Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [X] To Chairmen
(D) [-] No distribution

Datasheet for the decision of 6 February 2024

Case Number: T 1252/20 - 3.3.10

Application Number: 13802115.9

Publication Number: 2919826

IPC: A61L31/04

Language of the proceedings: EN

Title of invention:
VASCULAR EMBOLIC SYSTEM

Applicant:
3-D Matrix, Ltd.

Headword:
EMBOLIC SYSTEM / 3-D

Relevant legal provisions:
EPC Art. 54(5), 53(c)
Guidelines for examination G-VI, 7.1.1

Keyword:
Substance or composition - yes
Novelty - (yes)

Decisions cited:
G 0005/83, G 0002/08, T 2003/08, T 1758/15, T 1099/09, T 2369/10, T 2136/15, T 1345/18, T 0264/17

Catchword:
The question of whether a material or an object is a "*substance or composition*" in the sense of Articles 53(c) and 54(4)or (5) EPC should be decided, in the first place, on the basis of the claimed material or object as such. If this analysis leads to the conclusion that indeed a substance or composition is present, this requirement of Article 54(4) or (5) EPC is fulfilled. No additional restrictions relating to its mode of action are derivable from the EPC (reasoning, point 12) .

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1252/20 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 6 February 2024

Appellant: (Applicant)	3-D Matrix, Ltd. Kojimachi-HF Building 7F Kojimachi 3-2-4 Chiyoda-Ku Tokyo 102-0083 (JP)
Representative:	Fish & Richardson P.C. Highlight Business Towers Mies-van-der-Rohe-Straße 8 80807 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 9 December 2019 refusing European patent application No. 13802115.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	M. Kollmannsberger
	T. Bokor

Summary of Facts and Submissions

I. The applicant appealed the Examining Division's decision to refuse its patent application for lack of novelty, Article 54 EPC.

II. Claim 1 of the appellant's main request underlying the impugned decision, which corresponds to claim 1 of the appellant's main request in appeal on which the present decision is based, reads as follows:

"*A composition for use in reducing or eliminating cancerous cells in a subject by forming at least a partial blockage, lodging, occlusion or embolism in a blood vessel to deprive a tumor in the subject of blood supply, or in the treatment of patent ductus arteriosus (PDA) or major aortopulmonary collateral artery (MAPCA) in a subject, the composition comprising:*

a solution comprising an amphiphilic peptide in an effective amount and in an effective concentration to form a hydrogel under physiological conditions to allow at least a partial blockage of the biological vessel to effect embolization or cell necrosis therein,

wherein the peptide has an amino acid sequence of one of RADARADARADARADA (SEQ ID NO: 7), IEIKIEIKIEIKI (SEQ ID NO:8), and IEIKIEIKIEIKIEIKI (SEQ ID NO.9), and

wherein the concentration effective to allow at least partial blockage of the biological vessel comprises a concentration in a range of 0.1 weight per volume (w/v) percent to 3 w/v percent peptide."

III. Reference is made to the following documents:

D1: WO 2006/014570
D2: EP 2 345 433

IV. In its decision the Examining Division came to the conclusion that the peptide solutions defined in claim 1 of the applicant's main request did not qualify as "*substance or composition*" in the sense of Article 54(5) EPC, their mode of action being purely mechanical. The Examining Division referred in particular to decision T 1758/15 to support this view. This decision is also referred to in the Guidelines for Examination, G-VI, 7.1.1. Since the novelty exception under Article 54(5) EPC did not apply the claim had to be construed as claiming a device, suitable for being used in the method defined in the claim. The peptide solutions were known from D1 and D2 and they were suitable for the method defined in the claim. Thus, the independent claim of the main request lacked novelty. Similar considerations applied to the claims of the auxiliary requests on file.

V. In its statement setting out the grounds of appeal the appellant submitted arguments why the peptide solutions defined in the claim did qualify as "*substance or composition*" within the meaning of Articles 53(c) and 54(4) and (5) EPC. The novelty exception in Article 54(5) EPC should thus apply, and since the therapeutic methods defined in the claim were not disclosed in D1 or D2, the claimed subject-matter was new.

VI. During appeal proceedings the appellant filed new claim sets as main request and auxiliary requests 1-8. The Board stated in a communication that it intended to allow the appeal on the issue of novelty of claim 1 of the main request filed with the grounds of appeal. The

appellant agreed to a remittal of the case to the Examining Division for further prosecution and to the issuance of a decision in written procedure. The initial request for oral proceedings was withdrawn.

VII. The appellant's main request is the following:

To set aside the impugned decision and to grant a European patent on the basis of the main request, i.e. the claim set labelled "MAIN REQUEST", filed on 26 September 2023.

Reasons for the Decision

1. The appeal is admissible.

2. The application describes the use of self-assembling peptides in the treatment of various diseases. The amphiphilic peptides are applied as an aqueous solution via a catheter into a blood vessel and aggregate to form a hydrogel upon contact with body fluid. This hydrogel then blocks the blood vessel which induces necrosis of the tissue, see "summary of the invention" on page 1, lines 17-25. This embolization of blood vessels may be used to treat various pathological conditions, see page 2 line 27 to page 3 line 9.

3. Claim 1 of the main request is directed to compositions comprising solutions of specific peptides for use in the treatment of three different conditions, namely (i) cancer, (ii) patent ductus arteriosus (PDA) or (iii) major aortopulmonary collateral artery (MAPCA). The claim defines the use of a solution containing one of three specific peptides in a concentration effective to form a hydrogel under physiological conditions to allow

at least partial blockage of the biological vessel to effect embolism or necrosis.

4. The amphiphilic peptides defined in the claim, aqueous solutions thereof as well as hydrogels formed therefrom are already known from D1 and D2. This is undisputed.

5. The Examining Division refused the application for lack of novelty of the claim over D1 and D2. In its view the novelty exception available under Article 54(5) EPC concerning substances or compositions for a specific use in the treatment of the human body by therapy or surgery did not apply. The peptide solutions defined in the claim did not qualify as a "*substance or composition*" in the sense of Article 54(5) EPC, see points 52 and 61 of the decision. Thus, the use defined in the claim was not a limiting feature and the claim lacked novelty over D1 and D2.

The Board, however, is convinced that the peptide solutions defined in the claim do qualify as "substance or composition" in the sense of Article 54(5) EPC, and that thus the claimed subject-matter is novel over D1 and D2 due to the specific use defined therein. This will be reasoned in the following.

6. Substance or composition vs. device

6.1 According to Article 54(1) EPC an invention shall be considered new if it does not form part of the state of the art. However, Articles 54(4) and (5) EPC define a novelty exception for substances or compositions that do form already part of the state of the art. Substances or compositions may still be considered novel if claimed for use in a method referred to in Article 53(c) EPC, i. e., in a method for treatment of

the human or animal body by surgery or therapy or diagnostic methods practised on the human or animal body. Importantly, this novelty exception can only be invoked for substances or compositions, not for other products, e. g. medical devices. This is derivable from the wording of Articles 54(4)and (5) EPC, which specify a "*substance or composition*" whereas Article 53(c) EPC uses a broader definition for the subject-matter not covered by the exceptions to patentability defined in this article, namely "*products, in particular substances or compositions*".

Apart from being derivable from the wording of Articles 53(c), 54(4) and (5) EPC this limited applicability of Article 54(5) EPC is consistent case law of the Boards of Appeal, see e. g. T 1099/09, headword, T 2369/10, Reasons points 7 and 8.1, or T 1758/15, Reasons points 5.2.1 and 5.2.2. This was not a disputed issue in the present case and the Board sees no reason to call this into question.

6.2 The Examining Division based its reasons for the lack of novelty of claim 1 on the Guidelines for Examination, G-VI, 7.1.1. This passage of the Guidelines is derived from and cites decision T 1758/15. If a therapeutic effect was based exclusively on the macroscopic 3D-structure formed by a composition once inside the body, such a composition should be considered rather a device. In the present case the mode of action was purely physical and based on the macroscopic 3D-structure; the hydrogel formed in the body obstructed the blood vessel. The composition acted thus as a device in the human body and could not be considered a *substance or composition* in the sense of Articles 54(4) and (5) EPC. Following the interpretation of G 5/83 and T 2003/08, the "substance

or composition" had to be "the active agent or ingredient" of the particular specific medical use (point 55 of the decision of the Examining Division). Some indirect effects of the compound were not sufficient to make (the composition containing) the compound the "active principle" in the sense of decision T 1758/15. In this manner it was not the chemical composition of the compound, which was primarily the responsible for the therapeutic effect, but the 3D structure (point 58).

6.3 The question of what can be considered a "*substance or composition*" in the sense of Articles 54(4) and (5) EPC regularly emerges in cases before the Boards of Appeal. From the analysis of Articles 53(c) and 54(4) and (5) EPC as explained above it follows that not every object can be read on this definition, although of course every object, also a medical device, is in the end made up of substances and/or compositions. The decision G 5/83 which established the patentability of second medical indications and in fact served as the basis for Article 54(5) EPC (see T 1758/15, Reasons 5.2.5) also emphasised that the application of the special approach to novelty through the intended use is strictly limited to claims that are directed at substances or compositions intended for use in methods stipulated by Article 52(4) EPC 1973, corresponding to Article 53(c) EPC (G 5/83, Reasons 21, last sentence).

6.3.1 Decision T 1758/15 in turn relied on the findings of T 2003/08 and the criteria developed in it (see T 1758/15, Reasons 5.2.6). T 2003/08 concerned a ligand for immunoglobulins which was immobilized on a support in a column used for extracorporeal removal of immunoglobulins from blood. The Board first stated that G 5/83 required the substance or composition to be

responsible for the therapeutic effect, in the wording of T 2003/08, it had to be the "active agent". Then it concluded that in order for a material to be considered a substance or composition in the sense of the applicable provisions, which at that time were Articles 52(4) and 54 EPC 1973, it was decisive to establish (a) the means by which the therapeutic effect was achieved and (b) whether that what achieved the therapeutic effect was a chemical entity, or a composition of chemical entities, see point 18 of the decision's reasons. The Board came to the conclusion that the decisive agent was the ligand, which was a chemical entity responsible for the therapeutic effect. The ligand was thus considered a *substance or composition.*

6.3.2 These criteria (a) and (b) were further developed in the already cited decision T 1758/15. In this case, as outlined above, the macroscopic 3D-structure of the solidified implant material, rather than its chemical composition, was considered responsible for the therapeutic effect. According to this decision, in such a case the means to achieve the effect were not chemical, as required by criteria (a) and (b) of T 2003/08 and the filler material defined in the claim was not considered a substance or composition in the sense of Article 54(5) EPC. In the wording of T 1758/15, "*[t]hat the material has some indirect influence on the characteristics of the resulting solid structure does not make the material the active principle.*" (Reasons 5.2.8, third paragraph, emphasis by this Board).

6.3.3 Similar considerations were made in case T 2136/15 concerning a self-gelling injectable alginate, and in T 1345/18 concerning a filler material for the root channel of a tooth. Also in the latter case the cement-

like filler material was not held to be a "*substance or composition*" in the sense of Article 54(5) EPC. Its effect, the blocking of the root channel, was considered to be based on the macroscopic structure of the hardened cement rather than on the chemical properties of the material.

6.3.4 Thus, this line of case law imposes restrictions to what may fall under the definition of "*substance or composition*" in the sense of Article 54(5) EPC based on its mode of action. Whereas the materials underlying these cases, collagen fillers, alginates or bone glue, would, in everyday language, be seen as substances or compositions, they were not considered "*substances or compositions*" in the sense of Article 54(5) EPC since once inside the body they acted as a device.

6.3.5 In T 0264/17 a claim directed to an inert substance as a replacement for synovial fluid was allowed. Although no classical active agent was present, the chemical properties of the material were still considered to be responsible for the achieved therapeutic effect.

6.4 The appellant, in its statement setting out its grounds of appeal, brought forward various arguments emphasising the chemical nature of the peptide solutions defined in the claims. They argued that the embolizing effects were due to the better adhesion of the hydrogel formed. The better adhesion, in turn, could be attributed to the chemical structure of its components or to the chemical structure of the hydrogel once assembled inside the body of the patient, or even to the self-assembly process. The conclusions drawn in the appealed decision, based on the reasoning in case T 1758/15 and the cited part of the Guidelines G-VI, 7.1.1, would thus not apply to the present claims.

6.5 While the Board considers at least some of the appellant's arguments to have merit, it is convinced that the peptide solutions defined in the claim must be considered a "*substance or composition*" in the sense of Article 54(5) EPC already for more fundamental reasons. In the following, for reasons of brevity, also where only "substance" is mentioned, it is understood that a "substance or composition" within the meaning of Article 54(5) EPC is meant.

7. Definition of the claimed subject-matter

7.1 The subject-matter to be protected is defined by the claims in terms of technical features of the invention, Articles 84 and Rule 43(1) EPC. The independent claim defines a material in a liquid state, a solution containing peptides in specific amounts and concentrations. The claim does not define the material by any technical features which would be characteristic for a device, e. g. its shape. As also apparent from the explanation of the invention in the description, it is in liquid form that the material is administered to the patient. When administered, the material does not yet have the crucial shape of the plug fitting to the blood vessel, which will in the end result in the therapeutic effect aimed at. Thus, the material defined in the claim is evidently a "*substance or composition*". It is a shapeless liquid mixture of chemical entities and, already for this reason alone, it is not a device.

7.2 It is another matter that the peptide solution will, once used as defined in the present claim, transform itself into something which may *act as if it were a device.* In the present case, such a transformation is directly implied by the features of the claim, in that

the claim specifies that the initial solution is forming a hydrogel blocking mass under physiological conditions. However, it remains that the Board sees no good reason to consider the peptide solution defined as the protected object of the claim - the peptide solution **before** its actual use - *as a device*.

8. "Chemical" mode of interaction

8.1 The question can still be asked whether the "device-like", in particular the mechanical action of the claimed peptide solution once transformed into a hydrogel inside the body, would in itself be a reason to exclude the applicability of Article 54(5) EPC. The arguments of the Examining Division and also the reasoning in T 1758/15 appear to be directed more to the lack of chemical character of the mode of action. In other words, the main objection to the claimed peptide is not really the device character of the resulting hydrogel plug, but the fact that the therapeutic effect is not achieved by means of a chemical interaction with the human body.

8.2 At this point it is useful to point out that the exceptional approach to novelty of Article 54(5) EPC (and equally of Article 54(4) EPC) is not only applicable in case of therapeutic treatments, but also for treatments by surgery and for diagnostic methods. Decision G 5/83 addresses exclusively a therapy where a medicament is administered and its active agent achieves some therapeutic effect, such as treating an illness. The claim category endorsed by G 5/83 was also explicitly directed at the "use for manufacture of a medicament". However, with the adoption of the EPC 2000 it became clear that the novelty exception now generally encompassed all uses of a substance falling

under Article 53(c) EPC, e. g. also surgical treatments and diagnostic methods, meaning that the the scope of Article 54(5) EPC is broader (G 2/08, Reasons 6.5). This already speaks against a too narrow interpretation of "substance or composition", possibly limiting it to such uses where the mode of action is exclusively or at least predominantly chemical. In particular, the use of a substance in a surgical or diagnostic method may possibly involve various mechanisms of action which may not immediately appear comparable to a classical "chemical" reaction triggered by a medicament.

9. There is no legal basis for the mode of action as a criterion for qualifying a material or object as a substance or composition under Article 54(5) EPC.

9.1 Statutory provisions

First of all, according to their plain wording, none of Articles 54(4), 54(5) or 53(c) EPC require a material to act via a certain mechanism in order to be considered a "*substance or composition*".

9.2 G5/83

9.2.1 The above cited decisions T 2003/08 and T 1758/15 took as a starting point for their analysis the original decision G 5/83. Given that the adoption of Article 54(5) EPC had the explicit purpose to elevate the conclusions of G 5/83 directly into the EPC, on proper interpretation the presumed requirement of a chemical mode of action also had to apply for Article 54(5) EPC. Also the present Board considers that even if this decision of the Enlarged Board need no longer be treated as a formal legal source (G 02/08, Reasons 5.10.2 and 7.1.2), its considerations still apply.

9.2.2 However, the mode of action as the relevant criterion for judging whether a material is a "substance or composition" is not derivable from G 5/83. This decision allowed second medical use claims in the Swiss-type format. The Swiss-type claim format does indeed contain the expression "*substance or composition*". Yet, the case underlying G 05/83 dealt with the use of a specific chemical compound, so the definition of "*substance or composition*" and generally the scope of this expression was not a disputed issue and is not addressed in the decision in any detail. From point 10 of the reasoning in G 05/83, mentioning "*chemical substances and compositions*" in the context of therapy, the Board in case T 2003/08 concluded that at least chemical compounds should fall under this definition (T 2003/08, Reasons 15). This is anyway undisputed. No other direct reference to the possible nature of substances or compositions can be found in G 05/83. The requirement that the substance should be defined as a chemical compound, in the sense of defining it through its chemical composition, is certainly met in the present case.

9.2.3 At least if the substance itself is the key element in the therapeutic, surgical or diagnostic method (is "responsible" for the therapeutic effect, as formulated by T 2003/08, Reasons 17.), the ratio decidendi of G 5/83 is applicable to such substances, irrespective of their mode of action. The driving force behind G 5/83 was not the identification of subject-matter that had to be excluded from possible protection, but on the contrary, to confirm availability of a special protection form for such subject-matter that was seen as deserving protection but appeared to be unpatentable under the explicit provisions of the EPC 1973.

9.2.4 This conclusion concerning the overall aim of G 5/83 is immediately derivable from the statement of the Enlarged Board that allowing Swiss-type claims ("*the type of use claims now being considered*") by way of a special notion of novelty "*seems justifiable by analogy* [to the novelty concept of Article 54(4) EPC 1973)]" (Reasons 21, 3rd paragraph). The Board observes that the German and French versions (decisions G 1/83 and G 6/83, published together with G 5/83 in OJ EPO 1985, page 60) make it clear that the "justification" is directly derived from the general obligation to grant patent protection under Article 52(1) EPC 1973.

9.2.5 For the Enlarged Board such subject-matter deserving protection was the invention that the known substance could be used for new therapies. This is fully comparable to the present case - the real invention is not the peptide solution or the hydrogel plug formed therefrom, but the recognition that the peptide solution and the hydrogel plug can be used to treat other pathological conditions than previously.

9.3 Even the findings of later case law do not support the proposition that only some particular chemical action of the substance directly on the human body would qualify it as a substance for the purposes of Article 54(5) EPC.

9.3.1 Decision T 2003/08 defined functional requirements (a) and (b) (as set out in point 6.3.1 above) for assessing whether something was a "substance or composition" in the sense of a second medical use claim.

9.3.2 However, one has to keep in mind that these criteria were developed before the background of the underlying

case. The underlying claim was drafted in the "Swiss-type" format allowed by G 5/83. A Swiss-type claim was usually directed to the use of a substance or composition "*for the manufacture of a medicament*", whereas the claim underlying T 2003/08 was directed to the use of a ligand "*for the manufacture of a column*". A column, however, is difficult to read on the term "*medicament*". Moreover, the therapeutic method underlying the claim was carried out outside the body using a device (the blood washing column), the device containing the ligand as active agent immobilized on a support. Thus, it was not immediately apparent that the claim could be allowed under the provisions of G 05/83. It is against this background that the Board in T 2003/08 defined criteria (a) and (b) and, based on these criteria, finally allowed the claim.

9.3.3 Thus, criteria (a) and (b) were used to support the "substance or composition"-like nature of a material that may have been a borderline case given the claim language used and the applicable provisions at the time. T 2003/08 does not derive from G 5/83 that criteria (a) and (b) were to be applied to any material. In particular, the conclusion drawn in decision T 1758/15, namely to apply these mode-of action-criteria to materials for which their "substance-or composition"-like nature is already immediately apparent as such, is not justified.

9.4 In sum, neither the statutory provisions of the EPC, nor the original decision G 05/83 dictate or merely suggest to look into the mode of action of a material once applied to the human or animal body for deciding whether it qualifies as a "*substance or composition*".

10. In addition to the lack of a legal basis, the use of the mode of action as the decisive criterion seems problematic for several other reasons.

10.1 First of all, the material acting inside the body may not be the same than the material the claim is directed to. The material defined in the claim and the material acting inside the body may differ in composition or in some other relevant property. This is clearly so in the present case. The claim requires the presence of a peptide solution. Already for this reason the claim is not directed to any particulate or spheric form of a hydrogel formed from the peptide solution inside the body. The question to be asked is whether the peptide solution defined in the claim is a "*substance or composition*". This question is to be decided irrespective of whether any solidified macrostructure formed from the substance, upon application in a specific way, can also be considered a substance or composition, or should rather be seen as a device. In other cases even the chemical structure of the substance may not remain the same during the therapeutic use. The Board notes that there are classical drugs which are administered as inactive prodrugs, the active species only being formed in the body by metabolic processes. However, second medical use claims under Article 54(4) and (5) EPC are generally directed to the administered substance. Since it is this substance which is used in a method excluded under Article 53(c) EPC, such a claim drafting is entirely in line with Articles 54(4) and (5) EPC.

10.2 Secondly, the mechanism of action may not be understood in detail, or original assumptions about the mechanism of action may later turn out to be wrong. In the present case, although it would appear at first sight

that embolization of blood vessels is an entirely mechanical process, it is well possible that the surface structure of the hydrogel formed has some influence on the adherence of the hydrogel to the inside surface of the blood vessels. Even classical medicaments may trigger a therapeutic physiological reaction without the mechanism for it being fully understood. Nevertheless this is no hindrance for the application of Articles 54(4) and (5) EPC to such medicaments or to doubt their nature as "*substance or composition*". Neither Article 53(c) nor Articles 54(4) or (5) EPC require that the mechanism of action of a substance or composition be understood. The Board notes that not even the for the purpose of sufficient disclosure under Article 83 EPC it is required that the mechanism underlying a therapeutic use be disclosed or understood. The description of the patent (application) only needs to allow a skilled person to reproduce the substance and the use as defined in the claim.

10.3 Thirdly, a material may behave in different ways according to its mode of administration. A peptide solution, as defined in the claims, may form a hydrogel and act in a "mechanical" way when applied inside a blood vessel. However, peptides may also trigger other physiological reactions due to interactions with receptors or other biological structures in the body, possibly when applied via a different route. It appears odd to classify the very same material as a "*substance or composition*" or not depending on extrinsic factors not related to the material itself, but to its way of administration.

10.4 Finally, the result of such a restriction does not achieve the legislative purpose, namely to provide at least a complementary form of protection for an

otherwise recognisably useful invention in a field where, despite its excluded nature, technical development is otherwise highly desirable and beneficial and therefore patent protection should also be available for such development (similarly in T 1020/03, reasoning 46).

10.5 As outlined above, applying additional criteria, such as criteria (a) and (b) of decision T 2003/08, may possibly be useful in cases where it is not straightforward that the material in dispute can be read on the definition "substance or composition", as in the case underlying decision T 2003/08. However, applying such additional criteria is not *mandatory* under the EPC or G 05/83. In particular it is not mandatory to apply such criteria if the substance-or-composition-like nature of the material is already immediately apparent from the claimed material as such, as in the present case.

11. The Board does not overlook the fact that distinguishing devices from substances for the purposes of Article 54(5) EPC is indeed required, and this article should not be used to circumvent the usual assessment of novelty of devices. A pacemaker or a surgical scalpel made of a particular stainless steel alloy do not qualify as a "*substance or composition*", even if they are claimed for use in an arguably novel therapeutic or surgical method. However, there is no apparent reason to disqualify a solution of a peptide, i. e. a shapeless liquid defined without any device-like features, from the scope of Article 54(5) EPC.

12. In summary, the question of whether a material, or an object is a "*substance or composition*" in the sense of Articles 53(c) and 54(4)or (5) EPC should be decided,

in the first place, on the basis of the claimed material or object as such. If this analysis leads to the conclusion that indeed a substance or composition is present, this requirement of Article 54(4) or (5) EPC is fulfilled. No additional restrictions relating to its mode of action are derivable from the EPC.

13. Novelty of claim 1 of the main request under Article 54(5) EPC.

13.1 Claim 1 of the main request relates thus to a substance or composition for use in a method excluded under Article 53(c) EPC. This substance or composition is also "responsible" for the therapeutic effect (see T 2003/08, reasons 17); without its administration no therapy would take place.

13.2 The specific uses defined in the claim are not disclosed in D1 or D2.

13.2.1 D1 discloses peptides as defined in the claim and likewise that these may form a hydrogel after injection (see e. g. claims 7, 12-14 and 20 there). D1 discloses a number of possible uses of the hydrogel formed on pages 26-32, but not the therapeutic uses defined in the claim. The Examining Division concluded that the peptides of D1 are *suitable for* the claimed uses, see point 62 of its decision, and the Board agrees. However, that the peptides are suitable for the uses defined in the claim is not enough to deny novelty of the claim. Suitability may play a role when examining the novelty of a device. However, as set out above, the Board holds that the claim is not directed at a device.

13.2.2 D2 likewise discloses the use of peptides included in the claims as vascular embolization agents. However, D2

does not disclose the specific uses recited in the claim, see point 63 of the Examining Division's decision.

13.3 Thus, claim 1 of the appellant's main request is novel over D1 and D2 under Article 54(5) EPC.

14. Remittal

Claim 1 of the main request was refused for lack of novelty over D1 and D2 because the novelty exception under Article 54(5) EPC was considered not to apply. However, as set out above, the Board concludes that the peptide solutions defined in the claim qualify as substance or composition in the sense of Article 54(5) EPC. Thus, claim 1 of the main request is novel over D1 and D2 on account of the specific use of the peptide solution defined in the claim. Other patentability requirements may have to be assessed in view of this finding of the Board. The Board considers this to be a special reason which under Article 11 RPBA and Article 111 EPC justifies a remittal of the case to the Examining Division for further prosecution.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Examining Division for further prosecution.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated