Appeal decision

Appeal No. 2017-14063

Canada
Appellant Interface Biologics, Inc.

Patent Attorney HIRAKI & ASSOCIATES

The case of appeal against the examiner's decision of refusal for Japanese Patent Application No. 2015-206895, titled "ANTI-THROMBUS FORMABLE HOLLOW FIBER MEMBRANE AND FILTER" [Published on April 14, 2016 as Japanese Unexamined Patent Application Publication No. 2016-52525] has resulted in the following appeal decision.

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The present application is a patent application filed on October 21, 2015, which is a divisional of Japanese Patent Application No. 2015-020185 filed on February 4, 2015, which is a divisional of Japanese Patent Application No. 2014-051179 filed on March 14, 2014, which is a divisional of Japanese Patent Application No. 2013-516412 with an international filing date of May 14, 2010 (claiming priority based on the Paris Convention with a Foreign Patent Office receipt date of May 15, 2009 (US), United States). The history of the subsequent procedures is set forth as below:
September 2, 2016: Notice of reasons for refusal
January 18, 2017: Submission of written opinion
January 18, 2017: Submission of written amendment
May 12, 2017: Decision of Rejection
September 22, 2017: Submission of written amendment (hereinafter the amendment by this written amendment is referred to as "The Amendment".)
September 22, 2017: Submission of notice of appeal

No. 2 The Amendment

1 Details of the Amendment

(1) Claims 1 to 14 of the scope of claims on which an amendment was made by the written amendment on January 18, 2017 (hereinafter referred to as "before the Amendment") are recited as below:

"[Claim 1]

A blood tube comprising a basic polymer mixed with 0.005% to 10% (w/w) of a surface-modified polymer, said blood tube having an ability to prevent thrombus formation in contact with blood in a case of measuring with gamma count, said surface-modified polymer being represented by
Formula (VII):

FT-[B-(Oligo)]n-B-FT(VII)

[wherein
Oligo is polypropyleneoxide having a theoretical molecular weight of 500 to 2000 Daltons,
B is a hard segment formed from hexamethylenediisocyanate,
FT is polyfluoroorgano group,
n is an integer from 1 to 10]
"

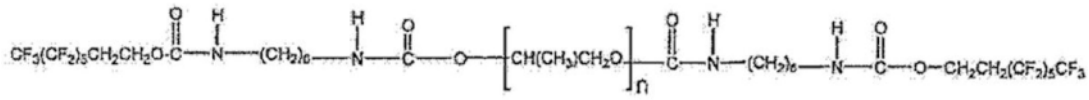
"[Claim 2]

The blood tube of Claim 1, wherein said basic polymer is polyvinylchloride."

"[Claim 3]

The blood tube of Claim 1 or 2, wherein said surface modifying polymer is VII-a:

[Chemical Formula 1]



[wherein molecular weight of the [CH(CH3)CH2O]n unit is 500 to 2000 Daltons]"

"[Claim 4]

The blood tube of any one of Claims 1 to 3, wherein adverse effects on a subject to whose blood passing through said blood tube is administered are reduced as compared to a control blood tube without said surface-modified polymer used in the same condition, and said blood tube differs from said control blood tube only by the presence of said surface-modified polymer."

"[Claim 5]

The blood tube of Claim 1 or 2, wherein n is an integer from 1 to 3."

"[Claim 6]

The blood tube of Claim 1 or 2, wherein FT is polyfuloroalkyl having a theoretical molecular weight of 100 to 1500 Daltons."

"[Claim 7]

The blood tube of Claim 1 or 2, wherein FT is CF3(CF2)rCH2CH2- (wherein r is 2 to 20)."

"[Claim 8]

The blood tube of Claim 1 or 2, wherein FT is CF3(CF2)s(CH2CH2O)χ- (wherein χ is 1 to 10, s is 1 to 20)."

"[Claim 9]

The blood tube of Claim 1 or 2, wherein FT is CHmF(3-m)(CF2)rCH2CH2- or CHmF(3-m)(CF2)s(CH2CH2O)χ- (wherein m is 0, 1, 2, or 3, χ is an integer from 1 to 10, r is an integer from 2 to 20, s is an integer from 1 to 20)."

"[Claim 10]

The blood tube of Claim 1 or 2, wherein FT is formed from 1H,1H,2H,2H-perfluoro-1-decanol, 1H,1H,2H,2H-perfluoro-1-octanol, 1H,1H,5H-perfluoro-1-pentanol, 1H,1H, perfluoro-1-butanol, or a mixture thereof."

"[Claim 11]

The blood tube of Claim 10, wherein FT is formed from 1H, 1H, 2H, 2H-perfluoro-1-octanol."
"[Claim 12]
The blood tube of Claim 1 or 2, wherein FT is (CF3)(CF2)5CH2CH2O-, (CF3)(CF2)7CH2CH2O-, (CF3)(CF2)5CH2CH2O-,CHF2(CF2)3CH2O-, or (CF3)(CF2)2CH2O-."
"[Claim 13]
The blood tube of Claim 3, wherein a molecular weight of [CH(CH3)CH2O]n unit is 1000 g/mol."
"[Claim 14]
The blood tube of any one of Claims 1 to 13 for the use in the treatment of a subject suffering from renal function disorder, wherein the use comprises the step of implementing the procedures selected from hemodialysis, hemofiltration, hemoconcentration, or hemodiafiltration for the subject."

(2) Claim 1 of the scope of claims after the Amendment (hereinafter referred to as "The Amended Invention") is set forth as below. (Note that the underlines are provided by the body to show the parts of amendment.)

"[Claim 1]
A blood tube comprising a <u>polyvinylchloride</u> mixed with 0.005% to 10% (w/w) of a surface-modified polymer, said blood tube having an ability to prevent thrombus formation in contact with blood in a case of measuring with gamma count, said surface-modified polymer being represented by
Formula (VII):
FT-[B-(Oligo)]n-B-FT(VII)
[wherein
Oligo is polypropyleneoxide having a theoretical molecular weight of 500 to 2000 Da,
B represents a hard segment formed from hexamethylenediisocyanate,
FT is a polyfluoroorgano group,
n is an integer from 1 to 10]"

2 Propriety of amendment
The Amendment aims to amend to the scope of claims before the Amendment. Claim 2 before the Amendment depends from Claim 1. Therefore, an invention according to Claim 2 before the Amendment is identical to an invention according to Claim 1 after the Amendment. Thus Claim 1 after the Amendment rewrites Claim 2 before the Amendment in an independent form. Consequently, the Amendment cancels Claim 1 before the Amendment, and makes Claim 2 before the Amendment Claim 1 after the Amendment. Thus the Amendment is made for the purpose of cancellation of a claim specified in Article 36(5) of the Patent Act as provided in Article 17-2(5)(i) of the Patent Act.
Therefore, the Amendment according to Claim 1 is made properly.

No. 3 Reasons for refusal stated in the examiner's decision
The reasons for refusal stated in the examiner's decision are that the invention according to Claim 2 of the present application could be easily made on the basis of the

invention disclosed in Cited Documents 1 to 2 that had been distributed or available to the public via a telecommunication line in Japan or foreign countries before a date of priority claiming (hereinafter referred to as "priority date".) by a person skilled in the art who had ordinary knowledge in the field of art to which the invention belongs . Thus Appellant should not be granted a patent for the Amended Invention under the provision of Article 29(2) of the Patent Act.

Cited Document 1: United States Patent No. 6127507
Cited Document 2: International Publication No. WO 2008-076345

No. 4 Cited Invention
1 Described matters in Cited Document 1

Cited Document 1 discloses the following matters: The Japanese translation and underlines are provided by the body.
(1) Column 3, lines 20 to 24
"It is a further object of the present invention to provide polymer compositions of fluoroalkyl surface-modifying macromolecules in admixture with a base polyurethane elastomer for use as medical implant devices having improved stability and acceptable blood compatibility."
(2) Column 3, lines 36 to 46
"Accordingly, in one aspect the invention provides a surface modifying macromolecule having a central portion and terminal groups, the central portion being a member selected from the group consisting of a soft central portion and a hard central portion, the central portion having a molecular weight of less than 5,000 and including a segmented oligomeric copolymer unit including at least one polar segment and at least one hydrophobic segment, and the terminal groups including α-ω terminal polyfluoro oligomeric groups. Preferably the oligomeric copolymer unit has a molecular weight of less than 5000, e.g. less than 2000, such as 200-1200."
(3) Column 4, lines 6 to 18
"Examples of typical base polymers of use in admixture with aforesaid SMM according to the invention include polyurethanes, polysulfones, polycarbonates, polyesters, polyethylene, polyproprylene, polystyrene, poly(acrylonitrile-butadienestyrene), polybutadiene, polyisoprene, styrenebutadiene-styrene block copolymers, styrene-isoprenestyrene block copolymers, poly-4-methylpentene, polyisobutylene, polymethyl-methacrylate, polyvinylacetate, polyacrylonitrile, polyvinyl chloride, polyethylene terephthalate, cellulose, and its esters and derivatives. Preferred segmented polymers include polyurethanes, polyester, polyethers, polyether-polyamides, and polyamides."
(4) Column 4, lines 19 to 25
"The admixed compositions according to the invention may be used as a surface covering for an article, or, most preferably, where the composition comprises a base polymer of a type capable of being formed into a self-supporting structural body or film, or woven or knit as a fiber, as a surface or in whole or in part of the article, preferably, a biomedical device or component thereof."
(5) Column 8, lines 14 to 20
"Examples and fabrication of products
The SMM's can be manipulated and handled for use with base polymers in the same manner as the polymers per se can be handled in the fabrication of article products.

The SMM may be admixed with, for example, polyurethane base polymer 1) by compounding methods for subsequent extrusion or injection molding of articles;"
(6) Column 8, lines 50 to 56
"SMMs, thus, contain, preferably as α-ω terminal groups, fluoropolymeric segments comprising a sequential group of carbon atoms containing fluorine atoms and constituting an oligomeric chain. Preferred perfluorinated alcohols of use in the practice of the invention are those of the general formula CF3(CF2)nCH2CH2OH, having a linear alkyl chain, wherein n is 5-9, most preferably C8F17CH2CH2OH."
(7) Column 14, lines 12 to 14
"EXAMPLE 6
HDI-PPO322I and mixtures with TDI/PCI/ED
Another PPO (polypropylene oxide diol) based system in addition to Example 1 which shows preferred performance is HDI-PP0322I. This material is similar to Example 1 except that it was synthesized with a different reactant stoichiometry and contains a fluoroalcohol with a different chain length. HDI-PP0322I was synthesized with PPO diol of molecular weight 1000, 1,6-hexamethylene diisocyanate (HDI), and the intermediate boiling fraction of the fluoroalcohol (BA-L)."
(8) Column 15, line 10 from the bottom to Column 16, line 3
"The interaction of a key protein, namely fibrinogen, involved in the blood coagulation response to biomaterials was shown to be significantly reduced (by 50% at a fibrinogen concentration of 0.01 mg/mL, by 25% at a fibrinogen concentration of 0.1 mg/mL, and by 15% at a fibrinogen concentration of 1.00 mg/mL). Since fibrinogen is a molecule that is crosslinked during the coagulation process and has been associated with surfaces that induce clot formation, the finding that the SMM modified surfaces reduce the amount of fibrinogen adsorption would indicate that the modified surfaces could have important blood compatibility characteristics and may reduce blood activation in medical devices."
(9) Column 23, lines 22 to 4 from the bottom
"EXAMPLE 15
Examples of biomedical articles that integrate the SMM to the polyurethane using aforesaid method 1) described above include the following articles that are in whole or in part made of polyurethane components or contain some polyurethane components, namely, cardiac assist devices, cardiac replacement devices, cardiac septal patches, intra-aortic balloons, percutaneous cardiac assist devices, extracorporeal circuits, A-V fistula, dialysis components (tubing, filters, membranes, etc.), aphoresis units, membrane oxygenator, cardiac by-pass components (tubing, filters, etc.), pericardial sacs, contact lenses, cochlear ear implants, sutures, sewing rings, cannulas, contraceptives, syringes, o-rings, bladders, penile implants, drug delivery systems, drainage tubes, pacemaker leads insulators, heart valves, blood bags, coatings for implantable wires, catheters, vascular stents, angioplasty balloons and devices, bandages, heart massage cups, tracheal tubes, mammary implant coatings, artificial ducts, craniofacial and maxillofacial reconstruction applications, ligaments, and fallopian tubes."
(10) Table 4 discloses a case where 1 to 10 weight% HDI-PRO322I as SMM is included in TDI/PCL/ED(polyesterurethane) as a basic polymer.

(11) According to the above item (7), it is obvious that HDI-PPO322I is obtained by a synthesis of PPO(hexamethylenediisocyanate)diol, 1,6-hexamethylene diisocyanate (HDI), and fluoroalcohol, and is written as the following chemical formula:
FT-[B-(Oligo)]n-B-FT
[wherein
Oligo is polypropyleneoxide,
B is made from hexamethylenediisocyanate,
FT is a polyfluoroorgano group.]

Further, according to the above item (2), a molecular weight of the oligomer copolymer is less than 2000, and thus it can be said that a molecular weight of polypropylenedioxide is less than 2000.

(12) According to the above item (2), it is obvious that hexamethylenediisocyanate (HDI) forms a hard central portion.

(13) According to the above item (8), as examples of biological medical articles where a basic polymer is integrated with SMM, an extracorporeal blood circulation circuit and a heart bypass article (tubing) are exemplified. Thus it is obvious that a tube for blood is assumed as one example of biological medical articles.

2 Cited Invention

Therefore, taking the common general knowledge into account and referring to the pointed matters (1) to (9), disclosed matter (10), and the findings (11) to (13), Cited Document 1 discloses the following invention. (Hereinafter referred to as "Cited Invention".)

"A tube for blood tube comprising a basic polymer mixed with 1% to 10% (w/w) of a surface-modified polymer, said tube having blood compatibility, said surface-modified polymer being represented by
Formula:
FT-[B-(Oligo)]n-B-FT
[wherein
Oligo is polypropyleneoxide having a molecular weight of less than 2000,
B represents a hard central portion formed from hexamethylenediisocyanate,
and FT is a polyfluoroorgano group]"

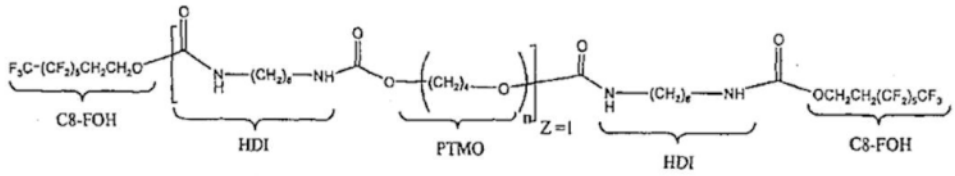
3 Described matters in Cited Document 2

The Cited Document 2 discloses the following matters: The Japanese translation and underlines are provided by the body. Note that Japanese translation is prepared by the body with reference to National Publication of International Patent Application No. 2010-513596 as the corresponding family member.

(14) Page 21, lines 3 to 8
"Example 1 1. Synthesis of SMM (8)
SMM (8), which includes a Poly (tetramethylene oxide), PTMO soft segment, has a degradation temperature of only 229°C and is included for comparison. The SMM(8) material can be synthesized as described in U.S. Patent No. 6,127,507. Both the prepolymer coupling and surface active group coupling were performed using dibutyl tin dilaurate as a catalyst."

(15) FIG. 16 discloses the following chemical formula as SMM(8).

SMM (8)



No. 5 Comparison

Comparing the Amended Invention and the Cited Invention, "1% to 10% (w/w) of a surface-modified polymer" of the Cited Invention corresponds to "0.005 to 10% (w/w) of a surface-modified polymer" of the Amended Invention from the viewpoint of its operation and function, and similarly, "a tube for blood" corresponds to "blood tube", and "blood compatibility" corresponds to "an ability to prevent thrombus formation in contact with blood", and "a hard central portion" corresponds to "a hard segment".

Further, "basis polymer" of the Cited Invention and "polyvinylchloride" of the Amended Invention have in common that they are "basic polymers".

Furthermore, regarding "Oligo", the Amended Invention has "a theoretical molecular weight of 500 to 2000 Da", whereas the Cited Invention has "a molecular weight of less than 2000". "Dalton" is a unified atomic weight unit. Thus both have in common that a theoretical molecular weight of "Oligo" is in a range of 500 to less than 2000 Da.

Consequently, there are the following corresponding and different features between the Amended Invention and the Cited Invention.

(Corresponding features)

"A blood tube comprising a basic polymer mixed with 0.005% to 10% (w/w) of a surface-modified polymer, said blood tube having an ability to prevent thrombus formation in contact with blood, said surface-modified polymer being represented by Formula (VII):

FT-[B-(Oligo)]n-B-FT(VII)

[wherein

Oligo is polypropyleneoxide having a theoretical molecular weight of 500 to 2000 Da,

B represents a hard segment formed from hexamethylenediisocyanate,

and FT is a polyfluoroorgano group]

"

(Different feature 1)

Regarding "basic polymer", the Amended Invention specifies it as "polyvinylchloride", whereas the Cited Invention does not specify it.

(Different feature 2)

Regarding a means for assessing "an ability to prevent thrombus formation", the Amended Invention specifies "in a case of measuring with gamma count", whereas the Cited Invention does not specify it.

(Different feature 3)

Regarding what "n" means, the Amended Invention specifies that "n is an integer from 1 to 10", whereas the Cited Invention does not specify it.

No. 6 Judgment

1 Different features

(1) Consideration is given to the above Different feature 1.

As in the above (3), an example of basic polymer includes polyvinylchloride.

Cited Document 1 only describes a case of a basic polymer of polyurethane or polyesterurethane, and thus it might be only an inventor's idea of the cited invention to use polyvinylchloride as a basic polymer.

However, when consideration is given to the fact that "polyvinylchloride" is used as a "basic polymer" of the Amended Invention, paragraph [0054] of the specification discloses the formation of a blood tube by mixing a surface-modified polymer of formula (VII) with polyvinylchloride; however, in "Best Mode for Implementing the Invention" of paragraphs [0092] to [0153], it only discloses a case where polysulfone is used as a basic polymer for forming a hollow fiber membrane or a blood filter. There is no description about a specific forming method to use polyvinylchloride as a basic polymer for forming a blood tube, and about any support on the basis of the experiment that the blood tube has a function and effect of an ability to prevent thrombus formation. Specifically, in the Amended Invention, the function and effect is not supported by the experiment to use "polyvinylchloride" as a "basic polymer" for forming a blood tube, and thus the use of polyvinylchloride must be said to be just an idea by an inventor of the Amended Invention.

Consequently, there is no difficulty for a person skilled in the art to use polyvinylchloride as a "basic polymer" of the Cited Invention, and to conceive of the constitution of the Amended Invention according to the above Different feature 1.

Additionally, in the written opinion submitted on January 18, 2017, Appellant alleges the effects of the Amended Invention on the basis of the experimental data of Table 1 in the declaration statement submitted with USPTO (Date of declaration: December 9, 2016). But there is neither discussion nor evidence that the experiment and its assessment were conducted before the priority date of the present application. Neither discussion nor evidence can be found in the declaration. Consequently, it must be said that the constitution of the Amended Invention according to the above Different feature 1 is just an idea without experimental support for the effects thereof as of the date of priority claiming of the present application.

(2) Consideration is given to the above Different feature 2.

As a means for assessing the circumstances of intravascular thrombus, it is well-known art to utilize a platelet label of radioactive indium; i.e., to measure with gamma count. Thus there is no difficulty for a person skilled in the art to utilize it as a means for assessing an ability of the Cited Invention to prevent thrombus formation. See, if necessary, the following documents, page 2, right column, lines 5 to 8, and page 7, right column, line 2 to page 8, left column, line 3.

Junichi Nagashima and five others, "A study of clinical benefit of scintigraphy by 111In-labeled platelet for elderlies", Geriatrics & Gerontology International, January 30, 1987, Vol. 24, No. 1, pp. 1-10

(3) Consideration is given to the above Different feature 3.

As in the above No. 4, 3(14) and (15), Cited Document 2 discloses that HDI(hexamethylenediisocyanate), PTMO (poly(tetramethyleneoxide)), and a polyfluoroorgano group constitute a linear molecular structure by a synthetic method of surface-modified polymer (SMM) described in Cited Document 1, and that a linear SMM(8) where a number of the repetitive units Z of HDI and PTMO is 1 is synthesized.

Consequently, a surface-modified polymer of Cited Invention is synthesized by a synthetic method of Cited Document 1. Thus, as in the above (10), there is no difficulty for a person skilled in the art not only to constitute HDI, PPO, (polypropyleneoxide) and a polyfluoroorgano group as a linear molecular structure, but also to conceive of including ones where a number of the repetitive units consisting of HDI and PRO "n" is 1.

(4) Further, even when comprehensively taking these different features into account, the function and effect caused by the Amended Invention only fall within a scope expected from the function and effect caused by Cited Invention, a technique described in Cited Document 2, and the above well-known techniques, and it cannot be said that the function and effect are particularly significant.

(5) Therefore, the Amended Invention was easily conceivable by a person skilled in the art on the basis of Cited Invention, a technique described in Cited Document 2, and the above well-known techniques, and thus Appellant should not be granted a patent for the Amended Invention under the provision of Article 29(2) of the Patent Act.

2 Appellant's allegation

In the notice of appeal submitted on September 22, 2017, Appellant alleges that "Excellent anti-thrombus property of blood tube of the present invention is a particularly significant function and effect unexpected from Cited Documents 1 and 2. Cited Documents 1 and 2 neither describe nor suggest that such particularly significant function and effect that may be caused by mixing a surface-modified polymer having a specific combination of a soft segment and a hard segment of Formula VII of the claims of the present application with PVC basic polymer. Therefore, when a reference is made to the description of Cited Documents 1 and 2, even a person skilled in the art could not have easily achieved the present invention."

However, the Amended Invention does not include "a soft segment", and thus an allegation is not based on the recitation of the claims. Further, the remaining points are considered in the above item 1, and thus the allegation is not acceptable.

No. 7 Closing

For the above reasons, the Amended Invention was easily conceivable by a person skilled in the art on the basis of Cited Invention and a technique described in Cited Document 2 and the above well-known technique, and thus Appellant should not be granted a patent for the Amended Invention under the provision of Article 29(2) of the Patent Act.

Therefore, the present application should be rejected without considering the inventions according to the other remaining claims.

Consequently, the appeal decision shall be made as described in the conclusion.

November 19, 2018

Chief administrative judge: NAGAYA, Yojiro
Administrative judge: ASHIHARA, Yasuhiro
Administrative judge: SETO, Kohei