Appeal decision

Appeal No. 2014- 13097

USA
Appellant ATRIUM MEDICAL CORPORATION

Osaka, Japan
Patent Attorney YAMAMOTO, Shusaku

Osaka, Japan
Patent Attorney MORISHITA, Natsuki

Osaka, Japan
Patent Attorney IIDA, Takatoshi

Osaka, Japan
Patent Attorney ISHIKAWA, Daisuke

Osaka, Japan
Attorney YAMAMOTO, Kensaku

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2011-531009, entitled "Cross-linked fatty acid-based biomaterials" [April 15, 2010 international publication, International Publication No. WO2010/042134, March 1, 2012 National Publication, National Publication of International Patent Application No. 2012-505025] has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

No. 1 History of the procedures

The application was filed on December 3, 2008 (priority claim under the Paris

Convention: October 10, 2008 (US), December 1, 2008 (US)) as an international filing date, a decision for refusal was issued on March 4, 2014, and an appeal against an examiner's decision of refusal was demanded and the written amendment was submitted on July 7, 2014.

No. 2 Decision of dismissal of written amendment submitted on July 7, 2014
[Conclusion of Decision to Dismiss Amendment]

The written amendment submitted on July 7, 2014 (hereinafter referred to as the "Amendment") shall be dismissed.

<Reason>
1 Details of amendment

The Amendment is to amend the scope of claims, with respect to Claim 1 according to the scope of claims, the Amendment comprising the amendment (hereinafter referred to as "Amended matter 1") from

"A coating for a medical device comprising a cross-linked fatty acid;

wherein the fatty acid comprises 5-50% C_{16} fatty acids;

and wherein the coating hydrolyzes in vivo into free fatty acids, glycerides, and glycerol," before Amendment of the case, to

"A coating for a medical device comprising a cross-linked fatty acid;

wherein the fatty acid comprises 5-50% C_{16} fatty acids;

wherein the coating comprises an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo;

wherein the coating does not contain an external cross-linking agent;

and wherein the coating hydrolyzes in vivo into free fatty acids, glycerides, and glycerol."

2 Purpose of amendment

The Amended matter 1 comprises adding (1) "the coating comprises an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo" and (2) "the coating does not contain an external cross-linking agent" as matters specifying the invention, the matter (1) is based on the statement of Claim 18 before Amendment of the case of "The coating of Claim 1 ..., comprising an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo," and the matter (2) is based on the statement of Claim 24 before Amendment of the case of "The coating of Claim 1 ..., not containing an external cross-linking agent."

Therefore, the Amended matter 1 does not introduce any new technical matter, and complies with the requirement as provided in Article 17-2(3) of the Patent Act.

Further, since the amendment limits the component in the coating and the inventions before and after amendment are identical to each other in terms of the field of industrial application and the problems to be solved, the amendment has the purpose to restrict in a limited way the scope of claims as provided in Article 17-2(5)(ii) of the Patent Act.

Accordingly, the Amended matter 1 complies with the requirements as provided in Articles 17-2(3) and (5) of the Patent Act.

3 Independent requirements for patentability

Since the Amended matter 1 corresponds to Article 17-2(5)(ii) of the Patent Act, we examine whether the Amended matter 1 complies with the provisions of Article 126(7) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 17-2(6) of the Patent Act.

(1) Invention relating to Claim with Amended matter 1

The invention claimed in the Claim 1 with the Amended matter 1 (hereinafter referred to as "Amended Invention") is as follow.

"A coating for a medical device comprising a cross-linked fatty acid;

wherein the fatty acid comprises 5-50% C_{16} fatty acids;

wherein the coating comprises an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo;

wherein the coating does not contain an external cross-linking agent;

and wherein the coating hydrolyzes in vivo into free fatty acids, glycerides, and glycerol."

(2) Cited Publication and the described matters

Publication A (International Publication No. WO2007/047781, Cited Document 1 of the examiner's decision) had been obviously distributed in a foreign country before the filing date (priority date) and describes following matters.

A

"SUMMARY OF THE INVENTION

What is desired is a drug delivery coating that can release and deliver a therapeutic agent in a sustained and preferably controlled fashion to the local tissue, without chronic inflammation due to either the therapeutic agent or break-down products of the coating. The present invention is directed toward various solutions that

facilitate addressing this need.

