Patent Right	Date	September 6, 2018	Court	Intellectual Property High Court, Third Division
	Case number	2017 (Gyo-Ke) 10210		
- A case in which, with regard to an invention titled "REFRESHING COMPOSITION FOR OPHTHALMOLOGY," the court affirmed conformance to the definiteness requirement because one can reasonably construe and infer what is indicated by the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" in the scope of the claims as of the filing date; weight average molecular weight, viscosity average molecular weight, number average molecular weight, etc., from the description of chondroitin sulfate or a salt thereof and the other polymeric compounds in the specification in view of the common technical knowledge of a person ordinarily skilled in the art.				

Case type: Rescission of Trial Decision of Invalidation

Result: Granted

References: Article 36, paragraph (6), item (ii) of the Patent Act

Number of related rights, etc.: Patent No. 5403850, Invalidation Trial No. 2015-800023 (The case), 2016 (Gyo-Ke) 10005 (First Judgment)

Summary of the Judgment

1 The case is a suit against trial decision that dismissed a request for the invalidation trial of a patent according to the invention titled "REFRESHING COMPOSITION FOR OPHTHALMOLOGY." The issue is whether or not there is a violation of the definiteness requirement.

2 The court decision rescinded the JPO decision in summary as follows.

The Corrected Descriptions lack description that clarifies what is indicated by the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of the description of 20,000 to 40,000" in the scope of the claims after the Correction as of the filing date; weight average molecular weight, viscosity average molecular weight, number average molecular weight, etc. Of course, in such a case, if one can reasonably construe the description of chondroitin sulfate or a salt thereof and the other polymeric compounds in the Corrected Descriptions and reasonably infer therefrom what the average molecular weight is in view of the common technical knowledge of a person ordinarily skilled in the art, one should construe in such a manner.

The Corrected Descriptions disclose that "chondroitin sulfate or a salt thereof used herein is a publicly-known polymeric compound with an average molecular weight of 5,000 to 500,000, more preferably 5,000 to 200,000, further preferably 5,000 to 100,000, particularly preferably 5,000 to 40,000. Such chondroitin sulfate or a salt thereof is commercially available. For example, sodium chondroitin sulfate available

from Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000) can be used." (paragraph [0021]).

Regarding the above "sodium chondroitin sulfate available from Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000)," in view of the fact that Seikagaku Corporation provided a numerical value of the weight average molecular weight with respect to the average molecular weight of sodium chondroitin sulfate available from the same company as of the filing date, and the numerical value publicly-known to a person ordinarily skilled in the art as an average molecular weight of sodium chondroitin sulfate available from the same company was a numerical value of the weight average molecular weight, the "average molecular weight" may be reasonably construed as meaning a weight average molecular weight. If so, it can be inferred that the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" in the scope of the claims after the Correction means a weight average molecular weight.

In addition, the average molecular weight of the other polymeric compound described in the paragraph preceding the above paragraph of the Corrected Descriptions can be reasonably construed as a weight average molecular weight, and it was a matter of common technical knowledge as of the filing date that the average molecular weight of polymeric compound was explicitly described by a weight average molecular weight in general. It can be said that these facts are also circumstances sufficient to support the above conclusion that the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" in the scope of the claims after the Correction means a weight average molecular weight.

Therefore, it is reasonable to find that the scope of the claims after the Correction conforms to the definiteness requirement.

Judgment rendered on September 6, 2018
2017 (Gyo-Ke) 10210 Case seeking rescission of JPO decision
Date of conclusion of oral argument: July 5, 2018

Judgment

Plaintiff: ROHTO Pharmaceutical Co., Ltd.
Defendant: Y

Main text

1 In a trial decision which Japan Patent Office had made on October 11, 2017 with regard to the case of Invalidation Trial No. 2015-800023, a part where the patent regarding the inventions according to Claims 1 to 6 of Patent No. 5403850 was invalidated should be rescinded.

2 The court costs shall be borne by the Defendant.

Facts and reasons

No. 1 Claims

The same as in the main text

No. 2 Outline of the case (Facts to be found from the evidences listed below and the entire import of the oral argument)

1 Development of procedures at the JPO

(1) Plaintiff filed a patent application entitled "REFRESHING COMPOSITION FOR OPHTHALMOLOGY" on June 7, 2005 (claiming priority benefit from June 8, 2004 (Japan)) (hereinafter, the filing date is "the filing date" and a priority date is "the priority date") and obtained on November 8, 2013 a registration of establishment of a paten right (Patent No. 5403850) (Number of claims: 6; hereinafter this patent is referred to as "the Patent." Exhibit Ko 85).

(2) Defendant requested for invalidating the patent with respect to all the claims of the Patent on February 5, 2015 with the Japan Patent Office, which request was assigned as the case of Invalidation Trial No. 2015-800023.

(3) JPO made a trial decision that dismissed a demand for trial on December 1, 2015 (hereinafter referred to as "First trial decision") and in response, Defendant filed a suit for seeking a rescission of the trial decision. The Intellectual Property High Court rendered a judgment on January 18, 2017 that the first trial decision should

be rescinded (hereinafter referred to as "first judgment") and the first judgment was made final and binding (Exhibit Ko 86).

(4) Plaintiff requested for correction of the Patent on September 4, 2017 (hereinafter referred to as "the Correction." Exhibit Ko 95).

(5) JPO accepted the Correction on October 11, 2017, and made a decision to the effect that the patents for the inventions according to Claims 1 to 6 should be invalidated (hereinafter referred to as "trial decision") and its certified copies were served for Plaintiff on October 19.

(6) Plaintiff filed a suit for the case seeking rescission of the trial decision on November 16, 2017.

2 The statement of the Claims

The statement of Claims 1 to 6 of the scope of the claims after the Correction is set forth as below (Exhibit Ko 95). The inventions according to Claims 1 to 6 are hereinafter referred to as "Corrected Invention 1," etc. according to the corresponding claim number. Further, the description after the Correction (Exhibit Ko 95) is referred to as "the Corrected Description," and the description before the Correction (Exhibit Ko 85) is referred to as "the description."

[Claim 1] A refreshing composition for ophthalmology comprising:

a) 0.01 w/v% or more to less than 0.1 w/v% compound selected from menthol, camphor, and borneol on a total weight basis;

b) 0.01 to 10 w/v% of at least one selected from potassium chloride, calcium chloride, sodium chloride, sodium hydrogen carbonate, sodium carbonate, magnesium sulfate, disodium hydrogen phosphate, sodium dihydrogen phosphate, and potassium dihydrogen phosphate; and

c) 0.001 to 10 w/v% chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000 to provide a cooling sensation when wearing a soft contact lens (except for one including a regional anesthetic).

[Claim 2] The refreshing composition for ophthalmology of Claim 1, further comprising 0.001 to 5 w/v% nonionic surfactant.

[Claim 3] The refreshing composition for ophthalmology of Claim 1 or 2, further comprising 0.0001 to 1 w/v% edetic acid or a salt thereof.

[Claim 4] The refreshing composition for ophthalmology of any one of Claims 1 to 3, further comprising 0.01 to 5 w/v% at least one selected from aminoethylsulfonate, glutamic acid, potassium aspartate, magnesium aspartate, sodium glutamate, glucose, and trehalose on a total weight basis.

[Claim 5] The refreshing composition for ophthalmology of any one of Claims 1 to 4 for ocular instillation or eye washing.
[Claim 6] A refreshing composition for ophthalmology comprising:
a) 0.01 w/v% or more to less than 0.1 w/v% compound selected from menthol, camphor, and borneol on a total weight basis;
b) 0.01 to 10 w/v% of at least one selected from potassium chloride, calcium chloride, sodium chloride, sodium hydrogen carbonate, sodium carbonate, magnesium sulfate, disodium hydrogen phosphate, sodium dihydrogen phosphate, and potassium dihydrogen phosphate; and
c) 0.001 to 10 w/v% chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000 for the use in constant users of a soft contact lens (except for one including a regional anesthetic).

3 Abstract of reasons of trial decision

The reason for trial decision is as per the attached written trial decision (copy). In summary, it accepted the Correction and determined that the scope of the claims did not conform to the requirement as provided in Article 36, paragraph (6), item (ii) of the Patent Act (hereinafter referred to as "definiteness requirement"), and thus the patent for the Corrected Inventions 1 to 6 should be invalidated because, even if one should reasonably construe from the common technical knowledge of a person ordinarily skilled in the art, it was indefinite as to what kind of average molecular weight was meant by "the average molecular weight" of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" of the scope of the claims after the Correction ([Claim 1] [Claim 6]).

4 Grounds for rescission

Errors in the finding and the determination of the definiteness requirement

(omitted)

No. 5 Judgment of this court

1 Each of the Corrected Inventions

(1) The scope of the claims after the Correction

The scope of the claims after the Correction is as described in the above No. 2-2.

(2) The statement of the Corrected Description

The Corrected Description generally has the following descriptions:

A Technical Field

The present invention relates to a refreshing composition for ophthalmology capable of providing a sufficient sensation of cooling when wearing a soft contact lens by application to the eyes when wearing a soft contact lens. (Paragraph [0001])

B Background Art

Freshener as represented by menthol is mixed in a refreshing composition for ophthalmology. In compounding a freshener, it is important to design formulation so that a comfort level of cooling sensation may be provided without involving an unpleasant stimulation. It is necessary to administer a high level of menthol sufficient to provide a proper level of cooling sensation even when it is subjected to sustained tear exchange; i.e., dilution and discharge due to tear fluid. However, an excessively high level of menthol involves unpleasant stimulation far beyond cooling sensation immediately after ocular instillation, and thus the amount of menthol to be mixed with a refreshing composition for ophthalmology is limited. (Paragraph [0002])

There are methods for improving the stimulation of menthol while maintaining sufficient cooling sensation without simply increasing a cooling agent such as menthol as seen above. However, these methods and eye washes are developed mainly for the purpose of exclusively providing cooling sensation to users who do not wear soft contact lens; i.e., users with unaided eye or users constantly using a hard contact lens. They do not take into account a problem caused particularly in wearing a soft contact lens at all. (Paragraph [0004])

Incidentally, there is the following particular problem in wearing a soft contact lens.

The cornea is a tissue rich in sensory nerves. Nerve density in the corneal epithelium is said to be about 300 to 600 times as high as in the skin. (Non-Patent Document 1). Therefore, the cooling sensation for users is affected by the extent of menthol contacting with the corneal surface. A diameter of hard contact lens is smaller than a corneal diameter, and corneal circumference is exposed even in wearing the hard contact lens, whereas a diameter of a soft contact lens is larger than the corneal diameter, and corneal surface is covered by the soft contact lens in wearing the soft contact lens. Therefore, users wearing a soft contact lens have particular difficulty in feeling cooling sensation as compared to the case of unaided eyes.

Further, the tear exchange rate of a rear surface of a lens (corneal side) to a part not covered with a lens (conjunctiva surface) drastically decreases in wearing a soft contact lens. In a hard contact lens, the tear exchange rate in the best fitting shows a

high value of 25.6 ±11.1 (%/min) comparable to the tear exchange rate in a lacrymal fluid meniscus of a healthy eye, whereas in a soft contact lens, even the tear exchange rate in the best fitting shows a low value of 16.5 ± 1.1 (%/min) (Non-Patent Document 2: Lens and Decrease in tear exchange rate). Therefore, the exchange of lacrymal fluid is significantly slow to have menthol reach a corneal central part via a lacrymal fluid layer located between a soft contact lens and the eye surface, which promotes the decrease in sensitivity to cooling sensation.
(Paragraph [0005])

So far, there has been known no refreshing composition for ophthalmology capable of providing a sufficient cooling sensation even when applying to eyes wearing a soft contact lens. Further, a method for promoting the tear exchange of a rear surface of a lens in wearing a soft contact lens is almost unknown. It has been extremely difficult to moderate stimulation while maintaining a necessary cooling sensation for a certain period in wearing a soft contact lens.

Furthermore, the formulation design is limited if it contains any component for which there is concern about an adverse effect (adsorption or deformation) on a soft contact lens, including a cooling agent such as menthol, an agent for local anesthetic action, a preservative such as tertiary ammonium such as benzalkonium chloride and a vaso-constricting drug such as tetrahydrozoline hydrochloride, naphazoline hydrochloride, or naphazoline nitrate. (Paragraph [0006])

C Problem to be solved by the invention

... The object of the present invention is to provide a refreshing composition capable of providing a sufficient cooling sensation even in wearing a soft contact lens. (Paragraph [0008])

D Means for solving the problem

The inventors have intensively investigated to solve the above problem and eventually found that a refreshing composition for ophthalmology comprising: a) 0.01 (w/v)% or more to less than 0.1 (w/v)% compound selected from menthol, camphor, and borneol on a total weight basis; b) inorganic salts; and c) at least one selected from hydroxyethyl cellulose with an average molecular weight of 200,000 to 2,500,000, methyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinylpyrolidone with an average molecular weight of 10,000 to 150,000, chondroitin sulfate or a salt thereof with an average molecular weight of 50,000 to 500,000, hydroxypropylmethyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinyl alcohol with an average molecular weight of 10,000 to 300,000 may provide a sufficient cooling sensation without involving stimulation even when

applied to an eye wearing a soft contact lens, and have completed the present invention. (Paragraph [0009])

The present invention has been made on the basis of this finding.

Specifically, the present invention is a refreshing composition for ophthalmology listed in the following (1) to (12).

(1) A refreshing composition for ophthalmology for providing a cooling sensation in wearing a soft contact lens, the composition comprising: a) 0.01 w/v% or more to less than 0.1 w/v% compound selected from menthol, camphor, and borneol on a total weight basis; b) inorganic salts; and c) at least one selected from hydroxyethyl cellulose with an average molecular weight of 200,000 to 2,500,000, methyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinylpyrolidone with an average molecular weight of 10,000 to 150,000, hydroxypropylmethyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinyl alcohol with an average molecular weight of 10,000 to 300,000, and chondroitin sulfate or a salt thereof with an average molecular weight of 5,000 to 500,000,

(2) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% hydroxyethyl cellulose with an average molecular weight of 200,000 to 2,500,000,

(3) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% methyl cellulose with an average molecular weight of 50,000 to 500,000,

(4) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% polyvinylpyrolidone with an average molecular weight of 10,000 to 150,000,

(5) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% hydroxypropylmethyl cellulose with an average molecular weight of 50,000 to 500,000,

(6) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% polyvinyl alcohol with an average molecular weight of 10,000 to 300,000,

(7) The refreshing composition for ophthalmology of (1), comprising 0.001 to 10 w/v% chondroitin sulfate or a salt thereof with an average molecular weight of 5,000 to 500,000,

(8) The refreshing composition for ophthalmology of any of (1) to (7), further comprising 0.001 to 5 w/v% nonionic surfactant.

(9) The refreshing composition for ophthalmology of any of (1) to (8), further comprising 0.0001 to 1 w/v% edetic acid or a salt thereof,

(10) The refreshing composition for ophthalmology of any one of (1) to (9), further

comprising 0.01 to 5 w/v% of at least one selected from aminoethylsulfonate, glutamic acid, potassium aspartate, magnesium aspartate, sodium glutamate, glucose, and trehalose on a total weight basis,

(11) The refreshing composition for ophthalmology of any one of (1) to (10) for ocular instillation or eye washing,

(12) A refreshing composition for ophthalmology for constant users of soft contact lens, the composition comprising: a) 0.01 w/v% or more to less than 0.1 w/v% compound selected from menthol, camphor, and borneol on a total weight basis; b) inorganic salts; and c) at least one selected from hydroxyethyl cellulose with an average molecular weight of 200,000 to 2,500,000, methyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinylpyrolidone with an average molecular weight of 10,000 to 150,000, hydroxypropylmethyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinyl alcohol with an average molecular weight of 10,000 to 300,000, and chondroitin sulfate or a salt thereof with an average molecular weight of 5,000 to 500,000,

Note that % in the description means w/v% unless otherwise specified. (Paragraph [0010])

E Effects of the Invention

The refreshing composition for ophthalmology of the present invention ... can provide a refreshing composition for ophthalmology for providing a cooling sensation in wearing a soft contact lens.

... The refreshing composition for ophthalmology of the present invention can provide an enough cooling sensation immediately after applying the composition to the eyes with moderate stimulation, and thus can provide a refreshing composition for ophthalmology for providing constant users for soft contact lens with a pleasant cooling sensation. Furthermore, the present invention can provide a sufficient cooling sensation by use of a small amount of menthol, and provide a safe refreshing composition for ophthalmology with no stimulation.

Furthermore, the refreshing composition for ophthalmology of the present invention may provide a cooling sensation without any stimulation of a cooling agent, and thus it can be used as a refreshing composition for ophthalmology for constant users of soft contact lens who have a damaged eye due to wearing of soft contact lens to provide a cooling sensation not only with an eye wearing a soft contact lens but also with an eye after taking off the soft contact lens. (Paragraph [0011])

F Best Mode for Carrying Out the Invention

The refreshing composition for ophthalmology of the present invention

comprises 0.01% or more to less than 0.1% of one or two or more compounds selected from menthol, camphor, and borneol on a total weight basis. ... (Paragraph [0012])

The refreshing composition for ophthalmology of the present invention comprises inorganic salts as an essential component. Such inorganic salts preferably include ... potassium chloride, calcium chloride, sodium chloride, sodium hydrogen carbonate, sodium carbonate, magnesium sulfate, disodium hydrogen phosphate, sodium dihydrogen phosphate, and potassium dihydrogen phosphate, and potassium chloride and sodium chloride are particularly preferable. (Paragraph [0013])

These inorganic salts may be used solely or in combination in the refreshing composition for ophthalmology of the present invention. The content is preferably 0.01 to 10% ... or so as a total amount of inorganic salts. If inorganic salts content is less than 0.01%, it is difficult to feel sufficient cooling sensation immediately after applying the composition to an eye. If they are 10 (w/v)% or more, it tends to cause excessive cooling sensation immediately after applying the composition to an eye, and may cause stimulation for some users. (Paragraph [0014])

The refreshing composition for ophthalmology of the present invention comprises a combination of specific polymers with specific molecular weight as an essential constituent. Specifically, the present invention comprises at least one selected from hydroxyethyl cellulose with an average molecular weight of 200,000 to 2,500,000, methyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinylpyrolidone with an average molecular weight of 10,000 to 150,000, hydroxypropylmethyl cellulose with an average molecular weight of 50,000 to 500,000, polyvinyl alcohol with an average molecular weight of 10,000 to 300,000, and chondroitin sulfate or a salt thereof with an average molecular weight of 5,000 to 500,000. (Paragraph [0015])

Hydroxyethyl cellulose used herein is a publicly-known polymeric compound with an average molecular weight of 200,000 to 2,500,000, more preferably 500,000 to 2,000,000, particularly preferably 800,000 to 1,500,000. Such hydroxyethyl cellulose is commercially available, and includes, for example, HEC-CF-G (average molecular weight of about 400,000), HEC-CF-H (average molecular weight of about 700,000), HEC-CF-V (average molecular weight of about 1,000,000), HEC-CF-W (average molecular weight of about 1,300,000), HEC-CF-X (average molecular weight of about 1,500,000), and HEC-CF-Y (average molecular weight of about 1,800,000), all of which are sold by Sumitomo Seika Chemicals Company, Limited. (Paragraph [0016])

Methyl cellulose used herein is a publicly-known polymeric compound with an average molecular weight of 50,000 to 500,000. Further preferably the average

molecular weight is 100,000 to 500,000, and particularly preferably 200,000 to 500,000. Such methyl cellulose is commercially available, and includes, for example, SM-15 (average molecular weight of about 70,000), SM-25 (average molecular weight of about 90,000), SM-50 (average molecular weight of about 110,000), SM-100 (average molecular weight of about 120,000), SM-400 (average molecular weight of about 170,000), SM-1500 (average molecular weight of about 290,000), and SM-4000 (average molecular weight of about 360,000), all of which are sold by Shin-Etsu Chemical Co., Ltd. as Metolose SM series. (Paragraph [0017])

Polyvinylpyrolidone used herein is a publicly-known polymeric compound with an average molecular weight of 10,000 to 150,000. Further preferably the average molecular weight is 20,000 to 150,000. Such polyvinylpyrolidone is commercially available. It includes, for example, Colidone 25 (average molecular weight of about 30,000), Colidone 30 (average molecular weight of about 50,000), Colidone 17PF (average molecular weight of about 90,000), and Colidone 90 (average molecular weight of about 120,000) etc., all of which are sold by BASF as Colidone Series. ... (Paragraph [0018])

Hydroxypropylmethyl cellulose used herein is a publicly-known polymeric compound with an average molecular weight of 50,000 to 500,000. Further preferably the average molecular weight is 100,000 to 500,000, and particularly preferably 200,000 to 500,000. Such hydroxyethyl cellulose is commercially available, and it includes, for example, 60SH-15 (average molecular weight of about 70,000), 60SH-25 (average molecular weight of about 90,000), 60SH-50 (average molecular weight of about 110,000), 60SH-100 (average molecular weight of about 120,000), 60SH-400 (average molecular weight of about 170,000), 60SH-1500 (average molecular weight of about 290,000), and 60SH-4000 (average molecular weight of about 360,000), all of which are sold by Shin-Etsu Chemical Co., Ltd. (Paragraph [0019])

Polyvinyl alcohol used herein is a publicly-known polymeric compound with an average molecular weight of 10,000 to 300,000. Further preferably the average molecular weight is 20,000 to 200,000, and particularly preferably 20,000 to 150,000. Such polyvinyl alcohol is commercially available. It includes, for example, Gohsenol EG05 (average molecular weight of about 30,000) and Gohsenol EG40 (average molecular weight of about 120,000), both of which are sold by The Nippon Synthetic Chemical Industry Co., Ltd. as Gohsenol Series. ... (Paragraph [0020])

Chondroitin sulfate or a salt thereof used herein is a publicly-known polymeric compound with an average molecular weight of 5,000 to 500,000, more preferably

5,000 to 200,000, further preferably 5,000 to 100,000, particularly preferably 5,000 to 40,000. Such chondroitin sulfate or a salt thereof is commercially available. For example, sodium chondroitin sulfate sold by Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000) can be used.

The content of chondroitin sulfate or a salt thereof in a refreshing composition for ophthalmology of the present invention is preferably 0.001 to 10%, more preferably 0.01 to 5%, particularly preferably 0.05 to 3%. (Paragraph [0021])

G Examples

[Table 6]

(Unit: g/100ml)

	Comparative Example 1	Comparative Example 11	Comparative Example 4	Example 19	Example 20	Example 21
1-menthol	0.005	0.003	0.020	0.020	0.020	0.020
d-camphor	0.003	0.001	0.005	0.005	0.005	0.005
d-borneol	0.002	0.001	0.010	0.010	0.010	0.010
Sodium chloride	-	0.5	0.5	0.5	0.5	0.5
Sodium chondroitin sulfate Average molecular weight of about 10,000	-	-	-	0.5	-	0.1
Sodium chondroitin sulfate Average molecular weight of about 20,000	-	0.5	-	-	0.5	0.2
Sodium edetate	0.005	0.005	0.005	0.005	0.005	0.005
Polysolvate 80	0.1	0.1	0.1	0.1	0.1	0.1
Sodium hydroxide / Hydrochloric acid	moderate amount	moderate amount	moderate amount	moderate amount	moderate amount	moderate amount
Purified water	moderate amount	moderate amount	moderate amount	moderate amount	moderate amount	moderate amount
pH	7.4	7.4	7.4	7.4	7.4	7.4
Unaide Cooling	×	Δ	○	◎	◎	◎

d eye (right after taking off SCL)	sensation immediately after ocular instillation						
	Stimulation immediately after ocular instillation	×	Δ	○	○	○	◎
SCL worn	Cooling sensation immediately after ocular instillation	×	×	×	◎	◎	◎
	Stimulation immediately after ocular instillation	◎	◎	◎	○	◎	◎

(Paragraph [0055])

As a result of the tests, the examples of the present invention comprising a combination of sodium chondroitin sulfate (average molecular weight: about 10,000) or/and sodium chondroitin sulfate (average molecular weight: about 20,000) achieved sufficient cooling sensation immediately after applying the composition to an eye, and thus demonstrated a high level of safety without stimulation. Further, it is known that the constant use of a soft contact lens causes the reduction of lacrymal fluid and disorder on the corneal surface. In particular, immediately after taking off a soft contact lens, the eyes are extremely sensitive to the cooling sensation of menthol, etc. It is confirmed that the composition can provide this extremely sensitive eye with a sufficient cooling sensation without involving stimulation. (Paragraph [0056])

2 Grounds for rescission (Errors in the finding and the determination of the definiteness requirement)

(1) Definiteness requirement

Article 36, paragraph (6), item (ii) of the Patent Act specifies that the statement of the claims should comply with the requirement that an invention for which a patent is sought should be definite. The spirit of this provision is to prevent such an inconvenient result that might unjustly impair a third party's benefit, which includes the loss of predictability as to what extent a right holder has an exclusive right due to an indefinite technical scope of an invention for which a patent is granted if the invention recited in the scope of the claims is indefinite. Further, whether or not an invention for which a patent is sought is definite should be determined from the viewpoint of whether or not the statement of the Claims is indefinite to the extent that might unreasonably harm a third party's benefit by taking into account the statement of the Claims as well as the description of the description and drawings attached to the application on the basis of the common technical knowledge as of the filing.

(2) Meaning of "average molecular weight"

A The concept of "average molecular weight" is not unambiguous, but is categorized into "weight average molecular weight," "number average molecular weight," "viscosity average molecular weight," etc. depending on the difference of measurement method, etc. Further, even the same polymeric compound does not necessarily have the same numerical values of weight average molecular weight, number average molecular weight, viscosity average molecular weight, etc., which may have different values. (Exhibits Ko 17, 27)

B The scope of the claims after the Correction and the Corrected Description only specify "average molecular weight" for chondroitin sulfate or a salt thereof, and they do not clarify what is meant by the "average molecular weight," weight average molecular weight, average molecular weight, viscosity number average molecular weight, etc.

Of course, each numerical value of average molecular weight for each product of each company is described as a weight average molecular weight for the other polymeric compounds described in the Corrected Description, including, for example, methyl cellulose (Paragraph [0017]), polyvinylpyrolidone (Paragraph [0018]), hydroxypropylmethyl cellulose (Paragraph [0019]), and polyvinyl alcohol (Paragraph [0020]). Each numerical value of this weight average molecular weight was publicly known (Exhibits Ko 61 to 64, 67). Therefore, it is inferred that a person ordinarily skilled in the art would construe the average molecular weights of these polymeric

compounds as the weight average molecular weights as of the filing date.

C According to the following facts, it is recognized that the average molecular weight of polymeric compound had been explicitly described with the weight average molecular weight in general as of the filing date.

(A) Japanese Unexamined Patent Application Publication No. 1998-139666 (Exhibit Ko 58, paragraph [0027]) with an Applicant of Sawai Pharmaceutical Co., Ltd. explicitly describes the "average molecular weight" of polyvinylpyrolidone (povidone) as "weight average molecular weight."

(B) Japanese Unexamined Patent Application Publication No. 2001-187731 (Exhibit Ko 61, paragraphs [0006] and [0007]) with an Applicant of Lion Corporation explicitly describes "average molecular weight" of hydroxyethyl cellulose, methyl cellulose, polyvinylpyrolidone, hydroxypropylmethyl cellulose, and polyvinylalochol as "weight average molecular weight."

(C) Japanese Unexamined Patent Application Publication No. 2002-154989 (Exhibit Ko 62, paragraph [0014]) with an Applicant of Lion Corporation explicitly describes the "average molecular weight" of cellullose-based polymeric compound as "weight average molecular weight."

(D) Japanese Unexamined Patent Application Publication No. 2001-125052 (Exhibit Ko 63, paragraph [0009]) with an Applicant of Lion Corporation explicitly describes the "average molecular weight" of polyvinyl-based polymeric compound and cellulose-based polymeric compound as "weight average molecular weight."

(E) Japanese Unexamined Patent Application Publication No. 2003-201241 (Exhibit Ko 64, paragraph [0016]) with an Applicant of ROHTO Pharmaceutical Co., Ltd. explicitly describes the "average molecular weight" of cellulose derivatives as "weight average molecular weight."

(F) Japanese Unexamined Patent Application Publication No. 2002-345929 (Exhibit Ko 65, [Claims]) with an Applicant of Senju Pharmaceutical Co. ,Ltd. explicitly describes the "average molecular weight" of cation polymer with a specific structure as "weight average molecular weight."

(G) Japanese Unexamined Patent Application Publication No. 2002-20320 (Exhibit Ko 66, paragraph [0009]) with an Applicant of Santen Pharmaceutical Co., Ltd. explicitly describes the "average molecular weight" of a polymer of a basic amino acid as "weight average molecular weight."

(H) The catalog titled "Pharmaceutical additive Metolose" prepared by Shin-Etsu Chemical Co., Ltd. (August 1994) (Exhibit Ko 67, page 6)

describes the "average molecular weight" of Metolose (hydroxypropylmethyl cellulose methyl cellulose) as "weight average molecular weight."

(I) Japanese Unexamined Patent Application Publication No. 2002-3384 (Exhibit Ko 60, paragraph [0017]), Japanese Unexamined Patent Application Publication No. 2003-252906 (Exhibit Ko 82, paragraph [0019]), and Japanese Unexamined Patent Application Publication No. 2004-210714 (Exhibit Ko 83, paragraph [0023]) with an Applicant of Seikagaku Corporation disclose that the "average molecular weight" of polysaccharides is generally represented by "weight average molecular weight."

(3) Chondroitin sulfate or a salt thereof

A Two companies of Maruha Corporation and Seikagaku Corporation had occupied the market for the manufacture and the sales of chondroitin sulfate or a salt thereof as of the filing date. (Exhibits Ko 11, 12)

B Sodium chondroitin sulfate produced by Seikagaku Corporation

(A) Prior to 2004, Seikagaku Corporation had usually provided a numerical value of weight average molecular weight when a user inquired about the average molecular weight of sodium chondroitin sulfate product (Exhibit Ko 100). It had also provided a numerical value of weight average molecular weight for the products with an average molecular weight of about 10,000, 20,000, and 40,000. According to this, it was a numerical value of weight average molecular weight that had been provided by Seikagaku Corporation as an average molecular weight of sodium chondroitin sulfate. It is also recognized that a numerical value publicly known to a person ordinarily skilled in the art was a numerical value of weight average molecular weight.

(B) Further, the patent publications with an Applicant of Seikagaku Corporation have the following description.

a Japanese Unexamined Patent Application Publication No. 1997-202731 (Exhibit Ko 59, paragraphs [0026] and [0045]) discloses that the "average molecular weight" of sulfated polysaccharides is preferably "weight average molecular weight," and describes the use of chondroitin sulfate from Seikagaku Corporation ("average molecular weight" of 10,000).

b International publication No. 01/12675 (Exhibit Ko 70, page 8, lines 13 to 19, page 9, lines 2 to 11) discloses that the "weight average molecular weight" of GAG (glycosaminoglycan or a salt thereof) is represented by "molecular weight" in the publication, and describes the use of chondroitin sulfate and sodium chondroitin sulfate with a specific "molecular weight" from Seikagaku Corporation for GAG.

c Japanese Unexamined Patent Application Publication No. 2003-160498 (Exhibit Ko 71; hereinafter referred to as "Exhibit Ko 71 publication" Paragraphs [0010] and [0042]) discloses that the "molecular weight" of glycosaminoglycan comprising chondroitin sulfate usually means "average molecular weight," and generally denotes "weight average molecular weight calculated from limiting viscosity," and describes the use of chondroitin sulfate with a specific "weight average molecular weight" from Seikagaku Corporation.

d Japanese Unexamined Patent Application Publication No. 2003-335801 (Exhibit Ko 73, hereinafter referred to as "Exhibit Ko 73 publication" Paragraphs [0008], [0024], and [0027] to [0029]) discloses that the "molecular weight" of glycosaminoglycan usually means "average molecular weight," and generally denotes "weight average molecular weight calculated from limiting viscosity," and describes the use of chondroitin sulfate and sodium chondroitin sulfate with a specific "average molecular weight" from Seikagaku Corporation.

e Japanese Unexamined Patent Application Publication No. 2000-65837 (Exhibit Ko 72, paragraph [0038]), International Publication No. 2004/081054 (International Publication Date: September 23, 2004) (Exhibit Ko 76, page 13, lines 11 to 12, page 17, lines 12 to 13), and Japanese Unexamined Patent Application Publication No. 2004-361144 (Exhibit Ko 77, paragraph [0062]) describe the use of chondroitin sulfate with a specific "weight average molecular weight" produced by Seikagaku Corporation.

C Sodium chondroitin sulfate produced by Maruha Corporation

(A) Around 2003 to 2004, Maruha Corporation measured the average molecular weight of sodium chondroitin sulfate (Lot. PUC-822, 829, 844, 845, 849, 850, and 855) all by viscosity average molecular weights, and sold them. No one was calculated by another measurement method. Further, the viscosity average molecular weight of each of the above products was 6,000 to 10,000. (Exhibit Ko 2)

(B) Maruha Corporation had usually provided a numerical value of viscosity average molecular weight in the past when a user had inquired about the average molecular weight of sodium chondroitin sulfate product (Exhibit Ko 43), and it is inferred that the user is encompassed into a person ordinarily skilled in the art. Thus, it is recognized that a numerical value publicly known to a person ordinarily skilled in the art as an average molecular weight of sodium chondroitin sulfate from Maruha Corporation as of the filing date was a numerical value of viscosity average molecular weight.

(4) Taking the above into account, the definiteness of the scope of the claims after the Correction is determined.

A The Corrected Description lacks description that clarifies what is indicated by the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of the description of 20,000 to 40,000" in the scope of the claims after the Correction as of the filing date, weight average molecular weight, viscosity average molecular weight, number average molecular weight, etc. Of course, in such a case, if one can reasonably construe the description of chondroitin sulfate or a salt thereof and the other polymeric compounds in the Corrected Descriptions and reasonably infer therefrom what the average molecular weight is in view of the common technical knowledge of a person ordinarily skilled in the art, one should construe in such a manner.

B As is discussed in the above item 1(2)F, the Corrected Description discloses that "chondroitin sulfate or a salt thereof used herein is a publicly-known polymeric compound with an average molecular weight of 5,000 to 500,000, more preferably 5,000 to 200,000, further preferably 5,000 to 100,000, particularly preferably 5,000 to 40,000. Such chondroitin sulfate or a salt thereof is commercially available. For example, sodium chondroitin sulfate available from Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000) can be used." (Paragraph [0021]).

Regarding the above "sodium chondroitin sulfate available from Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000)," in view of the fact that Seikagaku Corporation provided a numerical value of the weight average molecular weight with respect to the average molecular weight of sodium chondroitin sulfate available from the same company as of the filing date, and the numerical value publicly-known to a person ordinarily skilled in the art as an average molecular weight of sodium chondroitin sulfate available from the same company was a numerical value of the weight average molecular weight (the above item (3)B(A)), the "average molecular weight" may be reasonably construed as meaning a weight average molecular weight. If so, it can be inferred that the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" in the scope of the claims after the Correction means a weight average molecular weight. In addition, the average molecular weight of the other polymeric compound described in the paragraph preceding the above paragraph of the Corrected Descriptions can be reasonably construed as a weight average molecular weight (the above item (2)B), and it was a matter of common technical knowledge as of the filing

date that the average molecular weight of polymeric compound was explicitly described by a weight average molecular weight in general (The above item (2)C). It can be said that these facts are also circumstances sufficient to support the above conclusion that the average molecular weight of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" in the scope of the claims after the Correction means a weight average molecular weight.

C Therefore, it is reasonable to find that the scope of the claims after the Correction conforms to the definiteness requirement.

(5) Defendant's allegation

A Defendant argues that, even if a person ordinarily skilled in the art would understand that the average molecular weight of the other polymeric compounds described in the Corrected Description is shown as the weight average molecular weight, the Corrected Description lacks description of specific product name of sodium chondroitin sulfate, and thus it fails to specify what kind of average molecular weight the average molecular weight is for sodium chondroitin sulfate.

As seen in the above item (4)B, however, if one should reasonably construe the description of chondroitin sulfate or a salt thereof and the other polymeric compounds of the Corrected Description in view of the common technical knowledge of a person ordinarily skilled in the art without the description of specific product name of sodium chondroitin sulfate in the Corrected Descriptions, one should reasonably infer therefrom what kind of average molecular weight the average molecular weight of chondroitin sulfate or a salt thereof is. Thus, Defendant's allegation is not acceptable.

B Regarding sodium chondroitin sulfate produced by Seikagaku Corporation, Defendant argues that it was not ascertained as to what kind of average molecular weight the average molecular weight of sodium chondroitin sulfate produced by Seikagaku Corporation was. None of the reasons on which the Defendant relies is acceptable as set forth below:

(A) Defendant argues that "weight average molecular weight calculated from limiting viscosity" of Exhibit Ko 71 publication and Exhibit Ko 73 publication with an Applicant of Seikagaku Corporation means viscosity average molecular weight, and it was thus possible that Seikagaku Corporation might not distinguish weight average molecular weight from viscosity average molecular weight, and the numerical values Seikagaku Corporation alleged as weight average molecular weight might possibly include viscosity average molecular weight. However, the method of obtaining a relation expression of the weight average molecular weight and the intrinsic viscosity (the Court decision's note: the same meaning as the limiting

viscosity) and calculating a weight average molecular weight from this relation expression and the intrinsic viscosity of the measured sample was a matter of common technical knowledge as of the filing date (Exhibits Ko 101 to 103, 105). Thus, without doubt the "weight average molecular weight calculated from limiting viscosity" of Exhibit Ko 71 publication and Exhibit Ko 73 publication shows the weight average molecular weight.

In this regard, Defendant argues that each document of the above Exhibits Ko 101 to 103 describes a calculation method of viscosity average molecular weight, but each of the above documents explicitly describes the calculation of weight average molecular weight (mass average molecular weight is construed as having the same meaning). Further, the constant in the correlation between intrinsic viscosity and weight average molecular weight is not equal to the constant in the correlation between intrinsic viscosity and viscosity average molecular weight (Exhibit Ko 105), and thus it cannot be seen that the calculation method described in each of the above documents is a calculation method of viscosity average molecular weight.

(B) Defendant argues that it can be seen from the description of terminal group quantification (method) of Exhibit Otsu 1 Article cited by the catalog and the Kagaku Daijiten (Exhibit Otsu 2) that the "molecular weight" of the catalog is a number average molecular weight, and that Seikagaku Corporation had represented the average molecular weight of sodium chondroitin sulfate with number average molecular weight. However, Exhibit Otsu 1 Article only describes the separation and the quantification of aldose. It is silent about the quantification of the terminal group of polysaccharides sample. Therefore, it is difficult to construe the molecular weight of the catalog as number average molecular weight from Exhibit Otsu 1 Article. Rather, the preparer of the catalog of Seikagaku Corporation replied that the molecular weight of the catalog was a numerical value on the basis of weight average molecular weight (Exhibit Ko 84). There is no reason to find that this is false or incorrect. Therefore, the Defendant's allegation of the numerical value of "molecular weight" of the catalog being a number average molecular weight is not acceptable.

(C) Defendant argues that Exhibit Ko 71 publication, Exhibit Ko 73 publication, and domestic re-publication of PCT international publication No. WO2006/068146 (priority date: December 20, 2004, International Publication Date: June 29, 2006) (Exhibit Otsu 4) with an Applicant of Seikagaku Corporation describe molecular weight other than weight average molecular weight, and thus it cannot be said that the average molecular weight of sodium chondroitin sulfate produced by Seikagaku Corporation is a weight average molecular weight. However, Exhibit Ko

71 publication and Exhibit Ko 73 publication describe a weight average molecular weight of chondroitin sulfate or sodium chondroitin sulfate, as is found in the above item (A). Further, the above domestic re-publication of PCT international publication for patent application relates to an invention of a fraction or a method for producing the same of chondroitin sulfate or a salt thereof whose molecular weight has been lowered by a degrading enzyme. It does not refer to sodium chondroitin sulfate from Seikagaku Corporation. Thus, this description does not affect the meaning of average molecular weight of sodium chondroitin sulfate from this company. Further, the description of average molecular weight of sodium chondroitin sulfate from Seikagaku Corporation in the publication of unexamined patent applications, etc. with an Applicant of the same company should be construed as the description of average molecular weight of sodium chondroitin sulfate sold by the same company. The fact that the company describes chondroitin sulfate or a salt thereof of the same company as a weight average molecular weight in the publication of unexamined patent applications (the above item (3)B(C)) is consistent with the fact that the company had provided average molecular weight of sodium chondroitin sulfate with a weight average molecular weight (the above (3)B(A)).

(D) Defendant argues that it is a document by a person other than Seikagaku Corporation that properly shows the recognition of a person ordinarily skilled in the art with respect to the products sold by Seikagaku Corporation, and Japanese Unexamined Patent Application Publication No. 2000-191534 with an Applicant of Otsuka Pharmaceutical Co., Ltd. (Exhibit Ko 30) and Japanese Unexamined Patent Application Publication No. 1994-128289 (Exhibit Ko 31) with an Applicant of FUJIFILM Corporation uses viscosity average molecular weight and number average molecular weight for sodium chondroitin sulfate of the same company. However, in each of the above publications, the average molecular weights of sodium chondroitin sulfate and the other polymeric compounds referred in each of the publications are shown by viscosity average molecular weight or number average molecular weight for each publication in a unified manner. Thus, it can be seen that the inventor measured and described an average molecular weight according to the purpose of the use in the publications. Therefore, these descriptions do not affect the finding (the above item (3)B(A)) that Seikagaku Corporation provided a numerical value of weight average molecular weight for an average molecular weight of sodium chondroitin sulfate that had been provided by Seikagaku Corporation as of the filing date, and numerical values publicly known to a person ordinarily skilled in the art were also numerical values of weight average molecular weight.

(E) Defendant argues that the catalog of Seikagaku Corporation only refers to the "molecular weight," and it is thus inferred that the company sold products without the description of the average molecular weight of sodium chondroitin sulfate, and it was not unambiguously ascertained as to what kind of average molecular weight the average molecular weight of sodium chondroitin sulfate produced by Seikagaku Corporation was.

As is discussed in the above item (3)B(A), however, Seikagaku Corporation provided numerical values of weight average molecular weight when a user had inquired about the average molecular weight of sodium chondroitin sulfate product, and if product only describes molecular weight, it does not affect the finding of what kind of average molecular weight the average molecular weight of sodium chondroitin sulfate of the company is.

C Defendant argues that the market of sodium chondroitin sulfate was occupied by Seikagaku Corporation and Maruha Corporation, and the numerical value publicly known to a person ordinarily skilled in the art as an average molecular weight of sodium chondroitin sulfate of Maruha Corporation is a viscosity average molecular weight, and thus a person ordinarily skilled in the art could not determine that the average molecular weight in the context of "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" of the scope of the claims after the Correction was not a viscosity average molecular weight. However, the Corrected Description does not refer to sodium chondroitin sulfate from Maruha Corporation, nor provide description suggesting that the average molecular weight of chondroitin sulfate or a salt thereof means viscosity average molecular weight. Therefore, as seen in the above item (4)B, a person ordinarily skilled in the art should reasonably construe the description of chondroitin sulfate or a salt thereof and the other polymeric compounds of the Corrected Descriptions in view of the common technical knowledge, and should reasonably infer therefrom that the average molecular weight of chondroitin sulfate or a salt thereof was a weight average molecular weight.

Defendant argues that it is a substantial change of the scope of the claims to affirm the sufficiency of definiteness requirement by the Correction to delete the description of product manufactured by Maruha Corporation, and thus it is not reasonable. It can be seen from the description of "such chondroitin sulfate or a salt thereof is commercially available. For example, sodium chondroitin sulfate sold by Seikagaku Corporation (average molecular weight: about 10,000, average molecular weight: about 20,000, average molecular weight: about 40,000) and sodium chondroitin sulfate sold by Maruha Corporation (average molecular weight: about

7,000, etc.), etc. can be used." in the description (Paragraph [0021]) that the Correction includes: (1) the correction to exclude "and sodium chondroitin sulfate sold by Maruha Corporation (average molecular weight: about 7,000, etc.), etc." (Correction 5); and (2) the correction to replace "chondroitin sulfate or a salt thereof with an average molecular weight of 5,000 to 40,000" of Claims 1 and 6 with "chondroitin sulfate or a salt thereof with an average molecular weight of 20,000 to 40,000" (Corrections 1 and 3) (Exhibit Ko 95). It cannot be said that this substantially changes the scope of claims. Thus the Defendant's argument is not acceptable.

D Defendant argues that Japanese Unexamined Patent Application Publication No. 2006-129796 with an Applicant of Denki Kagaku Kogyo Kabushiki Kaisha (Exhibit Otsu 5) and its self-published document of the conference proceedings (Exhibit Otsu 7. May 1, 2004) describe a number average molecular weight of chondroitin sulfate, and thus a person ordinarily skilled in the art had used an average molecular weight of chondroitin sulfate ambiguously. However, the above description only describes an analysis result of number average molecular weight of sodium chondroitin sulfate synthesized by an enzymatic chemical method (Exhibit Otsu 5, [Claim 1] to [Claim 5], paragraphs [0007] and [0009] and Exhibit Otsu 7). It is not the description of chondroitin sulfate commonly practiced as a raw material of pharmaceutical product, etc. Therefore, it cannot be seen from this description as a matter of common technical knowledge of a person ordinarily skilled in the art about the meaning of general average molecular weight of chondroitin sulfate. Therefore, the Defendant's argument is not acceptable.

(6) Summary

As seen above, it is reasonable to find that the scope of the claims after the Correction conforms to the definiteness requirement, and thus the trial decision contains illegality to be rescinded, and thus the reason for rescission presented by Plaintiff has a point.

3. Conclusion

Therefore, the Plaintiff's claim has a point and thus shall be accepted, and the court sentences as in the formal adjudication.

Intellectual Property High Court, Third Division

Presiding Judge: TSURUOKA Toshihiko

Judge: TAKAHASHI Aya

Judge: TERADA Toshihiko