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**Datasheet for the decision  
of 11 July 2017**

**Case Number:** T 1758/15 - 3.2.08

**Application Number:** 03761283.5

**Publication Number:** 1536746

**IPC:** A61F13/00, A61F2/00, A61L31/04,  
A61L31/14

**Language of the proceedings:** EN

**Title of invention:**

FILLERS AND METHODS FOR DISPLACING TISSUES TO IMPROVE  
RADIOLOGICAL OUTCOMES

**Patent Proprietor:**

Incept, LLC

**Opponent:**

Q-Med AB

**Headword:**

**Relevant legal provisions:**

EPC R. 103(1)(a)  
RPBA Art. 11, 13  
EPC Art. 54(5), 53(c)

**Keyword:**

Substantial procedural violation - yes  
Reimbursement of appeal fee - (no)  
Remittal to the department of first instance - no  
Novelty - (no) - novelty of use - second (or further) medical  
use  
Exceptions to patentability - (yes) - method for treatment by  
surgery

**Decisions cited:**

T 2362/08, T 1717/13, G 0005/83, T 2003/08, T 1099/09,  
T 0773/10, T 2369/10, T 1069/11, T 1020/03, T 0826/06,  
G 0002/08, G 0001/07, T 0655/92

**Catchword:**



**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 1758/15 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 11 July 2017**

**Appellant:** Incept, LLC  
(Patent Proprietor) 6 Porter Lane  
Lexington, MA 02420 (US)

**Representative:** Finnie, Isobel Lara  
Haseltine Lake LLP  
Lincoln House, 5th Floor  
300 High Holborn  
London WC1V 7JH (GB)

**Respondent:** Q-Med AB  
(Opponent) Seminariegatan 21  
752 28 Uppsala (SE)

**Representative:** Awapatent AB  
P.O. Box 45086  
104 30 Stockholm (SE)

**Decision under appeal:** **Decision of the opposition division of the  
European Patent Office posted on 7 July 2015  
revoking European patent No. 1536746 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairwoman** P. Acton  
**Members:** C. Herberhold  
I. Beckedorf

## **Summary of Facts and Submissions**

- I. By its decision posted on 7 July 2015 the opposition division revoked European patent EP-B-1 536 746.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. Oral proceedings before the Board were held on 8 December 2016 and 11 July 2017. For the course taken by the proceedings, and in particular the issues discussed with the parties and the parties' initial requests, reference is made to the minutes of the oral proceedings.
- IV. At the end of the second oral proceedings the requests of the parties were as follows (excluding requests which were subsequently withdrawn):

The appellant requested that the decision under appeal be set aside and that the Board find that the opposition division committed a substantial procedural violation; further that the case be remitted to the opposition division immediately (i.e. before the Board discussed the case in substance), at least for further prosecution on inventive step; and that the patent be maintained in amended form on the basis of one of the sets of claims filed with letter of 9 June 2017 as main request, auxiliary requests 1 to 10 and auxiliary requests P0 to P10.

The respondent (opponent) requested that the appeal be dismissed.

- V. Claim 1 of the main request reads as follows:

"A biocompatible, biodegradable filler material for injection and for use in radiation treatment whereby the filler is injected into a space between a first tissue of a body and a second tissue, and whereby the first tissue is treated by radiation whereby the filler within the space reduces passage of radiation into the second tissue."

- VI. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that "for use in radiation treatment" has been replaced by "for use in radiation therapy treatment".
- VII. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that "for use in radiation treatment" has been amended to read "for prophylactic use in radiation treatment".
- VIII. Claim 1 of auxiliary request 3 further defines the radiation treatment by amending "for use in radiation treatment" to read "for use in radiation treatment of a first tissue of a patient's body to decrease radiation treatment induced side effects in a second tissue thereof, radiation treatment being a) brachytherapy radiation treatment for prostate cancer or gynecological cancer or b) external beam radiotherapy".

Furthermore, in the following part of the claim, the undetermined article "a" has been replaced with "the" where appropriate.

- IX. Claim 1 of auxiliary request 4 defines:

"A biocompatible, biodegradable filler material for injection and for use in a method of reducing radiation

treatment-induced side effects in a sensitive tissue of a patient's body wherein the method comprises displacing the sensitive body tissue relative to another body tissue that is the target of a radiation treatment by injecting the biocompatible, biodegradable filler material to a space between the sensitive body tissue and the target tissue and wherein the radiation treatment is a) brachytherapy radiation treatment for prostate or gynecological cancer or b) external beam radiotherapy, and whereby the target tissue is treated by radiation whereby the filler within the space reduces passage of radiation into the sensitive tissue".

X. Claim 1 of auxiliary request 5 reads as follows:

"A biocompatible, biodegradable filler material for injection and for use in radiation treatment of a first tissue of a patient's body to decrease radiation treatment induced side effects in a second tissue thereof, the radiation treatment being a) brachytherapy radiation treatment of prostate cancer or gynecological cancer or b) external beam radiotherapy whereby the filler is injected to a space between the first tissue of the body and the second tissue, and whereby the first tissue is treated by radiation whereby the filler within the space reduces passage of radiation into the second tissue, wherein biodegradation of the filler occurs between one week and twelve months after introduction of the filler into the body."

