

**Internal distribution code:**

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

**Datasheet for the decision  
of 8 May 2014**

**Case Number:** T 1022/10 - 3.3.10

**Application Number:** 01308349.8

**Publication Number:** 1192957

**IPC:** A61L31/10, A61L27/34

**Language of the proceedings:** EN

**Title of invention:**  
Coating for medical devices

**Patent Proprietor:**  
ETHICON, INC.

**Opponent:**  
Boston Scientific Corporation

**Headword:**  
Coating for medical devices /ETHICON

**Relevant legal provisions:**  
EPC Art. 56

**Keyword:**  
Inventive step - non-obvious solution

**Decisions cited:**

**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 1022/10 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 8 May 2014**

**Appellant:**  
(Patent Proprietor)

ETHICON, INC.  
U.S. Route 22  
Somerville,  
New Jersey 08876 (US)

**Representative:**

Kirsch, Susan Edith  
Carpmaels & Ransford LLP  
One Southampton Row  
London WC1B 5HA (GB)

**Respondent:**  
(Opponent)

Boston Scientific Corporation  
One Scimed Place MS A150  
Maple Grove MN 55311 (US)

**Representative:**

Vossius & Partner  
P.O. Box 86 07 67  
81634 München (DE)

**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted on 31 March 2010  
revoking European patent No. 1192957 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman** P. Gryczka  
**Members:** J.- C. Schmid  
F. Blumer

### **Summary of Facts and Submissions**

- I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the Opposition Division revoking European patent No. 1 192 957.
- II. With a letter dated 2 May 2014, the opponent withdrew its opposition and thus is no longer a party to the proceedings.
- III. In the decision under appeal, the Opposition Division held that the patent-in-suit disclosed the invention in a manner sufficiently clear and complete to be carried out by the person skilled in the art. The subject-matter of claim 1 of the then pending main request was novel over document

(3) US-A-4 816 339

on account of the features set forth in claim 1 relating to the percentages of vinylidene fluoride (VDF) and hexafluoropropylene (HFP) used to prepare the polyfluoropolymer. However, the claimed subject-matter lacked an inventive step starting from document (3) as the closest state of the art. The only difference between the subject-matter of claim 1 and the disclosure of document (3) was the claimed range of monomers VDF and HFP from which the copolymer was prepared. The problem underlying the patent-in-suit was the provision of an alternative polymer of VDF and HFP for use in a biocompatible coating for implantable medical devices. Copolymers of VDF and HFP were taught in document (3) as suitable coating material for implantable devices. The skilled person would therefore have expected that copolymers of VDF and HFP made from the monomers VDF and HFP in the claimed ratio would

also be suitable as coating material for implantable medical devices, with the consequences that the claimed subject-matter lacked an inventive step.

- IV. At the oral proceedings before the Board, held on 8 May 2014, the Appellant withdrew auxiliary requests 1, 4, 6 and 9 and defended the maintenance of the patent in suit on the basis of the claims of the main request and auxiliary requests 2, 3, 5, 7 and 8, all requests being filed with a letter dated 3 March 2014.

Independent claim 1 of the main request reads as follows:

"1. A biocompatible coating for use on implantable medical devices, said coating comprising:

a polyfluoro copolymer prepared from 50 to 85 weight percent of vinylidene fluoride and from 50 to 15 weight percent of hexafluoropropylene, based on the total monomer weight used to prepare said copolymer, wherein the amounts of vinylidene fluoride and hexafluoropropylene are effective to provide said coating with properties sufficient for use in coating implantable medical devices when said coated medical device is subjected to a maximum temperature of less than 100°C;

a solvent in which said polyfluoro copolymer is substantially soluble; and

a therapeutic and/or pharmaceutical agent."

- V. According to the Appellant, document (3) was not relevant to the present invention. This document related to vascular grafts and sought to provide elastomers to improve their luminal hydrophobicity, suturability, compliance, strength and elasticity. The grafts disclosed in document (3) had at least two

layers. A coating, i.e. the third layer on the outside of the second layer, was optional, and if present, needed to be porous to allow tissue ingrowth. The purpose of the present invention was however to provide coating compositions for medical implantable devices such as stents, which, hence, must possess physical and mechanical properties effective for use in such devices, in particular they must produce clear and adherent films. This was contrary to the purpose of the optional embodiment of document (3), which was to provide a porous coating.

Document (11) US-A-5 824 048, which related to coated stents, could be seen as the closest prior art. The technical problem underlying the invention was to provide an alternative polymer which allowed the production of a good quality coating. Document (11) provided a long list of possible polymers, but did not refer to VDF/HFP copolymers. VDF homopolymer was cited on column 5, line 41. However, this polymer produced films that adhered poorly to the stent and flaked off, as shown in the comparative example 1 of the patent-in-suit. There was no pointer in the cited prior art to the proposed solution, i.e. to a polyfluoro copolymer prepared 50 to 85 weight percent of VDF and from 50 to 15 weight percent of HFP, based on the total monomer weight used to prepare said copolymer in order to produce a good quality coating. Accordingly, the claimed subject-matter involved an inventive step.

VI. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request, or subsidiarily, on the basis of the claims of any of auxiliary requests 2, 3, 5, 7 and 8, all requests as filed with the letter dated 3 March 2014.

VII. At the end of the oral proceedings the decision of the Board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Main request*

2. *Sufficiency of disclosure of the invention and novelty*

Insufficiency of disclosure and lack of novelty were raised as grounds for opposition. In the decision under appeal, the Opposition Division, however, rejected these grounds. The Board on its own does not see any reason to take a different view.

3. Inventive step

3.1 Closest prior art

The patent-in-suit is directed to coatings comprising a therapeutic and/or pharmaceutical agent for implantable medical devices, in particular stents, with the aim of reducing thrombosis, restenosis or other adverse reactions.

Document (11) relates to a method for delivering a therapeutic substance to a body lumen utilizing an intravascular stent having a coating comprising a polymer and a therapeutic substance. This document discusses the problem of restenosis following angioplasty treatment (see column 1, lines 15 to column 2, line 6). The Board considers in agreement with the Appellant that document (11) represents the closest

prior art to the invention, and, hence takes it as the starting point in the assessment of inventive step.

The Opposition Division considered that document (3) was the closest prior art to the invention. However, document (3) relates to materials utilized in the production of implantable medical devices, in particular vascular grafts. The aim of document (3) is to improve luminal hydrophobicity, suturability, compliance, strength and elasticity (see column 1, lines 21 to 25). In particular embodiments, the outer surface of the graft may be coated with an elastomer which may comprise therapeutic agents (see column 8, line 31 to 47; claims 12 and 21). However, the purpose of this optional coating is to promote periprosthetic tissue ingrowth (see column 8, lines 35 and 36), which is the opposite purpose to that of the patent-in-suit of reducing thrombosis or restenosis. Accordingly, document (3) does not represent the closest prior art.

### 3.2 *Technical problem underlying the patent-in-suit*

Starting from document (11), the technical problem underlying the patent-in-suit is the provision of an alternative coating composition for stents.

### 3.3 *Proposed solution*

As a solution to this problem the patent proposes the coating composition of claim 1 which is characterized in that it comprises a polyfluoro copolymer prepared from 50 to 85 weight percent of VDF and from 50 to 15 weight percent of HFP, based on the total monomer weight used to prepare said copolymer.

### 3.4 *Success*

In view of the examples of the patent-in-suit, in particular example 7, the Board is satisfied that it is credible that the coating compositions of claim 1 are useful to coat stents.

### 3.5 *Obviousness*

It remains to be decided whether or not the proposed solution to that objective technical problem is obvious in view of the state of the art.

Document (11) teaches that the polymer chosen to coat the stent must be a polymer which is biocompatible and which minimizes irritation to the vessel wall when the stent is implanted (see column 5, lines 14 to 16), such as poly(lactic acid), poly(lactide-co-glycolide), poly(hydroxybutarate-co-valerate), silicones, polyurethanes, polyesters, vinyl homopolymers and copolymers, acrylate homopolymers and copolymers, polyethers and cellulosics (see claims 5 and 7). More specific polymers are listed on column 5, lines 16 to line 53, such as VDF homopolymers (line 41). However, VDF homopolymer films adhere poorly to stents and flake off (see example 1 of the patent-in-suit). Furthermore, there is no suggestion in document (11) that VDF/HFP copolymers, let alone a polyfluoro copolymer prepared from 50 to 85 weight percent of VDF and from 50 to 15 weight percent of HFP, based on the total monomer weight used to prepare said copolymer, may be suitable to provide good coatings for stents.

The skilled person would even be taught away by document (3) to consider VDF/HFP copolymers for coating stents. This document teaches that grafts may be coated



with an elastomer including VDF/HFP copolymers to provide a porous layer in order to promote periprosthetic tissue ingrowth (see column 7, line 3 to 14). In contrast, in the present invention, tissue ingrowth should be avoided on the coated stent in order to prevent restenosis. Accordingly, the skilled person faced with the problem to provide an alternative coating composition for stents would not have contemplated a composition comprising VDF/HFP copolymers.

Hence, the subject-matter of claim 1 is not obvious in the light of the prior art.

3.6 The Board is not aware of any further documents cited in the opposition proceedings which render the proposed solution obvious.

3.7 Therefore, the Board comes to the conclusion that the subject-matter of claim 1 of the main request, and for the same reason, that according to dependent claims 2 to 5, and that of claims 6 and 7 relating to a film prepared from the coating of claims 1 to 5, involve an inventive step within the meaning of Article 56 EPC.

*Auxiliary requests 2, 3, 5, 7 and 8*

4. Since the main request is considered to be allowable, it is not necessary to decide on the lower-ranking auxiliary requests.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside
2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the main request (claims 1 to 7) as filed with letter dated 3 March 2014 and a description yet to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated