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**Datasheet for the decision
of 1 December 2016**

Case Number: T 0186/15 - 3.3.10

Application Number: 09716636.7

Publication Number: 2259803

IPC: A61L15/32, A61L15/42, A61L15/44

Language of the proceedings: EN

Title of invention:
DEVICE FOR PROMOTION OF HEMOSTASIS AND/OR WOUND HEALING

Patent Proprietor:
Ferrosan Medical Devices A/S

Opponent:
Baxter Innovations GmbH

Headword:

Relevant legal provisions:
EPC Art. 107, 100(a), 56, 123(2), 123(3), 84, 100(b), 111(1)
RPBA Art. 12(4)

Keyword:

Admissibility of appeal - (yes)

Scope of the appeal - includes the ground defined in Article 100(a) EPC

Inventive step - (no) - main request, first and second auxiliary requests

Third auxiliary request - added subject-matter (no); sufficient disclosure (yes); novelty (yes); inventive step (yes); remittal (yes)

Decisions cited:

G 0001/88, G 0003/14, T 0020/81, T 0134/91, T 0409/91, T 0435/91, T 1621/09, T 0134/11

Catchword:



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Case Number: T 0186/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 1 December 2016

Appellant: Baxter Innovations GmbH
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1221 Wien (AT)

Representative: Sonn & Partner Patentanwälte
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Respondent: Ferrosan Medical Devices A/S
(Patent Proprietor) Sydmarken 5
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
28 November 2014 concerning maintenance of the
European Patent No. 2259803 in amended form.

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
T. Bokor

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division to maintain European patent No. 2 259 803 in the form of the then pending main request.

II. Notice of opposition had been filed on the grounds of insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings included the following:

D11: WO 2005/084650

D12: WO 90/13320

The documents filed during appeal proceedings included the following:

D29: WO 95/12371

IV. The opposition division concluded that the claimed invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and that the matrix of claim 1 was novel. Document D12 was the closest prior art, the problem underlying the claimed invention was providing an improved haemostatic matrix material, and the claimed solution, which was characterised by having a haemostatic material printed on it, was inventive having regard to the prior art.

V. The respondent (patent proprietor) filed with a letter dated 13 July 2016 the main request in these appeal

proceedings, which is identical to the main request in opposition proceedings, and first to twenty-fifth auxiliary requests, which replaced every auxiliary request then pending.

Claim 1 of the main request reads as follows:

"A matrix material comprising a surface and a plurality of open and interconnected cells, said matrix material comprising gelatine or collagen, wherein the surface of said matrix comprises at least one pharmaceutical composition printed onto said surface in individual and discrete locations, wherein said pharmaceutical composition comprises one or more haemostatic agents."

Claim 1 of the first auxiliary request reads as follows:

"A matrix material comprising a surface and a plurality of open and interconnected cells, said matrix material comprising gelatine or collagen, wherein the surface of said matrix comprises at least one pharmaceutical composition comprising thrombin printed onto said surface in individual and discrete locations".

Claim 1 of the second auxiliary request contains all the features of claim 1 of the first auxiliary request, adding that

"said matrix material being a gelatine or collagen sponge".

Claims 1, 13 and 14 of the third auxiliary request reads as follows:

"1. A matrix material comprising a surface and a plurality of open and interconnected cells, said matrix material comprising gelatine or collagen, wherein the surface of said matrix comprises at least one pharmaceutical composition comprising thrombin printed onto said surface in individual and discrete locations, wherein the surface of the matrix contains thrombin in the range of from 0.5 IU/cm² to 50 IU/cm².

13. A device comprising the matrix material printed with a pharmaceutical composition according to claims 1 to 12.

14. A method for making the device according to claim 13 comprising the steps of

a. providing a matrix material according to claims 1 to 12, and

b. printing a pharmaceutical composition comprising thrombin onto the surface of said matrix material at individual and discrete locations to achieve a surface of the matrix containing thrombin in the range of from 0.5 IU/cm² to 50 IU/cm²."

VI. The arguments of the appellant relevant for the present decision were the following:

The appellant was adversely affected by the decision of the opposition division, as it did not revoke the patent. For that reason, the appeal was admissible.