XI. Claim 1 of auxiliary request 6 defines:

"A biocompatible, biodegradable filler material for injection and for use in radiation treatment whereby the filler is injected into a space between a prostate

of a body and a rectum, and whereby the prostate is treated by radiation whereby the filler within the space reduces passage of radiation into the rectum.

XII. Claim 1 of auxiliary request 7 reads as follows:

"A biocompatible, biodegradable filler material for injection and for use in radiation treatment of a prostate of a patient's body to decrease radiation treatment induced side effects in a rectum thereof, the radiation treatment being a) brachytherapy radiation treatment for prostate cancer or b) external beam radiotherapy whereby the filler is injected to a space between the prostate of the body and the rectum, and whereby the prostate is treated by radiation whereby the filler within the space reduces passage of radiation into the rectum."

XIII. Claim 1 of auxiliary request 8 defines:

"A biocompatible, biodegradable filler material for injection and for use in radiation treatment selected from brachytherapy radiation treatment of prostate cancer or gynecological cancer or external beam radiotherapy whereby the filler is injected to a space between a first tissue of a body and a second tissue, and whereby the first tissue is treated by radiation whereby the filler within the space reduces passage of radiation into the second tissue, and wherein biodegradation of the filler occurs between one week and twelve months after introduction of the filler into the body and the filler comprises collagen, or hyaluronic acid, or is a member of the group consisting of polyethylene glycol, cellulose, alginate, gelatin and mixtures thereof."

XIV. Claim 1 of auxiliary request 9 is directed to:

"A method of injecting a biocompatible, biodegradable filler material to a space between a prostate of a body and a rectum prior to radiation treatment, whereby when the prostate is subsequently treated by radiation the filler within the space reduces passage of radiation into the rectum."

XV. Claim 1 of auxiliary request 10 differs from claim 1 according to auxiliary request 9 in the addition of a disclaimer:

"A method of injecting a biocompatible, biodegradable filler material to a space between a prostate of a body and a rectum prior to radiation treatment, whereby when the prostate is subsequently treated by radiation the filler within the space reduces passage of radiation into the rectum, excluding methods according to Article 53(c) EPC."

XVI. Claims 1 of auxiliary requests P0 to P10 differ from claims 1 of the main request to auxiliary request 10 in that in each of these claims a more detailed specification of the filler material has been added as follows:

"... wherein

(a) the filler material comprises an extracellular matrix molecule, wherein the extracellular matrix molecule is collagen; or

(b) the filler material comprises at least one polysaccharide, wherein the at least one polysaccharide is hyaluronic acid; or

(c) the filler material is polyethylene glycol; or



(d) the filler comprises a mixture of a first precursor and a second precursor that form a hydrogel."

XVII. The following document played a role for the present decision:

D37: FDA letter to Augmenix, Inc. dated 1 April 2015 regarding the "SpaceOAR System".

XVIII. The essential arguments of the appellant can be summarised as follows:

*Procedural violations by the opposition division*

During the oral proceedings the opposition division committed the following procedural violations (which will be discussed below in the reasons for this decision):

- a) The appellant had been arbitrarily denied the requested opportunity to file an additional request.
- b) The appellant's right to be heard had been violated because the opposition division had not provided any coherent explanation or rationale as to why the claim language used did not overcome the novelty objection in view of Article 54(5) EPC.
- c) The impugned decision was inconsistent and illogical, tantamount to lacking the reasoning required under Article 113(1) EPC.
- d) The opposition division had unexpectedly deviated from its preliminary opinion.

e) The *obiter dictum* rendered the decision inconsistent or raised a suspicion of partiality.

f) The opposition division had been partial.

*Remittal of the case to the opposition division*

Because of the procedural violations identified, the case should be remitted in accordance with Article 11 RPBA to afford the appellant the opportunity of two instances, in particular in view of the objections introduced for the first time with the *obiter dictum*. At the very least, the case should be remitted for evaluation of inventive step, which had not yet been discussed before the opposition division.

*Admission of the requests filed by the appellant with letter of 9 June 2017*

During the proceedings the appellant had always tried to deal with new objections immediately and appropriately. The requests and documents filed with letter dated 9 June 2017 were a reaction to issues first raised in the impugned decision's *obiter dictum* and elaborated on in the Board's communication dated February 2017. They were thus a timely response to the course of proceedings and should be admitted.

*Novelty, Article 54(5) EPC - main request, auxiliary requests 1-8, P0-P8*

The claim defined a material with several combined properties, namely being biocompatible, biodegradable, injectable, and a filler material i.e. capable of forming a 3-D structure. By these combined properties, the material was able to achieve a number of things: it

could be implanted in a single patient interaction, subsequently hold open a particular volume over a longer time, see paragraphs [0016], [0036], [0054] of the specification, thereby spacing away and inevitably shielding a sensitive tissue from radiation and further preventing tissue adhesion. It thus provided a prophylactic action benefiting healing. Thereafter, the material disintegrated without having to be extracted surgically.

All these positive effects were a direct consequence of the composition and directly related to the treatment. Importantly, the effects flowed from the chemistry, i.e. from the particular substance or composition used, and were not achievable by a device.

The filler material claimed thus fell under the term substance or composition in Article 54(5) EPC, which should take its normal meaning and not be artificially limited, thus making second medical use protection available for the claimed materials.

While it was true that G5/83 mentioned active ingredients, this was a relatively old decision concerned mainly with issues different from the definition of the terms "substance or composition". It was more relevant that the more recent G2/08, point 5.9.1.2 of the reasons, had explicitly clarified that there was no principle of narrow interpretation of exceptions. G2/08 further stated under point 5.10.9 of the reasons that there was indeed a "seamless fit", i.e. that if a method was excepted from patentability under Article 53(c) EPC, second medical use protection was available for a substance or composition for use in said method. T 2003/08 was likewise no obstacle to considering the claimed filler a substance or

composition. If anything this decision showed the Board's intention to interpret the term substance or composition in a broad way.

Thus, since in the present case the filler material had to be considered a substance and composition, it became novel by the specific use claimed being novel.

Therefore, the subject-matter of claim 1 according to the main request and according to auxiliary requests 1-8 and P0-P9 was novel in accordance with Article 54(5) EPC.

*Article 53(c), 84 EPC - auxiliary requests 9, 10, P9, P10*

Auxiliary requests 9, 10, P9 and P10 were restricted to the method of injection, with prophylactic and therapeutic steps not being part of the subject-matter, but only mentioned to define the function of the filler once injected at the particular site. The injection itself did not constitute a method of treating the human or animal body by surgery. Following the more narrow understanding of the term in G1/07 and in view of the position of the prostate and the rectum close to the skin, the injection had to be considered a safe routine intervention. As also evidenced by D37, page 8, "conclusions", the risk of a harmful event was low and the injection technique well established.

Therefore, the method should not be considered excluded from patentability as a treatment by surgery under Article 53(c) EPC.

In case only some methods covered by the claim would be regarded by the person skilled in the art as not

excluded from patent protection under Article 53(c) EPC, the disclaimer was intended to restrict the subject-matter to such allowable methods.

*Referral of questions to the Enlarged Board of Appeal*

It was further requested that several questions be referred to the Enlarged Board, in order to ensure uniform application of the law and to clarify a point of law of fundamental importance.

- XIX. The essential arguments of the respondent can be summarised as follows:

*No procedural violation by the opposition division*

None of the appellant's various complaints amounted to a procedural violation.

*No remittal of the case to the opposition division*

As the opposition division had not committed any procedural violation, there was no reason to remit the case. Indeed, remittal would be contrary to procedural efficiency. Thus the Board should deal with the substantive issues of the case directly in the appeal proceedings.

*The requests filed by the appellant with letter of 9 June 2017 - non-admission into the proceedings*

The requests had been filed late. The arguments to which they were a reaction had already been raised in the respondent's reply dated March 2016, i.e. before the Board's communication dated February 2017. Thus, the appellant could and should have reacted earlier,

and neither the requests nor the documents should be admitted into the proceedings.

*Novelty, Article 54(5) EPC - main request, auxiliary requests 1-8, P0-P8*

The EPC differentiated between products which were a substance or composition and products which were not. The difference was in the mode of action: whereas a substance or composition showed a chemical or biochemical interaction with the body, other products were active physically, not pharmacologically, chemically or immunologically.

When interpreting Article 54(5) EPC it had to be kept in mind that the legislator's intention in introducing that article had been to codify the case law of the Enlarged Board in G 5/83. This decision established - as recently confirmed in T 2003/08 - that the decisive criterion for a product to be considered a substance or composition was that it was an active ingredient or had an active principle. This was in no way invalidated by G 2/08, which ruled that the particular specific use in a second medical use claim should not be interpreted too narrowly, but which did not define what constituted a substance or composition.

In the present case, the principal mode of action of the filler was a physical displacement of the sensitive tissue. In particular paragraphs [0016], [0028], [0049] and claim 19 showed that the filler was indeed effective by increasing the distance and occupying a volume, i.e. by a physical effect of the accumulated mass and not due to its chemical constitution. There was furthermore no disclosure of any shielding effect of the filler material, such an effect being anyway

completely negligible for the substances mentioned. The spacing effects were present for any filler material, which further underlined that the effect was a physical one, independently of the particular chemistry of the filler. The filler was thus a device rather than a substance or composition in the sense of Article 54(5) EPC.

This was in accordance with the case law in cases T 2003/08 and T 773/10, both dealing with removal of particular metabolites from the body in an extracorporeal circuit. Whereas in the first case the principal mode of action was brought about by the chemical action of a ligand for human immunoglobulin coupled to a column, in the second case the effect was caused by a physical mode of action of the dialysis membrane. In accordance with the above criteria, second medical use protection was accepted for the chemically active ligand, whereas it was denied for the dialysis membrane, which did not have any active ingredient in the sense of G 5/83.

In this context it also had to be taken into account that every device was made of chemical materials, like the polypropylene of the sling in T 1099/09, which contributed to the device having a certain form, being bio-compatible or non-toxic. Biodegradability too was a typical device feature, as could be seen for example in the case of bioresorbable sutures. If these effects were to be taken into account as prophylactic effects of the material, indirect second medical use protection of any device would be possible, contrary to the wording of the EPC.

Instead, it was the principal mode of action which was decisive when assessing whether a product fell under

the terms "substance or composition" in the sense of Article 54(5) EPC, and which in the present case was the prevention of radiation-induced side-effects due to the displacement of sensitive tissue, i.e. due to the physical effect of the implanted 3D accumulated mass.

To conclude, the filler did not qualify as a substance or composition in the sense of Article 54(5) EPC, and the subject-matter of claim 1 of the requests was therefore not novel.

*Article 53(c), 84 EPC - auxiliary requests 9, 10, P9, P10*

The method claims clearly defined methods of treatment of the human or animal body by surgery. The prostate and the rectum constituted sensitive tissue located in a highly sensitive area. As could be seen from the table in D37, page 3, multiple substantial health risks were associated with the claimed injection. Auxiliary requests 9, 10, P9 and P10 therefore were not allowable in accordance with Article 53(c) EPC.

With respect to auxiliary requests 10 and P10, claiming a surgical method, while at the same time disclaiming methods according to Article 53(c) EPC, made the claim contradictory and thus unclear.

Consequently, auxiliary requests 9, 10, P9 and P10 were not allowable.

*Referral of questions to the Enlarged Board of Appeal*

The respondent could identify neither an inconsistency in the case law nor any point of law of fundamental



importance not yet dealt with by the Enlarged Board.  
There was thus no need to refer questions to it.

## **Reasons for the Decision**

1. Procedural violation
  - 1.1 Denial of the opportunity to file an additional request
    - 1.1.1 The appellant essentially complains that although the objection under Article 54(5) EPC had only been introduced by the respondent with submission dated 15 May 2015, the opposition division - after accepting two genuine and *bona fide* requests into the proceedings - arbitrarily refused to admit a further request, before even seeing it. The respondent, on the other hand, essentially argues that the opposition division never refused to entertain further requests because none had actually been filed, the extremely late filing of several auxiliary requests being in any case an abuse of procedure.
    - 1.1.2 It is uncontested that - during opposition proceedings - the line of argument that the use defined in claim 1 of the main request was not a "specific use in a method referred to in Article 53(c) EPC" was first introduced by the respondent with letter dated 15 May 2015, i.e. on the last date for making written submissions set in the summons dated 29 January 2015. In this context the Board agrees with the appellant that the fact that the argument was mentioned during examination proceedings does not make it part of the opposition proceedings.

In accordance with Rule 116(2), last sentence, EPC in conjunction with Rule 116(1), 4th sentence, EPC,

documents (i.e. requests) which meet (i.e. which are filed with the intention of meeting) the requirements of the Convention presented after the mentioned date need not be considered, unless admitted on the grounds that the subject of the proceedings has changed. In this context, it is noted that Rule 116 EPC refers to "facts and evidence" but not to new arguments - which can be made at any stage of proceedings (Case Law of the Boards of Appeal, 8th edition 2016, IV.C.1.3.4). Thus, the opposition division under Rule 116 EPC had discretion whether or not to admit the new requests submitted by the appellant.

- 1.1.3 A discretionary decision needs to be reasoned, i.e. it needs to take into account the relevant facts of the particular case and strike a balance between the interests of the parties.

It is thus worthwhile reviewing the relevant facts of the case:

- (a) During the oral proceedings, the opposition division - in exercising its discretion under Rule 116(1), (2) EPC - admitted two auxiliary requests into the proceedings (auxiliary request 2 and 3), which however it then found not allowable. In this context, the division announced explicitly that it would "allow a last chance for P to provide a set of claims complying with the formal requirements of Article 54(5) EPC" (minutes, page 12, 5th paragraph).

Then a third request was filed (auxiliary request 4) which was also admitted under Rule 116(1) and (2) EPC. It is evident from the decision, page 18, last paragraph - page 19, first

paragraph, that the opposition division considered auxiliary request 4 to be a fair attempt to overcome the objections raised. Ultimately auxiliary request 4 failed for non-compliance with Article 123(2) EPC (decision, page 19, second paragraph - page 20, first paragraph).

- (b) It further emerges from the minutes and the decision that the appellant explicitly requested to file an additional auxiliary request (decision, page 20, 3rd paragraph; minutes, page 17, penultimate paragraph). That request was refused because "the opposition division considered four attempts (Auxiliary requests 1-4) to overcome a single issue sufficient and will not admit an additional Auxiliary Request into the proceedings" (decision, page 21, first paragraph). The respondent's argument that no additional request was actually filed thus cannot hold, as the appellant was clearly prevented by the opposition division from doing so (minutes, p. 17, penultimate paragraph). To conclude, the filing of an amended auxiliary request was refused in advance, without seeing the amendment.

- 1.1.4 Therefore, - the appellant's explicit request to be allowed to file a further request having been refused upfront - the opposition division was not in a position to consider and weigh up in this respect the relevant facts of the particular case. Without knowing the content of the request, it was impossible e.g. to assess whether the amendments were appropriate, i.e. a fair attempt to overcome the objections, and whether or not the request was *prima facie* allowable.

The opposition division thus concluded, in an unjustified manner, that four auxiliary requests (of which only three had been filed during the oral proceedings) were enough. It thus did not exercise its discretion pursuant to Rule 116(2) and Article 114(2) EPC in a reasonable way, which constitutes a substantial procedural violation. Or, in the words of T 246/08 (albeit in the context of Rule 137(3) discretion): "There is a world of difference between a pre-emptive formal declaration that no (further) amendments will be admitted and advising the applicant that a discretionary power to permit or refuse amendments exists and will be exercised in the event that amendments are submitted."

- 1.1.5 To refuse any further amendment may be appropriate if it becomes evident after various unsuccessful amendments that the proprietor is not seriously trying to overcome the objections but is only delaying the proceedings. An opposition division may also ask the proprietor to present together requests addressing a specific issue that has already fully been discussed, in order to prevent subsequent filing of various consecutive requests (which might, in the absence of new developments, then be considered abusive).

In the present case, however, the decision to not admit the request was taken without the division having identified any signs of procedural abuse (decision, page 18, last paragraph to page 19, first paragraph) and without having seen the request. In fact, it was announced even before the filing of earlier *bona fide* auxiliary request 4, which was then admitted.

- 1.1.6 In T 1717/13, invoked by the respondent, the applicant's request to be allowed to file further

auxiliary requests did not arise from new attacks against the patent in suit and/or the submission of additional prior-art documents, but exclusively from the fact that the appellant's numerous attempts to rectify deficiencies under Article 123(2) EPC, on the basis of a detailed description of the embodiments, remained unsuccessful (reasons, point 1.5). Hence, the case is different from the present one, and its conclusion does not apply.

- 1.1.7 The Board thus comes to the conclusion that the opposition division committed a procedural violation in not exercising its discretion under Rule 116 EPC in a reasonable way.

Because the appeal is not deemed allowable (see below), the appeal fee is not reimbursed. In any case, during second oral proceedings the appellant withdrew its request for reimbursement.

2. No remittal to the opposition division

In accordance with Article 11 RPBA, if fundamental deficiencies like the one identified in point 1.1 above become apparent, a board remits the case to the department of first instance, unless special reasons present themselves for doing otherwise.

In the present case the Board comes to the conclusion that special reasons do indeed present themselves for not remitting the case. In reaching this conclusion, the Board took note of the other procedural deficiencies alleged by the appellant (see facts and submissions, XVIII, b-f). Even assuming, for the sake of the argument, that the decision under appeal suffered from those additional deficiencies as well,

the Board exercises its discretion under Article 11 RPBA to not remit the case to the opposition division for the following reasons:

Firstly, the patent is relatively old (earliest priority June 2002). A remittal in 2017, with continued opposition proceedings and a likely further appeal, would thus result in legal uncertainty for a large part of the patent's remaining term.

Secondly, even if the appellant had been given the requested opportunity to file a further request, under Rule 116 EPC the opposition division would have had discretion to not allow it into the proceedings. Such a discretionary decision would have been subject to only limited review by the Board, in accordance with G 7/93. The actual effect of the procedural violation on the first-instance proceedings is thus potentially relatively minor.

Thirdly, the facts and major lines of arguments are on the table. While it is true that the objections raised in the *obiter dictum* have not been discussed before the opposition division, these would hardly change the outcome of further opposition proceedings in the appellant's favour. A remittal would thus most likely only create a delay of several years, with the Board thereafter being confronted with essentially the same case. That would be contrary to procedural efficiency.

Under these circumstances, the Board chose to exercise its discretion under Article 111(1) EPC to also deal with the substantive issues. In this context, it is pointed out that under the EPC, there is no absolute right to have a case decided by two instances.

3. Admission of the appellant's requests filed with letter of 9 June 2017

The main issue of substance in this appeal, i.e. whether the filler qualifies as a substance or composition in the sense of Article 54(5) EPC, was first raised - apart from a mention in an *obiter dictum* of the impugned decision - with the respondent's reply dated 29 March 2016. However, with the Board's communication dated 26 July 2016, the focus of the case quickly turned to the alleged procedural violation, substantive issues coming back into play only with the Board's second communication of 2 February 2017. The requests and documents filed by the appellant with letter of 9 June 2017 are in reply to said second communication and within the time limit set therein. Moreover, despite their number, they focus on the objections raised by the Board and represent a *bona fide* attempt to overcome them. The Board thus decides to admit them into the proceedings.

4. The invention

The patent relates to a biocompatible, biodegradable, injectable filler material (e.g. collagen or hyaluronic acid) for use in a specific method. Said use / method comprises the injection of the filler material into a space between a first tissue of the body and a second tissue, the first tissue being subsequently treated by radiation, whereby the filler within the space reduces the exposure of the second tissue to radiation. For example, the rectum is displaced from the prostate by the filler material (see e.g. patent, paragraph [0061]), such that radiation therapy of the prostate can be performed with fewer side-effects on the rectal tissue (patent, paragraph [0072]).