What is also desired is a coating that can be bioabsorbed by cells and that can deliver a drug without inducing chronic localized inflammation to tissues (e.g., vascular tissue) that has been injured mechanically or by reperfusion injury, whereby the coating and the therapeutic agent are ingested and metabolized by the cell, as it consumes the breakdown products of the coating with the drug.

In various aspects, the present inventions provide methods for producing hydrophobic, non-polymeric cross-linked gel coatings comprising one or more therapeutic agents that facilitate the controlled loading of the one or more of therapeutic agent, sustained release of a therapeutic agent, and controlled release of a therapeutic agent the coating is ingested and absorbed. In various embodiments, provided are methods of tailoring the drug release profile of a hydrophobic, non-polymeric cross-linked gel by control of the curing conditions used to produce the cross-linked gel from a natural oil containing starting material; the use of a free radical scavenger in a natural oil containing starting material from which the gel is formed, or combinations thereof. In various embodiments, the methods of the present invention tailor the drug release properties of a hydrophobic, non-polymeric cross-linked gel coating by controlling the degree of cross-linking in the gel. In various embodiments, the methods of the present invention tailor the drug delivery properties of a hydrophobic, non-polymeric cross-linked gel coating by controlling the level of fatty acids, tocopherols, and soluble components in the cross-linked gel.
(Omitted)

In various aspects, the present inventions provide coated medical devices having a non-polymeric bio-absorbable drug release coating comprising one or more layers of hydrophobic cross-linked gel, wherein at least one of the cross-linked gel layers contains one or more therapeutic agents. In various embodiments, the drug release coating does not substantially decompose, in vivo, into either lactic acids or glycolic acid compounds. In various embodiments, the drug release coating hydrolyzes in vivo, into substantially non-inflammatory compounds. In various embodiments, the coated medical device is implantable in a patient to effect long term local delivery of the therapeutic agent to the patient. In various embodiments the delivery is at least partially characterized by the total and relative amounts of the therapeutic agent released over time. In various embodiments, the tailored delivery profile is controlled by the level of soluble components in the cross-linked gel. In various embodiments, the delivery profile is a function of the solubility and lipophilicity of the coating components and therapeutic agent in-vivo." (line 5 on page 4 to line 30 on page 5)

B

"The teachings herein demonstrate that cured fish oil soft tissue mesh coatings can allow for the ability to regulate the release profile of drug-loaded fish oil-based coatings from implantable devices. In various embodiments, the release profile can be controlled through changes in oil coating chemistry by varying coating composition and cure times. The teachings demonstrate that hydrophobic, non-polymeric cross-linked gels produced by 150°F curing for 3 days possess less peroxide/ether/carbon-carbon cross-links than those cured at 200°F curing for 24 hours. The teachings demonstrate that the cross-linking and gelation of the cured fish oil coatings can be directly dependent on the formation of hydroperoxides in the fish oil component, which increases with increasing temperature. Dissolution experiments presented herein have shown that drug release and coating degradation are more rapid for the cross-linked coatings produced using 150°F curing conditions as compared to those created employing the 200°F curing conditions." (line 31 on page 6 to line 10 on page 7)

C

"FIG. 7 schematically depicts various chemical structures of the fatty acid chains that were detected after saponification of the cured fish oil coating of Example 1." (lines 12 to 13 on page 8)

D

"Curing and Gel Formation

Several methods are available to cure the natural oil starting material containing one or more therapeutic agents to produce a non-polymeric cross-linked gel coating for a drug release and delivery coating in accordance with the present invention. Preferred methods for curing the starting material to produce a hydrophobic non-polymeric cross-linked gel coating of the present invention include, but are not limited to, heating (e.g., employing an oven, a broadband infrared (IR) light source, a coherent IR light source (e.g., laser), and combinations thereof) and ultraviolet (UV) irradiation. The starting material may be cross-linked through auto-oxidation.

(Omitted)

In accordance with various embodiments described herein, the coating component of the drug release coatings of the present invention is formed of a non-polymeric cross-linked gel, which can be derived from fatty acid compounds. The fatty acids include ω-3 fatty acids when the oil utilized to form the coating is fish oil or an analog or derivative thereof. As liquid fish oil is heated, autoxidation occurs with the absorption of oxygen into the fish oil to create hydroperoxides in an amount dependent upon the amount of unsaturated (C=C) sites in the fish oil. However, the

(C=C) bonds are not consumed in the initial reaction. Concurrent with the formation of hydroperoxides is the isomerization of (C=C) double bonds from cis to trans in addition to double bond conjugation. It has been demonstrated that hydroperoxide formation increases with temperature. Heating of the fish oil allows for cross-linking between the fish oil unsaturated chains using a combination of peroxide (C-O-O-C), ether (C-O-C), and hydrocarbon (C-C) bridges. The formation of the cross-links results in gelation of the coating. The heating also can also result in the isomerization of cis (C=C) bonds into the trans configuration. The (C=C) bonds can also form C-C cross-linking bridges in the glyceride hydrocarbon chains using a Diels-Alder reaction. In addition to solidifying the coating through cross-linking, both the hydroperoxide and (C=C) bonds can undergo secondary reactions converting them into lower molecular weight secondary oxidation byproducts including aldehydes, ketones, alcohols, fatty acids, esters, lactones, ethers, and hydrocarbons." (line 25 on page 26 to line 3 on page 29)

E

"Accordingly, in various embodiments, the drug release coating of the present inventions comprises a non-polymeric cross-linked gel derived from fatty acid compounds, such as those of fish oil, that includes a cross-linked structure of triglyceride and fatty acid molecules in addition to free and bound glycerol, monoglyceride, diglyceride, and triglyceride, fatty acid, anhydride, lactone, aliphatic peroxide, aldehyde, and ketone molecules. It is believed that there are a substantial amount of ester bonds remaining after curing in addition to peroxide linkages forming the majority of the cross-links in the gel. The coating degrades (e.g., by hydrolysis) into fatty acid, short and long chain alcohol, and glyceride molecules, which are all non-inflammatory and likewise can be consumable by cells, such as, e.g., smooth muscle cells. Thus, the coating is bio-absorbable and degrades into substantially non-inflammatory compounds. The amount of cross linking may be modulated by adjusting the curing temperature, curing duration, amount of antioxidant, exposure to UV radiation, or the presence of a drying oil.

Coating Bioabsorption

The bio-absorbable nature of the coating component of the drug release coatings of preferred embodiments of the present inventions results in the coating being completely absorbed over time by the cells of the body tissue. In various embodiments, there are substantially no substances in the coating, or in vivo conversion by-products of the coating which induce an inflammatory response, e.g., the coating converts in vivo into non-inflammatory components. For example, in various embodiments, the

coatings of the present invention upon conversion do not produce lactic acid and glycolic acid break-down products in measurable amounts. The preferred coatings are generally composed of, or derived from, ω-3 fatty acids bound to triglycerides, potentially also including a mixture of free fatty acids and vitamin E (α-tocopherol) The triglycerides are broken down by lipases (enzymes) which result in free fatty acids that can be transported across cell membranes. For example, FIG. 3 schematically depicts the base catalyzed hydrolysis of ester links in a triglyceride. Subsequently, fatty acid metabolism by the cell occurs to metabolize any substances originating with the coating. The bio-absorbable nature of the coating of the present invention results in the coating being absorbed over time, leaving only an underlying delivery or other medical device structure that is biocompatible. There is substantially no foreign body inflammatory response to the bio-absorbable coating or its break-down products in the preferred embodiments of the present invention." (line 13 on page 30 to line 13 on page 31)

F

"Examples

The following examples all employ a fish oil starting material. This starting material contained a mixture of varying chain length saturated and unsaturated fatty acids, glycerides, and triglycerides with an iodine value above 150 (a measure of the amount of chain unsaturation). The higher the iodine number, the more unsaturated the hydrocarbon chains. Specifically, the fish oil contained at least 18% of all the cis forms of 5, 8, 11, 14, 17-eicosapentaenoic acid (EPA) and 12% of the all cis forms of 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) fatty acids. The chemical structures of the fatty acid chains that were detected after saponification of the fish oil by GC/MS analysis provided in the manufacturer's certificate of analysis (Pronova, EPAX 3000 TG) are presented in FIG. 7. The certificate of analysis also showed that the fish oil possessed 27.59% saturated fatty acids, 23.30% monounsaturated fatty acids, and 45.05% polyunsaturated fatty acids, of which 40.63% were specifically ω-3 fatty acids.

In the various examples, the drug release coatings and tested coated medical devices were prepared generally as follows except as described otherwise in the specific example. A coated medical device was prepared by encapsulating an either Atrium Prolite or Prolite Ultra polypropylene mesh in liquid fish oil (EPAX 3000 TG) using a manual dipping and/or roller application. The samples were subsequently placed on a Teflon lined metal pan and cured.

Example 1: Characterization of a Coating

In Example 1, the coated medical devices were cured in a high airflow oven at a range of times and temperatures (standard conditions were 150°F for 3 days and 200°F

for 24 hours), after which the fish oil was converted into a cross-linked gel coating encapsulating the polypropylene mesh by a lipid autoxidation mechanism using heat as a catalyst.

FTIR, DSC, liquid and solid state C^{13} NMR, X-ray diffraction, GC/MS, and LC/MS analysis were performed on the EPAX 3000 TG fish oil coatings cured at 200°F for 24 hours.

FTIR Analysis:

FIG. 8 is an FTIR analysis, which illustrates a comparison of the uncured fish oil (801) with the final cured coating. The FTIR shows that the coating contained hydroxyl (800), methylene (805), methyl (805), trans C=C (810), and anhydride/aliphatic peroxide/lactone bonds (815 and 830). A complex carbonyl band shape was obtained and determined to contain ester (820), ketone (825), aldehyde (825), and fatty acid (800) byproduct absorptions in addition to detecting the presence of cross-linking as observed in the anhydride/lactone/aliphatic diacylperoxide band absorption. The position of the methylene bands showed that the hydrocarbon chains present in the coating were in a disordered state, which is consistent with a non-crystalline structure. Further, the cis C=C bonds in the fish oil starting material (835) were observed to be almost entirely consumed during the curing process. There was a corresponding increase in the trans C=C bonds (810) during the curing process. (Omitted)

Hydrolysis Testing

The experiments indicate that cured coatings of this example comprise mostly ester bonds in addition to lesser amounts of anhydride, lactone, and aliphatic peroxide bonds that will undergo hydrolysis in vivo to convert into smaller components over time. The following observations support the conversion of the cured coating using a hydrolysis mechanism, as shown in FIG. 3. These experiments, to assess the conversion of the cured coating, were conducted as follows.

A saponification reaction was performed in 0.1 M NaOH, pH>11 that is known to readily convert triglyceride esters into lower molecular weight fatty acids and alcohols (i.e., glycerol). The cured fish oil coating was confirmed to degrade by a hydrolysis mechanism after being placed in the NaOH solution and completely dissolved within 30 min, leaving bare polypropylene mesh behind.

To assess the differences in the degradation behavior of the coatings cured at 150°F and 200°F, samples of the cured fish oil encapsulated mesh samples were placed in a 0.1 M sodium phosphate buffer containing 0.1 M NaCl solution at pH=7.4 at both

37°C and 55°C. The coating cured at 200°F dissolved during an 18-day period at 55°C, whereas it took 12 weeks to dissolve at 37°C. The coating cured at 150°F dissolved during an 18-21 day period at 55°C.

To further assess the differences in the conversion behavior of the coatings cured at 150°F and 200°F, a 1×1" coating was placed into a 20 ml glass scintillation vial with 20 ml of 0.1 M NaOH, pH>11. The amount of time for the coating to be hydrolyzed and be dissolved into solution was determined to be approximately 14 minutes for the coating cured at 150°F and 19 minutes for the coatings cured at 200°F, which coincides with the FTIR spectral data where the coating cured at 200°F was more cross-linked and thus took longer to saponify in basic conditions.

FTIR spectra acquired of the converted cured coating in buffer solution were consistent with the production of fatty acid, fatty acid salts, and alcohols. A representative spectrum acquired of the hydrolyzed material at day 16 is shown in FIG. 13. This spectra illustrates significant differences in the OH (water and alcohols) band (1305), the CH_2 band (fatty acids and alcohols, 1310), the ester C=O band (1320), and the fatty acid C=O-O band (1325), when compared to the spectrum in FIG. 8." (line 24 on page 37 to line 17 on page 42)

G

"1. A coating for a medical device, wherein said coating comprises a hydrophobic, non-polymeric cross-linked gel, a therapeutic agent and a fatty acid.

2. A coating for a medical device, wherein said coating comprises a hydrophobic, non-polymeric cross-linked gel, a therapeutic agent and a fatty acid and release said therapeutic agent at a desired release rate in vivo.

3. A coating for a medical device, wherein said coating comprises a hydrophobic, non-polymeric cross-linked gel, a therapeutic agent, and a fatty acid, and decomposes in vivo into non-inflammatory components.

(Omitted)

30. The coating of any one of claims 1-29, wherein said coating is bioabsorbable.

31. The coating of any one of claim 1-29, wherein said coating is derived from a natural oil-containing starting material.

32. The coating of claim 31, wherein said natural oil-containing starting material is fish oil." (Claims)

H

"

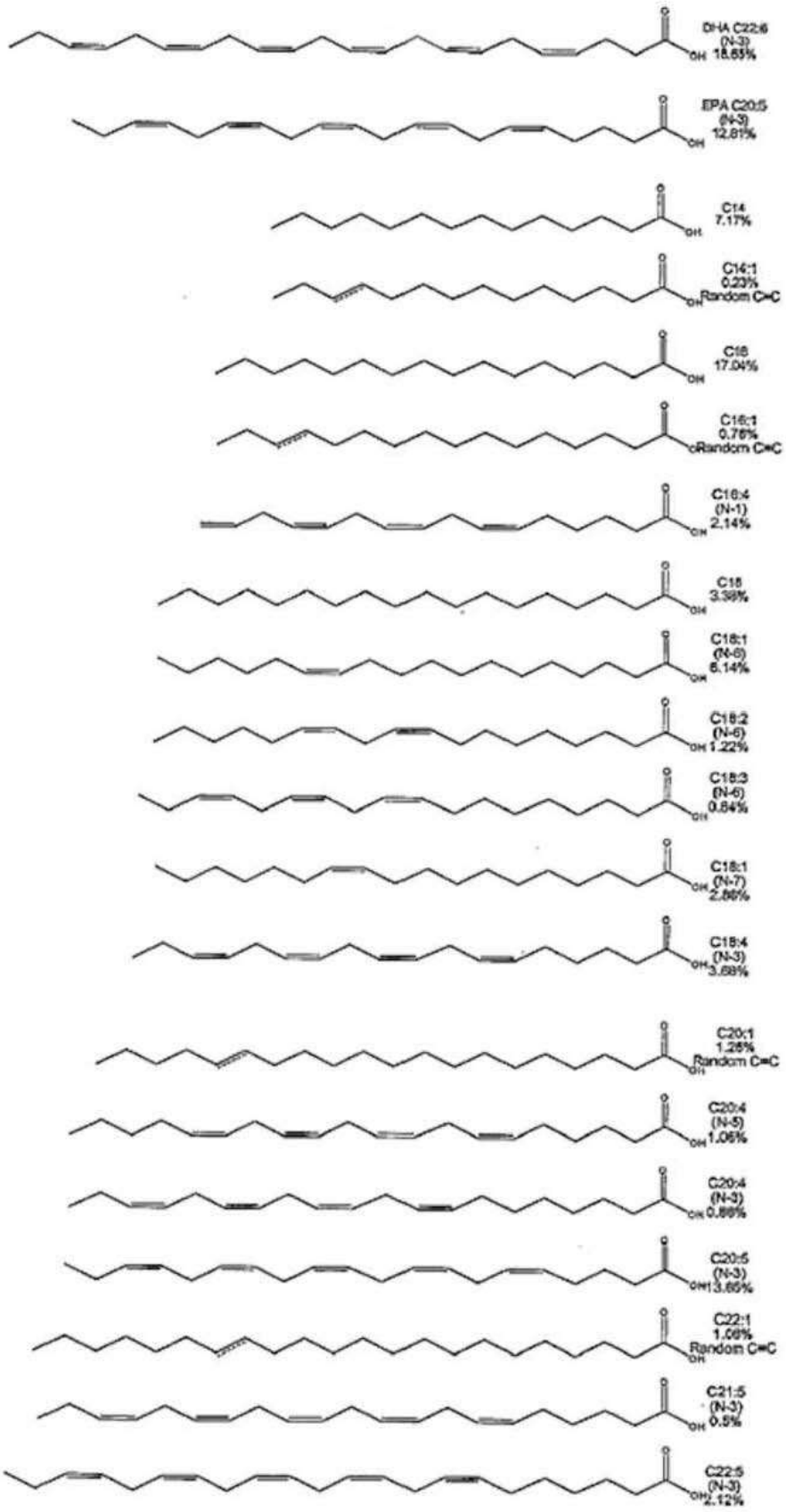
DHA C22:6
(N-3)
18.65%
EPA C20:5
(N-3)
12.61%
C14
7.17%
C14:1
0.23%
Random C=C
C16
17.04%
C16:1
0.76%
Random C=C
C16:4
(N-1)
2.14%
C18
3.38%
C18:1
(N-9)
6.14%
C18:2
(N-6)
1.22%
C18:3
(N-6)
0.84%
C18:1
(N-7)
2.66%
C18:4
(N-3)
3.68%
C20:1
1.25%
Random C=C
C20:4
(N-6)
1.06%
C20:4
(N-3)
0.88%
C20:5
(N-3)
3.65%
C22:1
1.06%
Random C=C
C21:5
(N-3)
0.5%
C22:5
(N-3)

FIG. 7"

(3) Invention described in Publication

In Publication A, it is described that the medical device coating comprising fatty acids is derived from a natural oil-containing starting material such as fish oil (above (2)A, G); the coating is produced by being cross-linked through auto-oxidation with heat, and does not need an external cross-linking agent (above (2)B, D, F); and the coating hydrolyzes in vivo into fatty acid, glyceride, substance derived from triglyceride being start material, and the like (above (2)E, F). FIG. 7 (above (2)H) schematically depicts various chemical structures of the fatty acid chains that were detected after saponification of the cured fish oil coating of Example 1 (above (2)C), and shows that 17.04%(C16)+0.76%(C16:1)+2.14%(C16:4)=19.94% of C_{16} fatty acids were contained. Considering the above, it is found that following invention (hereinafter referred to as "Invention described in Publication") is described in Publication A.

"A coating for a medical device comprising the coating comprises a cross-linked fatty acid; wherein the fatty acid comprises 19.94% of C_{16} fatty acids; wherein the coating does not contain an external cross-linking agent; and the coating hydrolyzes in vivo into components derived from triglyceride which is start material for free fatty acids and glycerides."

(4) Comparison

We compare the Amended Invention with the Invention described in Publication.

It was a well-known technical matter before the filing date (priority date) that, without exemplifying, "triglyceride" being starting material of the coating of the Invention described in Publication is converted to free fatty acids, glyceride, and glycerol by hydrolysis.

Further, it is described in Publication A that 19.94% of C_{16} fatty acids were detected after saponification of the cured fish oil coating; that is, the range of 5-50% of C_{16} fatty acids were contained.

Thus, the Amended Invention and the Invention described in Publication are corresponded in a point of

"A coating for a medical device comprising a cross-linked fatty acid;

wherein the fatty acid comprises 5-50% C_{16} fatty acids;

wherein the coating does not contain an external cross-linking agent;

and wherein the coating hydrolyzes in vivo into free fatty acids, glycerides, and glycerol.",

are briefly different in a following point.

Briefly different features:

In the Amended Invention, it is specified that the coating comprises an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo, on the other hand, the Invention described in Publication does not specify that.

(5) Judgment

The above-mentioned different features will be examined as follows.

The Amended Invention includes, in the Examples, "derived from fish oil" ([0153]), the Invention described in Publication is a coating containing fish oil starting material, similar to the Amended Invention, the fish oil includes fatty acids (above (2)D and E). Further, in the Examples of the Amended Invention, there is described an embodiment of "coated medical devices (e.g., a polypropylene mesh) were cured in a high airflow oven at 200°F for 24 hours, after which the fish oil was converted into a cross-linked biomaterial coating encapsulating the polypropylene mesh by oxidation of the C=C bonds present in the fish oil resulting in the formation of oxidative byproducts (i.e., hydrocarbons, aldehydes, ketones, glycerides, fatty acids) while largely preserving the esters derived from the original oil triglycerides." ([0153]) is stated. On the other hand, in examples of the Invention described in Publication, "the coated medical devices were cured in a high airflow oven at a range of times and temperatures (standard conditions were 150°F for 3 days and 200°F for 24 hours), after which the fish oil was converted into a cross-linked gel coating encapsulating the polypropylene mesh by a lipid autoxidation mechanism using heat as a catalyst." (above (2)F), similar to the Amended Invention. In this case, it is reasonable to understand that the Invention described in Publication comprises an amount of carboxylic acid groups sufficient to facilitate hydrolysis in vivo, to the same extent as the Amended Invention.

Therefore, relating to the above briefly different features, the Amended Invention and the Invention described in Publication are not substantially different.

(6) Summary

As described above, since there is substantially no different feature between the Amended Invention and the Invention described in Publication, the Amended Invention is the invention described in Publication and cannot obtain a patent under the provisions of Article 29(1)(iii) of the Patent Act. Therefore, the appellant should not be granted a patent for the Amended Invention independently at the time of patent application.

4 The demandee's allegation

The Appellant alleges in Reasons of appeal that "FIG. 7 shows the component of

fatty acids in fish oil starting material (line 25 on page 37), and this is not a ratio of fatty acids in the coating produced by curing such fish oil starting material." However, FIG. 7 is a figure which schematically depicts various chemical structures of the fatty acid chains that were detected after saponification of the cured fish oil coating of Example 1 (above 3(2)C), and this is a ratio of fatty acids in the coating produced. Therefore, the above allegation cannot be considered.

5 Conclusion

As described above, the Amendment violates the provisions of Article 17-2(6) of the Patent Act, and, therefore, it should be dismissed under the provisions of Article 53(1) of the Patent Act which is applied mutatis mutandis pursuant to the provisions of Article 159(1) of the Patent Act.

No. 3 The Invention

As concluded above No. 2, since the amendment by the written amendment submitted on July 7, 2014 is dismissed, the Invention is specified by matters described in Claims 1 to 61 respectively according to the scope of claims, which have been amended by the written amendment submitted on August 23, 2013. The invention according to Claim 1 (hereinafter referred to as the "Invention") is as follows.

"A coating for a medical device comprising a cross-linked fatty acid;

wherein the fatty acid comprises 5-50% C_{16} fatty acids;

and wherein the coating hydrolyzes in vivo into free fatty acids, glycerides, and glycerol."

No. 4 Judgment by the body

1 Cited Document and the described matters

Cited Document 1 (International Publication No. WO2007/047781) which was cited in the examiner's decision and had been obviously distributed in a foreign country before the filing date (priority date), is the same document as Publication A described in the above No. 2-3(2), and the matters of A to H summarized in the above No. 2-3(2) are described in the Cited Document 1.

2 Invention described in Cited Document 1

In Cited Document 1, the Invention described in Publication found in No. 2-3(3) is described.

3. Comparison/judgment

Comparing the Invention with the Invention described in Publication and taking into consideration the above No. 2-3(4), there is no different feature between the two inventions.

4 Summary

In that case, since there is no different feature between the Invention and the Invention described in Publication, the Invention is the invention described in Cited Document 1, and the appellant should not be granted a patent for the Invention under the provisions of Article 29(1)(iii) of the Patent Act.

No. 5 Conclusion

As described above, the present application should be rejected because of the above reasons, without examining other claims.

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

September 3, 2015

Chief administrative judge:	MATSUURA, Shinji
Administrative judge:	OGUMA, Koji
Administrative judge:	SEKI, Mihogi