

Appeal Decision

Appeal No. 2015-4779

Appellant ROHTO Pharmaceutical Co., Ltd.

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The case of appeal against the examiner's decision of refusal of Japanese Patent Application No. 2013-89552, entitled "Ophthalmic Composition" (the application published on July 18, 2013, Japanese Unexamined Patent Application Publication No. 2013-139485) has resulted in the following appeal decision:

Conclusion

The appeal of the case was groundless.

Reason

1. History of the procedures

The present application is a divisional application filed on April 22, 2013 from a patent application (Japanese Patent Application No. 2009-532212) whose international filing date is September 11, 2008 (priority claim: September 14, 2007 and February 8, 2008) to which reasons for refusal were noticed on June 11, 2014, a written opinion and a written amendment were submitted on August 6, 2014, a decision of refusal was issued on January 28, 2015, and an appeal against the Examiner's decision of refusal was requested on March 11, 2015.

2. The Invention

The inventions recited in Claims 1 to 13 of the present application are specified

by the matters stated in Claims 1 to 13 of the scope of claims, which have been amended by the written amendment dated August 6, 2014, and among them the invention recited in Claim 1 is as follows (hereinafter, referred to as "the Invention"):

"An eye drop solution for wearing contact lenses comprising (A) one or more members selected from the group consisting of a cellulose-based polymer, a vinyl-based polymer, polyethylene glycol, and dextran; and (B) a terpenoid, wherein the solution is used in the applications of both a contact lens wearing solution and an eye drop solution while wearing contact lenses without changing its composition.

3. Judgement by the body

(1) Cited publications and described matters therein

A. Japanese Unexamined Patent Application Publication No. 2006-241085 (Cited Document 1 of the examiner's decision, hereinafter referred to as "Publication 1"), which is a publication distributed before the application of the present application (before the priority date), describes the following matters:

(A) "[Claim 1]

A composition for mucosal application comprising sodium carboxymethyl cellulose and terpenoid.

...

[Claim 10]

The composition for mucosal application according to any one of Claims 1 to 9, wherein the composition is a nasal drop medicine, an eye drop preparation, an ophthalmic ointment preparation, a contact lens wearing solution, an eye wash preparation, or a contact lens care preparation."

(B) "[Advantageous Effects of Invention]

[0009]

The composition for mucosal application of the present invention can improve the wetting of the contact lens surface and the corneal surface by containing a terpenoid together with sodium carboxymethyl cellulose. Specifically, in combination with the excellent water-retaining action of carboxymethyl cellulose, it is possible to sustain wetness and maintain moisture. In addition, the composition of the present invention is a mucosal application composition having an excellent usability and an excellent effect in preventing or ameliorating diseases and symptoms in which the mucous membranes are in a dry state, such as dry eye, dry nose, and dry mouth."

(C) "[0024]

The composition for mucosal application of the present invention can be used

without specifying its use as long as it utilizes the effects of the invention. and can be used as a composition applied to mucous membranes, such as ophthalmic compositions, ... in various fields of pharmaceuticals, quasi-drugs, miscellaneous goods, or the like. For example, examples of the composition as an ophthalmic composition include eye drop preparations (medicines) (including eye drop medicines that can be used while wearing contact lenses, also referred to as eye drop preparations), eye wash preparations (medicines) (including eyewash medicines that can be used while wearing contact lenses, also referred to as eye wash preparations), eye ointment medicines, contact lens wearing solutions, contact lens care preparations (such as cleaning solutions, preservatives, disinfectants, and multipurpose solutions), Preferably, it is useful for nasal drop medicines, eye drop preparation, eye ointment preparation, contact lens wearing solutions, eye wash preparations, and contact lens care preparations. particularly preferably, it is useful for nasal drop medicines, eye drop medicines, eye wash medicines, and contact lens wearing solutions. Furthermore, from the viewpoint of improving water wetting of contact lenses, it is more useful for eye drop preparations, facial wash preparations, contact lens care preparation, and contact lens wearing solutions.

In the present specification, the contact lenses include all types of contact lenses, such as hard, soft, oxygen permeable hard, and color contact lenses."

(D) "[0044]

Examples

In each of Examples 1 to 9 in the table, the unit shall be described as g/100 ml. Also, in the table, the term "eye drop preparation" means an eye drop preparation (medicine), "eye wash preparation" means an eye wash preparation (medicine), "artificial spot" means an artificial tears-type eye drop preparation (medicine), "wearing solution" means contact lens-wearing solution, and "CL medicine" means contact lens care preparation. In each of these examples, the wetting was improved and the usability was thus improved.

...

[0046]

[Table 4]

	実施例2 (装着液)	実施例3 (CL用剤)
カルボキシメチルセルロースナトリウム (商品名 セロゲン AGガムM)	—	0.05
カルボキシメチルセルロースナトリウム (商品名 セロゲン P815C)	0.2	—
1-メントール	0.015	0.010
アミノエチルスルホン酸	0.5	—
塩化カリウム	0.08	0.050
塩化ナトリウム	0.15	1.000
リン酸水素ナトリウム	—	0.150
リン酸二水素ナトリウム	—	0.010
砂糖	0.90	—
砂糖	0.200	—
ソルビン酸カリウム	0.1	—
イソトナトリウム (日本薬局方)	0.05	—
ポリアルベート80	0.50	0.05
ポロキサマー407	0.50	0.05
20%ポリアキサメチレンピグメント液 (商品名 コスミンCQ)	—	0.0005
塩酸/水酸化ナトリウム	適量	適量
精製水	適量	適量
pH	7.0	7.48
浸透圧	350	320
粘度 mPa·sec(20℃)	10.1	2.0

実施例 2(装着液)

Example 2 (wearing solution)

実施例 3(CL用剤)

Example 3 (CL medicine)

カルボキシメチルセルロースナトリウム(商品名 セロゲン AGガムM)

Sodium Carboxymethyl

Cellulose (trade name: Cellogen AG-Gum M)

カルボキシメチルセルロースナトリウム(商品名 セロゲン P815C)

Sodium Carboxymethyl Cellulose

(trade name: Cellogen P815C)

1-メントール

l-Menthol

アミノエチルスルホン酸

Aminoethyl sulfonic acid

塩化カリウム

Potassium chloride

塩化ナトリウム

Sodium chloride

リン酸水素ナトリウム

Sodium hydrogen phosphate

リン酸二水素ナトリウム

Sodium dihydrogen phosphate

硼酸	Boric acid
硼砂	Borax
ソルビン酸カリウム	Potassium sorbate
エデト酸ナトリウム(日本薬局方) Pharmacopoeia)	Sodium edetate (Japanese
ポリソルベート 80	Polysorbate 80
ポリオキサマー 407	Poloxamer 407
20%ポリヘキサメチレンピグアミド液(商品名 コスモシル CQ)	20%
polyhexamethylenebiguanide solution (trade name: Cosmocil CQ)	
塩酸/水酸化ナトリウム	Hydrochloric acid/sodium hydroxide
精製水	Purified water
浸透圧	Osmotic pressure
粘度	Viscosity
適量	Appropriate amount

[0047]

[Table 5]

	実施例4 (点眼薬)
カルボキシメチルセルロースナトリウム (商品名 セロゲン PR-S)	0.5
l-メントール	0.02
d-カンフル	0.001
d-ボルネオール	0.005
ユーカリ油	0.010
ミント油	0.002
塩酸ナファゾリン	0.0015
メチル硫酸ネオスチグミン	0.004
マレイン酸クロルフェニラミン	0.03
塩酸ピリトキシン	0.08
酢酸トコフェロール	0.04
L-アスパラギン酸マグネシウム・カリウム	1.40
アミノエチルスルホン酸	0.80
柿酸	0.50
柿砂	0.1
濃塩化ベンザルコニウム液50 (日本薬局方)	0.015
クロロブタノール	0.2
ポリオキシエチレン硬化ヒマシ油60	0.3
塩酸/水酸化ナトリウム	適量
精製水	適量
pH	6.6
浸透圧	360
粘度 mPa・sec(20℃)	3.0

実施例 4(点眼薬)

Example 4 (eye drop preparation)

カルボキシメチルセルロースナトリウム(商品名 セロゲン PR-S) Sodium Carboxymethyl Cellulose
(trade name: Cellogen PR-S)

l-メントール

l-Menthol

d-カンフル

d-Camphor

d-ボルネオール	d-Borneol
ユーカリ油	Eucalyptus oil
ミント油	Mint oil
塩酸ナファゾリン	Naphazoline hydrochloride
メチル硫酸ネオスチグミン	Neostigmine methylsulfate
マレイン酸クロルフェニラミン	Chlorpheniramine maleate
塩酸ピリドキシン	Pyridoxine hydrochloride
酢酸トコフェロール	Tocopherol acetate
L-アスパラギン酸マグネシウム・カリウム	L-Magnesium aspartate, potassium
アミノエチルスルホン酸	Aminoethyl sulfonic acid
硼酸	Boric acid
硼砂	Borax
濃塩化ベンザルコニウム液 50(日本薬局方)	Concentrated benzalkonium chloride
solution 50 (Japanese Pharmacopoeia)	
クロブタノール	Chlorobutanol
ポリオキシエチレン硬化ヒマシ油 60	Polyoxyethylene hydrogenated castor oil
60	
塩酸/水酸化ナトリウム	Hydrochloric acid/sodium hydroxide
精製水	Purified water
浸透圧	Osmotic pressure
粘度	Viscosity
適量	Appropriate amount

[0048]

[Table 6]

	実施例5 (点眼薬)	実施例6 (点眼薬)
カルボキシメチルセルロースナトリウム (商品名 セロゲン P815C)	0.1	0.4
l-メントール	0.01	0.01
d-カンフル	0.002	0.002
ゲラニオール	0.001	—
ローズ油	—	0.003
塩酸テトラヒドロゾリン	0.03	—
シアノコバラミン	0.004	—
パントテール	0.08	—
コンドロイチン硫酸ナトリウム	0.30	0.30
スルファメトキサゾールナトリウム	—	2.2
塩化カリウム	—	0.1
塩化カルシウム	—	0.5
柿酸	1.50	0.90
柿砂	0.10	0.10
ポリオキシエチレン硬化ヒマシ油60	0.2	0.1
塩酸/水酸化ナトリウム	適量	適量
精製水	適量	適量
pH	6.2	7.3
浸透圧	230	360
粘度 mPa・sec(20℃)	5.2	70

実施例 5(点眼薬)

Example 5 (eye drop preparation)

実施例 6(点眼薬)

Example 6 (eye drop preparation)

カルボキシメチルセルロースナトリウム(商品名 セロゲン P815C) Sodium Carboxymethyl Cellulose (trade name: Cellogen P815C)

l-メントール

l-Menthol

d-カンフル

d-Camphor

ゲラニオール

Geraniol

ローズ油

Rose oil

塩酸テトラヒドロゾリン

Tetrahydrozoline hydrochloride

シアノコバラミン

Cyanocobalamin

パントール	Panthenol
コンドロイチン硫酸ナトリウム	Sodium chondroitin sulfate
スルファメトキサゾールナトリウム	Sulfamethoxazole sodium
塩化カリウム	Potassium chloride
塩化カルシウム	Calcium chloride
硼酸	Boric acid
硼砂	Borax
ポリオキシエチレン硬化ヒマシ油 60	Polyoxyethylene hydrogenated castor oil
60	
塩酸/水酸化ナトリウム	Hydrochloric acid/sodium hydroxide
精製水	Purified water
浸透圧	Osmotic pressure
粘度	Viscosity
適量	Appropriate amount

[0049]

[Table 7]

	実施例7 (人工点)	実施例8 (人工点)	実施例9 (人工点)
カルボキシメチルセルロースナトリウム (商品名セロファン F-SC)	0.20	0.1	0.6
トメントール	0.020	0.020	0.020
d-カンフル	0.010	0.010	0.010
ヒドロキシプロピルメチルセルロース	—	0.1	—
塩化カリウム	0.10	0.10	0.10
塩化ナトリウム	0.50	0.50	0.50
硼酸	0.60	0.60	0.60
硼砂	0.10	0.10	0.10
ポリオキシエチレン硬化ヒマシ油60	0.02	0.02	0.02
塩酸/水酸化ナトリウム	適量	適量	適量
精製水	適量	適量	適量
pH	7.7	7.7	7.7
浸透圧	308	308	352
粘度 mPa·sec(20℃)	3.1	5.0	10.8

実施例 7(人工点)	Example 7 (Artificial spot)
実施例 8(人工点)	Example 8 (Artificial spot)
実施例 9(人工点)	Example 9 (Artificial spot)
カルボキシルセルロースナトリウム(商品名 セロゲン F-SC) (trade name: Cellogen F-SC)	Sodium Carboxymethyl Cellulose
l-メントール	l-Menthol
d-カンフル	d-Camphor
ヒドロキシプロピルメチルセルロース	Hydroxypropyl methylcellulose
塩化カリウム	Potassium chloride
塩化ナトリウム	Sodium chloride
硼酸	Boric acid
硼砂	Borax
ポリオキシエチレン硬化ヒマシ油 60	Polyoxyethylene hydrogenated castor oil
60	
塩酸/水酸化ナトリウム	Hydrochloric acid/sodium hydroxide
精製水	purified water
浸透圧	Osmotic pressure
粘度	viscosity
適量	Appropriate amount

"

B. Japanese Unexamined Patent Application Publication No. 2007-77167 (Cited Document 9 of the examiner's decision, hereinafter referred to as "Publication 2"), which is a publication distributed before the application of the present application (before the priority date), describes the following matters:

"[Claim 1]

An ophthalmic composition comprising 0.05 to 3.0% by weight of polyvinylpyrrolidone having an average molecular weight of 500,000 or less and 0.05 to 0.3% by weight of a thickener and sorbic acid or a salt thereof, wherein the composition continuously adsorbs polyvinylpyrrolidone to an ionic contact lens to stably hold a tear film around the ionic contact lens for a long time.

[Claim 2]

The ophthalmic composition according to Claim 1, wherein the thickener is 0.01 to 0.3% by weight of hydroxypropyl methylcellulose.

.....

[Claim 5]

The ophthalmic composition according to any one of Claims 1 to 4, wherein the composition is an eye drop medicine or wearing solution for contact lenses.

[Claim 6]

A method of keeping a tear film around an ionic contact lens stable for a long time, the method comprising:

placing a drop of an eye drop solution for contact lenses in the eye, wherein the solution consists of an ophthalmic composition comprising 0.05 to 3.0% by weight of polyvinylpyrrolidone having an average molecular weight of 500,000 or less and 0.05 to 0.3% by weight of a thickener and sorbic acid or a salt thereof; or dropping the ophthalmic composition onto an ionic contact lens before wearing, or immersing the contact lens in a wearing solution consisting of the ophthalmic composition to continuously adsorb polyvinylpyrrolidone to the ionic contact lens.

[Claim 7]

A method of improving the water retention of ionic contact lenses, the method comprising:

placing a drop of an eye drop solution for contact lenses in the eye, wherein the solution consists of an ophthalmic composition comprising 0.05 to 3.0% by weight of polyvinylpyrrolidone having an average molecular weight of 500,000 or less and 0.05 to 0.3% by weight of a thickener and sorbic acid or a salt thereof; or dropping the ophthalmic composition onto an ionic contact lens before wearing, or immersing the contact lens in a wearing solution consisting of the ophthalmic composition.

[Claim 8]

The method according to Claim 6 or 7, wherein the thickener is 0.01 to 0.3% by weight of hydroxypropyl methylcellulose."

"[Technical field]

[0001]

The present invention relates to a system for stabilizing a tear film by stabilizing the tear film that exists around a contact lens (the front surface of the lens and the back surface of the lens) when the contact lens is worn, thereby removing the dryness and discomfort of the eyes of a contact lens wearer and providing the wearer with a good moisturizing feeling and wearing feeling."

"[0019]

Examples of the thickener of the present invention include methyl cellulose, hydroxypropyl methyl cellulose, polyvinyl alcohol, sorbitol, sodium carboxymethyl cellulose, hydroxyethyl cellulose, triisopropanolamine and the like, but the thickener is

not particularly limited as long as it is an additive having a thickening effect. ... "

"[0024]

When the ophthalmic composition is used as an eye drop solution, it is usually applied to the eye 2 to 5 times a day, 1 to 3 drops at a time. Furthermore, when wearing the contact lens, 1 to 2 drops of the present composition may be dropped onto a contact lens for use. When this ophthalmic composition is used as a wearing solution, it is used by immersing it in the wearing solution before wearing the contact lens. Furthermore, the ophthalmic composition is also applicable as a preservative or cleaning solution for contact lenses."

C. International Publication No. WO 2007-088783 (Cited Document 11 of the examiner's decision, hereinafter referred to as "Publication 3"), published before the application of the present application (before the priority date), describes the following matters:

"[1] An eye drop/wearing solution for soft contact lenses, which is an eye drop solution applicable to the eye wearing a soft contact lens or a wearing solution for the soft contact lens and does not substantially affect the specifications of the soft contact lens, wherein the solution has a titratable acidity of 3.0-5.0 mEq/L." (the scope of claims)

" [0035] In an eye drop/wearing solution for soft contact lenses according to the present invention, it is useful to add a thickener to adjust the viscosity of the fluid appropriately. Examples of such a thickener include: various gums, for example, polysaccharides such as chondroitin sulfate, hyaluronic acid, gluconic acid and salts thereof, mucopolysaccharides, and heteropolysaccharides; synthetic organic polymer compounds, such as polyvinyl alcohol, poly-N-vinylpyrrolidone, polyethylene glycol, polypropylene glycol, polyacrylamide, polyacrylic acid or a salt thereof, polymethacrylic acid or a salt thereof, and carboxyvinyl polymer; cellulose derivatives, such as hydroxyethyl cellulose, hydroxypropylmethyl cellulose, carboxymethyl cellulose, and methyl cellulose; and starch derivatives.

.....

[0037] In the present invention, the refrigerant is added for the purpose of giving a refreshing feeling at the time of instillation, eliminating a foreign body sensation and itching when wearing contact lenses, and the like. Examples of the refrigerant may include menthol, borneol, camphor, geraniol, eucalyptus oil, bergamot oil, fennel oil, peppermint oil, rose oil, cool mint, and the like."

"[0047] The eye drop/wearing solution for soft contact lenses according to the present

invention obtained as described above does not affect the change in specifications of the lenses even when the solution is placed in the eyes while wearing soft contact lenses or used as a wearing solution for soft contact lenses. (Even if the solution is attached to a soft contact lens or placed on a contact lens base-curved surface and worn on the eye.) Thus, the solution is comfortable to use, or it allows contact lenses to be easily worn. Then, the solution improves problems, such as deterioration of the fitting of the lens to the cornea due to such a change in specifications, further adsorption of the lens to the cornea, deterioration of tear exchange, and deterioration of wearing feeling. In addition, the solution exhibits a feature that the risk of exfoliation of the corneal epithelium due to removal of the contact lens while the contact lens is adsorbed on the cornea can be advantageously avoided.

[0048] The eye drop/wearing solution according to the present invention as described above is not only prepared and used as an eye drop solution or as a wearing solution, but also prepared and used as a combination of an eye drop solution and a wearing solution."

(2) The invention disclosed in Publication 1

In light of the descriptions of the above indications A(a) and (c) of Publication 1, Publication 1 discloses an invention of "an ophthalmic composition comprising sodium carboxymethyl cellulose and terpenoid" (hereinafter referred to as the "Cited Invention").

(3) Comparison / Judgment

The Invention and the Cited Invention are compared.

In light of the description of [0020] of the Detailed Description of the Invention in the specification of the present application, the "carboxymethyl cellulose" in the Cited Invention corresponds to the "cellulose-based polymer compound" in (A) of the Invention.

Further, in light of [0015] of the Detailed Description of the Invention in the specification, the "eye drop solution for wearing contact lenses" of the Invention can be said to be "an ophthalmic composition" because it means "an ophthalmic composition that has both the function as a contact lens wearing solution and the function as an eye drop solution that can be instilled while wearing contact lenses.

Then, in comparison of the Invention with the Cited Invention, the two are corresponding to each other in that "an ophthalmic composition comprising (A) one or more members selected from the

group consisting of a cellulose-based polymer, a vinyl-based polymer, polyethylene glycol, and dextran; and (B) a terpenoid." However, they are different from each other in the following point.

Different Feature:

In the Invention, the ophthalmic composition is "an eye drop solution for wearing contact lenses," and "the solution is used in the same composition for both contact lens wearing solution and eye drop solution while wearing contact lenses." On the other hand, in the Cited Invention, it is simply referred to as an "ophthalmic composition."

This different feature is to be discussed below.

Publication 1 states that the ophthalmic composition of the Cited Invention can be used as both "a contact lens wearing solution" and "an eye drop medicine that can be used while wearing contact lenses." (see the indication A(c)). Then, the examples (indication A(d)) describe exemplified formulations of contact lens wearing solution (Example 2), eye drop preparation (Examples 4 to 6), and artificial tears-type eye drop preparation (Examples 7 to 9), but these formulations are not particularly different from each other.

Furthermore, the above publications 2 and 3 describe embodiments in which one ophthalmic composition is used for both the contact lens wearing solution and the eye drop solution during contact lens wearing. Such usage is not exceptional.

The Invention specifies that " the solution is used in the same composition for both contact lens wearing solution and eye drop solution while wearing contact lenses." In "Test 3: Confirmation of usefulness of combination by prescription" ([0083] to [0083]), it merely discloses that when the eye drop solution for wearing contact lenses is used as a contact lens wearing solution, the eye drop solution for wearing contact lenses can also be used as an eye drop solution while wearing contact lenses. It does not show that it can be used in combination with any of other contact lens wearing solutions and eye drop solutions (i.e., a usage aspect in which it can be used as an eye drop medicine when using another contact lens wearing solution or used as another eye drop medicine when used as a contact lens wearing solution). Such usage does not exceed the usage described in the above Cited Documents 2 or 3.

Then, a person skilled in the art could easily conceive of using the ophthalmic composition of the Cited Invention as "an eye drop solution for wearing contact lenses "in the applications of both a contact lens wearing solution and an eye drop solution during wearing contact lenses without changing its composition."

Moreover, the effects obtained by the Invention cannot be said to be particularly unexpected.

Therefore, the Invention recited in Claim 1 of the application could be easily invented by a person ordinarily skilled in the art based on the inventions disclosed in Publications 1 to 3 and thus the Appellant should not be granted a patent under the provisions of Article 29(2) of the Patent Act.

4. Closing

As stated above, the application should be rejected without examining inventions disclosed in other claims because of the reasons stated above.

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

June 13, 2016

Chief administrative judge: OGUMA, Koji
Administrative judge: MATSUURA, Shinji
Administrative judge: SAITO, Mitsuko