5. Novelty, Article 54(5) EPC - main request, auxiliary requests 1-8, P0-P8

5.1 It is uncontested that in particular the filler "human collagen" is known in the art. In this context, paragraph [0058] of the specification states that "human collagen is commercially available from multiple manufacturers". Furthermore, "human collagen has been injected into the perineum in hope of improving urinary incontinence" (patent, paragraph [0022]). "Human collagen" is uncontestedly "biocompatible" and "biodegradable", making it a "filler material for injection" comprised in the state of the art and disclosed for at least one therapeutic method ("improving urinary incontinence") referred to in Article 53(c) EPC.

The subject-matter of claim 1 of the main request, auxiliary requests 1-8 and auxiliary requests P0-P8 can thus only be novel if it fulfils the requirements for



purpose-limited product protection according to Article 54(5) EPC.

Said article imparts novelty only to substances or compositions used in a method referred to in Article 53(c) EPC. It will be examined in the following whether the filler material claimed falls under the term "substance or composition" or not.

## 5.2 Interpretation of "substance or composition"

5.2.1 With respect to the wording of Articles 53(c) and 54(5) EPC (see in this context T 1099/09, Reasons point 3.3; T 2003/08, Reasons point 12 - the difference in wording of the respective articles is present in both EPC 1973 and EPC 2000), the Convention distinguishes between products which qualify as a "substance or composition" and products which do not. Purpose-related product protection is only available for the former.

5.2.2 Following this rationale, a consistent body of case law has evolved denying further medical use protection for devices (see e.g. T 1099/09, T 1069/11, T 773/10, T 2369/10, T 1314/05).

5.2.3 However, every device is ultimately made from chemical substances or compositions, just as e.g. the urethral sling of T 1099/09 is made from polypropylene. The substance or composition from which a device is made determines and influences the characteristics of the device, e.g. its biocompatibility or its mechanical properties, which then determine at least some of the effects the device has or does not have on the body.

5.2.4 Considering any material from which a device is made to be a "substance or composition" in the sense of Article

54(5) EPC would render pointless the distinction - directly derivable from the wording of the EPC itself - between products which are substances and compositions and products which are not. The Board thus comes to the conclusion that such a very broad interpretation is not correct, and that a narrower one is required.

- 5.2.5 In order to establish the legislator's intention behind the wording of Article 54(5) EPC 2000, it is worthwhile to have a look into its legislative history. The article was introduced into the Convention by the Munich diplomatic conference held in 2000. According to the "Synoptic presentation EPC 1973/2000 - Part 1: The Articles" (Official Journal, Special Edition No. 4, 2007, page 54, point 4), as well as to the *travaux préparatoires* (MR/2/00; MR/18/00; and MR/24/00, points 138-143), the legislator intended the case law developed by the EPO Enlarged Board of Appeal (i.e. decision G 5/83) to be enshrined in the Convention. The wording of Article 54(5) was hence intended to match as closely as possible the scope of protection provided by a Swiss-type claim.

This indicates that, in order to establish the required interpretation of the term "substance or composition", reference can be made to Enlarged Board of Appeal decision G 5/83 (OJ EPO 1985, 64), i.e. to "the case law evolved by the EPO Enlarged Board of Appeal".

It is true that the wording of Article 54(5) EPC ("for any specific use in a method referred to in Article 53(c)") includes "methods for treatment of the human or animal body by surgery and diagnostic methods", whereas the original Swiss-type formulation referred to "the manufacture of a medicament for a specified new and inventive therapeutic application" (G5/83, headnote 2).

However, the novelty of substances or compositions used in a new way in diagnostic and surgical methods was recognised in the case law before introduction of Article 54(5) EPC 2000, see e.g. T 655/92 for diagnostic and T 826/06 for surgical methods. Hence the same principles for defining the meaning of the term "substance or composition" apply to products used in any of the methods referred to under Article 53(c) EPC.

- 5.2.6 In analysing Enlarged Board of Appeal decision G 5/83, Board 3.3.04 (see T 2003/08, Reasons points 15-18) came to the conclusion that G 5/83 endorsed the interpretation of the term "substance or composition" as being "the active agent or ingredient" of the particular specific medical use (see G5/93, Reasons point 23; also point 20 refers to "the active ingredient").

With this interpretation in mind, Board 3.3.04 developed an approach to determine whether or not "a substance or composition" is used in a treatment (Reasons point 18), an approach which may also be helpful in the present case.

In particular, it suggested establishing (a) the means by which the therapeutic effect is achieved and (b) whether that which achieves the therapeutic effect is a chemical entity or composition of chemical entities.

- 5.2.7 The appellant has referred to G 2/08 (point 5.9.1 of the reasons) as allegedly advocating a broader interpretation of the term "substance or composition". However, the cited passage deals with interpretation of the term "any specific use" in Article 54(5) EPC, which according to G 2/08 should not be interpreted narrowly in the sense that only a disease not yet treated by the

known substance or composition could constitute a "specific use" within the meaning of that article. An interpretation of the term "substance or composition" in Article 54(5) EPC cannot be derived from this decision, nor can it invalidate the above considerations with respect to the term "substance or composition" derived from G 5/83.

It was further argued that G 2/08 (point 5.10.9 of the reasons) underlined the existence of a seamless fit: once a method fell under the exception in Article 53(c) EPC (which made claiming the method itself impossible), second medical use protection via Article 54(5) EPC became available. This is, however, only true for substances or compositions, because Article 54(5) EPC can only be applied to those. Products which are not a substance or composition in the above sense cannot profit from second medical use protection.

- 5.2.8 In the present case, the effect of the use of the filler material is the reduction of radiation-treatment-induced side effects on sensitive organs resulting from therapies and applications directed to another target organ (patent, paragraph [0010]). This technical effect is achieved by a mechanical displacement of the sensitive tissue relative to the target tissue, thereby increasing the distance between the two (patent [0016], [0028], [0049] and claim 19). The mechanical displacement is achieved by the accumulated mass of the filler material between the two tissues, i.e. by its 3D macrostructure being positioned at the particular implantation site.

The accumulated mass of the filler material does not, however, qualify as a chemical entity or composition of chemical entities in the sense of G 5/83. Although made

up of particular chemical molecules like collagen, which have some influence on the characteristics of the resulting mass (e.g. non-toxicity, biodegradability etc.), the effect is achieved by the macroscopic 3D form and the position of the mass (just as it is the positioning of the sling and not the capability of polypropylene to form such a sling which brings about the therapeutic effect of the urethral sling of T 1099/09). That the material has some indirect influence on the characteristics of the resulting solid structure does not make the material the active principle. The therapeutic effect still resides in the 3D structure achieved within the body, which merely "occupies a volume" in a certain position.

The effects mentioned by the appellant, such as holding open a particular volume for a longer period and distancing of sensitive tissue with disintegration of the accumulated mass after a specific time, are all effects of the 3D structure built up at the particular implantation site and only indirectly attributable to the particular substance from which said 3D structure is built. This is in accordance with the wording of the claims in the application as filed which refer to a medical device having at least a portion that has a shape substantially conforming to the body space it was injected into. Therefore, the filler qualifies as an initially viscous device rather than as a substance or composition.

5.2.9 Contrary to the appellant's submissions, the filler material of the present application is not disclosed as having a relevant radiation-reducing effect on the tissue which can be ascribed to its chemical properties. It is true that paragraph [0005] of the specification mentions "shielding". However, this

paragraph refers to the general issue of reducing radiation in tissues which are not to be treated by radiotherapy and enumerates in general all the parameters which are to be considered, namely: time, distance, and shielding. There is no other mention of a shielding effect of the filler material (unless mixed with further unspecified agents which block radiation, see paragraph [0040] last sentence).

Instead, as discussed above, the radiation-protecting effect is constantly ascribed to the physical displacement of the sensitive tissue, while the intrinsic shielding effect of the particular filler materials mentioned is of negligible relevance.

Therefore, the filler material cannot ascribe its therapeutic properties to this intrinsic, physical quality.

- 5.2.10 To conclude, the filler material claimed is not a substance or composition in the sense of Article 54(5) EPC.

Consequently, the use defined in claim 1 of the main request, as well as of auxiliary requests 1-8 and P0-P8, cannot be regarded as a differentiating feature, irrespective of whether or not the use has been further specified in the auxiliary requests.

The undisputedly commercially available collagen is therefore novelty-destroying for the main request, as well as for auxiliary requests 1-8 and P0-P8.

6. Articles 53(c), 84 EPC - auxiliary requests 9, 10, P9, P10

Claim 1 of these requests defines a method of injecting a biocompatible, biodegradable filler material into a space between the prostate and the rectum. As discussed in the FDA approval of a similar product (D37), this injection carries the risk of needle penetration and/or spacer material injection into the bloodstream, the bladder, the prostate, the rectal wall, the rectum or the urethra and may result in urine retention, bleeding, rectal mucosal damage, ulcers, necrosis, constipation, or rectal urgency (D37, page 3, Table "Identified Risks and Required Mitigations"). In view of these health risks, the injection claimed is a substantial physical intervention on the body which requires professional medical expertise and which entails substantial health risks even when carried out with the required professional care and expertise. In accordance with G 1/07, such methods are excluded from patentability pursuant to Article 53(c) EPC. Therefore, claim 1 of auxiliary requests 9, 10, P9 and P10 is not allowable.

It is noted that claims 1 of auxiliary requests 10 and P10 additionally comprise a disclaimer "excluding methods according to Article 53(c) EPC". In view of the above analysis, the disclaimer essentially deprives the claim of any content. In addition to not being allowable under Article 53(c) EPC, these claims are thus internally contradictory and hence not clear (Article 84 EPC).

7. Referral of questions to the Enlarged Board of Appeal

7.1 The appellant requested the referral of the following questions to the Enlarged Board of Appeal:

7.1.1 For clarifying a fundamental point of law:

a) Do decisions G 1/07 and G 2/08, taken together, establish that Articles 54(4) and (5) EPC applied to substances or compositions for use in any (or, in the case of Article 54(5) EPC, any specific) method of treatment of the human or animal body by surgery, whether or not the surgery or the use of the substances or compositions therein has a therapeutic effect?

b) If the answer to a) is positive, do any conditions apply to the application of Articles 54(4) and (5) EPC?

c) If the answer to a) is negative, is the position different in relation to substances or compositions for use in any (or any specific) method of treatment of the human or animal body that has elements of both surgery and therapy?

Another possibly more specific formulation of the above questions might be:

d) What are the criteria for a product to be a substance or composition for use in prophylaxis or surgery-prophylaxis, as opposed to a device, as ruled for example in T 2369/10?

7.1.2 There was further a divergence in the case law between T 2003/08 which possibly favoured a narrow understanding of Article 54(5) EPC and T 1020/03 which decided that a broad understanding should be applied.



In particular the question was whether a therapeutic effect was required of a substance or composition for use in any of the methods referred to in Article 53(c) EPC in particular a surgical method.

7.2 Questions regarding a fundamental point of law (point 7.1.1)

7.2.1 *ad a)*: Article 54(4) and (5) EPC allows patentability of any substance or composition, comprised in the state of the art, for use in a (specific) method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art. Article 53(c) EPC excludes from patentability methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. According to G 1/07, reasons 3.3.5, the definition given by the Enlarged Board in its opinion G 1/04 cannot be understood in the sense that the Enlarged Board thereby endorsed the view that the term "treatment by surgery" was limited to therapeutic surgery. Hence, it follows from Articles 54(4) and (5) and 53(c) and G 1/07 that Articles 54(4) and (5) can be applied to substances or compositions in any (specific) method of treatment of the human or animal body by surgery, whether or not the surgery or the use of the substances or compositions therein has a therapeutic effect.

As the question can be answered from the EPC and from a previous decision of the Enlarged Board, there is no need to refer it.

7.2.2 *ad b)* Article 54(4) and (5) EPC states that Articles 54(2) and (3) EPC do not exclude the patentability of any substance or composition, comprised in the state of

the art, for use in a (specific) method referred to in Article 53(c) EPC. It thus follows that the exceptions of Article 54(4) and (5) EPC apply only to substances or compositions, but not to products in general.

Again, the question can be answered from the EPC itself and a referral is not necessary.

7.2.3 *ad c)* As the answer to the first question is positive, there is no need to answer this third question.

7.2.4 *ad d)* As discussed above, it can be derived from decision G 5/83 that a "substance or composition" is "an active ingredient", i.e. it has an active principle. While this was originally decided in the context of a therapeutic method, with second medical use protection becoming available for surgical and diagnostic methods - first in the case law, then in the explicit wording of Article 54(4) and (5) EPC 2000 - this rationale equally applies to surgical and diagnostic methods, i.e. the substance or composition needs to be active in the method.

Thus, with respect to the abstract question formulated above, the Enlarged Board has already provided in G 5/83 the abstract criterion to identify a substance or composition in the sense of Article 54(5) EPC. Again, a referral is not required.

7.2.5 What remains is to apply the abstract criterion to the technical reality of the individual cases under consideration, a typical task for the examining and opposition divisions and the technical boards of appeal.

Therefore, answering the above question in the specific case of the present invention falls within the competence and duty of the Board.

- 7.2.6 Although this has not been argued by the appellant in the oral proceedings, the Board notes for the sake of completeness that the injectable filler of the present invention does not have an active principle with respect to the surgical method of its implantation. It is rather the passive object thereof. Even if a potential involvement in hydrodissection was assumed, this would be an effect of the accumulated filler mass at the implantation site, and not of the particular filler material (the "chemical" in the sense of T 2003/08).

Conversely, as an illustrative example of a substance or composition that has an active principle in the context of a surgical method, the case underlying T 826/06 may be cited. There, a dye (in this case a well-defined chemical) was used for selectively staining the outer surface of the anterior lens capsule (of the eye), thereby providing a clear distinction between the portion of the anterior lens capsule that was to be removed and the underlying lenticular material, which distinction facilitated the controlled opening of the anterior lens capsule" (T 826/06, reasons 5.2.1). In this case, the dye was (a) the means by which the selective staining facilitating the surgery was achieved, and (b) a chemical, thus qualifying as a substance or composition in the sense of what is now Article 54(5) EPC.

### 7.3 Alleged divergence in the case law

With respect to the above interpretation of the term "substance or composition", the Board does not see any divergence in the case law:

In T 2003/08 the deciding Board was dealing with a therapeutic application of a specific ligand for human immunoglobulin bound to a column. Being well aware of the distinction drawn in the case law between products which are substances or compositions, and products which are not, an approach was developed for determining whether a "substance or composition" (or a device) is used in a treatment, see point 18 of the reasons.

Conversely, in T 1020/03 it was never in question that insulin-like growth factor I (IGF-I) qualified as a substance or composition in the sense of Article 54(5) or G 5/83. Instead, the discussion focused on the level of detail required when defining an allowable second medical use claim for a composition which has already been suggested for some therapeutic use before. The level of detail specified in the second medical use had, however, not been an issue in T 2003/08.

Hence both decisions focus on the interpretation of different parts of what is now Article 54(5) EPC 2000, and the conclusions drawn are not at odds with each other.

Therefore, for deciding the case at hand there is no divergence in the case law requiring clarification by the Enlarged Board.

**Order**

**For these reasons it is decided that:**

1. The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated