Advisory Opinion

Advisory Opinion No. 2015-600028

Osaka, Japan Demandant

KOBAYASHI, Masaki

Kyoto, Japan Demandee

COSMED PHARMACEUTICAL CO. LTD.

The case of the advisory opinion on the technical scope of Japanese Patent No. 5687170 between the parties above is stated and concluded as follows.

Conclusion

A "microneedle patch storage container" shown in the photographs and drawings of Article A does not belong to the technical scope of the invention of Japanese Patent No. 5687170.

Reason

No. 1 Object of the demand

The object of the demand for the advisory opinion regarding the subject case is to demand the advisory opinion that a microneedle patch storage container shown in the photographs and drawings of Article A (hereinafter, referred to as "the article of Article A") does not fall within the technical scope of the invention according to claim 1 of Japanese Patent No. 5687170.

No. 2 History of the procedures and the patent invention

1 History of the procedures

Sep. 22, 2011	Application of the case	
Jul. 2, 2014	(Drafting date) Notice of reasons for refusal	
Sep. 4, 2014	Written opinion and written amendment	
Jan. 30, 2015	Registration of establishment	
Sep. 16, 2015	Request for the advisory opinion	
Oct. 8, 2015	(Drafting date) Delivery notice of a duplicate of the request for the	
	advisory opinion to the demandee, CosMED Pharmaceutical Co. Ltd	

Nov. 2, 2015 Written reply to the advisory opinion request from the demandee

2 The patent invention

The invention according to claim 1 of Japanese Patent No. 5687170 (hereinafter, referred to as "the patent invention") is recognized as, seen from the statements of the publication of Japanese Patent No. 5687170, the invention stated in claim 1 of the scope of claims of the publication, and its constitution is as follows when stated in a manner describing separately for each constituent component (hereinafter, each of them is referred to as such as "constituent component (A)").

(F) A microneedle patch storage container, comprising:

(A) one or a plurality of bottom surfaces recessed from a peripheral portion;

(B) a side face connecting the bottom surface and the peripheral portion; and

(C) a bottom-surface protruding portion protruding from the bottom surface, wherein

(D) a flexible release sheet portion of a microneedle patch is held by the bottom-surface protruding portion of each of the bottom surfaces, and wherein

(E) the bottom surface exists between the peripheral portion and the bottom-surface protruding portion.

3 Objective and effects and the like of the patent invention

It is recognized that the patent invention has an object to make a microneedle patch be "held hygienically and, in addition, in a manner not deteriorating its pharmaceutical benefit during a period from completion of its manufacturing to its use via a distribution process" (paragraph [0009]), a microneedle patch storage container is made to have the above-mentioned constitution, and, by this, it produces an effect that "a microneedle patch is held by the portion of a release sheet, and the micro needle portion does not come into contact with any portion of the container. Even if a microneedle patch is a flexible sheet, it can be held hygienically until the container is opened." (paragraph [0023]).

No. 3 The article of Article A

1 Written request for advisory opinion

In the written request for the advisory opinion, there is described the following matters as "explanation of the article of Article A" (page 3, line 13 to page 4, line 10).

"Explanation of the article of Article A

As shown in the following explanation, Article A is as follows when stating based on the patent invention.

<<(f) A microneedle patch storage container, comprising:

(a) two bottom surfaces (2) recessed from a peripheral portion (1);

(b) a side surface (3) connecting the bottom surfaces (2) and the peripheral portion (1); and

(c) a bottom-surface protruding portion (4) protruding from the bottom surfaces (2), wherein

(d) a flexible release sheet portion (13) of a microneedle patch (10) is held by the bottom-surface protruding portion (4) of each of the bottom surfaces (2), and wherein
(e) the peripheral portion (1) and the bottom-surface protruding portion (4) are in close contact with each other without having a space between them.>>>

* Explanation of (a)

As shown in the drawings and photographs of Article A, the article of Article A has << the two bottom surfaces (2) recessed from the peripheral portion (1)>>.

* Explanation of (b)

As shown in the drawings and photographs of Article A, the article of Article A has << the side surface (3) connecting the bottom surfaces (2) and the peripheral portion (1)>>.

* Explanation of (c)

As shown in the drawings and photographs of Article A, the article of Article A has <<the bottom-surface protruding portion (4) protruding from the bottom surfaces (2)>>.

* Explanation of (d)

As shown in the drawings and photographs of Article A, the article of Article A <<<hr/>holds a flexible release sheet portion (13) of the microneedle patch (10) by the bottom-surface protruding portion (4) of each of the bottom surfaces (2)>>.

* Explanation of (e)

As shown in the drawings and photographs of Article A, in the article of Article A, <<the peripheral portion (1) and the bottom-surface protruding portion (4) are in close contact with each other without having a space between them>>.

* Explanation of (f)

As shown in the drawings and photographs of Article A, the article of Article A is a <<micmedle patch storage container>>."

2 The drawings of Article A

(1) In the drawings of Article A, there are shown a "plan view", a "sectional view A" as a sectional view taking along line A-A of the plan view, and a "sectional view B" as a sectional view taken along line B-B of the plan view, respectively.

(2) From the plan view and the sectional view A, it is possible to perceive that, at lower positions in the vertical direction from a horizontal surface with a leader line "1" (hereinafter, referred to as "horizontal surface (1)"), two horizontal surfaces with a leader line "2" (hereinafter, referred to as "horizontal surfaces (2)") are formed right and left.

(3) From the sectional view A, it is possible to perceive that, from each of the horizontal surfaces (2) toward the horizontal surface (1), a step-like side part is formed.

Then, it is possible to perceive that, from the plan view and the sectional view A, this side part includes: a vertical surface formed in a manner extending from the outer perimeter fringe of each of the horizontal surfaces (2) toward the upper side (hereinafter, referred to as "a vertical surface A"); a horizontal surface with a leader line "4" (hereinafter, referred to as "a horizontal surface (4)") formed in a manner extending from the upper circumferential fringe of the vertical surface A toward a direction departing from each of the horizontal surfaces (2); and a vertical surface (4) and the inner circumferential fringe of the horizontal surface (1) (hereinafter, referred to as "a vertical surface (3)").

(4) From the plan view and the sectional view B, it is possible to perceive that a semicircular portion with a leader line "5" (hereinafter, referred to as "a portion (5)") forms a part of the horizontal surfaces (2).

(5) From the sectional view B, it is possible to perceive that each of the horizontal surfaces (2) includes, in the right-side side part in which the portion (5) is not formed: the vertical surface A formed in a manner extending from the outer perimeter fringe of each of the horizontal surfaces (2) toward the upper side; the horizontal surface (4) formed in a manner extending from the upper circumferential fringe of the vertical surface A and in a direction departing from each of the horizontal surfaces (2); and the vertical surface (3) formed between the outer perimeter fringe of the horizontal surface (4) and the inner circumferential fringe of the horizontal surface (1).

On the other hand, from the plan view and the sectional view B, it is possible to perceive that the left-side side part in which the portion (5) of the horizontal surfaces (2) is formed, comprises a vertical surface formed between the outer perimeter fringe of the horizontal surfaces (2) and the inner circumferential fringe of the horizontal surface (1) (hereinafter, referred to as "vertical surface B").

(6) In the plan view, portions of broken lines with a leader line "10" and "13" are shown, and it is possible to perceive, by seeing the sectional views A and B together, that each of these portions is a plate-like member.

Then, in the sectional view A, this plate-like member is placed on the horizontal surface (4) and supported by it, and, in the sectional view B, the right side of the plate-like member is placed on the horizontal surface (4) and supported by it. On the other hand, the left side of the plate-like member is not supported by any of members, and, thus, it can be perceived that it is in a floating state.

3 The photographs of Article A

(1) In the photographs of Article A, there are shown "an oblique perspective photograph 1" entitled "A state that the cap part is open before storing a microneedle patch", "an oblique perspective photograph 2" entitled "A state that the cap part is open after storing a microneedle patch", "an oblique perspective photograph 3" entitled "A state that the cap part is closed after storing a microneedle patch", and "a bottom surface photograph 4" entitled "A state that the cap part is closed after storing a microneedle patch".

(2) Although, in the oblique perspective photographs 1-3 and the bottom surface photograph 4, two white members are perceived, it is recognized that these members are microneedle patches, as seen from the statements of the titles.

(3) In the oblique perspective photographs 1-3 and the bottom surface photograph 4, there is perceived one member formed of a colorless transparent material, and it is recognized that this member is a microneedle patch storage container, as seen from the statements of the titles.

(4) In the oblique perspective photographs 2 and 3 and the bottom surface photograph 4, it is perceived that a microneedle patch is being stored in a microneedle patch storage container.

4 Finding matters

(1) Because the plate-like member shown in the plan view and the sectional views A and B of the drawings of Article A is described as "the microneedle patch (10)" in the above-mentioned 1, and the portion of the broken line with a leader line "10" is correlated with a microneedle patch, and, due to the matters of the above-mentioned 2(6) and 3(2), it is recognized that it is a microneedle patch.

Then, considering that an average microneedle patch has a release sheet arranged around it, it is recognized that the broken line portion of leader line "10" in the plan view and the sectional views A and B indicates a microneedle patch as a whole, and the broken line portion of leader line "13" indicates a release sheet portion of the microneedle patch.

(2) It is recognized that, from the description in the above-mentioned 1 that "the article of Article A is a <<microneedle patch storage container>>", and, from the matters of the above-mentioned 3(3)-(4), the member whose whole shape is shown in the plan view and the sectional views A and B of the drawings of Article A is a microneedle patch storage container.

(3) From the matters of the above-mentioned 2(6) and 4(1), it is recognized that at least part of the release sheet (13) of the microneedle patch (10) is supported by the horizontal surface (4).

5 Constitution of the article of Article A

As seen from the matters of the above-mentioned 1 to 4, when the constitution of the article of Article A is separately described in a manner corresponding to the separate description of the constituent components of the patent invention, the article of Article A includes the following constitution (hereinafter, referred to as such as "constitution (a)").

(f) A microneedle patch storage container, comprising:

(a) two horizontal surfaces (2) formed below a horizontal surface (1);

(b1) a vertical surface B connecting an outer perimeter fringe portion of each of the horizontal surfaces (2) to which a portion (5) is formed and an inner circumferential fringe of the horizontal surface (1);

(b2) a vertical surface A formed in a manner extending from an outer perimeter fringe of a portion of each of the horizontal surfaces (2) to which the portion (5) is not formed

toward an upper side; a horizontal surface (4) formed in a manner extending from an upper circumferential fringe of the vertical surface A in a direction departing from each of the horizontal surfaces (2); and a vertical surface (3) formed between an outer perimeter fringe of the horizontal surface (4) and the inner circumferential fringe of the horizontal surface (1), wherein

(d) a release sheet portion (13) of a microneedle patch (10) is supported by the horizontal surface (4).

With respect to identification of the article of Article A, the Demandant specifies, in the explanation of the article of Article A (refer to the above-mentioned 1), Article A as "(b) a side surface (3) connecting the bottom surfaces (2) and the peripheral portion (1)" and "(d) a portion of a flexible release sheet (13) of a microneedle patch (10) is held by the bottom-surface protruding portion (4) of each of the bottom surfaces (2)".

However, the surface with a leader line "3" shown in the plan view and the sectional view A of the drawings of Article A is, as has been described in the abovementioned 2(3), one formed between the outer perimeter fringe of the horizontal surface (4) and the inner circumferential fringe of the horizontal surface (1), and, thus, it cannot be said that it is a surface connecting the horizontal surfaces (2) and the horizontal surface (1), and, also, regarding the surface with a leader line "3" shown in the sectional view B, it cannot be said that it is a surface connecting the horizontal surfaces (2) and the horizontal surfaces (2) and the horizontal surface (1) as has been described in the above-mentioned 2(5).

Furthermore, whether or not a microneedle patch is one "having flexibility" cannot be confirmed from the drawings of Article A and photographs of Article A.

Accordingly, the above findings have been made based on these points.

No. 4 Comparison / judgment

1 Comparison / Judgment of each constituent component of the patent invention and each constitution of the article of Article A

It is obvious that "horizontal surface (1)", "horizontal surfaces (2)", "microneedle patch (10)", "release sheet (13)", "is supported" and "microneedle patch storage container" of the article of Article A correspond to "peripheral portion", "bottom surface", "microneedle patch", "release sheet", "is held" and "microneedle patch storage container" of the patent invention, respectively.

In addition, because the horizontal surface (4) of the article of Article A is a portion that comes into contact with the release sheet (13) of the microneedle patch (10),

it corresponds to the upper surface portion of the bottom-surface protruding portion of the patent invention.

(1) About constituent component (A)

It is recognized that the horizontal surfaces (2) of the article of Article A are "recessed" relative to the horizontal surface (1) of the article of Article A, because the article of Article A has "two horizontal surfaces (2) formed below a horizontal surface (1)" (refer to the above constitution (a)).

In view of the above, it can be said that the article of Article A is one that has two horizontal surfaces (2) recessed from the horizontal surface (1).

Accordingly, it can be said that the article of Article A has "one or a plurality of bottom surfaces recessed from a peripheral portion" that is the constituent component (A) of the patent invention.

Therefore, the article of Article A satisfies the constituent component (A).

(2) About constituent component (B)

When relation between the horizontal surfaces (2) and the horizontal surface (1) is examined in relation to a portion of the article of Article A to which the portion (5) is formed, it can be said that the two are directly connected by the vertical surface B (refer to the above-mentioned constitution (b1)).

In addition, when relation between the horizontal surfaces (2) and the horizontal surface (1) in relation to a portion of the article of Article A to which the portion (5) is not formed is examined, it can be said that the two are coupled to each other via a surface that reaches the vertical surface (3) from the vertical surface A through the horizontal surface (4) (refer to the above-mentioned constitution (b2)).

In view of the above, it can be said that, in the article of Article A, both of the portion of the vertical surface B and the portion including the vertical surface A, the horizontal surface (4) and the vertical surface (3) have side surfaces connecting the horizontal surfaces (2) and the horizontal surface (1).

Accordingly, it can be said that the article of Article A has "a side surface connecting the bottom surface and the peripheral portion" that is the constituent component (B) of the patent invention.

Therefore, the article of Article A satisfies the constituent component (B).

(3) About constituent component (C)

The horizontal surface (4) of the article of Article A is a surface formed in a manner extending from the upper circumferential fringe of the vertical surface A in a direction departing from each of the horizontal surfaces (2), the vertical surface A being formed in a manner extending from the outer perimeter fringe of each of the horizontal surfaces (2) toward the upper side. Therefore, it can be said that the horizontal surface (4) is a convex portion protruding from the horizontal surfaces (2).

In view of the above, it can be said that the article of Article A has a portion made up of the horizontal surface (4) protruding from the horizontal surfaces (2); that is, a bottom-surface protruding portion.

Accordingly, it can be said that the article of Article A has "a bottom-surface protruding portion protruding from the bottom surfaces" of the constituent component (C) of the patent invention.

Therefore, the article of Article A satisfies the constituent component (C).

(4) About constituent component (D)

As has been described in "About constituent component (C)" mentioned above, the horizontal surface (4) of the article of Article A can be said to be a bottom-surface protruding portion, and it holds a release sheet portion of a microneedle patch by its upper surface.

Accordingly, it can be said that the article of Article A has a function to "hold a flexible release sheet portion of a microneedle patch by the bottom-surface protruding portion of the bottom surfaces" of the constituent component (D) of the patent invention.

Therefore, the article of Article A satisfies the constituent component (D).

(5) About constituent component (E)

The article of Article A is constituted in a manner "comprising: vertical surface A formed in a manner extending from an outer perimeter fringe of a portion of each of the horizontal surfaces (2) to which the portion (5) is not formed toward an upper side; a horizontal surface (4) formed in a manner extending from an upper circumferential fringe of the vertical surface A in a direction departing from each of the horizontal surfaces (2); and a vertical surface (3) formed between an outer perimeter fringe of the horizontal surface (1)" (refer to the above-mentioned constitution (b2)), and, thus, the horizontal surfaces (2) do not exist between the horizontal surface (1) and the horizontal surface (4).

In view of the above, the article of Article A does not have the constitution that "the bottom surface exists between the peripheral portion and the bottom-surface protruding portion" of the constituent component (E) of the patent invention.

Accordingly, the article of Article A does not satisfy the constituent component (E).

(6) About constituent component (F)

The article of Article A has "a microneedle patch storage container" in the constitution (f), and it can be said that it has "a microneedle patch storage container" of the constituent component (F) of the patent invention.

Therefore, the article of Article A satisfies the constituent component (F).

2 Summary

As shown in the above-mentioned 1(1)-(6), the article of Article A does not satisfy the constituent component (E) of the patent invention literally, and, therefore, it cannot be said that the article of Article A belongs to the technical scope of the patent invention.

3 Doctrine of equivalent

Although, as examined in the above-mentioned 1(5), the article of Article A does not satisfy the constituent component (E) of the patent invention, the Demandant alleges that, about the above-mentioned constituent component (E) of the patent invention, the constitution of the article of Article A does not satisfy the requirement of equivalent in "Explanation to the effect that the article of Article A does not belong to the technical scope of the patent invention (doctrine of equivalent)" in "5 Statement of the demand" of the Written request for an advisory opinion. Therefore, this will be examined below.

When looking into the examination history of the patent of the case, a reasons for refusal was notified on Jul. 2, 2014 (Evidence A No. 1), and, in response to this, the demandee performed amendment including addition of a matter that "the bottom surface exists between the peripheral portion and the bottom-surface protruding portion" to claim 1 (Evidence A No. 2) on Sep. 4, 2014, and, in conjunction with this, submitted a written opinion (Evidence A No. 3). In this written opinion, the demandee has alleged that "<<th>bottom surface exists between the peripheral portion and the peripheral portion and the bottom-surface protruding bottom-surface protruding bottom surface exists between the peripheral portion, the demandee has alleged that "<<th>bottom surface exists between the peripheral portion and the bottom-surface protruding portion>> added to claim 1 is not described in any of the Cited Documents. ... (omitted) ... As shown in FIG. 2 and FIG. 4, in the present invention, the bottom surface

is provided between the peripheral portion and the bottom-surface protruding portion. This is a constitution needed for making a microneedle patch easily taken out from a storage container.... (omitted) ... When considering easiness of taking out a microneedle patch, it is more convenient to arrange the bottom surface between the bottom-surface protruding portion and the peripheral portion, and hold a portion of a release sheet that is close to the inner side by the bottom-surface protruding portion, because the microneedle patch can be easily pinched by fingers.... (omitted) There is no description or suggestion in any of the Cited Documents about making a storage container easily used by such constitution." (Evidence A No. 3, page 2, lines 9-27).

In view of the above, the demandee alleges that the patent invention is patentable due to specific constitution of the patent invention that "the bottom surface exists between the peripheral portion and the bottom-surface protruding portion", and, therefore, it is recognized that ones that have a bottom surface constitution different from this specific constitution are consciously excluded from the scope of claims.

Then, it is obvious that ones "comprising: a vertical surface A formed in a manner extending from an outer perimeter fringe of a portion of each of the horizontal surfaces (2) to which the portion (5) is not formed toward an upper side; a horizontal surface (4) formed in a manner extending from an upper circumferential fringe of the vertical surface A in a direction departing from each of the horizontal surfaces (2); and a vertical surface (3) formed between an outer perimeter fringe of the horizontal surface (4) and the inner circumferential fringe of the horizontal surface (1)", which corresponds to the constitution (b2) of the article of Article A (refer to the abovementioned constitution (b2)), fall under the category of ones that are consciously excluded from the scope of claims as is the case with the above-mentioned Cited Documents (Evidence A No. 4 to 8).

Therefore, because the article of Article A does not satisfy the requirement of equivalent (special circumstances such as conscious exclusion) held in the determination 1994 (Wo) 1083 by the Supreme Court (issued on Feb. 24, 1998), it cannot be said that it falls within the technical scope of the patent invention as an equivalent.

No. 5 Demandee's allegation

The demandee alleges in the written reply to the advisory opinion request on Nov. 2, 2015 that "Regarding in what way the article of Article A holds a microneedle patch, there are descriptions in the oblique perspective photographs 1-3 and bottom surface photograph 1 affixed to the written request for an advisory opinion. However,

important contents such as <<whether or not a microneedle patch is flexible>> and <<whether or not it is held at the release sheet portion by the bottom-surface protruding portion>> cannot be confirmed from these photographs".

However, regarding the former allegation, because the patent invention is an invention of a microneedle patch storage container, the allegation of the demandee relating to whether or not a microneedle patch is flexible does not have influence on judgment of belongingness of the advisory opinion of the case.

Also, regarding the latter allegation, as indicated in 4(3) of No. 3, and 1(3) and 1(4) of No. 4, it can be said that the article of Article A is one that "holds a release sheet portion by the bottom-surface protruding portion", and, thus, there is no reason in the allegation.

No. 6 Closing

Accordingly, the article of Article A does not belong to the technical scope of the patent invention.

Therefore, the advisory opinion shall be made as described in the conclusion.







The drawings of Article A

平面図 Plan view 折返部 Folded Part 蓋部 Cap part 断面図A(A-A線による) Sectional view A (taken along line A-A) 断面図B(B-B線による) Sectional view B (taken along line B-B)



イ号写真

料視写真1 (マイクロニードルバッチ収納前の蓋部が開いた状態)

斜視写真2 (マイクロニードルパッチ収納後の蓋部が開いた状態)



1

イ号写真 Photographs of Article A

斜視写真1 (マイクロニードルパッチ収納前の蓋部が開いた状態)

Oblique perspective photograph 1 (A state that the cap part is open before storing a microneedle patch)

斜視写真2 (マイクロニードルパッチ収納後の蓋部が開いた状態)

Oblique perspective photograph 2 (A state that the cap part is open after storing a microneedle patch)



斜視写真3 (マイクロニードルパッチ収納後の蓋部が閉じた状態)

底面写真4 (マイクロニードルパッチ収納後の蓋部が閉じた状態)



2

斜視写真3 (マイクロニードルパッチ収納後の蓋部が閉じた状態)

Oblique perspective photograph 3 (A state that the cap part is closed after storing a microneedle patch)

底面写真4 (マイクロニードルパッチ収納後の蓋部が閉じた状態)

Bottom surface photograph 4 (A state that the cap part is closed after storing a microneedle patch)

December 18, 2015

Chief administrative judge:	TAKAGI, Akira
Administrative judge:	HIRASE, Tomoaki
Administrative judge:	TAKESHITA, Kazushi