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**Datasheet for the decision
of 2 June 2016**

Case Number: T 1909/14 - 3.3.10

Application Number: 06766290.8

Publication Number: 2018195

IPC: A61L29/04, A61M25/10

Language of the proceedings: EN

Title of invention:

ANGIOPLASTY MEDICAL DEVICES MADE OF ELASTOMERIC MATERIAL

Patent Proprietor:

Invatec S.r.l

Opponent:

Kameke, Allard von

Headword:

Relevant legal provisions:

EPC Art. 56, 84, 83, 111(1)

Keyword:

Inventive step - (yes)

Clarity in opposition appeal proceedings

Sufficiency of disclosure - (yes)

Remittal to the opposition division (yes)

Decisions cited:

G 0003/14

Catchword:



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Case Number: T 1909/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 2 June 2016

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 16 July 2014
rejecting the opposition filed against European
patent No. 2018195 pursuant to Article 101(2)
EPC.**

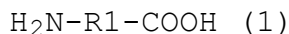
Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
F. Blumer

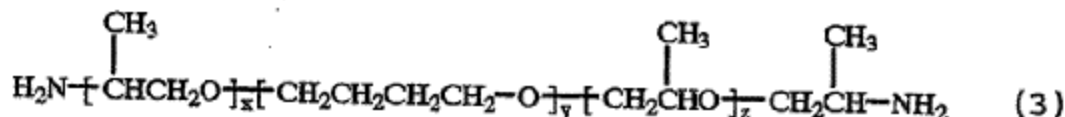
Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division rejecting the opposition against European patent No. 2 018 195.
- 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:
- D1: EP 1 482 011 A1
D2: EP 1 314 750 B1
D3: US 2002/0018866 A1
D5: US 5,585,057
D12: Handbook of Condensation Thermoplastic Elastomers, S. Fakirov, Ed., Wiley-VCH, 2005, pages 77-78, 101-102, 243-245, 263-264, 277-280 and 490-519
- IV. The main request of the respondent (patent proprietor) was filed as third auxiliary request with a letter dated 9 April 2015 during these appeal proceedings. Claim 1 thereof reads as follows:

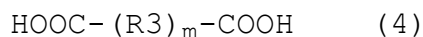
"A medical device for angioplasty, which is made of elastomeric material, characterized in that said elastomeric material comprises a polyamide-based polymer obtained from the polymerization of a compound forming polyamide blocks that is selected from the group consisting of an aminocarboxylic acid of Formula (1) and a lactam of Formula (2):



with a triblock polyetherdiamine compound of Formula (3):



and a dicarboxylic acid of Formula (4)



wherein the groups R1, R2 and R3 are each binding groups comprising a hydrocarbon chain therein that may be interrupted by one or more amide groups; x is an integer from 1 to 20; y is an integer from 4 to 50, z is an integer from 1 to 20; m is 0 or 1,

wherein said device is a balloon for angioplasty catheters."

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

Claim 1 was directed to a medical device for angioplasty which was a balloon for angioplasty catheters. However, such balloons could only represent a medical device in combination with other parts. For that reason, the subject-matter of claim 1 was not clear. This lack of clarity originated from the amendments made to claim 1 as granted, and for this reason could be examined in opposition appeal proceedings.

The patent in suit did not contain sufficient information to enable the skilled reader to determine tensile strength at break, maximum flexural load and average burst pressure, which were properties required by claims 22-24. For that reason, the claimed invention was not sufficiently disclosed to be carried out by a person skilled in the art.

Document D3 was the closest prior art. It disclosed balloons which differed from those of claim 1 in the nature of the elastomeric material which formed them. The technical problem underlying the claimed invention was merely to provide an alternative balloon for angioplasty catheter. The solution, which was characterised by the chemical nature of the elastomeric material, was obvious over document D3 alone, having regard to the structural similarity of the elastomeric material. The claimed invention was also obvious having regard to D1 and D2, which disclosed what properties a material needed to have to be suitable for balloons for angioplasty catheters; a further hint to the claimed subject-matter could be found in document D12. For that reason, the subject-matter of claim 1 was not inventive.

