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Datasheet for the decision of 8 February 2017

Case Number: T 1191/13 - 3.3.03

Application Number: 05793267.5

Publication Number: 1784434

IPC: C08F214/18, C08F214/22, A61L31/10

Language of the proceedings: EN

Title of invention:
POLYMERS OF FLUORINATED MONOMERS AND HYDROPHILIC MONOMERS

Patent Proprietor:
Abbott Cardiovascular Systems Inc.

Opponent:
Solvay Specialty Polymers Italy S.p.A.

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step - (yes)
Late-filed argument - admitted (no)

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Case Number: T 1191/13 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 8 February 2017

Appellant: (Patent Proprietor)	Abbott Cardiovascular Systems Inc. 3200 Lakeside Drive Santa Clara, CA 95054 (US)
Representative:	ZBM Patents - Zea, Barlocci & Markvardsen Plaza Catalunya, 1 08002 Barcelona (ES)
Respondent: (Opponent)	Solvay Specialty Polymers Italy S.p.A. Via Lombardia, 20 20021 Bollate (MI) (IT)
Representative:	Benvenuti, Federica Solvay S.A. Département de la Propriété Intellectuelle Rue de Ransbeek, 310 1120 Bruxelles (BE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 March 2013 revoking European patent No. 1784434 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Semino
Members:	M. C. Gordon
	C. Brandt

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division posted on 15 March 2013 revoking European patent number 1 784 434.

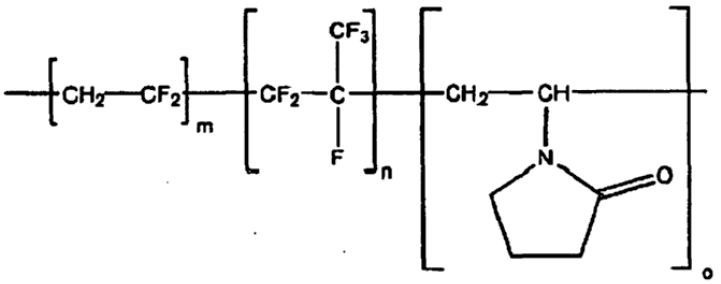
II. The patent was granted with a set of 14 claims, whereby claim 1 read as follows:

1. A biocompatible polymer comprising strength fluoro monomer, flexibility fluoro monomer and hydrophilic monomers, wherein the polymer has a structure of formula I:

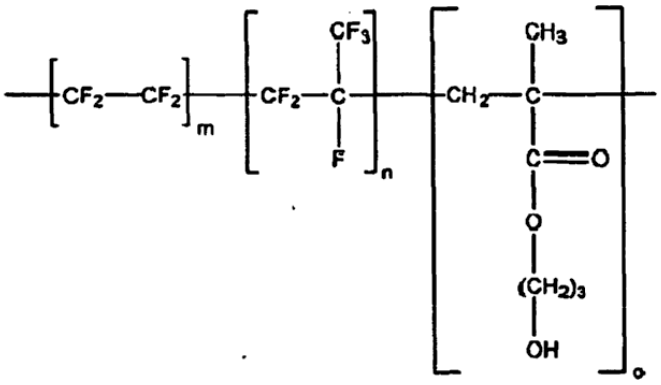
Formula I

and m, n and o are positive integers,
wherein the strength fluoro monomer is selected from the group consisting of $-CF_2-CF_2-$, $-CH_2-CF_2-$, $-CH_2-CHF-$, $-CF_2-CHF-$, -CHF-CHF-, or $-CF_2-CRF-$ where R can be phenyl, cyclic alkyl, heterocyclic, heteroaryl, fluorinated phenyl, fluorinated cyclic alkyl, or fluorinated heterocyclic, and
wherein the flexibility fluoro monomer is selected from the group consisting of $-CF_2-CRF-$, -CHF-CRF, and $-CF_2-CRH-$, where R is Cl, Br, I, C_2 to C_{12} short chain alkyl groups and C_2 to C_{12} fluorinated short chain alkyl groups, and the hydrophilic monomer is selected from the group consisting of vinyl monomers that bear a pyrrolidone group (s), carboxylic acid group(s), sulfonic acid group(s), sulfone group(s), amino groups(s), alkoxy group(s), amide group (s), ester group(s), acetate group(s), poly(ethylene glycol) group(s), poly(propylene glycol) group(s), poly(tetramethylene glycol) group(s), poly(alkylene oxide) group(s), hydroxyl group(s), or a substituent that contains a charge or one of pyrrolidone group(s), carboxylic acid group(s), sulfone group(s), sulfonic acid group(s), amino group(s), alkoxy group(s), amide group(s), ester group(s), acetate group(s), poly(ethylene glycol) group(s), poly(propylene glycol) group(s), poly(tetramethylene glycol) group(s), poly(alkylene oxide) group(s), hydroxyl group(s), and combinations thereof.

Claims 2 to 6 were formulated as dependent on claim 1 wherein claim 5 defined the biocompatible polymer as having a structure of "any" [sic] of formulae:



Formula II



Formula IV

Claims 7-10 were directed to various embodiments of a biocompatible polymer blend comprising the polymer of claim 1 and at least one other biocompatible polymer. Claims 11 and 12 were directed to implantable devices having a biocompatible coating comprising the biocompatible polymer of one or more of the preceding claims. Claims 13 and 14, dependent on claim 11, were directed to a stent wherein the coating further comprised a bioactive agent.

III. A notice of opposition against the patent was filed in which revocation on the grounds of Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(c) EPC was requested.

The following documents, *inter alia* were invoked in the

opposition:

D2: US-A-4 861 851
D15: US-A-5 290 548
D16: WO-A-02/32590
D18: Ullmann's Encyclopedia of Industrial Chemistry, VCH, 5th Edition 1988, pp 393, 402-405.

IV. The decision of the opposition division was based on amended sets of claims forming a main and first to third auxiliary requests. The second auxiliary request, which is the only request relevant for the present decision, was submitted during the oral proceedings on 7 February 2013 and consisted of 16 claims whereby claim 1 differed from claim 1 as granted in that the preamble to the claim read as follows:

"An implantable device formed from or comprising a coating formed from a biocompatible polymer comprising strength fluoro monomer, flexibility fluoro monomer and hydrophilic monomers, wherein the polymer is a random or block polymer and has a structure of formula I:".

Claims 2-11 were correspondingly amended to be directed to a device, in particular a drug delivery stent (claims 10 and 11). Claim 5 retained the dependency on claim 1 (see above).

Claim 12 was an independent claim directed to a polymeric coating or substrate comprising a bioactive agent and a biocompatible polymer defined employing the wording of claim 1. Claims 13-15 were directed to preferred embodiments of the coating or substrate of claim 12.

Claim 16, formulated as dependent on claim 12,

specified the structural formulae of granted claim 5.

V. The decision under appeal, as far as relevant to the present decision can be summarised as follows:

The second auxiliary request did not meet the requirements of Article 56 EPC. Closest prior art D15 related to medical devices prepared from a fluorocopolymer grafted with a hydrophilic monomer. The sole distinguishing feature was the structure of the polymer. It had not been shown, and was not credible, that the process of the patent in suit was simpler than that of D15. The patent in suit itself even considered grafting as a means to carry out modification of the polymer. Furthermore the operative claim did not specify a minimum amount of the hydrophilic monomer. Consequently no technical problem could be seen as having been solved over the entire scope of the claim and the objective problem was to provide a further implantable medical device. The provision of such devices prepared from or coated with a polymer as specified in operative claim 1 - in particular in view of the absence of any limitation on the amount of hydrophilic monomer - was obvious. It was derivable from the cited example of D15 that perfluorinated ethylene/propylene copolymer (FEP) was considered to be an alternative to grafted FEP. Any FEP copolymer that included a small amount of a hydrophilic monomer would thus be considered to be just an obvious equivalent to FEP for preparing implantable medical devices.

VI. The patent proprietor (appellant) lodged an appeal against the decision. Together with the statement of grounds of appeal, sets of claims forming a main request and four auxiliary requests were submitted. The main request corresponded to the second auxiliary

request considered by the opposition division however with the amendment that claims 5 and 16 were now formulated as independent claims, i.e. the dependency on claims 1 and 12 respectively had been removed.

VII. In its reply the opponent (respondent) maintained objections pursuant to Article 56 EPC in respect of all the independent claims relying on the teachings of D15 as the closest prior art, D16 and D18.

VIII. The board issued a summons to attend oral proceedings and a communication setting out its provisional view of the case.

IX. With letters of 11 and 19 January 2017 the appellant submitted a total of nine sets of claims forming a main request and eight auxiliary requests. The main request was unchanged compared to that submitted with the statement of grounds of appeal. A further document (D20: Misra B.N, *et al* Journal of Applied Polymer Science, 1995, vol. 56, pp. 1133-1139) was submitted.

X. The respondent made a further written submission with letter dated 31 January 2017. Document D21 (US-A-3 008 920) was submitted.

XI. Oral proceedings were held before the Board on 8 February 2017.

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

The patent in suit and D15 addressed different problems and employed different approaches. D15 aimed at providing articles with low tissue adhesion whereas the patent in suit was concerned with providing drug

permeability. D15 modified the surface of articles by introducing grafts of polymeric chains containing hydrophilic groups whereby the grafting process led to a modification of the polymer structure thus potentially changing properties such as flexibility. In contrast the patent in suit incorporated the hydrophilic modifying monomer within the backbone of the polymer resulting in a different polymer structure to that of either the starting or final polymer of D15. Although the patent in suit did contain a passage relating to grafting this passage concerned embodiments no longer falling under the claims. The most relevant example of D15, relating to modified fluoropolymer articles, was directed to the production of catheters which devices were intended for temporary insertion into the body, but were not to be considered as implantable devices as addressed by the patent in suit which devices were intended to be left permanently in the body.

By means of the distinguishing features an improvement in drug permeability was obtained. Furthermore the process leading to the polymers of the patent in suit was simpler than that of D15, since no subsequent grafting step of the finished polymer or articles prepared therefrom was required.

D15 contained no hint or pointer to polymers with the structure as defined in the operative claims and in particular no indication of such a structure in order to provide improved drug permeability.

The argument that FEP and grafted FEP were equivalent was incorrect and based, if at all on interpreting the teaching of D15 in the light of the teachings of the patent in suit which constituted an unallowable *ex post*

facto analysis.

The absence of any numerical limitation on the amount of hydrophilic comonomer was not of significance since the examples of the patent showed that even very small contents of hydrophilic monomer led to an increase in permeability. The effect of small amounts of hydrophilic monomers on the overall properties of the polymer was also derivable from D15. Regarding the influence of the different monomers on the properties of the polymer, the position of the respondent that toughness and flexibility were equivalent, or influenced by the same factors, was disputed.

XIII. The arguments of the respondent can be summarised as follows:

D15 covered a wide range of medical devices including devices to be implanted into the body. A catheter should also be considered to be an implantable device.

The polymers of D15, example 13 and the patent were based on the same monomers. It was only the monomers that determined the properties of a polymer. Once the monomers had been defined, it was immaterial for the final properties of the polymer what method was used to prepare the polymer or the resulting structure of the polymer (*inter alia* block polymerisation or graft polymerisation). The patent itself presented grafting as a route to provide the target polymers.

The claims were not limited to polymers having a technical effect as no minimum level was specified for the hydrophilic monomer. Further there were no comparative tests showing any effect of the claimed polymers. The preparation of the terpolymers as defined

in the claims was not necessarily simpler than the preparation of the polymers of D15, in particular taking into account that the patent itself considered grafting as one route to obtain said polymers.

The incorporation of monomers such as HFP (hexafluoropropylene) into the polymer, which monomers were known, e.g. from D18, to reduce the tendency of the polymer to crystallise and hence improve toughness was an obvious route to increase flexibility. From D16 and D18 it was known that a large range of monomers could be used to impart flexibility to polymers.

The introduction of monomers which enhanced hydrophilicity would also improve absorption and hence drug permeability. The polymer structure according to the patent was in the end a simple equivalent to that of D15.

During the oral proceedings it was further submitted - for the first time - that the teaching of D2 relating to random polymers based on fluorinated monomers and hydrophilic monomers addressed the provision of materials having (gasoline) permeability and thus was also relevant.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request, or, alternatively, on the basis of any of the first to eighth auxiliary requests, all requests filed with letter dated 19 January 2017.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Main request - inventive step

1.1 The patent in suit relates to polymers for coating implantable (medical) devices such as stents (paragraph [0001]). Further examples of implantable devices are discussed in paragraph [0037] of the patent and include among others (internal) prostheses, heart valves, shunts and pacemaker electrodes. It is explained in the introduction to the patent that materials are known which exhibit good mechanical properties and acceptable biocompatibility but have low permeability to drugs, which is disadvantageous when the device is used for drug delivery, e.g. a drug delivery stent. Although this problem can be addressed by incorporation of hydrophilic polymers as blends, these can leach out due to their solubility meaning a loss of the biobeneficial function. Furthermore incorporation of such polymers can influence the mechanical properties of the materials forming the devices (paragraph [0006]). These problems of existing implantable devices and materials therefor are addressed according to claim 1 of the patent by provision of a block or random terpolymer of three types of monomers, defined as a "strength" fluoromonomer, a "flexibility" fluoromonomer and a "hydrophilic" monomer.

1.2 Polymers for preparing medical devices are known from D15, in particular example 13, which by common consent represents the closest prior art. Among the medical devices mentioned in D15 in general, with no restriction to specific polymers (column 7, line 15ff) are instruments, devices, implants and ocular lenses. D15 addresses primarily the question of tissue

compatibility and low adhesion, i.e. for ease of insertion and withdrawal without causing tissue damage. Permeability to drugs is not discussed or addressed in D15 (column 1 lines 20-24, survey of the background art in columns 1-5 and statement of object and summary of the invention at column 5, lines 22-32, column 7 lines 36-43). D15 is not restricted to (per)fluorinated main chain polymers but relates in general to hydrophilic surface modification or a wide variety of polymers employed in medical applications (column 7, line 15ff). According to column 9, line 11 concentrations of hydrophilic grafting agent as low as 0.1-0.5% are sufficient to impart hydrophilicity to the surface.

According to example 13 of D15 a catheter is prepared from a polymer of FEP (perfluorinated ethylene/ propylene copolymer) which is grafted with hydrophilic monomer (dimethylacrylamide or methoxypolyethylene glycol monomethacrylate).

1.3 The subject matter of operative claim 1 is distinguished from the disclosure of example 13 of D15 in that the polymer is a block or random copolymer wherein all three classes of monomers are present in the polymer backbone. It is also observed that one of the monomers employed in the example of D15 (hexafluoropropylene) is not encompassed by operative claim 1.

1.4 The problem solved

There is no direct experimental evidence of any technical effect arising compared to the polymers of D15. The examples of the patent either relate to the synthesis of the terpolymers (examples 1, 2) or have the form of a "prophetic" example (example 3) relating

to the - potential - application of a coating formed from the terpolymer to a stent. Indeed the text does not unequivocally indicate what has been done, but employs language of the form "to apply the...layer.. spray apparatus such as...can be used; during the process...the stent can be optionally rotated...or can be moved" (paragraph [0043]).

Equally there is no evidence that the claimed compositions is not suitable for the purpose indicated in the patent, notwithstanding the lack of a restriction on the amounts of the three comonomers. All arguments to this effect from the respondent are speculative. Furthermore the evidence provided by D15, column 9 cited above, is that even very small amounts of hydrophilic monomers will exert an effect on the properties of the polymer.

Under these circumstances the technical problem to be solved can be formulated as the provision of further polymers suitable for the preparation or coating of (implantable) medical devices.

For the sake of this formulation of the problem it is not necessary to consider in detail what constitutes an implantable device, although the board considers that this term has to be applied to articles designed to be left for extended periods or permanently within the body as opposed to devices inserted temporarily and then withdrawn at the conclusion of treatment (e.g. as in the case of a catheter, disclosed in the cited example of D15).

The defined problem is solved according to claim 1 by a terpolymer in which the monomers conferring strength, flexibility and hydrophilicity are incorporated into

the main chain of the polymer rather than having the hydrophilicity conferring monomer grafted onto a polymer chain formed from the other two monomers.

1.5 Obviousness

The respondent argued that the structure in claim 1 and that in D15 were in fact equivalent and that the only factor influencing the properties of the polymer was the nature of the monomers regardless of the method employed to prepare the polymer and the resulting structure of the polymer. No evidence was advanced to support this position which appears to be inconsistent and incompatible with the general knowledge and understanding in the polymer field according to which the distribution and structure of monomer units within a polymer exerts a significant effect on the properties of the resulting material.

Indeed D15 does not relate to block terpolymers and has no teaching which would suggest such a structure. In particular the focus of D15 is to carry out surface modification of an existing polymer to render the material hydrophilic and biocompatible, which definitely points in a different direction to that of a block copolymer structure.

Moreover it has not been shown that any other document would teach that a hydrophilic monomer could be incorporated in the chain of a copolymer intended for medical use such as those of D15.

Document D16 also relates to grafting of hydrophilic monomers onto a main chain polymer or article and does not envisage incorporating the hydrophilic monomer within the polymer chain (claim 1, page 2 first

paragraph).

D18 is an encyclopedia reference discussing the base polymers of D15 (hexafluoropropylene and tetrafluoroethylene copolymers) and reports that incorporation of hexafluoropropylene imparts toughness to the polymer. The respondent argued this meant also that the resulting polymers exhibited flexibility. However it was disputed by the appellant that toughness and flexibility were in fact synonymous or identical and the respondent did not demonstrate that this was in fact the case. According to the board's understanding these two properties do indeed reflect different aspects of a material's behaviour and there is no indication in any of the documents that a product which is reported to exhibit toughness would necessarily also be flexible. In any case the document does not teach incorporation of the hydrophilic monomer within the polymer chain.

It was also argued by the respondent that FEP (the base polymer of example 13 of D15) and grafted FEP would be understood by the skilled person as being equivalents or interchangeable. However this argument, insofar as understood by the board, appeared to rely on interpreting the disclosure of example 13 of D15 in the light of the teachings of the patent in suit rather than the teachings of a prior art document. Hence this argument by the respondent constitutes an inadmissible *ex post facto* approach. This argument is in any case at odds with the teaching of document D20 submitted by the appellant which indicates that the introduction of grafts necessarily alters the structure of the base polymer due to abstraction of substituents and introduction of peroxy groups (D20, "Results and Discussion" and the structural formulae shown in that

section). According to the teaching of the patent it is precisely these substituent groups - which are extracted by the grafting process - which confer on the polymer the property of "flexibility". D21, cited by the respondent also teaches that grafting requires modification of the pre-existing polymer backbone in order to introduce sources of radicals (column 1, lines 13-17). Consequently the cited documents rather than indicating that grafting would leave the basic structure of the polymer unchanged actually suggests that the grafting would in some way materially affect the structure and hence the properties of the polymer. As a consequence the argument of the respondent that FEP and grafted FEP should be considered as equivalents is untenable.

Regarding the argument that the patent in suit itself envisaged grafting as a means to form the polymers, it is noted that such a passage does indeed exist (paragraph [0026], penultimate sentence). However this statement is incompatible with the subject-matter of the claims, since the indicated structure cannot be obtained by a grafting process. It appears that this is a "legacy" statement inadvertently left over from the application as filed and not adapted prior to grant, since the originally filed claims did not specify the structure of the polymer. Consequently the presence of this statement cannot serve to show that grafting is taught as a route to obtain the polymers as now defined.

Finally the respondent at the very end of the oral proceedings before the board invoked for the first time in the appeal proceedings D2. This document does not relate to medical devices but to gasoline resistant materials for the automotive sector (D2, column 1,

lines 7-31, column 2, lines 27-29). Even if, as argued by the respondent, there would be some structural similarities between the polymers of D2 and those of the patent in suit, it was not shown, nor is it credible, that this document would be relevant to the technical field of the invention. Under these circumstances the board elected to use its discretion not to admit the new newly formulated attack based on D2 to the procedure (Article 13(1) RPBA).

1.6 The subject-matter of claim 1 therefore meets the requirements of Article 56 EPC.

1.7 The further independent claims 5, 12 and 16 relate to the same basic structure of polymer, differences in the permissible monomer units notwithstanding and the above reasoning and conclusion applies *mutatis mutandis* to these claims. As no separate attack and no additional arguments have been submitted by the respondent, there is no need for the Board to elaborate further on this issue.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the main request (claims 1 to 16) as filed with letter dated 19 January 2017 and after any necessary consequential amendment of the description.

The Registrar: The Chairman:

P. Martorana D. Semino

Decision electronically authenticated