The appeal was not limited to the ground of opposition defined by Article 100(b) EPC. The appellant substantiated the ground defined in Article 100(a) EPC with respect to novelty and inventive step in the

grounds of opposition and in the statement of grounds of appeal. For that reason, the objections under Article 100(a) EPC were part of these appeal proceedings.

There was no exceptional situation in the present case which could justify document D29, filed with the statement of grounds of appeal, being held inadmissible by the board.

Article 12(4) RPBA only referred to "facts, evidence or requests", not to arguments. For that reason, new arguments raised during appeal proceedings could not be held inadmissible.

The patent in suit disclosed that Surgiflo, which was a flowable paste, was a matrix material according to claim 1, but it did not disclose how to print on it, and it was not apparent how to print on it, since the state of the art only disclosed printing on solid or gel-like substrates. For this reason, the patent in suit did not contain sufficient information to enable a skilled person to carry out the invention throughout the whole scope of claim 1. Thus, the claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the art.

The appellant considered that document D29 was the closest prior art but if, nevertheless, document D12 were considered to be closer, the problem underlying the invention as claimed in the main, first and second auxiliary requests was merely providing an alternative matrix material. However, even if it were acknowledged that the claimed matrixes were an improvement in terms of homogeneous distribution over those of D12, such an

improvement was obvious having regard to D11. For that reason the subject-matter claimed was not inventive.

Claims 1, 2 and 14 of the third auxiliary request contained added subject-matter. The amount of thrombin required by said claims was only disclosed in the application as originally filed in combination with the absence of fibrin and/or fibrinogen, which was not a feature of the amended claims. In addition, said amount of thrombin was not disclosed in the application as originally filed either in combination with a method for preparing such matrixes (claim 14) or with a sponge (claim 2).

Claim 14 of the third auxiliary request was not clear due to the use of the articles "the" and "a" in its wording.

With respect to inventive step of the invention as claimed in the third auxiliary request, document D29 was the closest prior art and the problem underlying the claimed invention was providing an alternative matrix, as paragraphs [0026] to [0029] of the patent in suit were mere assertions, lacking any experimental evidence. In addition, the patent in suit did not define what should be understood as stickiness, or how it was to be measured. Thus, the claimed matrix material lacked an inventive step for the same reasons as in the preceding requests.

VII. The arguments of the respondent relevant for the present decision were the following:

The appeal was not admissible. By stating during opposition proceedings that the claims as filed with the response to the grounds of opposition were

acceptable to it, the respondent had accepted the decision of the opposition division.

If the appeal were considered admissible, its scope should be limited to the ground of opposition under Article 100(b) EPC as the appellant, even knowing from a preliminary opinion issued by the opposition division that it was minded to maintain the patent in amended form, had filed further arguments only with respect to the alleged lack of sufficiency of the patent's disclosure.

Documents D21-D31, filed with the statement setting out the grounds of appeal, should not be admitted into the proceedings, as they could have been filed during opposition proceedings. By filing these documents only in appeal, the appellant was trying to deprive the respondent from defending its case before two instances. That was an abuse of procedure.

The board should exercise its discretion not to admit into the proceedings document D32, filed one month before the oral proceedings, as there was no reason for filing it so late.

Lastly, every argument of the appellant in the appeal proceedings which had not been part of the opposition proceedings should be disregarded.

If any of the afore-mentioned documents or arguments were admitted, or the issue of added subject-matter discussed, the case should be remitted to the opposition division to allow the respondent to properly defend its case, and to have all the relevant issues decided by two instances.

Despite the presence of Surgiflo as one embodiment of the matrix material required by claim 1, the skilled reader would simply disregard this information, as printing on Surgiflo in its flowable state was not possible. The patent in suit contained enough information to enable the skilled person to print a haemostatic agent on a matrix material according to claim 1. For this reason, the claimed invention was sufficiently disclosed for it to be carried out by a person skilled in the art.

Document D12 was the closest prior art for all the requests on file, and disclosed matrix materials which did not have a homogeneous distribution of haemostatic agent, which was a problem if a matrix was cut into small pieces. The problem of providing a matrix material with an improved distribution of haemostatic agent was solved by printing said agent on the matrix surface. The skilled person would not have combined the teaching of a document such as D11 with that of D12, as the former related to wound healing, which took longer than haemostasis. For these reasons, claim 1 of the main request was inventive.

With respect to auxiliary requests 1 and 2, the problem underlying the claimed invention was providing a matrix material with a more homogeneous distribution and improved stickiness. Paragraph [0026] of the patent in suit showed that this problem was credibly solved by the claimed matrix material, and there was no pointer towards the claimed solution, which required thrombin printed on the matrix surface. The subject-matter of these requests was thus inventive.

Document D12 was the closest prior art for the matrix material of claim 1 of the third auxiliary request but

if, nevertheless, document D29 was considered closer, the problem underlying the claimed invention was to provide a matrix material containing thrombin which improved stickiness. The solution, which was a matrix containing a specific amount of thrombin printed on it, was not obvious having regard to the prior art, and thus inventive.

During the oral proceedings before the board of appeal, which took place on 1 December 2016, the appellant withdrew its request for apportionment of costs.

VIII. The final requests of the parties were the following:

The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested:

- rejection of the appeal as inadmissible;
- alternatively, that the appeal be dismissed (i.e. that the patent be maintained in an amended form on the basis of the claim set held allowable by the opposition division, filed again as its main request with a letter dated 13 July 2016);
- non-admission of the opposition ground under Article 100(b) EPC;
- non-admission of documents D21-D32 into the proceedings;
- non-admission of fresh arguments based on D1-D20, not brought forward by the appellant during opposition proceedings;
- remittal to the opposition division if any of the documents and arguments objected to were admitted by the board;

- maintenance of the patent in amended form on the basis of any of the first to twenty-fifth auxiliary requests filed with a letter dated 13 July 2016.

IX. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

Admissibility of the appeal

1. With the response to the grounds of opposition on 22 January 2014, i.e. at the earliest opportunity during opposition proceedings, the respondent filed a new main request.

On 27 February 2014, the opposition division summoned the parties to oral proceedings, providing a full substantiation of its view that the subject-matter of the main request of the respondent was novel and inventive, and the claimed invention sufficiently disclosed.

With a letter dated 30 September 2014, the appellant withdrew its request for oral proceedings in view of the amendments made, submitted further arguments on the issue of sufficiency of disclosure, and explicitly maintained its request that the patent be revoked.

2. The respondent requested that the appeal be rejected as inadmissible, since the appellant was not adversely affected by the decision of the opposition division within the meaning of Article 107 EPC, having tacitly accepted that the opposition division would follow its opinion as expressed in the annex to the summons to

oral proceedings and decide that the main request fulfilled the requirements of the EPC.

- 2.1 However, during the opposition proceedings, the appellant merely withdrew its request for oral proceedings. It unambiguously stated that it wanted to continue the proceedings (page 1, first paragraph), explicitly upheld its request that the patent be revoked in full (page 3, last paragraph), and provided arguments as to why the claimed invention was not sufficiently disclosed.

As the opposition division decided to maintain the patent in the form of the then pending main request, the appellant is adversely affected by the decision, and its appeal is thus admissible (Article 107 EPC).

Scope of the appeal

3. The respondent requested that, if the appeal were considered admissible, its scope be limited to the ground of opposition under Article 100(b) EPC. The opponent only had a right to appeal issues which had been properly raised in opposition. As the appellant filed no arguments with respect to the grounds under Article 100(a) EPC in response to the positive preliminary opinion of the opposition division, it could not further rely on this ground in these appeal proceedings. Attempting to have a full re-hearing of the case before the board was an abuse of procedure.
4. However, Article 100(a) EPC was a ground of opposition originally invoked and sufficiently substantiated in opposition proceedings, whose admissibility was not called into question before the opposition division. The division took a decision on novelty and inventive

step in the decision under appeal on the basis of the evidence and arguments provided by the parties. The fact that the appellant did not reply to the preliminary opinion of the opposition division on these issues does not mean that it agreed with the conclusions of the opposition division on the question of novelty and inventive step. Under these circumstances, the board does not see any reason why the appellant could not rely on the grounds of opposition defined in Article 100(a) EPC in these appeal proceedings (see also G 1/88).

5. The respondent cited T 299/89 in support of its case. However, this decision dealt with a situation where only part of the claimed subject-matter was opposed, which differs from the present case, as the notice of opposition requested revocation of the patent in suit in its entirety. This argument thus cannot succeed.

Admissibility of documents D21-D31 in the appeal proceedings

6. Documents D21-D31 were filed with the statement setting out the grounds of appeal.
 - 6.1 The admission of documents D21-D28, D30 and D31 was not discussed at the oral proceedings before the board and neither the appellant during the oral proceedings before the board nor this decision relies on any of them. For this reason, it is not necessary to decide whether any of these documents should be held inadmissible.
 - 6.2 With respect to D29, the respondent argued that, as the appellant was already aware of the negative opinion of the opposition division after the summons to oral proceedings, it should have filed this document already

during opposition proceedings. By filing it only on appeal, it could deprive the respondent from defending its patent before two instances, which represented an abuse of procedure.

- 6.3 In favour of the appellant, the board decided to make use of its discretion to admit D29 into the proceedings. The respondent had ample opportunity to take a position on this document, it does not change the appellant's case, and the outcome of the analysis on inventive step is in essence the same irrespectively of whether D29 or D12 is considered closer to the claimed invention (see point 28. below), so that this discretionary decision does not have any adverse effect on the respondent.

Admission of document D32

7. The appellant requested that the board make use of its discretionary power under Article 13(1) RPBA not to admit document D32 into the proceedings.

Document D32 was filed in the context of the novelty of the main request with regard to D2, in order to provide evidence on the structure of collagen hydrogels, which is not relevant for the present decision. For this reason, it is not necessary to examine whether or not D32 should be admitted into the proceedings.

Admission of new arguments

8. The respondent requested that the board disregard any new line of argument of the appellant which had not been presented before the opposition division.

Among the arguments raised by the appellant for the first time in these appeal proceedings, only those based on D29 have any bearing on the present decision.

As the board decided to admit D29 into the proceedings (see point 6.2 above), the arguments based on this document are also part of these appeal proceedings.

The respondent relied on T 1621/09 in support of its request. However, T 1621/09 dealt with a situation in which a new argument by a party had the effect of amending its case. In the present situation, the admissibility of D29 and the arguments based on it do essentially not change the appellant's case (see point 6.3 above).

Main request, inventive step

9. Claim 1 of the main request is directed to a matrix material whose surface comprises at least one pharmaceutical composition comprising a haemostatic agent printed onto it in individual and discrete locations.

10. Closest prior art

The opposition division and the respondent considered that document D12 was the closest prior art; the appellant argued that document D29 came closer to the claimed invention. In favour of the respondent, it will be considered that document D12 is the closest prior art.

Document D12 discloses haemostatic sponges comprising thrombin. The sponges of D12 are prepared by injecting into them, at multiple sites, an aqueous solution of

thrombin, followed by air-drying (see steps 1 to 3 on page 15).

It has not been disputed that the sponges of D12 differ from the matrix material of claim 1 in that thrombin is not printed onto its surface in individual and discrete locations.

11. Technical problem underlying the invention

At the oral proceedings before the board, the respondent defined the technical problem underlying the claimed invention as providing an improved matrix material with a more uniform distribution of the homeostatic agent, which remains constant even if the matrix is cut in small portions.

12. Solution

The solution to this technical problem is the matrix material of claim 1, having a pharmaceutical composition comprising one or more haemostatic agents, and characterised in that the composition is printed onto its surface in individual and discrete locations.

13. Success

13.1 The appellant considered that the problem of providing a homogeneous distribution of haemostatic agent that will be maintained even if cut into small pieces was already solved by the sponge of document D12, and the problem underlying the claimed invention was merely to provide an alternative matrix material.

13.2 The question of whether or not the problem of providing a uniform distribution had already been solved in all

aspects by the sponge of D12 can be left aside, since the board holds that, even if the technical problem as defined in point 11. above is solved, the proposed solution is still obvious in view of the state of the art, for the reasons explained below.

14. Document D11 discloses (page 17, lines 10-12) printing of substances on wound dressings. Said printing applies a regular pattern of micro-droplets separated by a constant distance, which allows homogeneous and reliable kinetics even if the dressing is cut into pieces (page 17, lines 14-15). The skilled person, trying to obtain an absorbent matrix which includes a haemostatic active component such as thrombin homogeneously distributed, would consider applying the technique of D11 to the sponges of document D12 and thus arrive at the claimed invention without using inventive skills.
- 14.1 The respondent argued that the skilled person was deterred from combining the teaching of D11 with that of D12, as document D11 related to the field of wound dressings, not of haemostasis. Wound healing lasted months or years, whereas haemostasis was concerned with stopping bleeding within seconds or minutes. Figures 4 and 5 of document D11 showed that the release of active components from wound dressings lasted hours. Thus, the skilled person would not print on a haemostatic sponge requiring a very fast release of the haemostatic agent.
- 14.2 Figures 4 and 5 of document D11 disclose the release of different compounds from a wound dressing (page 19, lines 25-30). A comparison of curve A, which corresponds to a matrix having an active ingredient printed on the dressing, and curve C, which relates to a matrix having the same amount of active component

impregnated in it, shows that release is faster when printed. This effect is achieved not only for longer periods of time, like those involved in wound healing, but also for short times, as required by haemostasis.

The skilled person, knowing from D12 that the release of thrombin impregnated into a haemostatic sponge is fast enough for haemostasis, finds in D11 the teaching that if thrombin is printed on the matrix surface it will be released even faster and its distribution will be more homogeneous, arriving thus at the claimed invention.

- 14.3 The board concludes for these reasons that the skilled person would have combined the teaching of document D12 with that of D11 and arrived at the claimed invention without requiring inventive skills, with the consequence that the matrix material of claim 1 is not inventive and thus the main request is not allowable.

First auxiliary request, inventive step

15. Claim 1 of the first auxiliary request differs from claim 1 of the main request only in that the haemostatic agent it requires is defined as being thrombin.

16. Closest prior art

In favour of the respondent, it will be considered, in line with its arguments, that document D12 is the closest prior art.

17. Technical problem underlying the invention

The respondent has defined the technical problem underlying the claimed invention as providing a matrix material with a more uniform distribution of haemostatic agent, which makes it possible to improve the stickiness of the matrix.

18. Solution

The solution to this technical problem is the claimed matrix material, characterised in that it has thrombin printed on its surface in individual and discrete locations.

19. Success

The respondent relied on the disclosure in paragraph [0026] for showing that the problem formulated in point 17. above had been credibly solved by the features of claim 1.

However, paragraph [0027] discloses that stickiness enhancement is only achieved within a specific surface concentration range, namely from 0.5 to 50 IU/cm², which is not a feature of claim 1. For this reason alone, it is not credible that the second part of the problem as defined in point 17. is solved by the matrix material of claim 1.

20. Reformulation of the technical problem

According to the case law, alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, Reasons 3, last paragraph). As the alleged improvement in terms of enhanced stickiness would not be achieved by every

matrix material of claim 1, the technical problem as defined above needs to be reformulated.

The problem underlying the claimed invention is thus seen as being to provide a matrix material with a uniform distribution of haemostatic agent.

21. Solution

The proposed solution is the matrix material comprising thrombin of claim 1, characterised in that thrombin is printed on its surface in individual and discrete locations.

22. For the reasons already explained with respect to the main request (see points 14. to 14.3 above), this solution is not inventive, as required by Article 56 EPC, with the consequence that the first auxiliary request is not allowable.

Second auxiliary request, inventive step

23. Claim 1 of the second auxiliary request merely restricts the subject-matter of claim 1 of the first auxiliary request by requiring the matrix material to comprise a collagen or gelatin sponge.

As document D12 relates to a matrix in the form of a sponge (page 1, line 3), preferably a gelatin sponge (page 9, line 5), the problem-solution analysis does not differ from that for the first auxiliary request. Thus, claim 1 of the second auxiliary request is not inventive, as required by Article 56 EPC, with the consequence that this request is not allowable.

Third auxiliary request

24. Amendments

24.1 Claim 1 of the third auxiliary request is directed to a matrix material comprising gelatin or collagen, whose surface comprises thrombin printed onto it in an amount of from 0.5 to 50 IU/cm².

Claim 1 finds a basis in the combination of claims 1, 2, 3 and 15 as originally filed, and the passage in the description, page 8, line 32. Although claims 3 and 15 as originally filed are not mutually dependent, they refer to the most preferred matrix material and the most preferred haemostatic agent and, for this reason, their combination does not represent any non-disclosed technical information.

24.2 The appellant argued that the passage on page 8, line 32, which referred to the amount of thrombin per surface unit, was combined with the requirement of the absence of fibrin and/or fibrinogen (page 8, lines 27-29). As this limitation was not included in claim 1 of the third auxiliary request, it contained technical information going beyond that of the application as originally filed.

However, the passage on page 8, line 27-19 is not combined with that on line 32 disclosing the amount of thrombin per surface area which allows a sticky effect to be obtained. The skilled person reading these passages concludes that a favourable sticky effect can be obtained within a particular range of surface concentration, and that such effect can make fibrin and fibrinogen redundant, but not that they should be necessarily excluded from the composition. For this

reason, the description of the application as originally filed does not make the absence of these components mandatory, and claim 1 finds the required basis in the application as originally filed.

- 24.3 The appellant further argued that the application as originally filed did not disclose, in combination, a sponge having the amount of thrombin required by claim 1. For this reason, dependent claim 2 did not find the required basis in the application as originally filed.

However, collagen and gelatin sponges are the most preferred embodiments with respect to the matrix (page 68, lines 24-26), and the skilled reader would consider these embodiments as combined with other aspects of the invention, such as the preferred haemostatic agent of the pharmaceutical composition (thrombin) or its amount.

- 24.4 The appellant further argued that claim 14, directed to a method for making the device containing the matrix material according to claim 1, had no basis in the application as originally filed, as the amounts of thrombin required by it (0.5 to 50 IU/cm²) were not disclosed in combination with a method for making a device.

However, it is not disputed that these amounts are disclosed in combination with the matrix of claim 1. This inherently makes available to the skilled reader a method for preparing matrixes having the required amounts of thrombin. Thus, such a method finds the required basis in the application as originally filed.

- 24.5 As no other objections have been raised, and the board sees no reason to raise any objection of its own

motion, it concludes that the claims of the third auxiliary request have the basis required by Article 123(2) EPC.

24.6 It has not been disputed that the requirements of Article 123(3) EPC are also fulfilled, and the board is satisfied that it is the case.

25. Clarity

25.1 The appellant has argued that claim 14 of the third auxiliary request lacked clarity, as step b required printing a pharmaceutical composition comprising thrombin onto the surface of said matrix [...] to achieve a surface of the matrix containing thrombin in the range of [...]. The use of the definite and indefinite articles in the same sentence made this claim unclear.

However, there is no apparent lack of clarity arising from the wording of claim 1. It requires printing a pharmaceutical composition comprising thrombin on the matrix, anywhere, printing leading to a surface of said matrix containing the amount required by claim 1, independently of whether other surfaces have been also printed and of the amount applied to them.

25.2 It is thus concluded that the amendments made to claim 1 do not introduce any lack of clarity (Article 84 EPC).

26. Sufficiency of disclosure

26.1 The claimed invention relates to a matrix material comprising gelatin or collagen containing thrombin printed onto its surface.

The description of the patent in suit discloses different materials as suitable for the claimed invention; among them Surgiflo is mentioned ([0244], [0293], [0520] in the context of example 2, item 24 on page 64, 167 on page 75, and 257 on page 80).

It was not disputed during the oral proceedings before the board either that Surgiflo is a flowable paste, or that printing on such a paste in its flowable state is not possible.

- 26.2 According to the case law, the requirements of sufficiency of disclosure are met only if the claimed invention can be performed by a person skilled in the art over the whole area claimed without undue burden, using common general knowledge and having regard to the information in the patent in suit (T 409/91, OJ 1994, 653, Reasons 3.5; T 435/91, OJ 1995, 188, Reasons 2.2.1).

In the present case, it needs to be examined whether the patent in suit and common general knowledge provide sufficient information allowing the skilled person to print pharmaceutical compositions comprising thrombin on matrix materials comprising a surface, a plurality of open and interconnected cells, and gelatin or collagen.

- 26.3 The appellant argued that Surgiflo, which was a flowable paste and thus could not be printed on, was explicitly disclosed as a matrix according to claim 1 and, for this reason, the claimed invention was not sufficiently disclosed with respect to all embodiments within the ambit of claim 1.

However, it is immediately apparent to the skilled reader that a flowable paste is not suitable for printing. The skilled reader would thus consider that such a matrix material represents a mistake in the disclosure and disregard this information. For that reason, the presence of this obviously unworkable embodiment does not impair the sufficiency of the technical information contained in the patent.

The appellant has not argued that the alleged lack of sufficiency extended to the whole scope of the subject-matter claimed. The patent in suit contains sufficient information to enable the skilled person to select suitable matrix materials and pharmaceutical compositions comprising thrombin; printing of biological materials is a well-established technique (D11). As acknowledged by the respondent, "in individual and discrete locations" does not have any meaning going beyond the inevitable result of using a printer.

26.4 The appellant relied on T 409/91 in support of its argument that the absence of essential features in a claim resulted in lack of sufficient disclosure. Although lack of sufficiency can arise for this reason, this does not conversely imply that the mere absence of an essential feature renders a disclosure insufficient, and each case should be examined on its merits. For the reasons explained above, it is considered that the claimed invention is sufficiently disclosed.

26.5 In a further line of argument, the appellant argued that, having regard to claim 1, the skilled reader could not determine whether a hydrogel would or would not represent a matrix required by the claimed invention, as it could not be determined whether it

contained open and interconnected pores, as required by claim 1. However, this is an issue of clarity which does not render the claimed invention insufficiently disclosed, as the skilled person is able to identify gelatin or collagen matrix materials having open and interconnected pores, such as sponges, suitable for the claimed invention.

26.6 It is thus concluded that the subject-matter of claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

27. Novelty

27.1 There are no objections from the appellant with respect to the novelty of the claims of the third auxiliary request.

None of the documents on file discloses a matrix material containing thrombin printed on it. For this reason alone the claims of the third auxiliary request are novel, as required by Article 54 EPC.

28. Inventive step

Claim 1 is directed to a matrix material comprising thrombin printed onto it in individual and discrete locations in a surface concentration in the range of from 0.5 to 50 IU/cm².

28.1 Closest prior art

The respondent considered that document D12 was the closest prior art and the appellant argued that, if the board considered that document D12 did not disclose a

matrix material comprising a haemostatic agent on its surface but only within the matrix, document D29 came closer to the claimed invention.

In favour of the appellant, the invention as claimed in the third auxiliary request will be examined under the assumption that document D29 comes closer to the claimed invention. The analysis, however, would not differ if D12 were considered to be the closest prior art.

It has not been disputed that document D29 discloses a matrix material containing haemostatic agents on its surface, which differ from the subject-matter of claim 1 in that said agents have not been printed onto said surface in individual and discrete locations. The board sees no reason to differ.

28.2 Technical problem underlying the invention

During the oral proceedings before the board, the respondent formulated the technical problem underlying the claimed invention as to provide a matrix material which allows stickiness to be improved (paragraph [0026] of the patent in suit).

28.3 Solution

The solution to this technical problem is the claimed matrix material containing 0.5 to 50 IU/cm² thrombin on its surface, characterised in that thrombin has been applied onto it by printing.

28.4 Success

28.4.1 The respondent relied on paragraphs [0026], [0027] and

[0029] of the patent in suit to show that the problem as formulated in point 28.2 above had been credibly solved by the features of claim 1. These passages disclose that an improved stickiness is achieved if 0.5 to 50 IU/cm² thrombin is printed on it, and that said sticky effect could not be obtained if thrombin was sprayed on it.

- 28.4.2 The appellant argued that these paragraphs lacked any experimental detail, and thus merely amounted to an unsubstantiated assertion. For this reason, it was not credible that the problem as defined above was solved by the matrix material of claim 1.