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

The lack of clarity alleged by the appellant was already present in the claims as granted and thus excluded from examination in opposition appeal proceedings.

The properties required by claims 22-24 could be determined following the teaching provided in the patent in suit. In addition, these properties were

customary in the field of balloons and the skilled person would find no difficulty in measuring them.

Document D5 related to balloon catheters and disclosed a polymer having more structural similarity to that required by claim 1, so that it was closer than D3 to the claimed invention and thus represented the closest prior art. The problem underlying the claimed invention was providing improved balloons for angioplasty catheters.

If, nevertheless, document D3 were to be considered the closest prior art and the problem underlying the claimed invention were to be considered as merely providing alternative balloons for angioplasty catheters, the solution, which was characterised by the chemical nature of the required elastomer, was inventive as there was no hint in the prior art to modify the elastomer.

- VII. Oral proceedings before the board of appeal took place on 2 June 2016.
- VIII. The final requests of the parties were the following:
- The appellant requested that the decision under appeal be set aside and that European patent No. 2 018 195 be revoked.
 - The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed as third auxiliary request with letter dated 9 April 2015, or, subsidiarily, on the basis of any of the first to eighth auxiliary requests, the first to third auxiliary requests having been filed

as second to fourth auxiliary requests with letter dated 26 February 2016, and the fourth to eighth auxiliary requests as first, second, fourth, fifth and sixth auxiliary requests with letter dated 9 April 2015.

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

Reasons for the Decision

1. The appeal is admissible.

Amendments

2. Claim 1 of the main request results from the combination of claims 1 and 23 as originally filed, in which the feature "polyether diamine triblock" has been replaced by "triblock polyetherdiamine" and the feature "or parts thereof" has been deleted.

Claim 1 results from the combination of claims 1 and 22 as granted.

The requirements of Article 123(2) and (3) EPC are thus fulfilled.

Clarity

3. Claim 1 of the main request is directed to a medical device which is a balloon for angioplasty catheters.

The appellant argued that claim 1 was directed to a balloon which represented the complete medical device. However, an isolated balloon could not be a complete medical device. The subject-matter of claim 1 was, for

that reason, not clear.

However, claim 1 of the main request results from the combination of the features of claims 1 and 22 as granted. Claim 22 reads "the medical device according to any claim 1 to 19, wherein said device is a balloon for angioplasty catheters". Thus, any alleged lack of clarity was already present in the claims as granted and is for this reason excluded from examination in these opposition appeal proceedings (G 3/14, OJ EPO 2005, A102).

Sufficiency of disclosure

4. The appellant argued that the patent in suit did not contain sufficient information to allow the skilled reader to determine the tensile strength at break required by claim 24, the average burst pressure required by claim 23, and the maximum flexural load required by claim 22, as the test methods described in paragraphs [0041] and [0058] were irreproducible, and the missing information could neither be found in the available prior art, nor was part of the general technical knowledge. In particular, the appellant criticised lack of disclosure regarding the type of specimen on which the measurements should be carried out, and on its dimensions. For that reason, the claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the art.

5. However, the appellant's insufficiency arguments related only to the methods for determining the maximum flexural load, tensile strength at break, and average burst pressure. The appellant failed to provide reasons why this alleged deficiency prevented the skilled reader from carrying out the invention, and no such

reason is immediately apparent. Any lack of accuracy of the results obtained by the measurements is an issue under Article 84 EPC, which is excluded from examination in opposition appeal proceedings.

Inventive step

6. Closest prior art

Claim 1 is directed to a balloon for an angioplasty catheter comprising an elastomeric material comprising a polymer obtainable from the polymerisation of the building blocks (1) or (2) with (3) and (4). The claimed balloons are made of a flexible material having a high degree of resistance [0005].

The opposition division and the appellant considered that document D3 was the closest prior art. The respondent, however, argued that document D5 was closer to the claimed invention.

Document D3 is directed to balloons for catheters utilised in angioplasty formed of PEBA (polyamide/polyether block copolymers) [0022]. The balloons of D3 are relatively soft and have a high rupture pressure [0009].

Document D5 relates to medical devices, in particular to tubing that exhibits improved properties suitable for devices such as catheters (column 1, lines 11-14). Document D5 mentions "balloon catheters" on column 2, line 6, but the remainder of D5 focuses on tubing components (column 5, lines 11-15). From that disclosure, the skilled person concludes that D5 refers to the catheter part of balloon catheters, not to the balloon part.

As document D3 relates to the same type of medical devices (balloons), whereas document D5 focuses on tubing for angioplasty devices, it is concluded that document D3 is closer than D5 to the claimed invention.

Document D3 discloses balloons for angioplasty catheters made of elastomeric material comprising a polymer obtainable by polymerising a dicarboxylic polyamide and a polyether [0023]. The polyamide is preferably nylon 12 [0024]. Since nylon, which is obtainable from blocks (2) as in claim 1, needs to be in the form of a "dicarboxylic polyamide" [0022], it necessarily contains a diacid block. The polyether part preferably contains a poly(tetramethylene) segment [0025], which corresponds to the repeating group under the index "y" in formula (3) according to claim 1. Said polyether part does not contain isopropoxy units and does not have amino terminal groups, as required by block (3) of claim 1. The polyether and polyamino sections are linked by ester groups.

7. Technical problem underlying the invention

The parties had different views as to the formulation of the technical problem effectively solved by the claimed invention.

In the following, it will be examined whether the subject-matter of claim 1 is inventive under the assumption that the technical problem underlying the claimed invention is merely to provide a further balloon for angioplasty catheters. If the solution to this problem is not obvious, it will not be necessary to examine whether a more ambitious problem has also

been solved.

8. Solution

The solution to this technical problem is the claimed balloon for angioplasty catheters made of elastomeric material obtainable from an aminocarboxylic acid or lactam, a dicarboxylic acid and a polyether, characterised in that its polyamide and polyether units are linked by amide linkages, in that the polyether component is a polyetherdiamine of formula (3), and in that the diacid component is of formula (4).

9. Success

Having regard to the data provided in the examples, the problem mentioned under point 7 above is considered to be successfully solved by the balloon of claim 1 of the main request. This has not been challenged by the appellant.

10. 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.

10.1 It has not been disputed that document D3 discloses balloons, preferably made of PEBAX (a polyamide/polyether/polyester block copolymer). These balloons differ from the balloon of claim 1 in the nature of the required elastomeric material. The polymer required by claim 1 contains a polyether block of formula (3), having isopropoxy units, and a terminal amino group, which is linked to the polyamide block by amide linkages. In contrast, that of D3 contains a polyether block that does not contain said isopropoxy units, and which terminates in an hydroxy moiety, linked to the

polyamide block by ester linkages. Starting from D3, several structural modifications are required in order to arrive at the claimed subject-matter, which is thus not obvious having regard to D3 alone.

The polymers required by claim 1 are those disclosed in documents D1 and D2. However, neither document D1 nor document D2 disclose any application in the field of medical technology. D1, [0041] [0042], and D2, [0035] [0036], refer to the manufacture of soles of shoes, gears, connectors and sealing material to be employed in electronic-precision instruments and to sheet materials and sealing materials to be employed in the car industry, mirror boots of automobiles and uniform rate joint boots. None of these applications remotely relates to medical technology, let alone angioplasty, and still less hints at balloons suitable for it. For this reason alone, the board concludes that the skilled person would not seek in document D1 and D2 a material suitable for a balloon for an angioplasty catheter.

The claimed subject-matter is thus inventive over the combination of the teaching of documents D3 and D1 or D2.

- 10.2 The appellant saw in document D12 a hint which would have led the skilled person to combine the teaching of documents D3 and that of D1 or D2. D12 refers to PEBAX (see 3.1, pages 501-503), which was the polymer of the balloons of the closest prior-art document D3. D12 disclosed on page 502 that PEBAX was suitable for the manufacture of sports goods, footwear, mechanical components, tubing and belting, which were the same type of applications as disclosed in documents D1 and D2. Thus, it was obvious for the skilled person that the polymers of D1 and D2 represented a suitable

replacement for PEBAX.

However, document D12 does not provide any information to the skilled person over and above that of documents D1 and D2. The fact that PEBAX could also be suitable for applications other than balloons for angioplasty fails to teach the skilled person that any polymer which could also be suitable for those applications could represent a material appropriate for balloons for angioplasty catheters. This argument of the appellant is thus not convincing.

10.3 The appellant argued that document D3 taught that the linkages between the polyamide and the polyether parts of the polymer could not only be ester moieties but also amide linkages [0022]. By replacing said ester units in the formula given in said paragraph with amide linkages, the skilled person would arrive at the claimed invention without using inventive skills. The claimed subject-matter was thus not inventive over the disclosure of document D3 alone.

However, by merely replacing ester with amide linkages in the formula of document [0022] the skilled person would not yet arrive at the claimed invention, as the required polymer has an isopropoxide unit in the ether segment which is not taught by D3, and a diacid constituent of a specific structure which cannot be found in said document either.

10.4 The appellant also argued that the properties of the balloons disclosed in D3 derived only from the presence of the so-called hard segment (polyamide) and soft segment (polyether) [0023]. As long as these units were present in the polymer, it would retain the properties suitable for balloons. The claimed balloons contained a

polymer having said units and structurally very similar to that of D3 and, for that reason, represented obvious alternatives thereto.

However, even small modifications to a molecule can lead to polymers having very different properties. For that reason, the skilled person could not foresee whether a different elastomer could still be suitable for the manufacture of balloons for angioplasty catheters. In addition, as explained in the previous point, there is no hint in the prior art towards the specific elastomer required by claim 1.

- 10.5 The appellant further argued that the data provided in document D2 with respect to tensile strength at yield point, hardness, bending modulus of elasticity, elongation at break, stress relaxation, elastic percentage of elongation and water absorption taught the skilled person that the material of D2 was suitable for balloons for angioplasty catheters. The skilled person would look for alternative materials having the desired properties in neighbouring fields such as that represented by D1 and D2. As the material disclosed in these documents has properties desirable for balloons for angioplasty catheters, he would have combined the teaching of D3 with that of D2 and thus arrived at the claimed invention without using inventive skills.

The respondent explained during the oral proceedings that a material having tensile strength at *break* could be suitable for balloons. D2 refers, however, to tensile strength at *yield*. The appellant did not contest this argument.

In addition, the patent in suit discloses that a material for a balloon should be flexible and elastic

[0033]. It should also be thin [0037] and have a high burst pressure [0037]. Document D2 does not disclose whether the polymers required by claim 1 could form thin layers; it only refers to sheets and tubes without any indication of their thickness. Document D2 does not refer, either, to burst pressure or to any magnitude that could be related to it. Such a property is, however, crucial in the manufacture of balloons, as reflected not only in the patent in suit but also in paragraph [0030] of document D3. Already for these reasons, the skilled person would not have any motivation to replace the material of the balloons of D3 with those disclosed in documents D1 and D2.

10.6 The appellant argued that the burst pressure was influenced by the processing. For that reason, the claimed invention could not rely on achieving a higher burst pressure, as such enhancement could not always be achieved.

However, as explained above (see point 7), the examination of inventive step has been carried out under the assumption that no improvement has been achieved, either in terms of burst pressure or of other properties.

10.7 The board thus concludes that the state of the art does not provide a hint towards the claimed solution, and thus that the skilled person would only have combined the teaching of documents D3 and D1 or D2, which have different objectives, with knowledge of the invention. For that reason, the claimed balloons are inventive, as required by Article 56 EPC.

Remittal

11. Although the respondent has submitted a description said to be adapted to the claims of the main request, it only contains page 2 of the contested patent. It appears that further amendment is still required, see for example paragraph [0032]. Under these circumstances, the board decided to remit the case to the opposition division for the adaptation of the description. The parties had no objection to such remittal.

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 on the basis of the claims of the main request, filed as third auxiliary request with letter dated 9 April 2015, and a description yet to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated