Date	July 15, 2010	Court	Intellectual Property High Court, Third Division
Case number	2009 (Gyo-Ke) 10238		
A case in which the court rescinded the trial decision of the Japan Patent Office (JPO) on the grounds that there was an error in the JPO decision ruling that: (i) the experimental results submitted during the trial proceedings should not be taken into consideration; and (ii) even by taking said experimental results into consideration, the claimed invention cannot be found to achieve an unexpected, remarkable effect			

References:
Article 29, paragraph (2) of the Patent Act

The court rescinded the trial decision of the Japan Patent Office (JPO), holding as follows.

(1) In the context of the determination as to whether or not the plaintiff's claimed invention could have been easily conceived of, the description originally attached to the plaintiff's application can be understood as explaining the effect of the claimed invention that can be achieved by designating "2-Phenylbenzimidazole-5-sulfonic acid" as "UV-B filter." Accordingly, this case should be judged as a case where it is allowable to take into consideration the experimental results presented as Reference 1 in the supplementary statement of the reasons for the request for a trial, submitted by the plaintiff in the trial proceedings. Therefore, there is an error in the JPO decision ruling, to the contrary, that said experimental results should not be taken into consideration.

(2) By taking said experimental results into consideration, the claimed invention can be found to achieve a particularly unexpected, remarkable effect that a person ordinarily skilled in the art could not have expected as compared with the cited invention, and it is deemed that the claimed invention could not have easily been conceived of by referring to the cited invention. Consequently, there is an error in the JPO decision ruling that the claimed invention could not achieve any unexpected, remarkable effect but could have been easily conceived by referring to the cited invention.

Judgment rendered on July 15, 2010

2009 (Gyo-Ke) 10238, Case of Seeking Rescission of a JPO Decision

Date of conclusion of oral argument: May 27, 2010

Judgment

Plaintiff: *The Procter & Gamble Company*

Counsel patent attorney: SOGA Michiharu

Same as above: FURUKAWA Hidetoshi

Same as above: SUZUKI Norikazu

Same as above: KAJINAMI Jun

Same as above: OYA Kazuhiro

Same as above: Iino Satoshi

Defendant: Commissioner of the Japan Patent Office

Designated representative: ITO Koji

Same as above: HOSHINO Shoei

Same as above: NAKATA Toshiko

Same as above: KOBAYASHI Kazuo

Main Text

1. The JPO decision rendered regarding Trial against Examiner's Decision of Refusal No. 2007-5283 on March 31, 2009, shall be rescinded.

2. The defendant shall bear the court costs.

Facts and reasons

No. 1 Claims

The same as the main text of this judgment.

No. 2 Facts undisputed by the parties

1. Progress of procedures at the JPO

On July 29, 1999, the plaintiff filed an international patent application (the "Application"; priority claim: July 30, 1998 (priority date); United States (priority country)) in relation to an invention titled "sunscreen composition." However, the plaintiff received an examiner's decision of refusal on November 15, 2006, and filed a request for a trial against the examiner's decision of refusal (Trial against Examiner's Decision of Refusal No. 2007-5283) on February 19, 2007.

On March 31, 2009, the JPO rendered a decision to the effect that "the request for a trial in question is to be dismissed" (additional period: 90 days; hereinafter referred to as the "JPO Decision"). A certified copy of the JPO Decision was serviced to the plaintiff on April 14 of the same year.

2. Scope of claims

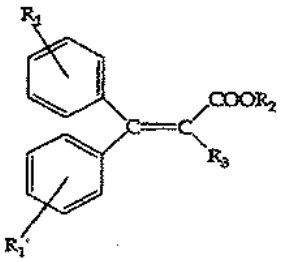
The statement of Claim 1 in the scope of claims (number of claims: 9) in the description (hereinafter the description together with the drawings is referred to as the "Description") amended by a written amendment pertaining to the Application dated May 9, 2005 (Exhibit Ko No. 4) is as follows (hereinafter the invention claimed in Claim 1 is referred to as the "Invention"; the underlined sections indicate the amended parts).

"[Claim 1] A composition suitable for use as sunscreen comprising:

[a] a safe and effective amount of a UVA-absorbing dibenzoylmethane sunscreen active ingredient;

[b] a safe and effective amount of a stabilizing agent with the formula

[Chemical formula 1]



wherein R_1 and R_1' are independently in the para or meta position and are independently a hydrogen atom or a straight- or branched chain C_1 to C_8 alkyl radical, R_2 is a straight- or branched-chain C_2 to C_{12} alkyl radical; and R_3 is <u>said</u> stabilizing agent that is a hydrogen atom or a CN radical;

[c] a UVB sunscreen <u>active</u> ingredient that is <u>0.1 to 4% by weight of 2-phenyl-benzimidazole-5-sulfonic acid</u>; and

[d] a carrier suitable for application to the skin;

wherein the mole ratio of <u>said stabilizing agent</u> to said UVA-absorbing dibenzoylmethane sunscreen active ingredient is less than 0.8 and wherein <u>said</u> composition is <u>substantially</u> free of <u>be</u>nzylidene camphor derivatives."

3. Reasons for the JPO Decision

The reasons for the JPO Decision are as indicated in a copy of the written JPO Decision attached to this judgment. The outline of the determination in the JPO Decision is as follows.

(1) The JPO found common features/differences between the Invention and the invention (hereinafter referred to as the "Cited Invention") stated in Publication of Unexamined Patent Application No. 1997-175974 (Exhibit Ko No. 1; hereinafter referred to as "Cited Reference A") as follows.

A. Common features

"Being a 'composition suitable for use as sunscreen comprising:

[a] a safe and effective amount of a UVA-absorbing dibenzoylmethane sunscreen active ingredient;
[b] a safe and effective amount of a α-cyano-β, β-diphenylacrylate stabilizing agent; and
[d] a carrier suitable for application to the skin;
wherein the mole ratio of said stabilizing agent to said UVA-absorbing dibenzoylmethane sunscreen active ingredient is less than 0.8 where the amount of said UVA-absorbing dibenzoylmethane sunscreen active ingredient is 1% or more and wherein said composition is substantially free of benzylidene camphor derivatives'" (line 8 to line 17 of page 4 of the written JPO Decision)

B. Differences

"The Invention 'comprises a UVB sunscreen active ingredient that is 0.1 to 4% by weight of 2-phenyl-benzimidazole-5-sulfonic acid' while the Cited Invention is stated as 'voluntarily comprising a common UV-B filter'" (line 17 to line 20 of page 4 of the written JPO Decision).

(2) The JPO made the following determination concerning the ease of making an invention set forth in Article 29, paragraph (2) of the Patent Act.

A. Prior to the priority date of the Application, it had been well-known that "2-phenyl-benzimidazole-5-sulfonic acid" is one of the representative "UV-B filters" (UV-B absorbing agents), that products containing it have already been sold and that 2-phenyl-benzimidazole-5-sulfonic acid is used in combination with other well-known UV absorbing agents. In that case, it is a simple matter to select "2-phenyl-benzimidazole-5-sulfonic acid" out of the "representative UV-B filters" according to the statements in Cited Reference A, "voluntarily comprising at least one kind of common UV-B filter …" and "there is no limitation on the selection of materials used for filtering UV-B ray."

B. Then, in relation to the amount combined in doing so, Cited Reference A states that "about 1 to 12% by weight of UV-B filter exists." Therefore, a person ordinarily skilled in the art can accordingly specify said amount as "about 0.1 to 4% by weight," which overlaps said range.

C. The Description merely states an example of the manufacturing of a cosmetic as a working example, and includes only general statements about the effect of the Invention and does not state the effect based on objective specific numerical data. In addition, there is no specific statement about the effect achieved by specifying "UV-B filter" as "2-phenyl-benzimidazole-5-sulfonic acid" in the Description. Therefore, it is impossible to determine based on the statements in the Description that an especially unexpected effect was produced.

Incidentally, the effect relating to the SPF or PPD of the Invention (composition of Claim 1), which is stated as [Reference 1] in the written supplement of grounds for filing a request for a trial dated March 19, 2007, cannot be taken into account because there is no specific statement

about the effect achieved by specifying "UV-B filter" as "2-phenyl-benzimidazole-5-sulfonic acid" in the Description. Even taking said effect into account, it is considered natural to confirm SPF or PPD when selecting "2-phenyl-benzimidazole-5-sulfonic acid" out of representative components as a UV-B filter because SPF or PPD itself is an indicator of the effect against UV rays. Therefore, it is impossible to consider such effect relating to SPF or PPD as an especially unexpected effect that a person ordinarily skilled in the art cannot predict (line 23 of page 4 to line 10 of page 6 of the written JPO Decision).

No. 3 Allegations of the parties

1. Plaintiff's allegations concerning grounds for rescission of the JPO Decision

As follows, the JPO Decision contains [i] an error in its determination to the effect that the experiment result stated in the written supplement of grounds for filing a request for a trial cannot be taken into account and [ii] an error in its determination to the effect that the Invention has no prominent function and effect even taking into account the experiment result stated in [Reference 1] in question. The JPO erred in its determination concerning the ease of making an invention set forth in Article 29, paragraph (2) of the Patent Act. Therefore, the JPO Decision should be rescinded.

(1) Error in the determination to the effect that the experiment result stated in the written supplement of grounds for filing a request for a trial cannot be taken into account

With regard to the effect of the Invention achieved by specifying "UV-B filter" as "2-phenyl-benzimidazole-5-sulfonic acid," the description originally attached to the application for the Application (hereinafter referred to as the "Original Description") does not clearly state such effect by indicating numerical values, etc. However, based on the statements in the Original Description, a person ordinarily skilled in the art can understand that the effect of the Invention is stated therein. Therefore, the result of the experiment stated in [Reference 1] (hereinafter referred to as the "Reference 1 Experiment" in some cases) in the written supplement of grounds for filing a request for a trial submitted by the plaintiff should be taken into account. The JPO Decision contains an error in its determination to the effect that said result cannot be taken into account.

A. In relation to the function and effect of the Invention, the Original Description states as follows: "It has surprisingly now been found that the compositions of the invention, which comprise a UVA-absorbing dibenzoylmethane sunscreen active ingredient, a defined stabilizing agent, a UVB sunscreen active ingredient, and a carrier, and which are substantially free of benzylidene camphor derivatives, provide excellent stability (especially photostability), efficiency, and UV protection efficacy (including both UVA and UVB protection), in a safe, economic and aesthetically appealing (particularly on-skin transparency without undue skin irritation) manner" (Exhibit Ko No. 3; paragraph [0011]). This is a qualitative statement

concerning the function and effect of the composition of the Invention. In addition, there is the following statement in the Original Description in relation to UVB sunscreen active ingredients (UV-B filters): "Preferred UVB sunscreen active ingredients are selected from the group consisting of 2-phenyl-benzimidazole-5-sulfonic acid, TEA salicylate, octyl dimethyl PABA, zinc oxide, titanium dioxide, and mixtures thereof. A preferred organic sunscreen active ingredient is 2-phenyl-benzimidazole-5-sulfonic acid" (Exhibit Ko No. 3; paragraph [0025]).

Moreover, as indicated in the well-known examples (Exhibits Ko No. 2-1 to No. 2-9) indicated in the JPO Decision, given that "2-phenyl-benzimidazole-5-sulfonic acid" is one of the various "UV-B filters" stated in parallel, it is natural to understand that the reason why it is preferred to select and use "2-phenyl-benzimidazole-5-sulfonic acid" from among various publicly known "UV-B filters" is that the function and effect stated in the Original Description is further improved thereby.

Then, taking into account that SPF and PPD (PA in Japan) had been recognized as the indicators of UV protection efficacy in the relevant technical field and their measurement methods had been known prior to July 30, 1998, which is the priority date of the Application, it is naturally possible to presume the levels of SPF and PPD that compositions with excellent UV protection efficacy would show. Then, as alleged by the defendant, taking into account that it is concluded that a composition with SPF50+ and PPD8+ has excellent UV protection efficacy in consideration of the technical significance relating to SPF and PPD, a person ordinarily skilled in the art can easily presume that a composition with excellent UV protection efficacy would show SPF of around "50+" and PPD of around "8+."

Therefore, even if the SPF and PPD of the sunscreen composition of the Invention using "2-phenyl-benzimidazole-5-sulfonic acid" are not specifically stated in the Description, the SPF and PPD of said composition can be easily presumed by considering the statements in the Description and the state of the art as of the Application filing date.

B. In response to this, the defendant alleges as follows: Based on the fact that it is stated in paragraph [0022] in the Description that "… Preferred compositions retain at least about 85%, more preferably at least about 90%, of their initial UV absorbance after irradiation with approximately 2 J/cm^2 per desired SPF unit of broad band UV radiation, e.g., 30 J/cm^2 for an SPF 15 composition," it seems that the scope including SPF 15 was assumed in the Description; it is thus reasonable to consider that SPF will not be significantly far from this value even if it exceeds said value in a preferred case; therefore, a person ordinarily skilled in the art cannot infer that the effect as alleged by the plaintiff whereby SPF exceeds the upper limit thereof, 50, is stated in the Description.

However, the aforementioned paragraph merely indicates one example as it states that "e.g. …," and merely explains the evaluation standard for the photostability test of the composition of

the Invention. It does not state the SPF of the composition of the Invention itself. Therefore, there is no ground for the defendant's allegation.

C. As mentioned above, the result of the Reference 1 Experiment in the written supplement of grounds for filing a request for a trial should be taken into account. The JPO Decision contains an error in its determination to the effect that said result cannot be taken into account.

(2) Error in the determination to the effect that the Invention has no prominent function and effect even taking into account the result of the Reference 1 Experiment

A. In general, SPF indicates UVB protection efficacy, and PPD indicates UVA protection efficacy. The higher they are, the greater broad spectrum (both UVA and UVB ranges) UV protection efficacy is determined to be achieved. According to the result of the Reference 1 Experiment in the written supplement of grounds for filing a request for a trial, the SPF of the Invention (Working Example 1) is dramatically higher than that of conventional products (Comparative Examples 1 to 4), specifically, by about 3 to 10 times. The PPD of the Invention is also higher, specifically, by about 1.1 to 2 times. Furthermore, sunscreen compositions are also required to ensure that UV protection efficacy is not deteriorated due to ultraviolet irradiation (photostability). The Invention maintains dramatically higher SPF and PPD than that of conventional products even after ultraviolet irradiation.

B. In this action, according to the result of an experiment concerning Comparative Examples 5 and 6, which was conducted by the plaintiff (hereinafter referred to as the "Additional Comparative Experiment" in some cases), as shown in the "Additional Comparative Experiment Composition Data" attached to this judgment, it can be said that the Invention has a prominent function and effect. The data of the Additional Comparative Experiment is the data of a comparative experiment concerning Comparative Example 5 (water in which 1% 2-phenyl-benzimidazole-5-sulfonic acid is dissolved) and Comparative Example 6 (a composition comprising 1% 2-phenyl-benzimidazole-5-sulfonic acid alone as a sunscreen active ingredient together with other components). Their detailed compositions are as indicated in the "Additional Comparative Experiment Composition Data" (also includes the result of the Reference 1 Experiment) attached to this judgment. In addition, the preparation method, evaluation method, experimenter, etc. of these sunscreen compositions are as indicated in the "Preparation Method, Evaluation Method, Experimenter, etc. of Sunscreen Compositions in the Experiments" attached to this judgment.

The results of measuring the in vitro PPD score and in vitro SPF score using the aforementioned compositions are as indicated in the "Table of Measurement Results of the Additional Comparative Experiment" attached to this judgment. For Comparative Examples 5 and 6, which comprise 2-phenyl-benzimidazole-5-sulfonic acid alone as a sunscreen active ingredient, not only the in vitro PPD score but also the in vitro SPF score is low, and sufficient

broad spectrum UV (UVA and UVB) protection efficacy cannot be achieved. Therefore, the Invention produces a prominent function and effect (achievement of markedly excellent broad spectrum UV protection efficacy and photostability) by combining 2-phenyl-benzimidazole-5-sulfonic acid with other specific components to make them act on each other.

C. Despite the existence of a prominent function and effect as mentioned above, only on the grounds that UV protection efficacy could be confirmed by SPF, etc., which are general indicators, the JPO determined that the aforementioned effect is within the scope that a person ordinarily skilled in the art could predict. Therefore, the JPO Decision is erroneous. That is, in the field of sunscreen compositions, the effect on UV rays (UV protection efficacy) is considered as one of the important performances, and research and development are actively conducted for the purpose of improving UV protection efficacy. Taking this into account, the JPO Decision contains an error in its determination to the effect that the UV protection efficacy of the Invention as indicated by using SPF and PPD is within the scope that a person ordinarily skilled in the art could predict on the grounds that SPF and PPD are generally used as the indicators of UV protection efficacy and that these values can naturally be confirmed.

2. Defendant's counterargument

(1) Regarding an error in the determination to the effect that the experiment result stated in the written supplement of grounds for filing a request for a trial cannot be taken into account

A person ordinarily skilled in the art cannot infer the effect of the Invention relating to SPF or PPD stated as [Reference 1] in the written supplement of grounds for filing a request for a trial on the basis of the statements in the Original Description. Therefore, the JPO Decision contains no error in its determination to the effect that the result of the Reference 1 Experiment cannot be taken into account.

A. Regarding SPF and PPD

In general, "SPF" is an abbreviation for "Sun Protection Factor," and it indicates UVB protection level. It is indicated by the ratio between the minimal erythema dose (MED; minimal dose of ultraviolet rays required to cause sunburn that can be barely recognized in 16 to 24 hours after ultraviolet irradiation) of skin protected by a sunscreen and that of unprotected bare skin (Exhibit Otsu No. 1; page 72 to page 75). In paragraph [0020] in the Original Description (Exhibit Ko No. 3), it is also stated that "SPF is a commonly used measure of photoprotection of a sunscreen against erythema. SPF is defined as the ratio of the ultraviolet energy required to produce minimal erythema on protected skin to that required to produce the same minimal erythema on unprotected skin in the same individual."

Then, there is usually an upper limit of the reading of SPF, and "50+" is the highest (Exhibit Otsu No. 1; page 72 to page 75). On the other hand, "PPD" is an abbreviation for "Persistent

Pigment Darkening," and it indicates UVA protection level. It is used to compare skin protected by a sunscreen and unprotected skin in terms of the persistent pigment darkening dose that appears on the skin after UVA irradiation. This ratio is called PPD (PPD rating) or UVA protection factor (Exhibit Otsu No. 2), and it is synonymous with PFA (Exhibit Otsu No. 1; page 75 to page 77). In Japan, PPD is described as "PA (protection grade of UVA)," and is usually indicated as "PA+" (having UVA protection efficacy), "PA++" (having considerable UVA protection efficacy) and "PA+++" (having excellent UVA protection efficacy). If these indications are converted into PPD, they correspond to "2 to 4," "4 to 8" and "8+," respectively (Exhibit Otsu No. 1; page 75; Exhibit Otsu No. 2).

In this manner, both SPF and PPD (PA in Japan) are widely known as useful indicators for protecting skin from the harm of ultraviolet rays in the relevant technical field. People select different sunscreens according to the time, place and occasion by using SPF and PPD (PA classification) as guides (Exhibit Otsu No. 1; page 102 to page 105).

B. Regarding the point that a person ordinarily skilled in the art cannot infer the experiment result stated in the written supplement of grounds for filing a request for a trial based on the Original Description

According to the experiment result stated in the written supplement of grounds for filing a request for a trial, in Working Example 1, SPF is close to 60 both before UV irradiation (59.4) and after UV irradiation (57.6), and these values correspond to "50+," which is the upper limit of SPF. In addition, PPD exceeds 10 both before UV irradiation (16.0) and after UV irradiation (13.7), and these values correspond to "8+," which is the upper limit of PPD. Therefore, the SPF and PPD of Working Example 1 in the Reference 1 Experiment can be regarded as high in the relevant technical field.

However, as mentioned below, the SPF or PPD of the Invention stated as the result of the Reference 1 Experiment in the written supplement of grounds for filing a request for a trial are not recognized as the values that a person ordinarily skilled in the art can infer based on the statements in the Original Description.

(A) In the Original Description, there are merely statements concerning a prescription example called "[Working example]" and a preparation method in paragraphs [0054] to [0057] as specific statements concerning a sunscreen composition using "2-phenyl-benzimidazole-5-sulfonic acid," and there is neither a statement whereby the function and effect of the relevant composition can be objectively understood based on such indicators as SPF and PPD nor a qualitative statement.

(B) In paragraph [0011] in the Original Description (Exhibit Ko No. 3), it is stated with regard to the "compositions of the invention" that "It has … been found that the compositions … provide excellent stability (especially photostability), efficiency, and UV protection efficacy

(including both UVA and UVB protection), in a safe, economic and aesthetically appealing (particularly on-skin transparency without undue skin irritation) manner." There is a qualitative statement about the effect produced by the compositions as a whole.

However, as the aforementioned "compositions" have not been amended since the filing of the Application, they are understood as meaning the "composition" stated in Claim 1 in the Original Description, that is, a composition using "a safe and effective amount of a UVB sunscreen active ingredient selected from the group consisting of organic sunscreen active ingredients, inorganic physical sunblocks, and mixtures thereof." Therefore, the statement cannot be regarded as being limited to compositions using the specific "2-phenyl-benzimidazole-5-sulfonic acid" as a UVB sunscreen.

In addition, the aforementioned statement in paragraph [0011] is merely general, and is not sufficient to enable a person ordinarily skilled in the art to presume the level of SPD and PPD.

The required UV protection efficacy should differ depending on the circumstances. For example, in the case of intense leisure activities, such as mountain climbing in summer and sea bathing, only sunscreen compositions with the highest level of values, that is, SPF50 (or 50+) and PA+++, can be regarded as producing "excellent" UV protection efficacy. However, in daily life, including daytime walks and shopping, even sunscreens with SPF10 and PA+ are recognized as producing "excellent" UV protection efficacy, and sunscreens used on such occasions are not required to contain the highest levels (Exhibit Otsu No. 1; Figure 4-12 on page 104). Therefore, it is not always the case that a sunscreen that produces "excellent" UV protection efficacy necessarily has the highest level of SPF (50+) and PPD (8+) (which is technically synonymous with "PA+++" (Exhibit Otsu No. 2)).

(C) In paragraph [0025] in the Original Description, it is stated that preferred UVB sunscreen active ingredients to be blended in the Invention are five kinds of substances, specifically, general-purpose organic substances (2-phenyl-benzimidazole-5-sulfonic acid, TEA salicylate and octyl dimethyl PABA) and inorganic substances (zinc oxide and titanium dioxide) and that the three of these, "2-phenyl-benzimidazole-5-sulfonic acid," zinc oxide and titanium dioxide, are more preferred.

However, in paragraph [0022] in the Original Description, it is stated that "Preferred compositions retain at least about 85%, more preferably at least about 90%, of their initial UV absorbance after irradiation with approximately 2 J/cm^2 per desired SPF unit of broad band UV radiation, e.g., 30 J/cm^2 for an SPF 15 composition." In light of this, it seems that the scope including SPF15 was assumed in the Original Description. It is thus considered that SPF will not be significantly far from this value even if it exceeds said value in a preferred case. Consequently, the matters which a person ordinarily skilled in the art can presume based on the statements in the Original Description are considered as follows: [i]

"2-phenyl-benzimidazole-5-sulfonic acid," "zinc oxide" and "titanium dioxide" can be selected as the components of a "UV-B filter," as those that produce almost the same level of effect; [ii] The function and effect are consistently within the scope indicated by the general expression stated in paragraph [0011] and SPF does not significantly exceed 15. Consequently, the SPF and PPD in the result of the Reference 1 Experiment exceed the scope that a person ordinarily skilled in the art can infer.

C. As mentioned above, it is not recognized that a person ordinarily skilled in the art can infer the effect of the Invention relating to SPF or PPD stated in the result of the Reference 1 Experiment based on the statements in the Description. Therefore, the JPO Decision contains no error in its determination to the effect that the result of the Reference 1 Experiment cannot be taken into account.

(2) Regarding an error in the determination to the effect that the Invention has no prominent function and effect even taking into account the result of the Reference 1 Experiment

A. Prior to the priority date of the Application, "2-phenyl-benzimidazole-5-sulfonic acid" had been widely known as a "UV-B filter" and had already been placed on the market by various product names. Therefore, a person ordinarily skilled in the art can naturally blend "2-phenyl-benzimidazole-5-sulfonic acid" in the Cited Invention as a suitable "UV-B filter."

According to Exhibit Otsu No. 1, SPF and PPD (PA in Japan) had been recognized as the indicators of UV protection efficacy in the relevant technical field prior to July 30, 1998, which is the priority date of the Application. Their measurement methods had also been known. In Japan, SPF had already been indicated since 1992 and PA had already been indicated since 1996 (Exhibit Otsu No. 1; see page 72). Therefore, it is easy for a person ordinarily skilled in the art to confirm the effect of a limited number of sunscreen compositions prepared by using representative UV-B filters by measuring the values of the indicators of UV protection efficacy using such measurement methods.

Consequently, the function and effect of the Invention are those that can be confirmed in relation to structures which a person ordinary skilled in the art can naturally make on the basis of usual measurement methods. Therefore, it is impossible to say, through confirmation of the function and effect based on the result of the Reference 1 Experiment, that the function and effect of the Invention are especially prominent ones that a person ordinarily skilled in the art can hardly predict.

B. According to the matters stated below, it had been well-known that a combination of multiple UV protection agents would produce a synergy effect.

(A) There are the following statements in Exhibits Ko No. 2-1 and No. 2-3, which were cited as well-known examples in the JPO Decision.

"The compound used according to the invention can be employed as the only UV absorber[s] in the corresponding preparations; however, it can also be employed in combination with other UV absorbers, in particular UV-B absorbers, for achieving a UV-A/B wide-band absorption, or with non-photostable dibenzoylmethane derivatives (e.g. butylmethoxy-dibenzoyl-methane or 4-isopropyldibenzoylmethane) for stabilization thereof. …" (Exhibit Ko No. 2-1; paragraph [0050]).

"[Effect of the invention] The measured SPF of the emulsion prepared by the method of the invention is considerably higher than expected. For example, it was shown that the in vitro SPF of an emulsion that contains 4% titanium dioxide and does not contain organic sunscreens is 6. Previous experience shows that SPF is increased to 12 by adding 3% phenylbenzimidazole sulfonic acid (product name: Eusolex 232) to a composition. In fact, it was revealed that the SPF of an emulsion that contains a combination of 4% titanium dioxide and 3% Eusolex 232 that was prepared by the method of the invention is higher than 15" (Exhibit Ko 2-3; paragraph [0028]).

(B) In addition, there is the following statement in Exhibit Ko No. 8-2, which the plaintiff presented as evidence showing well-known art prior to the filing of the Application.

"The average protection factor obtained as a result of considering the compositions of various products is shown in Table 1 below.

[Table 1] (omitted)

The aforementioned result clearly indicates the synergy effect obtained by using Products 1 and 2 that are based on the invention. The sun protection factor of the relevant product is prominently improved in all cases compared to the mere total of the sun protection factors of corresponding comparative products that contain any one of the blockers" (Exhibit Ko No. 8-2; paragraphs [0024] to [0025]).

(C) According to the statements in Exhibits Ko No. 2-1, No. 2-3 and No. 8-2 above, it is common in the relevant technical field to prepare a sunscreen composition by combining and blending multiple UV protection agents in expectation of a certain degree of synergy effects, such as reinforced stability and improvement of the final SPF. Therefore, the determination in the JPO Decision is also reasonable based on the aforementioned technical background.

C. Inconsistency between the result of the Reference 1 Experiment/result of the Additional Comparative Experiment and the working examples in the Description

The Reference 1 Experiment and the Additional Comparative Experiment (hereinafter these experiments are referred to as the "Experiments" in some cases) are not consistent with the Working Example I or II in the Description in terms of the composition and preparation method. That is, Working Example 1 in the result of the Reference 1 Experiment and Working Example I or II in [Table 1] in paragraph [0055] in the Description are not consistent with each other in

terms of the blending quantity of three kinds of components of the relevant sunscreen composition, specifically, UVA filter, UVB filter and stabilizer. In addition, components other than the aforementioned three differ in the blending quantity of "glycerin," "triethanolamine," "methylparaben," etc. that are common to each. Furthermore, in Working Example 1 in the results of the Experiments, "C12-15 alcohol benzoate," which is not stated at all in the Description, is used in large amounts.

Next, regarding the preparation method of sunscreen compositions, a water phase was prepared by mixing components "at room temperature conditions" in the Experiments. On the other hand, in the working examples in the Description, a water phase was prepared by "heating" components "to 80℃." Moreover, an oil phase was prepared by "mixing" components "while heating" them "to 70℃" in the Experiments, while it was prepared by "heating" components "to 80℃" in the working examples in the Description. In addition, regarding the temperature when adding a premix containing "ensulizole" (phenylbenzimidazole sulfonic acid)," it is stated as "room temperature" in relation to the Experiments, while it is stated as "about 45℃" in the Description. Furthermore, in the Experiments, a large quantity of water, "70 parts by mass of water," was used when preparing a water phase (Premix 1). On the other hand, in the working examples in the Description, only "4% water" was used, and a large quantity of water was added at the last stage when a water phase and an oil phase were mixed and the blending of all components was completed.

In this manner, the results of the Experiments do not directly indicate the function and effect relating to Working Example I or II that are specifically stated in the Description.

The results of the Experiments indicate the function and effect of sunscreen compositions that were prepared by using a different composition and a different method. Therefore, they do not indicate that the effect of the invention was prominent.

Moreover, it cannot be said that the result of an experiment on one mere example that contains specific components at a specific blending ratio (Working Example 1 in the Experiments) indicates the function and effect of the Invention in relation to the entire scope of claims.

D. It is not reasonable to say that only achieving a high SPF and PPD necessarily means achieving an excellent function and effect in the technical field of sunscreens. The reasons therefor are as follows.

(A) There are the following statements in Exhibits Otsu No. 1, No. 3 and No. 4 (the underlined portion was added in this judgment).

"(d) Upper limit of the values indicated

It has been decided that if the SPF of a sample is over 50 and the lower 95 percent confidence limit is over 51.0, the SPF of the sample is to be indicated as 50+ and that if said

lower limit is less than 51.0, the SPF of the sample is to be indicated as 50. The reasons for adopting the indication, 'SPF50+,' are explained as follows in the commentary of the new JCIA method: '[i] The measurement error is still large in relation to measurement values that are higher than a certain level, and [ii] SPF 50 is considered to be sufficient to ensure the prevention of sunburn that is the function of sunscreen cosmetics; however, it was made possible to attach the indication, SPF50+, to sunscreen cosmetics that clearly have a more potent effect than those with SPF50, taking into consideration people who are very sensitive to ultraviolet rays and regions where ultraviolet rays are very strong.' In addition, it is also taken into account that there is the upper limit (30+) of SPF in the United States and Australia" (Exhibit Otsu No. 1; the third line from the bottom of page 86 to line 8 of page 87).

"New JCIA method

On the other hand, in the Japanese market, the value of SPF indicated has steadily become higher year after year. It has become obvious that the higher the SPF is, the larger the difference in SPF measured by the JCIA method may be.

Therefore, the Japan Cosmetic Industry Association (JCIA) started holding discussions on the revision of the JCIA method at the Ultraviolet Task Force in October 1997. As a result of repeated discussions, the JCIA made changes to the measurement conditions in order to enhance the reliability of measurement of a high level of SPF as mentioned above. However, the JCIA decided to set the upper limit of SPF indication because the measurement error is still large in relation to measurement values that are higher than a certain level and because, from an international standpoint, there is the upper limit of indicated SPF in the United States, Australia and New Zealand. The JCIA set the upper limit as SPF50+" (Exhibit Otsu No. 1; line 11 to the last line of page 95).

"SPF30 is sufficient for normal skin. Even for very sensitive skin, SPF is up to around 60 at the highest. Making SPF even higher has negligible difference on the effect. Trying too hard to make SPF extremely high will place a burden on the skin and sacrifice the good feeling acquired when using a sunscreen cosmetic. It is important to select products with appropriate SPF according to the time, place and occasion. It is also necessary to start taking measures against ultraviolet rays at the earliest possible time" (Exhibit Otsu No. 3; fourth line from the bottom of page 107 to line 3 of page 108).

"SPF indicates whether skin reddens when a UV protection cosmetic is applied to the skin and how many times greater the amount of ultraviolet rays the skin was exposed to in comparison with skin to which a UV protection cosmetic is not applied. SPF is indicated by a numerical value. In measuring SPF, test subjects are human, and a light source whose UVB region is similar to that of sunlight is used. A sample is applied to part of the skin, and not applied to another part. Ultraviolet rays are then irradiated on the skin, and skin reaction is

observed 16 to 24 hours after the irradiation. The amount of ultraviolet light on the reddened skin area is considered as the minimal erythema dose (MED). SPF is calculated by the ratio between the MEDs of both parts. SPF51 or higher is indicated as SPF50+ because of the non-necessity of cosmetics with an extremely high SPF in practice and for the purpose of avoiding meaningless numerical competition" (Exhibit Otsu No. 4; line 3 to line 13 of page 140 on the upper side).

(Although Exhibit Otsu No. 1 was issued in 2000, it states that a problem concerning indication of a high level of SPF had already been recognized before 1997. In addition, Exhibit Otsu No. 3 was issued on August 10, 1998, which was 11 days after the priority date of the Application. Furthermore, Exhibit Otsu No. 4 was issued in 2009. Consequently, there is no difference in the evaluation concerning the value of SPF50+ between the priority date of the Application and at present.)

(B) According to the statements in Exhibits Otsu No. 1, No. 3 and No. 4 above, there is no need to make SPF unnecessarily high for ordinary sunscreen use. In fact, there is a risk that this could make SPF less reliable as an indicator of the ultraviolet absorption effect because the measurement error increases as the measured SPF becomes higher. In addition, it can be said that trying too hard to make SPF higher places a burden on the skin and sacrifices the good feeling acquired when using a sunscreen cosmetic. Actually, a high level of SPF, 50+, is required for sunscreens only in limited cases, such as participation in intense leisure activities under strong ultraviolet rays, including sports under the blazing sun and sea bathing, and in cases of persons with skin that is very sensitive to ultraviolet rays. SPF required for sunscreens that are used by those who have normal skin in daily life, including walking and regular outdoor activities, is around 10 to 30. Making the SPF higher than this has a negligible effect. Such understanding concerning SPF also conforms to the background whereby the upper limit of SPF was set as "50+" because the measurement error increases as the measured SPF becomes higher and for the purpose of avoiding meaningless numerical competition.

E. The function and effect of the Invention alleged by the plaintiff, that is, SPF being "50+," is not based on the data of an in vivo experiment on humans but based on the data of an in vitro experiment using artificial skin test substrate. Therefore, it is not clear whether SPF50+ can be obtained when the composition (Working Example 1) of the Invention is used on humans. However, even if it can be obtained, a problem with the reliability of data and deterioration of the good feeling acquired when using a sunscreen cosmetic are expected. Consequently, it is not reasonable to immediately determine that the function and effect of the sunscreen composition are prominent based only on the fact that the value of the indicator of UV protection efficacy is unnecessarily high at 50+.

F. Summary

According to the above, even if the result of the Reference 1 Experiment can be taken into account, it cannot be said that the function and effect of the sunscreen composition of the Invention are prominent. Therefore, it cannot be said that the JPO overlooked the prominent function and effect of the Invention and erred in its determination concerning Article 29, paragraph (2) of the Patent Act.

No. 4 Court decision

This court considers as follows: [i] In determining whether the Invention could have been easily conceived of by a person ordinarily skilled in the art, the Original Description can be considered as stating the effect of the Invention achieved by specifying "2-phenyl-benzimidazole-5-sulfonic acid" as a "UV-B filter"; therefore, this case should be determined to be the case where it is permitted to take into account the result of the Reference 1 Experiment in the written supplement of grounds for filing a request for a trial, which was submitted by the plaintiff in the trial proceedings, in relation to the content of the effect of the Invention; consequently, the JPO Decision contains an error in its determination, which goes against this determination, to the effect that said result should not be taken into account; [ii] In addition, taking into account said result, the Invention produces an especially unexpected prominent effect that a person ordinarily skilled in the art cannot predict compared to the Cited Invention; therefore, the Invention should be considered as one that could not be easily made based on the Cited Invention; consequently, the JPO Decision contains an error in its determination to the effect that the Invention cannot be regarded as producing an unexpected prominent effect and that a person ordinarily skilled in the art could have easily made the Invention based on the Cited Invention. The reasons therefor are as follows.

1. Regarding an error in the determination to the effect that the experiment result in the written supplement of grounds for filing a request for a trial cannot be taken into account

(1) The JPO Decision is based on the grounds that the Invention does not fulfill the requirement under Article 29, paragraph (2) of the Patent Act.

It should not be permitted for an applicant to allege or prove the "effect of an invention" by submitting an experiment result, etc. after filing the application in relation to a determination concerning whether the invention fulfills the requirement under Article 29, paragraph (2) of the Patent Act, despite the non-existence of a statement concerning the "effect of the invention" in the description originally attached to the application, unless there are special circumstances. This is because permitting such an act goes against the purpose of the patent system, that is, granting a patent right (exclusive right) in return for the disclosure of an invention.

Moreover, although the effect of an invention claimed in an application is not a matter required under the description requirements for a description under the current Patent Act, it is usually considered as an important element to be considered in determining whether the

invention claimed in the application has an inventive step in comparison with prior art. Whether an invention claimed in an application has an inventive step is determined based on whether the invention claimed in the application contains the technical content that cannot be easily conceived of based on publicly known art, from the perspective of whether the problem to be solved and means for solving the problem are presented. It can be said that the question of whether the problem to be solved and means for solving the problem as mentioned above are presented has the relationship neither too close to nor too remote from the question of what the "effect of the invention" is. In consideration of this point, it should be said that it is not permitted to take into account an experiment result, etc. that was supplemented after the filing of the Application in determining whether the Invention has an inventive step in relation to the "effect of the invention," which was not made clear in the Original Description, unless there are special circumstances, because it leads to a breakdown in the equity between the applicant and third parties.

On the other hand, it is on the basis of the aforementioned purpose of the patent system and request for equity between the applicant and third parties, etc. that an experiment result, etc. that has been supplemented after the filing of an application must not be taken into account in relation to the "effect of the invention" in determining whether the invention has an inventive step. Therefore, aside from the cases where there is no statement concerning the "effect of the invention" in a description originally attached to the application, if there are statements sufficient for a person ordinarily skilled in the art to recognize the "effect of the invention" or if there are statements on which a person ordinarily skilled in the art can infer the "effect of the invention," it should be permitted to take into account an experiment result, etc. that has been supplemented after the filing of the application unless such result, etc. goes beyond the scope of such statements. Whether it is permitted to do so should be determined from the aforementioned standpoint of equity.

(2) This case is considered from the perspective mentioned above.

There is the following statement in the Original Description (Exhibit Ko No. 3; paragraph [0011]) in relation to the function and effect of the Invention: "It has surprisingly now been found that the compositions of the invention, which comprise a UVA-absorbing dibenzoylmethane sunscreen active ingredient, a defined stabilizing agent, a UVB sunscreen active ingredient, and a carrier, and which are substantially free of benzylidene camphor derivatives, provide excellent stability (especially photostability), efficiency, and UV protection efficacy (including both UVA and UVB protection), in a safe, economic and aesthetically appealing (particularly on-skin transparency without undue skin irritation) manner."

In addition, there is the following statement in the Original Description (Exhibit Ko No. 3; paragraph [0025]) in relation to UVB sunscreen active ingredients (UV-B filters): "Preferred

UVB sunscreen active ingredients are selected from the group consisting of 2-phenyl-benzimidazole-5-sulfonic acid, TEA salicylate, octyl dimethyl PABA, zinc oxide, titanium dioxide, and mixtures thereof. A preferred organic sunscreen active ingredient is 2-phenyl-benzimidazole-5-sulfonic acid."

Furthermore, "2-phenyl-benzimidazole-5-sulfonic acid" is publicly known as one of the various "UV-B filters" stated in parallel (Exhibits Ko No. 2-1 to 2-9).

In light of the statements above, it can be said that when seeing the Original Description, a person ordinarily skilled in the art naturally recognizes that the effect of the Invention in which "2-phenyl-benzimidazole-5-sulfonic acid" is selected as a "UV-B filter" is to further improve broad spectrum UV protection efficacy and photostability.

On the other hand, according to the result of the Reference 1 Experiment, the function and effect of the Invention are as follows: [i] The SPF and PPD of the Invention (Working Example 1) correspond to "50+" and "8+," respectively; compared to conventional products (Comparative Examples 1 to 4), the SPF of the Invention is dramatically higher by about 3 to 10 times and the PPD thereof is also higher by about 1.1 to 2 times (the Invention has excellent broad spectrum UV protection efficacy); [ii] The Invention maintains dramatically high SPF and PPD compared to conventional products even after ultraviolet irradiation (the Invention has excellent photostability). The Invention has a prominent effect in these points.

Certainly, the following special effect of the Invention that was indicated by the result of the Reference 1 Experiment is not clearly stated in the Original Description: The SPF of the Invention is dramatically higher than that of conventional products by about 3 to 10 times and the PPD thereof is also higher than that of conventional products by about 1.1 to 2 times. However, this case can be regarded as the case where, when seeing the Original Description, a person ordinarily skilled in the art can recognize that the Invention is one that has the effect of further improving broad spectrum UV protection efficacy and photostability. Therefore, it is permitted to take into account an experiment result, etc. that was supplemented after the filing of the Application as a premise of determining whether the Invention has an inventive step. In addition, this case cannot be regarded as the case where taking into account such result, etc. harms the equity between the applicant and third parties.

(3) Determination concerning the defendant's allegations

A. The defendant alleges as follows: The "compositions" mentioned in the aforementioned paragraph [0011] are understood as meaning the "composition" stated in Claim 1 of the Original Description, that is, a composition using "a safe and effective amount of a UVB sunscreen active ingredient selected from the group consisting of organic sunscreen active ingredients, inorganic physical sunblocks, and mixtures thereof," in light of the fact that said paragraph has never been amended since the filing of the Application; said paragraph is not a statement

limiting said compositions to compositions using "2-phenyl-benzimidazole-5-sulfonic acid," which was specified as a UVB sunscreen after the amendment.

However, the defendant's allegation is unacceptable. That is, there is the following statement in paragraph [0012] amended by the written amendment dated May 9, 2005 (Exhibit Ko No. 4): "The invention relates to a composition suitable for use as sunscreen comprising: [a] …; [b] …; [c] a UVB sunscreen active ingredient that is 0.1 to 4% by weight of 2-phenyl-benzimidazole-5-sulfonic acid; and [d] …." Therefore, the "compositions" mentioned in paragraph [0011] are also understood as those defined by the statement of Claim 1 in the scope of claims, and the amendment is effective retroactively as of the Application filing date. Therefore, the defendant's aforementioned allegation is unacceptable.

B. In addition, the defendant also alleges that the statement in paragraph [0011] is a mere general statement concerning the effect of the Invention and that it is impossible to presume the specific level of SPF and PPD of the Invention based on the Original Description.

However, the defendant's allegation is unacceptable. That is, on the premise of the defendant's allegation, if the effect is stated in the Original Description in a qualitative manner or if values are not explicitly stated therein, it becomes impossible to presume that the effect of the Invention is stated. Thus, it becomes impossible to take into account an experiment result submitted subsequently. Such result forces the applicant to bear an excessively heavy burden, eliminates the opportunity for objective verification based on experiment results and runs counter to the aforementioned principle of equity, taking into consideration the fact that the applicant can neither know with what cited inventions the invention will be compared in the future as of the filing of the application nor what reasons the panel, etc. will give. Therefore, the defendant's allegation is unacceptable.

C. Furthermore, the defendant alleges as follows. According to the statement in paragraph [0022] in the Description, "… Preferred compositions retain at least about 85%, more preferably at least about 90%, of their initial UV absorbance after irradiation with approximately 2 J/cm^2 per desired SPF unit of broad band UV radiation, e.g., 30 J/cm^2 for an SPF 15 composition …," the scope including SPF15 was assumed in the Description. Therefore, it is reasonable that a person ordinarily skilled in the art understands that SPF does not largely exceed 15. Consequently, a person ordinarily skilled in the art cannot infer the effect of the Invention relating to SPF or PPD as indicated by the result of the Reference 1 Experiment based on the statements in the Description.

However, the defendant's allegation is unacceptable. That is, the statement in paragraph [0022] in the Description relates to the stability of UV absorbance in relation to the photodecomposition of the composition of the Invention. It is a mere explanation of a preferred way of maintaining UV absorbance by using the composition of the Invention in the case of

SPF15 as an example. It cannot be regarded as indicating that the SPF of the composition of the Invention remains around 15.

(4) As mentioned above, this case can be regarded as the case where, when seeing the Original Description, a person ordinarily skilled in the art can recognize that the Invention is one that has the effect of further improving broad spectrum UV protection efficacy and photostability. Consequently, it cannot be regarded as the case where equity between an applicant and third parties is harmed if an experiment result, etc. that has been supplemented after the filing of the application is taken into account as a premise of determining whether the invention has an inventive step.

The JPO Decision contains an error in its determination to the effect that the result of the Reference 1 Experiment should not be taken into account.

2. Regarding an error in the determination in the JPO Decision to the effect that the Invention has no prominent function and effect even taking into account the result of the Reference 1 Experiment

This court determines as follows: According to the results of the Experiments, the function and effect of sunscreen compositions pertaining to the Invention (achievement of excellent broad spectrum UV protection efficacy and photostability) should be considered as being unexpectedly prominent to a person ordinarily skilled in the art, and the JPO Decision contains an error in its determination, which goes against this, to the effect that said function and effect are within the scope that a person ordinarily skilled in the art could predict because UV protection efficacy could be confirmed by using SPF, etc., which are general indicators. The reasons therefor are as follows.

(1) According to the result of the Reference 1 Experiment ("Result of the Reference 1 Experiment" attached to this judgment) included in the written request for a trial amended by a written amendment dated March 19, 2007 (Exhibit Ko No. 6), Working Example 1 in [Table 1] corresponds to the composition of the Invention. Comparative Example 1 was obtained by replacing ensulizole ("2-phenyl-benzimidazole-5-sulfonic acid") in Working Example 1 with water of the same amount as ensulizole. Comparative Examples 2 to 4 were prepared by replacing ensulizole ("2-phenyl-benzimidazole-5-sulfonic acid") in Working Example 1 with "octinoxate," "oxybenzone" or "m*ethylbenzylidene camphor" of the same amount as ensulizole. Looking at SPF and PPD values indicated in [Table 2], the following can be recognized as mentioned above: [i] The SPF of the Invention (Working Example 1) corresponds to "50+" and the PPD thereof corresponds to "8+"; compared to conventional products (Comparative Examples 1 to 4), the SPF of the Invention is* dramatically higher by *about 3 to 10 times* and the PPD thereof is also higher by about 1.1 to 2 times (the Invention has excellent broad spectrum UV protection efficacy); [ii] The Invention maintains a dramatically higher level of SPF and

PPD compared to conventional products even after ultraviolet irradiation (the Invention has excellent photostability).

(2) On the other hand, according to the result of the Additional Comparative Experiment conducted by the plaintiff while this action is pending, the result of measuring the in vitro SPF score and in vitro PPD score of Comparative Example 5 (water in which 1% 2-phenyl-benzimidazole-5-sulfonic acid is dissolved) and Comparative Example 6 (a composition which contains 1% 2-phenyl-benzimidazole-5-sulfonic acid alone as a sunscreen active ingredient and also contains other components that are not sunscreen active ingredients; the detailed composition thereof is as indicated in the "Additional Comparative Experiment Composition Data") is as indicated in the "Table of Measurement Results of the Additional Comparative Experiment" attached to this judgment. For Comparative Examples 5 and 6 that contain 2-phenyl-benzimidazole-5-sulfonic acid alone as a sunscreen active ingredient, not only the in vitro PPD score but also the in vitro SPF score is low. It can be said that they cannot achieve sufficient broad spectrum UV (UVA and UVB) protection efficacy (entire import of argument).

Incidentally, with regard to the preparation method, evaluation method, experimenter, etc. of the sunscreen compositions in the Experiments, the plaintiff has made clear that they are as indicated in the "Preparation Method, Evaluation Method, Experimenter, etc. of Sunscreen Compositions in the Experiments" attached to this judgment. It can be said that there is no sufficient evidence to affect the reliability of the Experiments at this stage where no stakeholder with experimental capability, etc. can prove the opposite in detail.

(3) In that case, the Invention can be regarded as having a prominent function and effect (achievement of prominently excellent broad spectrum UV protection efficacy and photostability) that a person ordinarily skilled in the art cannot predict as a result of a mutual action between 2-phenyl-benzimidazole-5-sulfonic acid and other specific components caused by combining them.

Consequently, the JPO Decision contains an error in its determination to the effect that the function and effect are within the scope that a person ordinarily skilled in the art could predict because UV protection efficacy could be confirmed by using SPF, etc., which are general indicators.

(4) Determinations concerning the defendant's individual allegations

A. In response to this, the defendant alleges as follows: "2-phenyl-benzimidazole-5-sulfonic acid" in the Invention is a "UV-B filter" that had been widely known prior to the priority date of the Application; SPF and PPD (PA in Japan) had been recognized as the indicators of UV protection efficacy in the relevant technical field, and their measurement methods had also been known; therefore, it is the first thing a person ordinarily skilled in the art conducts to measure

the values of the indicators of UV protection efficacy in relation to a limited number of sunscreen compositions that were prepared by using such a representative UV-B filter, by using the aforementioned measurement methods to confirm said effect; consequently, the function and effect of the Invention cannot be regarded as an especially prominent one that a person ordinarily skilled in the art cannot predict based only on such confirmation of the function and effect.

However, the defendant's allegation is unacceptable. Even if "2-phenyl-benzimidazole-5-sulfonic acid" in the Invention is a known "UV-B filter," it can be confirmed that, in the Invention, "2-phenyl-benzimidazole-5-sulfonic acid" produces an unexpectedly excellent synergy effect (effect of Working Example 1 in the Reference 1 Experiment), which significantly exceeds the UV protection efficacy peculiar to "2-phenyl-benzimidazole-5-sulfonic acid" (effect of Comparative Examples 5 and 6 in the Additional Comparative Experiment) and that of relevant other components (effect of Comparative Example 1 in the Reference 1 Experiment) as mentioned above, when being combined with other specific components. Therefore, the fact that a known "UV-B filter" was used in the Invention does not serve as a reason for denying the existence of a prominent effect. In addition, even if a method of evaluating such a prominent effect is well-known, it does not serve as a reason for denying the prominent effect of the Invention.

B. Moreover, the defendant alleges that the synergy effect alleged by the plaintiff cannot be regarded as falling under a prominent effect because, in the technical field of the Invention, it is common to make a sunscreen composition by combining and blending multiple UV protection agents in expectation of a certain degree of synergy effects, such as reinforced stability and improvement of the final SPF (Exhibits Ko No. 2-1, No. 2-3 and No. 8-2).

However, the defendant's allegation is unacceptable. Even if development of other technologies with a synergy effect is common in the same technical field, it does not serve as a reason for affirming that the Invention could have been easily conceived of, in light of the aforementioned prominent effect of the Invention.

C. Furthermore, the defendant also alleges that the Experiments are not reasonable as they are not consistent with Working Example I or II in the Description in terms of the composition and preparation method.

However, the defendant's allegation is unacceptable for the following reasons.

(A) Working Example 1 in the result of the Reference 1 Experiment and Working Example I or II in [Table 1] in paragraph [0055] in the Description are not consistent with each other in terms of the blending quantity of three kinds of components of the relevant sunscreen composition, specifically, UVA filter, UVB filter and stabilizer. In addition, they also differ in the blending quantity of "glycerin," "triethanolamine," "methylparaben," etc.

However, as long as the scope of the Invention is not limited to Working Example 1 and the aforementioned blending quantity in the Experiments is included in the structure of the Invention, the effect of Working Example 1 in the result of the Reference 1 Experiment can be regarded as the effect of the Invention. Therefore, the defendant's allegation itself is unreasonable.

(B) In Working Example 1 in the results of the Experiments, "C12-15 alcohol benzoate," which is not stated at all in the Description, is used in large amounts. However, as long as it is stated in the Description in relation to "optional components" that "The compositions of the invention may contain a variety of other ingredients such as those conventionally used in a given product type provided that they do not unacceptably alter the benefits of the invention" (Exhibit Ko No. 3; paragraph [0031]), use of "C12-15 alcohol benzoate" can be regarded as a matter that is within the scope that a person ordinarily skilled in the art can voluntarily design. Therefore, the aforementioned difference is not sufficient to deny the reliability of the Experiments.

(C) Regarding the preparation method of sunscreen compositions, a water phase was prepared by mixing components "at room temperature conditions" in the Experiments. On the other hand, in the working examples in the Description, a water phase was prepared by "heating" components "to 80°C." Moreover, an oil phase was prepared by "mixing" components "while heating" them "to 70°C" in the Experiments, while it was prepared by "heating" components "to 80°C" in the working examples in the Description. In addition, regarding the temperature when adding a premix containing "ensulizole" (phenylbenzimidazole sulfonic acid)," it is stated as "room temperature" in relation to the Experiments, while it is stated as "about 45°C" in the Description. Furthermore, in the Experiments, a large quantity of water, "70 parts by mass of water," was used when preparing a water phase (Premix 1). On the other hand, in the working examples in the Description, only "4% water" was used, and a large quantity of water was added at the last stage when a water phase and an oil phase were mixed and the blending of all components was completed. However, the defendant's allegation cannot be adopted as long as there is no ground for denying the reliability of the Experiments on the grounds of existence of a difference in the preparation method as pointed out by the defendant even on the basis of all pieces of evidence in this case.

D. The defendant also alleges that it is also impermissible to allege a synergy effect arising from a combined use that is neither disclosed nor is suggested in the Original Description, in light of the purpose of the patent system, i.e., granting a patent right in return for the disclosure of an invention on the basis of the first-to-file system.

However, the defendant's allegation is unacceptable. As mentioned above, there are the following statements in the Original Description: "It has surprisingly [now] been found that the compositions … provide excellent stability (especially photostability), efficiency, and UV

protection efficacy (including both UVA and UVB protection) …" (Exhibit Ko No. 3; paragraph [0011]); "A preferred organic sunscreen active ingredient is 2-phenyl-benzimidazole-5-sulfonic acid" (Exhibit Ko No. 3; paragraph [0025]). Therefore, it can be said that a person ordinarily skilled in the art can understand that the composition of the Invention, which contains "2-phenyl-benzimidazole-5-sulfonic acid" as a UVB filter in combination with other specific components, has excellent UV protection efficacy and can produce a synergy effect that exceeds the total of the effects of the components of the composition. Consequently, the defendant's aforementioned allegation is unacceptable.

E. Moreover, the defendant also alleges that it cannot be said that the result of an experiment on a mere example that contains specific components at a specific blending ratio (Working Example 1 in the Experiments) indicates the function and effect of the Invention in relation to the entire scope of claims.

However, requiring confirmation of the effect of an invention through experiments in relation to the entire scope of claims requires excessive experiments for the proof of the effect, and it is not reasonable from the perspective of protection of inventions. Consequently, the defendant's allegation is unacceptable.

F. The defendant also alleges as follows: There is no need to make SPF high for the ordinary use of sunscreens; there is rather the risk that SPF will become less reliable as an indicator of the ultraviolet absorption effect because the measurement error increases as the measured SPF becomes higher; in addition, trying too hard to make SPF higher places a burden on the skin and sacrifices the good feeling acquired when using a sunscreen cosmetic; therefore, it is not reasonable to recognize a sunscreen as producing an excellent function and effect based only on a high level of SPF (50+) and PPD (8+).

However, the defendant's allegation is unacceptable. Even if making SPF higher rather has disadvantages, such as placing a burden on the skin and sacrificing the good feeling acquired when using a sunscreen cosmetic, it is sufficient to cope with such disadvantages separately. Such elements never affect the determination concerning whether the Invention could have been easily conceived of by a person ordinarily skilled in the art. The defendant's allegation itself is thus unreasonable.

G. The defendant also alleges that it is not clear whether SPF50+ can be achieved when the composition (Working Example 1) of the Invention is used on humans because the function and effect of the Invention alleged by the plaintiff, that is, SPF being "50+," are not based on the data of an in vivo experiment on humans but based on the data of an in vitro experiment using artificial skin test substrate.

However, if the composition shows an excellent effect in the data of an in vitro experiment using artificial skin test substrate, it can be inferred as also having a relatively excellent effect

when used on human skin. Therefore, the defendant's allegation is not sufficient to deny the reliability of the results of the Experiments.

(5) Summary

As mentioned above, it is permitted in this case to take into account the result of the Reference 1 Experiment. According to said result (including the result of the Additional Comparative Experiment), the Invention can be recognized as one that produces an especially unexpected prominent effect that a person ordinarily skilled in the art cannot predict compared to the Cited Invention. Therefore, the JPO Decision contains an error in its determination to the effect that said effect cannot be regarded as an unexpected prominent effect. This error affects the conclusion of the JPO Decision. Therefore, the JPO Decision should be rescinded.

3. Conclusion

On these grounds, there is reason for the grounds for rescission alleged by the plaintiff. Therefore, the JPO Decision shall be rescinded. The judgment shall be rendered in the form of the main text.

Intellectual Property High Court, Third Division

Presiding judge: IIMURA Toshiaki

Judge: SAIKI Norio

Judge: TAKEMIYA Hideko

(Attachment) "Result of the Reference 1 Experiment"

1. Preparation of compositions

Compositions were prepared by blending components shown in Table 1 below.

[Table 1]

	Working Example 1	Comparative Example 1	Comparative Example 2	Comparative Example 3	Comparative Example 4
Ensulizole[1)]	1%				
Octinoxate			1%		
Oxybenzone				1%	
M*ethylbenzylidene camphor*					1%
Avobenzone[2)]	2%	2%	2%	2%	2%
*Octo*crylene[3)]	1.5%	1.5%	1.5%	1.5%	1.5%
C12-15 alcohol benzoate (oily skin softener / solvent)	12%	12%	12%	12%	12%
Glycerin (moisturizer)	5%	5%	5%	5%	5%
Triethanolamine (pH adjuster)	0.85%	0.85%	0.85%	0.85%	0.85%
Pemulen (registered trademark) TR-1 (polymeric emulsifier)	0.425%	0.425%	0.425%	0.425%	0.425%
Benzyl alcohol (preservative)	0.35%	0.35%	0.35%	0.35%	0.35%
Methylparaben	0.15%	0.15%	0.15%	0.15%	0.15%
Water	Up to 100%	Up to 100%	Up to 100%	Up to 100%	Up to 100%

1) 2-phenyl-benzimidazole-5-sulfonic acid

2) 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane

3) 2-ethylhexyl-2-cyano-3,3-diphenylacrylate

2. Evaluation of broad spectrum UV (UVA and UVB) protection efficacy

(1) Evaluation method

UVB protection efficacy was evaluated based on SPF, while UVA protection efficacy was evaluated based on PPD (persistent pigment darkening).

(2) Evaluation procedures

The aforementioned compositions of 1 mg/cm^2 were applied to hydration synthetic collagen and were dried for 15 minutes under ambient conditions. After that, the broad spectrum UV protection efficacy of the aforementioned samples before UV irradiation was evaluated by using Labsphere UV-1000S.

Then, the aforementioned samples were irradiated by UV for 45 minutes by using artificial ultraviolet light emitted from a 1,000W Oriel Xenon Arc Solar Simulator. Here, UVB/UVA light sources were used in SPF evaluation through filter correction. In addition, in PPD evaluation, UVA light source was used through filter correction.

Next, the broad spectrum protection efficacy of the aforementioned samples after UV irradiation was evaluated by using Labsphere UV-1000S.

Incidentally, SPF and PPD were calculated based on the absorbance curve decided by Labsphere UV-1000S.

(3) Evaluation result

The result of the aforementioned evaluation for the compositions of Working Example 1 and Comparative Examples 1 to 4 is shown in Table 2.

[Table 2]

		SPF	PPD
Working Example 1	Before UV irradiation	59.4	16.0
	After UV irradiation	57.6	13.7
Comparative Example 1	Before UV irradiation	7.0	9.0
	After UV irradiation	5.6	7.8
Comparative Example 2	Before UV irradiation	9.5	8.6
	After UV irradiation	6.3	6.6
Comparative	Before UV	6.8	7.8

Example 3	irradiation		
	After UV irradiation	5.9	7.3
Comparative Example 4	Before UV irradiation	15.7	14.1
	After UV irradiation	10.6	10.0

As shown in Table 2, the composition of Working Example 1 (a composition containing 2-phenyl-benzimidazole-5-sulfonic acid) had significantly higher SPF and PPD, compared to the compositions of Comparative Examples 1 to 4. Therefore, the composition of Working Example 1 can be regarded as having significantly excellent broad spectrum UV (UVA and UVB) protection efficacy.

(Attachment) "Additional Comparative Experiment Composition Data"

	Experiment data stated in the written supplement of grounds for filing a request for a trial					Additional comparative experiment data	
	Working Example 1	Comparative Example 1	Comparative Example 2	Comparative Example 3	Comparative Example 4	Comparative Example 5	Comparative Example 6
Ensulizole[1)]	1%	-	-	-	-	1%	1%
Octinoxate	-	-	1%	-	-	-	-
Oxybenzone	-	-	-	1%	-	-	-
M*ethylbenzylidene camphor*	-	-	-	-	1%	-	-
Avobenzone[2)]	2%	2%	2%	2%	2%	-	-
*Oct*ocrylene[3)]	1.5%	1.5%	1.5%	1.5%	1.5%	-	-
C12-15 alcohol benzoate (oily skin softener / solvent)	12%	12%	12%	12%	12%	-	12%
Glycerin (moisturizer)	5%	5%	5%	5%	5%	-	5%
Triethanolamine (pH adjuster)	0.85%	0.85%	0.85%	0.85%	0.85%	0.6%	0.85%
Pemulen (registered trademark) TR-1 (polymeric emulsifier)	0.425%	0.425%	0.425%	0.425%	0.425%	-	0.425%
Benzyl alcohol (preservative)	0.35%	0.35%	0.35%	0.35%	0.35%	-	0.35%
Methylparaben	0.15%	0.15%	0.15%	0.15%	0.15%	-	0.15%

Water	Up to 100%	Up to 100%	Up to 100%	Up to 100%	Up to 100%	Up to 100%	Up to 100%

1) 2-phenyl-benzimidazole-5-sulfonic acid

2) 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane

3) 2-ethylhexyl-2-cyano-3,3-diphenylacrylate

(Attachment) "Table of Measurement Results of the Additional Comparative Experiment"

		In vitro SPF score	In vitro PPD score
Working Example 1	Before UV irradiation	59.4	16.0
	After UV irradiation	57.6	13.7
Comparative Example 1	Before UV irradiation	7.0	9.0
	After UV irradiation	5.6	7.8
Comparative Example 2	Before UV irradiation	9.5	8.6
	After UV irradiation	6.3	6.6
Comparative Example 3	Before UV irradiation	6.8	7.8
	After UV irradiation	5.9	7.3
Comparative Example 4	Before UV irradiation	15.7	14.1
	After UV irradiation	10.6	10.1
Comparative Example 5	Before UV irradiation	10.4	1.1
	After UV irradiation	8.1	1.0
Comparative Example 6	Before UV irradiation	9.5	1.0
	After UV irradiation	7.7	1.0

(Attachment) "Preparation Method, Evaluation Method, Experimenter, etc. of Sunscreen Compositions in the Experiments"

(1) Preparation method of sunscreen compositions

A. Sunscreen composition of Working Example 1

<Process 1> Premix 1 was obtained by mixing 70 parts by mass of water, 5 parts by mass of glycerin, 0.35 parts by mass of benzyl alcohol and 0.15 parts by mass of methylparaben at room temperature conditions and by then slowly adding 0.425 parts by mass of Pemulen (registered trademark) TR-1 and further mixing it.

<Process 2> Premix 2 was obtained by mixing 2 parts by mass of avobenzone, 1.5 parts by mass of octocrylene and 12 parts by mass of C12-15 alcohol benzoate while heating them to 70°C.

<Process 3> At room temperature conditions, Premix 2 obtained through Process 2 was added to Premix 1 obtained through Process 1 and was stirred for one minute.

<Process 4> Premix 3 was obtained by mixing 6.725 parts by mass of water, 1 part by mass of ensulizole and 0.85 parts by mass of triethanolamine at room temperature conditions.

<Process 5> A sunscreen composition was obtained by, at room temperature conditions, adding Premix 3 obtained through Process 4 to a mixture obtained through Process 3 and stirring it for one minute.

B. Sunscreen composition of Comparative Example 1

<Process 1> Premix 1 was obtained by mixing 70 parts by mass of water, 5 parts by mass of glycerin, 0.35 parts by mass of benzyl alcohol and 0.15 parts by mass of methylparaben at room temperature conditions and by then slowly adding 0.425 parts by mass of Pemulen (registered trademark) TR-1 and further mixing it.

<Process 2> Premix 2 was obtained by mixing 2 parts by mass of avobenzone, 1.5 parts by mass of octocrylene and 12 parts by mass of C12-15 alcohol benzoate while heating them to 70°C.

<Process 3> At room temperature conditions, Premix 2 obtained through Process 2 was added to Premix 1 obtained through Process 1 and was stirred for one minute.

<Process 4> A sunscreen composition was obtained by, at room temperature conditions, adding 0.85 parts by mass of triethanolamine and 7.725 parts by mass of water to a mixture obtained through Process 3 and stirring it for one minute.

C. Sunscreen composition of Comparative Example 2

<Process 1> Premix 1 was obtained by mixing 70 parts by mass of water, 5 parts by mass of glycerin, 0.35 parts by mass of benzyl alcohol and 0.15 parts by mass of methylparaben at room temperature conditions and by then slowly adding 0.425 parts by mass of Pemulen (registered trademark) TR-1 and further mixing it.

<Process 2> Premix 2 was obtained by mixing 2 parts by mass of avobenzone, 1.5 parts by mass

of octocrylene, 12 parts by mass of C12-15 alcohol benzoate and 1 part by mass of octinoxate while heating them to 70°C.

<Process 3> At room temperature conditions, Premix 2 obtained through Process 2 was added to Premix 1 obtained through Process 1 and was stirred for one minute.

<Process 4> A sunscreen composition was obtained by, at room temperature conditions, adding 0.85 parts by mass of triethanolamine and 6.725 parts by mass of water to a mixture obtained through Process 3 and stirring it for one minute.

D. Sunscreen composition of Comparative Example 3

A sunscreen composition was obtained by the same method as in C above though oxybenzone was used instead of octinoxate in Process 2 in C above.

E. Sunscreen composition of Comparative Example 4

A sunscreen composition was obtained by the same method as in C above though m*ethylbenzylidene camphor* was used instead of octinoxate in Process 2 in C above.

F. Sunscreen composition of Comparative Example 5

<Process 1> Premix 1 was obtained by mixing 5 parts by mass of water, 1 part by mass of ensulizole and 0.6 parts by mass of triethanolamine at room temperature conditions.

<Process 2> A sunscreen composition was obtained by, at room temperature conditions, adding 93.4 parts by mass of water to Premix 1 obtained through Process 1 and stirring it for one minute.

G. Sunscreen composition of Comparative Example 6

<Process 1> Premix 1 was obtained by mixing 70 parts by mass of water, 5 parts by mass of glycerin, 0.35 parts by mass of benzyl alcohol and 0.15 parts by mass of methylparaben at room temperature conditions and by then slowly adding 0.425 parts by mass of Pemulen (registered trademark) TR-1 and further mixing it.

<Process 2> At room temperature conditions, 12 parts by mass of C12-15 alcohol benzoate was added to Premix 1 obtained through Process 1 and was stirred for one minute.

<Process 3> Premix 2 was obtained by mixing 5 parts by mass of water, 1 part by mass of ensulizole and 0.85 parts by mass of triethanolamine at room temperature conditions.

<Process 4> A sunscreen composition was obtained by, at room temperature conditions, adding Premix 2 obtained through Process 3 and 5.225 parts by mass of water to a mixture obtained through Process 2 and stirring it for one minute.

(2) Evaluation method of sunscreen compositions

<Process 1> A sample for evaluation was obtained by applying 1 mg/cm^2 of each sunscreen composition to Vitro Skin (IMS Testing Group; United States) by using a wet-type fingertip and then drying it for 15 minutes under atmospheric conditions. Four samples for evaluation were prepared with respect to each sunscreen composition.

<Process 2> The absorbance of the aforementioned samples for evaluation was measured by using Labsphere's UV-1000S or UV-2000S (succession machine of UV-1000S). The in vitro SPF scores and in vitro PPD scores (before UV irradiation) were calculated based on the obtained absorbance curves. The calculated scores for the four samples for evaluation were averaged to obtain the final score.

<Process 3> The aforementioned samples for evaluation were irradiated by UV for 45 minutes by using artificial ultraviolet light emitted from a Solar Light's LS1000 Solar Simulator or an Oriel's Xenon Arc Solar Simulator. Here, UVB/UVA light sources through filter correction were used for the samples for evaluation of in vitro SPF scores. UVA light source through filter correction was used for the samples for evaluation of in vitro PPD scores. In addition, UV irradiation was set in a manner that power density with no load is $6.07 \times 10^{-3} W/cm^2$ and energy density is $1 J/cm^2$ when they are measured by using an OL756 spectroradiometer.

<Process 4> For the samples after UV irradiation in Process 3, their in vitro SPF scores and in vitro PPD scores (after UV irradiation) were calculated in the same manner as in Process 2.

(3) Experimenter, place of experiment and date of experiment

A. Working Example 1 and Comparative Examples 1 to 4 (the Reference 1 Experiment)

(A) Experimenter

T

One of the inventors of the invention claimed in the Application. Entered The Procter & Gamble Company after graduating from the Department of Chemical Engineering at Rensselaer Polytechnic Institute (Troy, New York, the United States), and has engaged in the research and development of personal care products for 24 years (in particular, research and development of sunscreens for 16 years). Also now engaging in the research and development of personal care products as a research fellow.

(B) Place of experiment

Sharon *Woods Innovation Center, The Procter & Gamble Company*

(C) Date of experiment

August 2005

B. Comparative Examples 5 and 6 (Additional Comparative Experiment)

(A) Experimenter

F

Entered The Procter & Gamble Company after graduating from the Department of Chemistry at the University of Miami (Oxford, Ohio, the United States). Has engaged in the research and development of personal care products for 10 years. Also now engaging in the research and development of personal care products as a senior researcher.

(B) Place of experiment

Sharon *Woods Innovation Center, The Procter & Gamble Company*

(C) Date of experiment

February 2010