However, the appellant has not provided any technical reason why the statement in the patent in suit could not be accepted at face value, while it is normally the task of the opponent to prove that facts stated in the patent are not true. The respondent has explained that the good haemostatic times obtained (see example 3) derived in part from the good adhesion of the claimed matrix material. In the absence of evidence to the contrary, and of any technical reason why it should not be the case, the problem mentioned under point 28.2 above is considered to be successfully solved by the matrix material of claim 1 of the third auxiliary request.

- 28.4.3 The appellant further argued that there was no indication as to how stickiness was to be understood, or how to measure it. For this reason, the disclosure of the patent in suit did not plausibly show that the problem as formulated above was credibly solved.

However, the appellant has failed to explain which problems would arise in determining stickiness, which

is not an unusual property in the context of haemostatic agents (see [0026], lines 34-35 of the patent in suit).

- 28.4.4 The appellant argued that it was known that thrombin degraded fibrinogen into fibrin, and that this was the origin of the stickiness, which was achieved irrespective of the method used for applying thrombin onto the surface.

The appellant has not provided evidence on the action of thrombin on fibrinogen. In addition, as mentioned above, there is no evidence on file which could cast doubt on the statement in the patent in suit that stickiness is increased by printing thrombin on a matrix.

- 28.4.5 Lastly, the appellant argued that stickiness was not a property of the claimed matrix material, but was only apparent in contact with wound fluids, which was not a feature of claim 1.

However, claim 1 is directed to a matrix material, not to a method. It has not been called into question that this claim contains all the features of the material necessary to solve the problem underlying the claimed invention. It is sufficient for the problem to be considered as solved that the claimed material has an enhanced stickiness when used in haemostasis.

- 28.5 It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious in view of the state of the art.

None of the evidence provided by the appellant referred to stickiness, let alone linked stickiness to the mode

of application of a pharmaceutical composition on a matrix material. For this reason alone, it is concluded that the skilled person, trying to obtain an enhanced stickiness, would not consider applying thrombin to a matrix material by printing in order to solve the problem posed, with the consequence that the matrix material of claim 1 is inventive, as required by Article 56 EPC.

For the same reasons, a device comprising said matrix material (claims 13, 15 and 16), a method for making said device (claim 14), and a container comprising said material (claim 17) are also inventive.

Remittal

29. According to Article 111(1) EPC, a board may either exercise any power within the competence of the department which was responsible for the appealed decision, i.e. decide on all issues, or remit the case to the first instance for further prosecution. Thus, the EPC does not guarantee the parties an absolute right to have all the issues of a case considered by two instances.

29.1 The respondent requested that the case be remitted to the opposition division if any new argument based on the evidence forming part of the opposition proceedings, or any document filed during appeal proceedings, was considered as part of these appeal proceedings.

29.2 The decision of the board with respect to the main request and the first and second auxiliary requests is based on document D12 as closest prior art, which was considered the closest prior art during opposition

proceedings by the respondent and the opposition division. This decision further relies on document D11, put forward by the respondent for discussion during opposition proceedings, in the response to the grounds of appeal, and during the oral proceedings before the board. Since the examination of these requests has been carried out taking into account only evidence put forward in opposition proceedings, the board does not consider a remittal with regard to these requests to be necessary.

- 29.3 The respondent also requested during the written proceedings that the case be remitted for examination of any amendment. The respondent did not however rely on this request during the oral proceedings, and the board decided to make use of its discretion not to remit the case for this purpose.
- 29.4 With respect to the examination of the third auxiliary request on the issue of inventive step, the board decided in favour of the respondent even taking into consideration the content of document D29, which was not part of the opposition proceedings. For this reason, the board also decided to make use of its discretion not to remit the case despite the respondent's request.
- 29.5 The board notes, however, that the description needs to be adapted to the claims of the third auxiliary request (see for example [0240]) and remits the case to the opposition division for the adaptation of the description (Article 111(1) EPC).

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 maintain the patent in amended form on the basis of claims 1-17 of the 3rd auxiliary request filed with letter dated 13 July 2016 and a description and drawings to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated