Appeal Decision

Appeal No. 2020-1374

Appellant: TUBITAK
(Turkiye Bilimsel Ve Teknolojik Arastirma Kurumu)

Patent Attorney SUGIMURA, Kenji

Patent Attorney TSUKANAKA, Tetsuo

The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2016-566732, entitled "A Composition for Producing Intraocular Lens (IOL) and a Lens Manufacturing Method" [International Publication No. WO2015/170278 published on November 12, 2015, and National Publication of International Patent Application No. 2017-514964 published on June 8, 2017] has resulted in the following appeal decision.

Conclusion

The appeal of the case is groundless.

Reasons

I. History of the procedures

This application (hereinafter referred to as "the present application") is an application (JP H2016-566732A) with the international filing date of May 7, 2015 (priority claim: May 7, 2014, Turkey [TR]), the reasons for refusal were notified on October 30, 2017, the written opinion and the written amendment were submitted on April 5, 2018, the reasons for refusal were notified on September 28 of the same year, the written opinion and the written amendment were submitted on April 02, 2019, the decision of refusal was made on September 25, 2019, a request for appeal against an examiner's decision of refusal was filed on January 31, 2020, and the written amendment (regarding formality requirements) for a Written Request for Appeal against Examiner’s Decision of Refusal was submitted on February 13 of the same year.

II. Description of the scope of claims

The description of the scope of claims of the present application is described in

Claims 1-11 of the scope of claims amended by means of the written amendment made on April 2, 2019. Claim 1 is described as follows.

"[Claim 1]
A composition, used in a method for manufacturing a lens by photopolymerization, which is suitable for intraocular use, and has flexibility, low cost, hydrophobicity, high refractive index value, UV-blocking characteristics, and a smooth surface, wherein the composition comprises:

20-80 weight percent of acrylate and/or methacrylate-based oligomer as a binder,

5-40 weight percent of acrylate and/or methacrylate-based monomer as a reactive diluent,

1-5 weight percent of acrylate and/or methacrylate-based UV-blocking agent for absorbing light, and

0.1-5 weight percent of photoinitiator for initiating a reaction."
(Hereinafter, the invention specified by Claim 1 is called "the invention of the present application," and in addition, the description of this application is called "the description of the present application.")

III. Reasons for refusal in original Decision

The reasons for refusal in the original Decision include Reasons 1 and 2 in the notice of reasons for refusal on September 28, 2018, and this application should be rejected according to Reasons 1 and 2.

The summary of Reason 1 is as follows: the inventions according to Claims 1, 4, 7, and 8 of the present application are inventions described on the basis of Cited Document 1 (International Publication No. 2005/029161) published in Japan or other foreign countries prior to the filing of the application, which could have been easily made by a person skilled in the art prior to the filing of the application. Therefore, the inventions cannot be granted a patent under the provisions of the Patent Act Article 29(2).

The summary of Reason 2 is as follows: the description of Claims 1-11 of the scope of claims of the present application does not satisfy the requirements specified in the Patent Act Article 36(6)(i).

IV. Determination by the panel

The panel determines that the present application should be rejected according to the same reason as the aforementioned Reason 1 or Reason 2.

The reasons are as follows.

1. Regarding Reason 1

(1) Matters described in Cited Document 1 (International Publication No. 2005/029161) and finding of Cited Invention

A. Matters described in Cited Document 1

(A) Regarding intraocular lens material

"[0001] The present invention relates to an ophthalmic lens material such as a contact lens and an intraocular lens, and in particular, to a silicone-based non-aqueous ophthalmic lens material. ...

[0003] It is disclosed that ... is used as a soft intraocular lens material with high refractive index, excellent flexibility and shape recovery, and low adhesiveness ... a copolymer including an aromatic group-containing (meth)acrylate such as phenoxyethyl acrylate, a hydrophilic monomer, and the like is used as a material for an intraocular lens (for example, JP H11-56998A). ...

[0006] An purpose of the present invention is to provide an ophthalmic lens material, which is not only transparent, but also has low adhesiveness, is safe without being adsorbed to the cornea when worn, is excellent in ease of operation (which cannot stick to a finger), and is excellent in shape stability due to an appropriate balance of strength and flexibility or elasticity."

"[0098] The ophthalmic lens material of the present invention has low adhesiveness, is safe without being adsorbed to the cornea when worn, and is excellent in ease of operation. In addition, as described above, due to an appropriate balance of strength and flexibility or elasticity, the ophthalmic lens material has shape stability while maintaining strength, and appropriate flexibility, so that such an effect of good stability when worn can be achieved in a balanced manner."

(b) Regarding polymerizable ultraviolet absorber

"[0080] In addition, the copolymer component may be polymerized for the purpose of imparting ultraviolet absorptivity to the lens, coloring the lens, or cutting off light in a partial wavelength region of visible light. A polymerizable ultraviolet absorber, a polymerizable dye or a polymerizable ultraviolet absorbing dye can be blended.

[0081] Specific examples of the polymerizable ultraviolet absorber include, for example, benzophenone-based polymerizable ultraviolet absorbers such as 2-hydroxy-4-(meth)acryloyloxybenzophenone, 2-hydroxy-4-(meth)acryloxy-5-tert-butylbenzophenone, 2-hydroxy-4-(meth)acryloxy-2', 4'-dichlorobenzophenone, and 2-hydroxy-4-(2'-hydroxy-3'-(meth) acryloyloxy propoxy)benzophenone; benzotriazole-

based polymerizable ultraviolet absorbers such as 2-(2'-hydroxy-5'-(meth)acryloyloxyethylphenyl)-2H-benzotriazole, 2-(2'-hydroxy-5'-(meth) acryloyloxyethylphenyl)-5-chloro-2H-benzotriazole, 2-(2'-hydroxy-5'-(meth)acryloxypropylphenyl)-2H-benzotriazole, and 2-(2'-hydroxy-5'-(meth) acryloyloxypropyl-3'-tert-butylphenyl)-5-chloro-2H-benzotriazole; salicylic acid derivative-based polymerizable ultraviolet absorbers such as 2-hydroxy-4-methacryloyloxymethyl benzoate; polymerizable ultraviolet absorbers such as 2-cyano-3-phenyl-3-(3'-(meth)acryloxyphenyl)methyl propenoate; and
so on. These polymerizable ultraviolet absorbers can be used alone or in combination of two or more. ...

[0084] Since the blending amount of the polymerizable ultraviolet absorber, the polymerizable dye, and the polymerizable ultraviolet absorbing dye varies depending on the thickness of the lens, it cannot be determined in a general way, but it is preferably 3 weight percent or less in the total copolymer component, especially 0.1-2 weight percent. If the blending amount is more than 3 weight percent, the physical properties of the lens, such as strength, tend to decrease, and in consideration of the toxicity of ultraviolet absorbers and dyes, contact lenses in direct contact with living tissues or intraocular lenses buried in a living body tend to be unsuitable as an ophthalmic lens material. ..."

(c) Regarding polymerization initiator

"[0086] The method for producing an ophthalmic lens material of the present invention includes, for example: blending a compound (a), an alkoxy-containing acrylate (b), a phenyl acrylate or phenoxyalkyl acrylate (c), and an amphipathic component or other components to be added as needed; adding a free radical polymerization initiator thereto; and performing polymerization by a conventional method.

[0087] The conventional method refers to, for example, after the free radical polymerization initiator is blended, gradual heating is performed in the temperature range of room temperature to about 130°C, and a method for irradiating electromagnetic waves such as microwaves, ultraviolet rays, and radioactive rays (γ rays). . During heating polymerization, the temperature may be raised stepwise. The polymerization may be performed by a bulk polymerization method, by a solvent polymerization method using a solvent or the like, or by another method.

[0088] Specific examples of the free radical polymerization initiator include, for example: azobisisobutyronitrile, azodimethylvaleronitrile, benzoyl peroxide, tert-butyl hydroperoxide, cumene hydroperoxide, and the like. These free radical polymerization initiators can be used alone or in combination of two or more. In addition, when the

polymerization is performed by using light or the like, it is preferable to further add a photopolymerization initiator or sensitizer such as 2-hydroxy-2-methyl-2-phenylpropane-1-one. The blending amount of the polymerization initiator or sensitizer is about 0.001-2 parts by weight with respect to 100 parts by weight of all copolymerization components, preferably 0.01-1 parts by weight."

(d) Regarding the content of acrylic acid

"[0062] The content of the alkoxy-containing acrylate (B) in all the copolymer components is preferably 2-70 weight percent, and more preferably 10-60 weight percent. If the content of the alkoxy-containing acrylate (B) is less than 2 weight percent, the adhesiveness of the ophthalmic lens tends not to be sufficiently reduced; and if said content exceeds 70 weight percent, the strength of the obtained material is reduced, and the ophthalmic lens tends to be easily damaged.

...

[0068] The content of the phenylalkylacrylate or phenoxyalkyl acrylate (C) in all the copolymer components is preferably 3-30 weight percent, and more preferably 5-20 weight percent. When the ratio of the phenylalkylacrylate or phenoxyalkyl acrylate (C) is less than 3 weight percent, the effect of reinforcing the strength of the obtained material tends to be hardly obtained; and when said ratio exceeds 30 weight percent, the flexibility tends to be reduced."

(e) Regarding examples and comparative examples

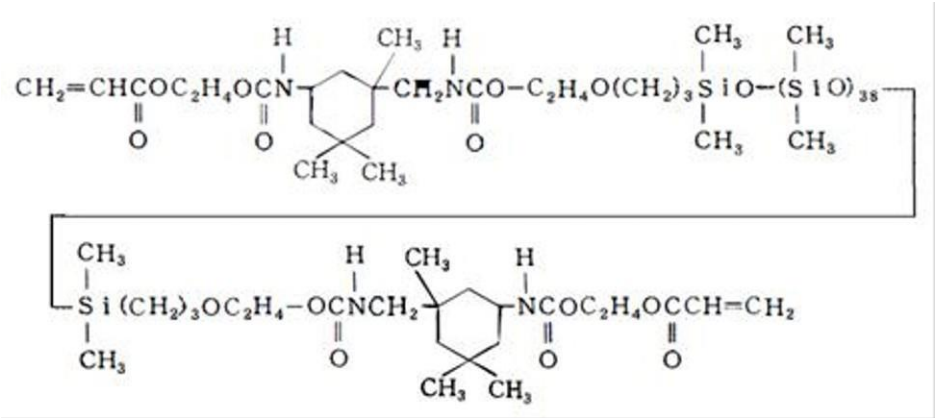
[0099] Examples 1-8 and Comparative Examples 1-6

The ophthalmic lens component, in which 0.2 parts by weight of 2-hydroxy-2-methyl-1-phenylpropane-1-one as a polymerization initiator is mixed with respect to 100 parts by weight of the copolymerizable component shown in Table 1, is injected into a mold having the shape of a contact lens. The mold is made of polypropylene, corresponding to a contact lens of approx. 14 mm in diameter and 0.1 mm in center thickness. Next, this mold is irradiated with ultraviolet light for 10 minutes for photopolymerization to obtain a contact lens-shaped polymer. All of these have a moisture content of less than 10%. In Examples 1-4, an amphiphilic component is blended in order to improve the compatibility of the blended components. The following evaluation is performed about the obtained polymer. The results are shown in Table 1.

[0100] In addition, the abbreviations in Table 1 indicate the following compounds.

MAUS:

[0101] [Formula 14]



[0102] MTGA: methoxytriethylene glycol acrylate

2-MTA: 2-methoxyethyl acrylate

2-ETA: 2-ethoxyethyl acrylate

POEA: 2-phenoxyethyl acrylate

PHGA: phenylhexaethylene glycol acrylate

MNGA: methoxynonyl ethylene glycol acrylate

2-EHA: 2-ethylhexyl acrylate

DMAA: dimethylacrylamide

LA: lauryl acrylate

[0106] [Table 1]

表　1

		実施例								比較例					
		1	2	3	4	5	6	7	8	1	2	3	4	5	6
(A)	MAUS	40	40	40	40	40	50	40	50	100	40	40	60	40	40
(B)	MTGA	20	30	20	20	−	−	−	−	−	60	−	−	−	−
	2−MTA	−	−	−	−	50	40	−	−	−	−	−	40	−	−
	2−ETA	−	−	−	−	−	−	50	40	−	−	−	−	−	−
(C)	POEA	5	15	5	20	10	10	10	10	−	−	−	−	15	15
(B')	PHGA	−	−	−	−	−	−	−	−	−	−	−	−	30	−
	MNGA	−	−	−	−	−	−	−	−	−	−	−	−	−	30
両親媒性成分	2−EHA	35	15	15	20	−	−	−	−	−	−	−	−	15	15
	DMAA	−	−	20	−	−	−	−	−	−	−	−	−	−	−
他	LA	−	−	−	−	−	−	−	−	−	−	60	−	−	−
透明性		○	○	○	○	○	○	○	○	○	×	○	○	×	×
粘着性		○	○	○	○	○	○	○	○	×	○	×	○	○	○
応力（MPa）		0.3	0.5	0.6	0.4	0.6	0.8	0.4	0.4	−	−	0.4	0.5	−	−
伸び（%）		43	77	116	50	85	55	50	35	−	−	62	26	−	−
ヤング率（MPa）		0.7	0.8	0.8	0.9	0.8	1.8	1.0	1.4	−	−	0.7	2.2	−	−

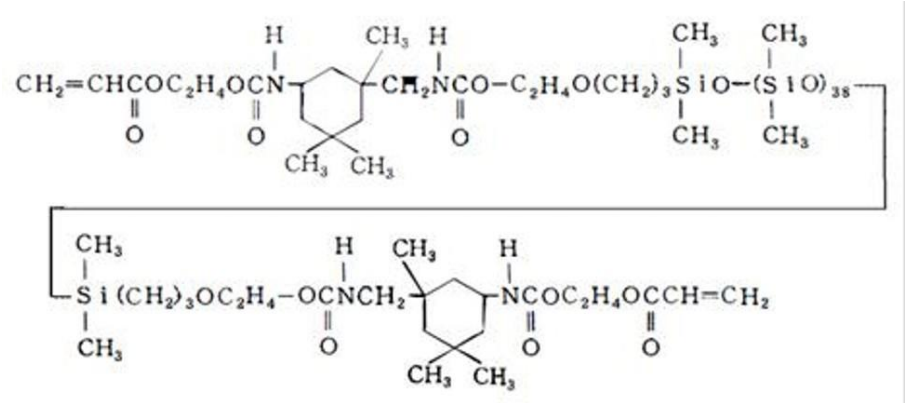
表 1	Table 1
実施例	Example
比較例	Comparative example
両親媒性成分	Amphipathic component
他	Others
透明性	Transparency
粘着性	Adhesiveness
応力	Stress
伸び	Elongation
ヤング率	Young modulus

B. Finding of cited invention

In paragraphs [0099]-[0106] of summarization (e) of Cited Document 1, as Example 8, it is described that the ophthalmic lens component, in which 50 parts by weight of MAUS shown as [Formula 14], 40 parts by weight of 2-ETA(2-ethoxyethyl acrylate), and 10 parts by weight of POEA (2-phenoxyethyl acrylate) in a total of 100 parts by weight are mixed with 0.2 parts by weight of 2-hydroxy-2-methyl-1-phenyl propane-1-one as the polymerization initiator, is injected into the mold having the shape of a contact lens; and then, the ultraviolet light is irradiated to the mold for 10 minutes for photopolymerization to obtain the contact lens-shaped polymer.

Thus, Cited Document 1 is considered to describe the following invention (hereinafter referred to as "cited invention")

"An ophthalmic lens component for use in a method for producing a contact lens-shaped polymer by photopolymerization, comprising: 50 parts by weight of "MAUS" represented by the following formula, 40 parts by weight of 2-ethoxyethyl acrylate, 10 parts by weight of 2-phenoxyethyl acrylate, 0.2 parts by weight of 2-hydroxy-2-methyl-1-phenyl propane-1-one as a polymerization initiator.



"

(2) Comparison and determination

A. Comparison

The invention of the present application is contrasted with the cited invention.

"MAUS" of the cited invention is an acrylate-based compound, in which isocyanate at position 1 of two isophorone diisocyanates is bonded to hydroxyethyl acrylate arranged at the tail end of a molecule via a urethane bond, and methyl isocyanate at position 3 is bonded to dimethylpolysiloxane which is arranged in the center of the molecule and has hydroxyethoxypropyl at both ends via a urethane bond.

This "MAUS" has acrylate and dimethylpolysiloxane as an oligomer to which 39 siloxane units are bonded (-O-Si(CH_3)$_2$)-), and therefore is considered to be equivalent to the "acrylate and/or methacrylate-based oligomer" in the invention of the present application, having a function as the "binding agent" in the invention of the present application.

"49.9%" [= 50 ÷ (50 + 40 + 100.2) × 100] obtained by converting the content of this "MAUS" into "50 parts by weight" is the same as "20-80 weight percent" in the invention of the present application.

The "2-ethoxyethyl acrylate" and "2-phenoxyethyl acrylate" in the cited invention are both fall under the category of "acrylate-based monomer". Considering that claim 6 of the scope of claims and paragraph [0022] of the present application exemplify "ethoxyethyl methacrylate" (replaced with 2-ethoxyethyl methacrylate) and "phenoxyethyl methacrylate" (replaced with 2-phenoxyethyl methacrylate), the aforementioned acrylates in the cited invention are considered to be equivalent to the "acrylates and/or methacrylate-based monomers" in the invention of the present application, having a function as the "reactive diluent" in the invention of the present application.

Since paragraph [0088] of summarization (c) of Cited Document 1 describes " when the polymerization is performed by using light or the like, … a photopolymerization initiator … such as 2-hydroxy-2-methyl-2-phenyl propane-1-one," the "2-hydroxy-2-methyl-1-phenyl propane-1-one" in the cited invention as the "polymerization initiator" is equivalent to the "photoinitiator for initiating a reaction" in the invention of the present application. The content "0.2 parts by weight" of the "2-hydroxy-2-methyl-1-phenyl propane-1-one" in the cited invention converted into "0.2%" by weight [= 0.2 ÷ (50 + 40 + 10 + 0.2) × 100] is the same as the "0.1-5 weight percent" in the invention of the present application.

The "ophthalmic lens component" in the cited invention is a composition containing a plurality of components, and therefore is equivalent to the "composition" in the invention of the present application.

The "lens" in the invention of the present application is a polymer produced by photopolymerization, and therefore is the same as the "polymer" in comparison with the "contact lens-shaped polymer" in the cited invention.

Thus, the two are identical in the following point:

"A composition for use in a method for producing a polymer by photopolymerization, comprising:

20-80 weight percent of acrylate and/or methacrylate-based oligomer as a binder,

acrylate and/or methacrylate-based monomer as a reactive diluent, and

0.1-5 weight percent of photoinitiator for initiating a reaction."

The two differ in the following points:

The invention of the present application includes "1-5 weight percent of acrylate and/or methacrylate-based UV-blocking agent for absorbing light," and the "lens" has " UV-blocking characteristics "; whereas, the cited invention does not include "acrylate and/or methacrylate-based UV-blocking agent," and the "contact lens-shaped polymer" does not have the " UV-blocking characteristics " (Difference 1).

The invention of the present application includes "5-40 weight percent" of "acrylate and/or methacrylate-based monomer" as the reactive diluent; whereas, the cited invention includes "40 parts by weight of 2-ethoxyethyl acrylate and 10 parts by weight of 2-phenoxyethyl acrylate" (Difference 2).

In the invention of the present application, the polymer produced by photopolymerization is specified as the "lens suitable for intraocular use, and having flexibility, low cost, hydrophobicity, high refractive index value, and a smooth surface," but is specified as the "contact lens-shaped polymer" in the cited invention (Difference 3).

B. Determination

(a) Difference 1

Paragraph [0080] of summarization (b) of Cited Document 1 describes that "the copolymer component may ... for the purpose of imparting ultraviolet absorptivity to the lens ... the polymerizable ultraviolet absorber can be blended ... ." Paragraph [0081] of the same document describes that "Specific examples of the polymerizable ultraviolet absorber include, for example: benzophenone-based polymerizable ultraviolet absorbers such as 2-hydroxy-4-(meth)acryloyloxybenzophenone ...; benzotriazole-based polymerizable ultraviolet absorbers such as 2-(2'-hydroxy-5'-(meth)acryloxyethylphenyl)-2H-benzotriazole ...; salicylic acid derivative-based polymerizable ultraviolet absorbers such as 2-hydroxy-4-methacryloyloxymethyl benzoate; polymerizable ultraviolet absorbers such as 2-cyano-3-phenyl-3-(3'-(meth)acryloxyphenyl)methyl acrylate." Paragraph [0084] of the same document describes that "Since the blending amount of the polymerizable ultraviolet absorber ... varies depending on the thickness of the lens, it cannot be determined in a general way, but it is preferably 3 weight percent or less in the total copolymer component, especially 0.1-2 weight percent."

Thus, for the purpose of imparting ultraviolet absorptivity to the polymer, a person skilled in the art could easily conceive that the "ophthalmic lens component" in the cited invention further contains 3 weight percent or less of polymerizable ultraviolet absorbers such as 2-(2'-hydroxy-5'-(meth)acryloxyethylphenyl)-2H-benzotriazole, i.e., "1-5 weight percent" of " acrylate and/or methacrylate-based UV-blocking agent for absorbing light" exemplified as Difference 1, thus possessing the "UV-blocking characteristics."

(b) Difference 2

Regarding the content of "2-ethoxyethyl acrylate" in the cited invention, paragraph [0062] of summarization (d) of Cited Document 1 describes that "The content of the alkoxy-containing acrylate (B) in all the copolymer components is preferably 2-70 weight percent, and more preferably 10-60 weight percent." In paragraph [0068] of the same document, regarding the content of "2-phenoxyethyl acrylate" in the cited invention, the feature "preferably 3-30 weight percent, more preferably 5-20 weight percent" is described, and it is described that from the viewpoint of the adhesiveness, strength and flexibility of the lens material, the content of the aforementioned acrylic acid is set.

Thus, on the basis of the aforementioned descriptions, a person skilled in the art would easily conceive that in the cited invention, in order to optimize the adhesion, strength and flexibility of the lens material, the content of "2-ethoxyethyl acrylate" and

the content of "2-phenoxyethyl acrylate" are adjusted again, and the total amount reaches, for example, the range of "5-40 weight percent."

In addition, even with reference to the description of the present application, the technical significance of setting the content of "acrylate and/or methacrylate-based monomer as a reactive diluent" in the range of "5-40 weight percent" is not found. Therefore, it is not considered that a particularly remarkable effect is exerted by adopting this numerical range.

(c) Difference 3

According to the description "The ophthalmic lens material in the present invention ... an appropriate balance of strength and flexibility or elasticity" in summarization (a) of Cited Document 1, the "polymer" in the cited invention has appropriate strength, flexibility or elasticity, and therefore can be said to have the "flexibility."

In addition, the "polymer" in the cited invention contains dimethyl polysiloxane, and therefore has "hydrophobicity" to a certain extent. This "polymer" is intended to be used as an intraocular lens as also described in paragraph [0001] of summarization (a) and paragraph [0084] of summarization (b), and therefore can be said to have a "smooth surface" that is suitable for an organism or a "high refractive index" commonly required in an intraocular lens.

In addition, "low cost" is a required property not only of the ophthalmic lens material, but of all products offered to consumers.

In conclusion, a person skilled in the art could easily conceive that the "polymer" obtained by performing "photopolymerization" on the "ophthalmic lens component" in the cited invention is used for the "lens" which is "suitable for intraocular use, and has flexibility, low cost, hydrophobicity, high refractive index value, and a smooth surface" exemplified in Difference 3.

(d) Effect of the invention of the present application

The description of the present application does not describe any example, does not disclose any composition that specifies the invention of the present application, and does not specifically disclose that the lens having flexibility, low cost, hydrophobicity, high refractive index value, UV-blocking characteristics, and a smooth surface can be manufactured by adopting the matters specifying the invention of the present application. Therefore, it is not considered that the invention of the present application exerts the effect beyond the expectation of a person skilled in the art.

(e) Allegations of the appellant

a.

The appellant alleges in the Written Request for Appeal against Examiner's Decision of Refusal that "the invention of Cited Document 1 is not intended to protect eyes by blocking light of a specific wavelength using a UV-blocking agent (i.e., a ultraviolet absorber). In Cited Document 1, the -blocking agent or absorber is used as an absorber for activating a photoinitiator; whereas, in the present application, this use is different from the use of the ultraviolet blocker or absorber as a material that absorbs light to protect eyes."

However, paragraph [0080] of summarization (b) of Cited Document 1 describes that the "polymerizable ultraviolet absorber" is blended into the copolymer component "for the purpose of imparting ultraviolet absorptivity to the lens." In addition, paragraph [0004] of JP 2003-84242A published prior to the priority date (May 7, 2014) of the present application, as the common technical knowledge, describes that "in recent years, the following ophthalmic lens, especially intraocular lens is marketed: in order to protect eyes from harmful ultraviolet rays, an ultraviolet absorber that blocks light below 400 nm is mixed or chemically bonded into the lens material to reduce the amount of ultraviolet rays incident into the eyes, thereby achieving the function of protecting the eyes from harmful ultraviolet light."

Thus, it is naturally understood that the "polymerizable ultraviolet absorber" in the cited invention is for the purpose of imparting ultraviolet absorptivity to the lens, thereby blocking the harmful ultraviolet rays incident into the eyes.

In addition, paragraph [0086] of summarization (c) of Cited Document 1 describes that "The method for producing an ophthalmic lens material of the present invention includes ... adding a free radical polymerization initiator … and performing polymerization by a conventional method." Paragraph [0087] of the same document describes that "the conventional method refers to, for example, after the free radical polymerization initiator is blended, gradual heating is performed in the temperature range of room temperature to about 130°C, and a method for irradiating electromagnetic waves such as microwaves, ultraviolet rays, and radioactive rays (γ rays)." Since the manufacture of the ophthalmic lens material in Cited Document 1 also includes a method without using a photoinitiator, it cannot be interpreted as that the "polymerizable ultraviolet absorber" in Cited Document 1 is used exclusively as the "activated photoinitiator absorber."

Therefore, the aforementioned allegations of the appellant are groundless.

b.

The appellant alleges in the Written Request for Appeal against Examiner’s Decision of Refusal that "Cited Document 1 neither teaches nor suggests a method capable of using an ultraviolet absorber and a photopolymerization initiator at the same time," "since polymerization of an ultraviolet-curable composition is very difficult, the photoinitiator and the ultraviolet absorber are generally not combined," and "due to its specific composition, the composition of the present invention can use the ultraviolet-blocking agent and the photoinitiator at the same time, and the photoinitiator is activated in the same region as the ultraviolet-blocking agent that blocks light ... If a specific chemical substance is selected, the selected photoinitiator and ultraviolet-blocking agent are specifically combined as a specific combination, then the photoinitiator cannot be activated in the same region as the ultraviolet-blocking agent that blocks light."

However, There is no mention in the Cited Document 1 that contraindicates the .combined use of the "polymerizable ultraviolet absorber" described in paragraphs [0080] and [0084] of summarization (b) and the "photopolymerization initiator such as 2-hydroxy-2-methyl-2-phenyl propane-1-one" described in paragraph [0088] of summarization (c). Furthermore, it is not found that the common technical knowledge "the photoinitiator and the ultraviolet absorber are generally not combined" pointed out by the appellant also exists at the time of the priority date (May 7, 2014) of this application.

In addition, according to Example 5 of JP H2007-504854A issued prior to the priority date of this application, a compound comprising benzotriazole methacrylic acid (which is an ultraviolet absorber according to paragraph [0019]) and Irgacure-784 (which is a photoinitiator according to paragraph [0020]) is photocured to prepare an ultraviolet absorber-containing hydrogel having a high refractive index for IOL application. Considering that paragraphs [0019] and [0020] of the aforementioned gazette exemplify the preparation that can use various ultraviolet absorbers and photoinitiators, it is not considered that the combined use of the ultraviolet-blocking agent and the photoinitiator is regarded by a person skilled in the art as a matter requiring superior ingenuity.

Therefore, the aforementioned allegations of the appellant are groundless.

(3) Summary

In conclusion, the invention of the present application could be easily made by a person skilled in the art on the basis of the cited invention, i.e., the invention described in Cited Document 1, and therefore cannot be granted a patent under the provisions of the Patent Act Article 29(2).

2. Regarding Reason 2

(1) Interpretation of of the Patent Act Article 36(6)(i) (premise)

"Whether the statement of the scope of claims satisfies the Support Requirement of a Description should be determined by considering, through comparison of the statement of the scope of claims and the statement of the detailed explanation of the invention, whether the invention described in the scope of claims is the invention described in the detailed explanation of the invention that is within the scope for which a person ordinarily skilled in the art can recognize, based on the statement of the detailed explanation of the invention, that the invention can solve the problem to be solved by the invention, and also by considering whether the invention described in the scope of claims is an invention within the scope which a person ordinarily skilled in the art can recognize, in light of the common general technical knowledge as of the time of filing the application, that the invention can solve the problem to be solved by the invention, even without the statement and indication thereof."

even if there is no such description or suggestion (2005 (Gyo-Ke) No. 10042 Collegial Decision). Therefore, Based on this methodology, it will be examined as follows.

(2) Matters described in the description of the present application

A. [Technical Field]

[0001]

The present invention relates to a composition and a method for manufacturing a lens, which are used for producing an intraocular lens (IOL) in the fields of medical treatment, ophthalmology, cataract, and cataract surgery, and the intraocular lens (IOL) mainly has flexibility and biocompatibility, and has long-term preservation.

B. [Problem to be solved by the invention]

[0012]

[Detailed description of the invention] The present invention relates to a composition and a method for manufacturing a lens, which are used for producing an intraocular lens (IOL) in the fields of medical treatment, ophthalmology, cataract, and cataract surgery, and the intraocular lens (IOL) mainly has flexibility and biocompatibility, and has long-term preservation.

[0013]

Another objective of the present invention is to realize a composition and a method for producing an intraocular lens, which can provide an intraocular lens having ultraviolet-blocking properties using a reactive functional group-containing composition that can

react in an ultraviolet region of 300-475 nm.

[0014]

Another objective of the present invention is to produce a lens using thermal polymerization and/or photopolymerization (UV/ultraviolet LED/light-emitting device or UV/LED), and/or by combining the two methods.

[0015]

Another objective of the present invention is to provide an intraocular lens composition and an intraocular lens production method for obtaining an intraocular lens having a high refractive index.

[0016]

Another objective of the present invention is to provide an intraocular lens composition and an intraocular lens production method for producing a one-piece hydrophobic intraocular lens.

[0017]

Another objective of the present invention is to provide an intraocular lens composition and an intraocular lens production method for producing an intraocular lens using a photopolymerization process.

[0018]

Another objective of the present invention is to provide an intraocular lens composition and a production method for obtaining two different types of white and yellow lenses, based on blending materials and blending ratios thereof.

C. [Means for solving problems]

[0019]

[Detailed description of the invention]

The present invention relates to a composition using photopolymerization and a method for manufacturing a lens, and provides a lens having ultraviolet-blocking properties, a smooth surface, flexibility, high refractive index value, low cost, hydrophobicity, and no glistening problem that occurs as a result of cutting. ...

[0020]

The composition of the present invention comprises: 20-80 weight percent of acrylate and/or methacrylate-based oligomer component as a binder in the composition, 5-40 weight percent of acrylate and/or methacrylate monomer component as a reactive diluent, 1-5 weight percent of acrylate and/or methacrylate-based ultraviolet-blocking component as an ultraviolet-blocking agent, and 0.1-5 weight percent of photoinitiator for initiating a photopolymerization process.

[0021]

The oligomer used in the composition of the present invention is 20-80 weight percent, and has a urethane acrylate and/or urethane methacrylate-based structure.

[0022]

The monofunctional acrylate and/or methacrylate-based reactive monomer contained in the composition of the present invention is in the range of 5-40 weight percent, and may use substances with various structures such as methacrylic acid, methyl carbitol methacrylate, phenoxyethyl methacrylate, octyl methacrylate, methyl methacrylate, hydroxyethyl methacrylate, ethoxyethyl methacrylate, ethylene glycol dimethacrylate, N-vinyl pyrrolidone, allyl methacrylate, N, N-dimethylacrylamide, glycerol methacrylate, and tetraethylene glycol dimethacrylate.

[0023]

The ultraviolet-blocking component contained in the composition of the present invention is 1-5 weight percent in the composition. As the ultraviolet-blocking agent in the preferred implementation of the present invention, substances with various structures such as ethyl 2-(4-benzoyl-3-hydroxyphenoxy)acrylate, 4-methacryloyloxy-2-hydroxybenzophenone, 2-(2'-hydroxy-5'-methyl acryloyloxyethylphenyl)-2H-benzotriazole, coumarin, and polyarylene ether are used.

[0024]

The composition of the present invention contains a photoinitiator for initiating photopolymerization. The photoinitiator in the composition of the present invention has a ratio of 0.1-5 weight percent, and may use substances with various structures such as 2, 4, 6-trimethylbenzoyldiphenylphosphine oxide, (2-benzyl-2-N-dimethylamino-1-(4-morpholinopropane-1), (hydroxycyclohexyl)
phenyl ketone, 2-benzyl-2-N-dimethylamino-1-(4-morpholinophenyl)-1-butanone, benzene, dimethyl ketal, isopropylbenzoin ketal, 2-n-propoxy-9H-9-thioxanthene, and ethyl 4-(dimethylamino)benzoate.

[0025]

The intraocular lens obtained using the composition of the present invention provides a flexible and hydrophobic lens having a polymer structure. The refractive index of the lens is 1.5 or more. The one-piece (integrated) lens does not suffer from the diffusion problem and is produced in an economical manner by means of photopolymerization.

[0026]

The present invention relates to a composition using photopolymerization and a method for manufacturing a lens, and provides a lens having a smooth surface, ultraviolet-blocking properties, flexibility, high refractive index value, low cost, and hydrophobicity. All the aforementioned lenses are thermoformed and shaped by cutting in combination

with laser. This method includes the steps of: preparing the composition, placing the composition in a forming mold, curing the composition by photopolymerization, taking out the cured composition from the forming mold, and extracting the composition taken out from the forming mold with isopropyl alcohol and performing sterilization.

[0027]

In the manufacturing method of the present invention, the composition includes: 20-80 weight percent of (1 or 2 or more types of) acrylate and/or methacrylate-based oligomer as a binder, 5-40 weight percent of acrylate and/or methacrylate-based monomer as a reactive diluent, 0.1-5 weight percent of photoinitiator for initiating a reaction, and 1-5 weight percent of acrylate and/or methacrylate-based ultraviolet-blocking agent as a ultraviolet absorbing component. The composition is preferably transferred into a quartz forming mold. The molded composition transferred into the mold is cured by photopolymerization.

In a preferred embodiment of the present invention, the ultraviolet ray, the LED, or both the UV ray and the LED are used as a light source for the photopolymerization process. After the curing operation, the composition (lens) is taken out from the forming mold and extracted in isopropanol. Finally, disinfection is performed by sterilizing this product.

[0028]

The intraocular lens obtained in the present invention has a polymer structure with flexible and hydrophobic properties. The refractive index of the lens is 1.5 or more. The one-piece (integrated) lens does not suffer from the diffusion problem and is produced in an economical manner by means of photopolymerization.

(3) Determination by the panel

A. Problems of the invention of the present application

In the description of the present application, paragraph [0012] describes that "... relates to a composition ... for manufacturing ... an intraocular lens (IOL) ... mainly has flexibility and biocompatibility, and has long-term preservation," paragraph [0013] describes that "Another objective of the present invention is to realize a composition ... provide an intraocular lens having ultraviolet-blocking properties ...," paragraph [0015] describes that "Another objective of the present invention is to provide an intraocular lens composition ... for obtaining an intraocular lens having a high refractive index," paragraph [0016] describes that "Another objective of the present invention is to provide an intraocular lens composition ... for producing a one-piece hydrophobic intraocular lens," and paragraph [0017] describes that "Another objective of the present invention is to

provide an intraocular lens composition ... using a photopolymerization process." Therefore, it is considered that the problem of the invention of the present application is to provide a composition for producing an intraocular lens (IOL) using a photopolymerization process; and the intraocular lens (IOL) has flexibility, biocompatibility, and long-term preservation, and further has ultraviolet-blocking properties, high refractive index, and hydrophobicity.

B. Examination

(a) Whether a person skilled in the art could realize that the problem of the invention of the present application can be solved according to the description of the invention

Paragraph [0021] of the description of the present application describes that "the oligomer used in the composition of the present invention is 20-80 weight percent, and has a urethane acrylate and/or urethane methacrylate-based structure." In paragraphs [0022]-[0024] of the same document, the "acrylate and/or methacrylate-based monomer," the "acrylate and/or methacrylate-based ultraviolet-blocking agent," and the "photoinitiator" that can be used in the invention of the present application are exemplified by compound names. However, there is no description at all about what kind of chemical structure the "acrylate and/or methacrylate-based oligomer" can specifically use.

In addition, in the description of the present application, there is no specific description about whether the "acrylate and/or methacrylate-based oligomer," the "acrylate and/or methacrylate-based monomer," the "acrylate and/or methacrylate-based ultraviolet-blocking agent," and the "photoinitiator" as the matters specifying the invention of the present application contribute to any of these effects that are helpful to solve the problem of the invention of the present application, i.e., the "flexibility," the "biocompatibility," the "long-term preservation," the "high refraction index," and the "hydrophobicity," and there is no specific description about the action mechanism.

Furthermore, the description of the present application does not describe any example, and does not describe any composition that specifies the invention of the present application.

Thus, it is not considered that the description of the present application describes that a person skilled in the art could confirm that the invention of the present application can solve the aforementioned problem "providing a composition for producing an intraocular lens (IOL) using a photopolymerization process, the intraocular lens (IOL) having flexibility, biocompatibility, and long-term preservation, and further having ultraviolet-blocking properties, high refractive index, and hydrophobicity."

(b) Whether a person skilled in the art could realize that the problem of the invention of the present application can be solved according to the common technical knowledge at the time of filing the application

Even with reference to the common technical knowledge at the application date (May 7, 2015) of the present application, it is not considered that a person skilled in the art could realize from the description of the "acrylate and/or methacrylate-based oligomer" described in paragraph [0021] of the description of the present application or the exemplified compounds described in paragraphs [0022]-[0024] of the same document that, any of the "acrylate and/or methacrylate-based oligomer," the "acrylate and/or methacrylate-based monomer," the "acrylate and/or methacrylate-based ultraviolet-blocking agent," and the "photoinitiator" as the matters specifying the invention of the present application achieve these effects that are helpful to solve the problem of the invention of the present application, i.e., the "flexibility," the "biocompatibility," the "long-term preservation," the "high refraction index," and the "hydrophobicity."

In addition, although the invention of the present application comprises a composition with 20 weight percent of "acrylate and/or methacrylate-based oligomer," the upper limits of the "acrylate and/or methacrylate-based monomer," "acrylate and/or methacrylate-based ultraviolet-blocking agent," and the "photoinitiator" are respectively 40 weight percent, 5 weight percent, and 5 weight percent. In view of the point that it is only 70 weight percent even when all chemicals are added up, it cannot be denied that there is a possibility that the invention of the present application includes a range that cannot solve the aforementioned problem.

Thus, even with reference to the common technical knowledge at the time of filing the application, it is not considered that the invention of the present application is within the scope in which a person skilled in the art could realize that the aforementioned problem can be solved according to the detailed description of the invention of the present application or the suggestion thereof.

(c) Summary

In conclusion, the invention of the present application cannot be said to be the invention described in the detailed description of the present application.

(4) Allegations of the appellant

The appellant alleges in the Written Request for the Written Request for Appeal against Examiner’s Decision of Refusal that "the chemical structure of urethane acrylate

and/or the chemical structure of urethane methacrylate is well-known in the document, and a person skilled in the art could understand the chemical structure thereof if the chemical name thereof is exemplified. Therefore, it is not considered that it is necessary to disclose the structures thereof in the description. The urethane acrylate and/or methacrylate-based oligomer is used in many studies, most of which do not disclose the chemical structures or provide information on the chemical properties thereof." "The composition and the method for producing the composition are obvious to the extent that they can be worked by a person skilled in the art, and specific examples as a basis for showing the expected effect are not necessary. In addition, the appellant submits the result of comparing the lens manufactured by the composition and manufacturing method of the present application with the commercially available product as the test result when responding to the previous notification of reasons for refusal."

However, the description of the present application does not describe the chemical structures of the "urethane acrylate and/or urethane methacrylate," and does not describe the specific compound names thereof. As acknowledged by the appellant in the Written Request for Appeal against Examiner’s Decision of Refusal, considering that "the chemical structure, function and molecular weight, and composition of acrylic oligomer(s) ... , the wavelength region of an ultraviolet lamp, or other important parameters will affect the product characteristics of the final product," to make a person skilled in the art realize that the invention of the present application can solve the aforementioned problem, it can be said that at least the "acrylate and/or methacrylate-based oligomer" that can be used in the invention of the present application needs to be specifically disclosed in the “detailed description of the invention" of the description, including the action mechanism thereof. However, as described in the aforementioned (3)B(a), there is no such description or suggestion in the “detailed description of the invention” of the description.

In addition, in the description of the present application, there is not only no description at all of examples that can quantitatively, objectively, and specifically recognize the effects related to of the aforementioned problem, and it is not considered that a person skilled in the art could realize from the description of the matters specifying the invention of the present application or the description in paragraphs [0021]-[0024] of the description of the present application that, any of the "acrylate and/or methacrylate-based oligomer," the "acrylate and/or methacrylate-based monomer," the "acrylate and/or methacrylate-based ultraviolet-blocking agent," and the "photoinitiator" achieve these effects that are helpful to solve the problem of the invention of the present application, i.e., the "flexibility," the "biocompatibility," the "long-term preservation," the "high

refraction index," and the "hydrophobicity."

In addition, in the test result described in the written opinion on April 5, 2018, the blending components and blending amounts of the composition used for the test are unclear, and it is also unclear whether the composition has the matters specifying the invention of the present application. Therefore, it cannot be confirmed that the test results are based on the description of the present application.

Therefore, all the allegations of the appellant are groundless.

(5) Summary

As described above, the description of Claim 1 of the scope of claims is not properly stated, and therefore does not comply with the Patent Act Article 36(6)(i) and does not satisfy the requirements specified in the Patent Act Article 36(6) (main paragraphs).

V.Conclusion

As described above, the invention of the present application (the invention according to Claim 1) cannot be granted a patent; and in addition, the description of Claim 1 of the present application does not satisfy the requirements specified in the Patent Act Article 36(6). Therefore, it is not necessary to examine other claims, and this application should be rejected.

Therefore, the Appeal Decision shall be made according to the conclusion.

July 21, 2021

Chief administrative judge: SUGIE, Wataru
Administrative judge: FUKUI, Satoru
Administrative judge: HASHIMOTO, Shigekazu