particles", L. M. Liz-Marzán *et al.*; Langmuir, Vol. 12 (1996); pages 4329 to 4335;

D3: "Controlled method for silica coating of silver colloids. Influence of coating on the rate of chemical reactions", T. Ung *et al.*; Vol. 14 (1998), pages 3740 to 3748

D6: "Surface-enhanced Raman spectroscopy using metallic nanostructures", T. Vo-Dinh; Trends in Analytical Chemistry, Vol. 17 (1998), pages 557 to 582

B1: "Surface-enhanced Raman scattering of a Cu/Pd alloy colloid protected by poly(N-vinyl-2-

pyrrolidone)", P. Lu *et al.*; Langmuir Vol. 15 (1999), pages 7980 to 7992

B2: "The role of Triton X-100 as an adsorbate and a molecular spacer on the surface of silver colloid: A surface-enhanced Raman scattering study", P. Matejka et al.; Journal of Physical Chemistry, Vol. 96 (1992), pages 1361 to 1366

A1: "Experimental Annex 1", filed with the letter dated 23 April 2012

A2: "Experimental Annex 2", filed with the letter dated 23 April 2012.

IV. With the statement setting out the grounds of appeal the appellant submitted sets of claims amended according to a main and first to third auxiliary requests and requested that the decision under appeal be set aside and a patent be granted.

V. In reply to a telephone consultation with the rapporteur of the Board, the appellant submitted with the letter dated 29 July 2015 an amended set of claims 1 to 17 and amended pages 2 to 4, 6, 7, 13, 15 and 16 of the description replacing the corresponding application documents of the main request, and pages 19 and 20 of the description as originally filed being cancelled.

VI. Claim 1 and dependent claim 11 of the main request read as follows:

" 1. A particle comprising a metal nanoparticle having bound to it a surface-enhanced spectroscopy (SES)-active analyte, characterized in that the metal nanoparticle and the (SES)-active analyte bound to it are surrounded by an encapsulant, and in that said metal nanoparticle

is comprised of a metal selected from the group consisting of Au, Ag, Cu, Na, Al, and Cr."

" 11. The particle of any one of claims 1 to 8, wherein said encapsulant comprises a polymer, preferably a polymer that does not interfere with the SERS activity."

Claims 2 to 10 of the main request are dependent claims referring back to claim 1, claim 12 is directed to a method of manufacturing the particles of any one of claims 1 to 11, and method claims 13 to 16 and use claim 17 are directed to different activities all involving the use of a particle as defined in claim 1.

The wording of the claims of the auxiliary requests is not relevant to the present decision.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - Amendments*

In its decision the examining division found that the set of claims then on file complied with the requirements of Article 123(2) EPC in respect of the content of the application as originally filed. The application was filed as a divisional application of the earlier European patent application No. 07007315.0 (publication No. 1804053) which in turn was filed as a divisional application of the earlier European patent application No. 00970656.5 (published with the

international publication No. WO 01/25758), and in its decision the examining division found that the set of claims underlying the decision under appeal also complied with the requirements of Article 76(1) EPC in respect of the content of these two earlier European applications. The Board concurs with these findings of the examining division. In addition, apart from minor clarifications and amendments of an editorial nature, the set of claims amended according to the present main request differs from the set of claims underlying the decision under appeal only in that

- the feature of claims 1, 9, 12 and 15 according to which the metal nanoparticle is "associated with" a SES-active analyte has been amended in the corresponding present claims to specify that the metal nanoparticle has "bond to it" the SES-active analyte (cf. page 7, lines 6 to 8 of the application as filed),

- method claim 15, directed to a method of encoding the reaction history of a solid support using particles having the features defined in the claim, now contains an explicit reference to the particles defined in claim 1, and

- the second alternative defined in the previous dependent claim 11 ("[...] preferably a polymer that does not interfere with the SERS activity or add significant complexity to the Raman spectrum") has been deleted (see point VI. above).

None of these amendments has an effect on the examining division's finding that the set of claims comply with the requirements of Articles 76(1) and 123(2) EPC.

The description has been brought into conformity with the claimed invention (Article 84 and Rule 42(1) (c) EPC) and the pertinent prior art has been appropriately acknowledged in the introductory part of the description (Rule 42(1) (b) EPC).

The Board is therefore satisfied that the application documents amended according to the main request comply with the formal requirements of the EPC.

3. *Main request - Sufficiency of disclosure*

3.1 The invention pertains to the field of surface-enhanced spectroscopy (SES), and more particularly to the field of SES-active composite nanoparticles, and claim 1 is directed to a particle comprising a SES-active analyte bound to a metal nanoparticle, both the analyte and the nanoparticle being surrounded by an encapsulant. In addition, according to dependent claim 11 the encapsulant "comprises a polymer, preferably a polymer that does not interfere with the SERS activity".

In its decision the examining division held that a particle as defined in claim 1 with an encapsulant comprising a polymer as defined in dependent claim 11, and more particularly with a polymer that does not interfere with the surface-enhanced Raman spectroscopy activity, was not sufficiently disclosed within the meaning of Article 83 EPC.

3.2 With the statement setting out the grounds of appeal the appellant submitted that, due to the expression "preferably" in the formulation of dependent claim 11, the preferred feature constituted only an illustrative and non-limiting feature and therefore an optional feature that does not restrict the claimed subject-matter. According to the appellant's contention, the preferred feature would not be relevant for the assessment of sufficiency of disclosure.

The Board, however, cannot accept the appellant's submissions to the effect that preferred or optional features defined in a claim should be disregarded in the assessment under Article 83 EPC. According to the established case law the requirement of sufficiency of disclosure defined in Article 83 EPC is only complied with if the disclosure of the invention allows the skilled person to perform, without undue burden, essentially all the embodiments covered by the claimed invention (see "Case law of the Boards of Appeal", EPO, 7th ed., 2013, Chapter II, section C-4.4). This applies in particular to the specific particular embodiments of an invention defined in dependent claims pursuant to Rule 43(3) EPC (see for instance decision T 1011/01, point 2.3 of the reasons) and, by the same token, to any optional feature defined in a claim since such a feature also constitutes, by its very nature, a particular embodiment of the claimed invention, irrespective of whether the optional feature is qualified as being "preferred" or not.

3.3 The main aspect raised by the examining division as regards the issue of sufficiency of disclosure of the invention defined in claims 1 and 11 is that the skilled person would have to perform a sequence of three steps in order to carry out the invention defined in dependent claim 11, namely

i) the selection of the appropriate polymer,

ii) the selection of the appropriate solvent for the polymer, and

iii) the selection of the appropriate thickness of the polymer encapsulant.

The Board, however, is not convinced by the examining division's reasoning that the skilled person would not have been able to implement the claimed invention, and

in particular to implement the sequence of steps i) to iii) mentioned above.

3.3.1 First, it is noted that, as observed by the examining division in its decision, the disclosure of the application focuses mainly on encapsulants made of glass and that the description does not contain any specific example of the manufacture of the claimed particles with an encapsulant made of polymer. This finding alone, however, does not amount to an insufficient disclosure of the claimed invention as long as the skilled person would be able, without undue burden and without the exercise of inventive step, to manufacture the claimed particles with a polymer encapsulant, following, for instance, the three steps i) to iii) mentioned by the examining division, on the basis of the common general knowledge in this art.

3.3.2 As regards step i), the invention defined in dependent claim 11 requires that the encapsulant of the particle comprises a polymer, and according to a preferred feature of the claim the polymer does not interfere with the SERS activity. The skilled person would understand that the latter feature constitutes, by its very nature, not the formulation of a result to be achieved, but a selection rule to the effect that, when putting into practice the preferred feature, the polymer for the encapsulant should be selected among those polymers that do not interfere with the SERS activity involved in the claimed particles. Therefore, starting with a predetermined metal nanoparticle and a predetermined SES-active analyte having the characteristics defined in claim 1, the skilled person would select among the available polymers a polymer adapted to encapsulate the claimed particle and, optionally, satisfying the functional condition defined in dependent claim 11, i.e.

a polymer that does not interfere with the SERS activity. As mentioned by the appellant and undisputed by the examining division, at the priority date of the application the skilled person had at his disposal standard reference books in the field of Raman spectroscopy with information on the SERS characteristics of polymers. In particular, the appellant has referred during the proceedings to the "Handbook of Fourier transform Raman and infrared spectra of polymers", A. H. Kuptsov *et al.*, Elsevier, 1998, in which the spectral characteristics, including the Raman spectrum, of hundreds of common polymers are listed in detail. In view of this information readily available to the skilled person working in this field, the Board is of the opinion that, depending on the excitation wavelength and the range of wavelengths of operation determined by the SES-active analyte, the skilled person would have had no difficulty in selecting a polymer suitable for the manufacture of a particle as defined in dependent claim 11, i.e. suitable for encapsulating a metal nanoparticle and a SES-active analyte as defined in claim 1, and preferably without detriment of the SERS activity of the particle as formulated in the optional feature defined in dependent claim 11.

Therefore, the Board cannot follow the examining division's view that finding and selecting suitable polymers satisfying the functional definition given in dependent claim 11 would constitute an undue burden for the skilled person or would require carrying out an extensive research program.

3.3.3 As regards the solvent to be selected according to step ii) referred to above, the Board shares the appellant's opinion that it pertains to the common general knowledge

of the skilled person to select the appropriate solvent according to the characteristics of the polymer.

The Board concurs with the examining division that the skilled person confronted with the problem of forming an encapsulant as claimed with a polymer selected as specified in point 3.3.2 above would have to adjust the experimental conditions to ensure the formation of the polymer encapsulant covering the particles, but there is no technical argument or evidence that this task would involve more than routine experimentation or would amount to an undue burden for the skilled person. On the contrary, the appellant submitted during the first-instance proceedings the results of two experimental tests (documents A1 and A2) in which particles as defined in claim 1 were manufactured with an encapsulant made of a polymer, and the experimental conditions used in these tests do not appear to go beyond the conventional conditions that the person skilled in this field would have considered on the basis of his general knowledge. The examining division objected that the experimental tests reported in documents A1 and A2 involve a polymer and a solvent having specific characteristics, but the Board cannot follow this objection because an experimental test requires, by its very nature, the use of specific materials and, in addition, the characteristics of the specific materials used in the experimental tests (an anionic polymer in a water solvent system, and a polystyrene with an organic solvent (MeCN) and a radical initiator (AIBN)) do not allow the conclusion that the selection of the materials would require technical considerations going beyond the common technical practice in this field.

3.3.4 As regards step iii) relating to the selection of the thickness of the polymer encapsulant, in its decision

the examining division held that the features defined in dependent claim 11 relating to the encapsulant being composed of a polymer not interfering with the SERS activity would not allow the skilled person to select and adjust the appropriate thickness of the polymer.

However, as submitted by the appellant, sufficiency of disclosure within the meaning of Article 83 EPC is to be assessed on the basis of the application as a whole. The application already indicates values of the thickness of the encapsulant between 1 and 40 nm, and preferably between 3 and 10 nm (see present dependent claim 5), and this disclosure constitutes an explicit guidance as to the suitable values of the thickness of the encapsulant. In addition, the description of the application teaches in respect of the encapsulant that "coatings that are too thick - on the order of 1 micron or more - might preclude obtaining intense Raman spectra. Coatings too thin might lead to interference in the Raman spectrum of the analyte by the molecules on the encapsulant surface" (page 8, fourth paragraph); although this teaching is disclosed in the context of encapsulants made of glass (page 8, third and fifth paragraphs) and not of a polymer as required in dependent claim 11, the skilled person would understand that similar considerations apply to polymer encapsulants. The experimental tests submitted by the appellant during the first-instance proceedings (documents A1 and A2) and based on particles as claimed having a coating of a polymer encapsulating the particles show that working within the range of thicknesses disclosed in the application leads to encapsulated particles without essentially altering the SERS activity of the particles.

In these circumstances, the Board is satisfied that the aforementioned teaching in the description provides

sufficient technical guidance enabling the skilled person to select the appropriate thickness of the polymer encapsulant so that the features required by dependent claim 11 are achieved. If necessary, SERS measurements would be sufficient to find an appropriate value of the thickness of the encapsulant, and the corresponding encapsulant having the appropriate value of the thickness can be manufactured by adjusting the experimental conditions.

3.3.5 It also follows from the above analysis that the amount of experimentation required for carrying out each of steps i) to iii) was not unduly burdensome and that consequently, contrary to the examining division's opinion, the sequence of these three steps would not have required the exercise of inventive step or an amount of experimentation that would have gone up exponentially with each step.

3.3.6 It is finally noted that, as submitted by the appellant, it was already known in the prior art, and more specifically in the field of SERS, to encapsulate nanometre-sized metal particles with a polymer, as shown in document B1 (title, abstract, section "Introduction", and "Scheme 1" on page 7981) and in document B2 (title, abstract and section "Introduction"), these two documents disclosing and discussing different techniques for the formation of polymer-protected metal and bimetallic colloids for use in SERS. In the Board's view, the fact that in the present case the polymer encapsulates not only a metal particle but a metal particle having bond to it a SES-active analyte does not fundamentally change the encapsulating technique of metal nanoparticles disclosed in these documents. Thus, documents B1 and B2 constitute evidence that is at variance with the examining division's contention that

the skilled person would be confronted with significant difficulties or would have to exercise inventive skills when trying to encapsulate with a polymer a metal nanoparticle having bound to it a SES-active analyte in order to carry out the claimed invention.

3.4 In its decision the examining division, in the context of the assessment of sufficiency of disclosure of claims 1 and 11, also referred to other technical aspects which, in its opinion, were not sufficiently disclosed within the meaning of Article 83 EPC. In particular, the examining division held that there is no guidance in the application as to which polymers "solve the objective technical problem" and as to how to select the appropriate polymers since they need to be "easily derivatizable [*sic*] to be of any use".

These technical aspects, however, are not defined in claims 1 and 11 and consequently, as submitted by the appellant, they are not to be considered in the assessment under Article 83 EPC of the invention defined in claims 1 and 11. Indeed, the requirement of sufficiency of disclosure set forth in Article 83 EPC relates to the invention defined in the claims, and in particular to the combination of structural and functional features of the claimed invention, and there is no legal basis for extending such a requirement to also encompass other technical aspects possibly associated with the invention (in particular, technical features or effects mentioned in the description) but not required by the claimed subject-matter. Thus, such technical aspects might be pertinent in the assessment of other requirements of the EPC (in particular, the requirements of Article 84 and 56 EPC, see for instance decision T 2001/12, point 4.4 of the reasons), but the question of whether the disclosure of the application

would enable the skilled person to achieve such non-claimed technical aspects cannot legitimately be raised under Article 83 EPC (see decision T 2001/12, *supra*, point 3.4 of the reasons).

3.5 The examining division also expressed in an *obiter dictum* of the decision its view that there is no evidence in the application that all the metals listed in claim 1, i.e. Au, Ag, Cu, Na, Al and Cr, are suitable for SERS.

Although the examining division raised this issue under Article 84 EPC, the Board understands the objection as rather pertaining to the requirements of Article 83 EPC. In any case, the examples of the application (see Fig. 4 to 8 and the corresponding description) and also the experimental tests (documents A1 and A2) submitted by the appellant and considered in points 3.3.3 and 3.3.4 above show that Au and Ag are suitable for SERS. In addition, the documents of the state of the art considered during the first-instance proceedings constitute further supporting evidence that nanoparticles of the metals specified in claim 1 are appropriate for use in SERS. In particular, document D1 discloses the use of gold and silver colloids as metal nanoparticles in SERS (title, page 4903, second column, second paragraph, and Fig. 1 to 3), and document D6 discloses that "with visible-wavelength excitation, the SERS phenomenon occurs most efficiently on surfaces of precious metals (Ag, Au, Cu) [...]. Certain transition metals that have been shown to be SERS-active include Pt and Ni [...]. Other materials, such as [...] Na, [...] and Al, have also been investigated for SERS." (page 561, first column, second paragraph). As regards the last of the metals listed in claim 1, i.e. the transition metal Cr, the Board considers that in view of

the aforementioned disclosures relating to the specific use in SERS of Au, Ag, Cu, Na and Al and to the general use of further transition metals, and in the absence of any specific technical argument or evidence in support of the examining division's view, there is no basis for rendering plausible, let alone conclusive, that the invention defined in claim 1 cannot be carried out on the basis of the transition metal Cr playing the role of the SERS-active metal.

3.6 It follows from the above considerations and conclusions that the Board does not find persuasive the examining division's view that the claimed invention is not sufficiently disclosed within the meaning of Article 83 EPC.

4. *Main request - Other issues*

4.1 In its first official communication the examining division raised objections of lack of novelty and of lack of inventive step of the claimed subject-matter with regard to documents D1, D2 and D3. Subsequently, the appellant contested the examining division's findings in this respect, and during the remaining proceedings this issue was no longer addressed by the examining division. It therefore appears that the objections were no longer maintained by the examining division. This conclusion is further supported by the fact that analogous objections were also raised by the examining division with regard to the subject-matter claimed in the grand-parent application giving rise to the present divisional application (cf. point 2 above), and that, in response to the counter-arguments of the appellant, these objections were no longer maintained by the examining division as the grand-parent application was finally granted with a claim 1 essentially directed

to particles similar to those claimed in the present case but requiring an encapsulant made of glass (see claim 1 of the European patent No. 1226422).

In any case, the Board notes the following:

- Document D1 discloses an immunoassay readout method based on the SERS-derived signal from reporter molecules that are immobilized with biospecific species on gold colloids (abstract, Scheme 1 on page 4904, and Fig. 1 to 3). The document, however, is silent as to any encapsulation of the gold colloids.

- Document D2 discloses gold nanoparticles coated - and therefore encapsulated - with a thin layer of silica (abstract and Fig. 1), and teaches the use of silane coupling agents as surface primers for modifying the particle surface to make it vitreophilic (Fig. 1 and page 4330, first column, first paragraph). Document D3 discloses silica-coated particles of silver and of alloys of silver and gold (abstract). There is, however, no reference in documents D2 and D3 to the use of SERS or to the use of SES-active compounds.

Thus, none of documents D1, D2 and D3 discloses particles composed of a SES-active analyte bound to a metal nanoparticle, wherein both the analyte and the metal nanoparticle are surrounded by an encapsulant as defined in claim 1. In addition, none of documents D1 to D3 or the remaining documents on file suggests the claimed encapsulated particles, nor the technical improvements associated therewith (see description, page 2, lines 22 to 39 together with page 4, line 27 *et seq.*). Dependent claims 2 to 11 are directed to particular embodiments of a particle as defined in claim 1, claim 12 is directed to a method of manufacture of a particle as defined in claim 1, and claims 13 to 17 are

directed to methods and uses of a particle as defined in claim 1.

The Board concludes that the set of claims of the main request defines patentable subject-matter over the available prior art within the meaning of Article 52(1) EPC.

4.2 The Board is also satisfied that the application documents amended according to the main request and the invention to which they relate meet the remaining requirements of the EPC within the meaning of Article 97(1) EPC.

5. Having regard to the above considerations, the Board concludes that the decision under appeal is to be set aside and a patent be granted on the basis of the present main request.

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 with the order to grant a patent in the following version:

   - claims: No. 1 to 17 submitted with the letter dated 29 July 2015;

   - description: pages 1, 5, 8 to 12, 14, 17 and 18 as originally filed, and pages 2 to 4, 6, 7, 13, 15 and 16 submitted with the letter dated 29 July 2015, pages 19 and 20 as originally filed being cancelled; and

   - drawings: sheets 1/4 to 4/4 as originally filed.

The Registrar: The Chairman:

M. Kiehl B. Müller

Decision electronically authenticated