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Datasheet for the decision of 7 December 2023

Case Number: T 1608/21 - 3.3.10

Application Number: 16198801.9

Publication Number: 3178501

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Language of the proceedings: EN

Title of invention:
ELUTING MEDICAL DEVICES

Patent Proprietor:
W. L. Gore & Associates, Inc.

Opponent:
KNOX IP B.V.

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54(2)

Keyword:
Novelty - (no)

Decisions cited:

Catchword:

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Boards of Appeal

Chambres de recours

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

Case Number: T 1608/21 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 7 December 2023

Appellant: (Opponent)	KNOX IP B.V. Eindhoven (NL)
Representative:	Jilderda, Anne Ayolt LIOC Patents & Trademarks Zwaanstraat 31 L 5651 CA Eindhoven (NL)
Respondent: (Patent Proprietor)	W. L. Gore & Associates, Inc. 555 Paper Mill Road Newark, DE 19711 (US)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 July 2021 rejecting the opposition filed against European patent No. 3178501 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant-opponent lodged an appeal against the opposition division's decision rejecting the opposition against European patent No. 3 178 501.

II. Notice of opposition had been filed on grounds including lack of novelty and inventive step (Article 100(a) EPC).

III. The following documents are relevant to the present decision:

D2 US 2008/015500 A1
D4 WO 2010/036694 A1
D8 US 5,269,755 A

IV. Claim 1 of the patent as granted, which is the respondent-patent proprietor's main request, reads as follows:

"A balloon catheter comprising:

a. a balloon comprising a coating and a therapeutic agent on an outer surface of said balloon;

b. a sheath disposed around said balloon wherein said sheath has a microstructure composed of nodes interconnected by fibrils and wherein said sheath possesses a variably permeable microstructure, wherein in an unexpanded state, the sheath substantially limits transfer of said therapeutic agent;

c. wherein said coating and therapeutic agent are disposed between the surface of the balloon and the

sheath; and

d. wherein when said sheath is expanded by the balloon, said sheath allows transfer of said coating and therapeutic agent through the permeable microstructure of the sheath."

V. The opposition division concluded that claim 1 of the patent as granted was novel. Document D4 disclosed a balloon catheter having features a, c and d required by claim 1 and having a sheath with a variably permeable microstructure which limited transfer in an unexpanded state; however, the sheath disclosed in D4 lacked a microstructure composed of nodes interconnected by fibrils, as required by claim 1.

VI. With the reply to the grounds of appeal, the respondent-patent proprietor filed its first to fourteenth auxiliary requests, which corresponded to those pending before the opposition division.

Claim 1 of the first auxiliary request is identical to claim 1 of the patent as granted.

Claim 1 of the second auxiliary request has the features of claim 1 of the main request and in addition requires the sheath to be treated with a wetting agent.

Claim 1 of the third auxiliary request requires the sheath to be imbibed with a wetting agent.

Claim 1 of the fourth auxiliary request has all the features of claim 1 of the preceding request and in addition requires the balloon to comprise a hydrophilic coating.

Claim 1 of the fifth auxiliary request has all the features of claim 1 of the fourth auxiliary request and requires the hydrophilic coating of the balloon to comprise a therapeutic agent.

Claim 1 of the sixth auxiliary request has the features of claim 1 of the fifth auxiliary request and further requires the sheath to wet out.

Claim 1 of the seventh auxiliary request has all the features of claim 1 of the patent as granted and in addition requires the sheath to comprise an expanded fluoropolymer or expanded polyethylene.

Claim 1 of the eighth auxiliary request requires the sheath to comprise ePTFE or expanded polyethylene.

Claim 1 of the ninth auxiliary request has the features of claim 1 of the second and eighth auxiliary requests.

Claim 1 of the tenth auxiliary request has the features of claim 1 as granted and requires the sheath to comprise ePTFE and to be treated with a wetting agent.

Claim 1 of the eleventh auxiliary request has the features of claim 1 as granted and requires the sheath to comprise an expanded fluoropolymer or expanded polyethylene and the material of the sheath to have been processed to close the microstructure in an unexpanded state.

Claim 1 of the twelfth auxiliary request has the features of claim 1 as granted and requires the sheath to comprise ePTFE or expanded polyethylene and the material of the sheath to have been processed to close

the microstructure in an unexpanded state.

Claim 1 of the thirteenth auxiliary request has the features of claim 1 of its preceding request and in addition requires the material of the sheath to have been processed by compaction to close the microstructure in an unexpanded state.

Claim 1 of the fourteenth auxiliary request has the features of claim 1 as granted and requires the sheath to comprise ePTFE and the material of the sheath to have been processed by compaction to close the microstructure in an unexpanded state.

VII. The sole point of disagreement between the parties with regard to the issue of novelty was whether the sheath of the balloon catheter disclosed in D4 had a microstructure composed of nodes interconnected by fibrils. It was undisputed that D4 disclosed all the other features of claim 1 of the main request.

VIII. The appellant-opponent argued that the patent did not define the feature of a node. The feature requiring the microstructure to be composed of nodes interconnected by fibrils thus included any structure containing small or slender fibres intersecting with one another such as those disclosed in D4. Claim 1 of the main request and of auxiliary request 1 was therefore not novel.

D4 disclosed a sheath having hydrophilic substances, which was equivalent to having a wetting agent. Claim 1 of auxiliary request 2 was not novel for this reason.

IX. The respondent-patent proprietor argued that the structure arising from an electrospinning process such as that used for the sheath in D4 was a randomised,

non-woven material in which the fibrils were not interconnected. It thus could not be considered to be composed of nodes interconnected by fibrils, as required by claim 1. Claim 1 of the main request was thus novel. The same arguments applied to claim 1 of auxiliary request 1.

The balloon catheter in claim 4 of the patent as granted, which corresponded to claim 1 of the second auxiliary request, further differed from that in D4 by requiring the sheath to contain a wetting agent. Although D4 disclosed the use of hydrophilic substances in connection with the sheath, their role was protective, not as a wetting agent. Claim 1 of auxiliary request 2 was thus novel.

The respondent-patent proprietor did not file any arguments with regard to novelty or inventive step with respect to the third to fourteenth auxiliary requests beyond those applying to its higher-ranked requests.

X. The respondent-patent proprietor informed the board that it would not be attending the oral proceedings, which took place on 7 December 2023. It requested a decision based on the written record.

XI. The parties' final requests were as follows:

The appellant-opponent requested that the decision under appeal be set aside and that European patent No. 3 178 501 be revoked.

The respondent-patent proprietor requested that the appeal be dismissed, or that the patent be maintained with the claims of one of the first to fourteenth

auxiliary requests, all auxiliary requests as filed with the reply to the grounds of appeal.

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

Reasons for the Decision

1. The appeal is admissible.

2. Novelty over D4

2.1 It was undisputed that the balloon catheter in claim 1 of the main request could only be novel over that disclosed in D4 on account of the feature requiring its sheath to have a microstructure composed of nodes interconnected by fibrils. D4 discloses all the other features of claim 1.

2.2 When acknowledging novelty, the opposition division considered that a skilled person would have understood the feature of claim 1 requiring the microstructure of the sheath to have nodes and fibrils to mean those observed in a sheath made of materials such as ePTFE (see point 6.2 of the contested decision).

It was undisputed that ePTFE has the microstructure required by claim 1. The wording "nodes interconnected by fibrils" is also used in the prior art to refer to ePTFE (D2, paragraph [0007]; D8, column 5, lines 8 and 9).

However, the feature in the claim solely requiring nodes interconnected by fibrils does not limit the material of the sheath to having the specific structure observed in an ePTFE sheath. Such a restricted

interpretation is not supported by the claim and the description of the invention in the patent.

2.3 The respondent-patent proprietor argued that the sheath of D4 lacked a microstructure composed of nodes interconnected by fibrils. The result of the electrospinning process was a non-woven in which the fibrils were not interconnected. In such a disordered web of fibrils, the fibrils could move relative to one another by sliding in order to create gaps for the therapeutic agent to be released. This structure did not contain the required nodes interconnected by fibrils as it was a nodeless structure.

2.4 However, the sheath disclosed in D4 is a fibrous matrix (page 1, line 15) produced by a method such as electrospinning (page 4, line 14). Figure 16 is a representation of the expandable members according to D4. Figure 16g shows the structure of the electrospun stock upon inflation. Figure 16 discloses a material made of fibrils and regions at which different fibrils converge. In the absence of any precise definition of the term "nodes", these regions at which the fibrils are interlaced can be considered as nodes. D4 thus discloses a sheath having the features required by claim 1.

2.5 The balloon catheter in claim 1 is thus not novel and the ground in Article 100(a) EPC precludes the maintenance of the patent as granted.

3. Auxiliary requests

3.1 Claim 1 of the first auxiliary request corresponds to claim 1 of the patent as granted. The arguments in the previous point thus apply. The first auxiliary request

is not allowable for the same reasons as the main request.

3.2 Claim 1 of the second auxiliary request further requires the sheath to have been treated with a wetting agent. Page 17, line 29 of D4 discloses that the fibrils of the sheath could contain hydrophilic substances. These substances are wetting agents.

The respondent-patent proprietor argued that D4 disclosed these hydrophilic substances in a different role, namely that of protecting the sheath and preventing premature elution of the therapeutic agent. For this reason, the hydrophilic substances in D4 were not wetting agents and claim 1 was novel.

However, a hydrophilic substance enhances the interaction between the sheath and the surrounding aqueous media and is thus a wetting agent even if D4 discloses it as having a different or an additional role.

The balloon catheter in claim 1 of the second auxiliary request is not novel and this request is thus not allowable.

3.3 The respondent-patent proprietor requested a decision on the written record.

The opposition division concluded that none of the grounds for opposition precluded the maintenance of the patent as granted. This implies that there is no decision by the opposition division on any of the auxiliary requests submitted by the respondent-patent proprietor that the board could review.

Furthermore, on appeal the respondent-patent proprietor has not put forward any arguments as to why claim 1 of the third to fourteenth auxiliary requests should be considered novel if the board were to disagree with the opposition division's conclusion.

The opposition division examined inventive step under consideration of a distinguishing feature which the board considers to be disclosed in D4. On appeal, the respondent-patent proprietor has not put forward any arguments as to why, if the balloon catheter in claim 1 of these requests were to be novel, it should be considered inventive.

Under these circumstances, the board cannot allow any of these requests either, as there is no argument on the written file as to why the conclusion on these requests should differ from that explained with respect to the main request and the first and second auxiliary requests.

4. Conclusion

The ground for opposition in Article 100(a) EPC precludes the maintenance of the patent as granted and none of the auxiliary requests is allowable.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chair:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated