

Note: When any ambiguity of interpretation is found in this provisional translation, the Japanese text shall prevail.

## 9. Case Examples Relating to Extension of Patent Term (Article 67ter(1) (i) of Patent Act)

In the provision of extension of patent term, to clarify an operation of a judgment in a case where the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been necessary to obtain for the working of the patented invention (Article 67ter(1) (i) of Patent Act), the judgment, applicant's response, and so on will be described below by referring to specific examples.

(Points of Concern)

The present "Case Examples" was made for the purpose of explanation as to an operation of a judgement in a case where the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been necessary to obtain for the working of the patented invention. For this reason, in each Case, it is to be noted that some modifications, e.g., simplification, are made in descriptions of the patented invention pertaining to an application for registration of extension, in order for easy understanding of the explanation.

### List of Cases

(In the list, "○" represents that the application shall not be refused pursuant to Article 67ter(1) (i) of Patent Act; and "×" represents that the application shall be refused pursuant to Article 67ter(1) (i) of Patent Act.)

Case Number	Title of Invention	Contents of Disposition	Judgement
Case 1	Analgesics	Approval of manufacturing and distribution of pharmaceutical product	○
Case 2	Analgesics	Approval of manufacturing and distribution of pharmaceutical product	○
Case 3	Analgesics	Approval of manufacturing and distribution of pharmaceutical product	○
Case 4	Injection for Pain Relief	Approval of manufacturing and distribution of pharmaceutical product	○
Case 5	Injection for Pain Relief	Approval of manufacturing and distribution of pharmaceutical product	○

## Annex A Case Examples Relating to Extension of Patent Term

Case 6	Anticancer	Approval of manufacturing and distribution of pharmaceutical product	×
Case 7	Syringe	Approval of manufacturing and distribution of pharmaceutical product	○
Case 8	Syringe	Approval of manufacturing and distribution of pharmaceutical product	○
Case 9	Method for manufacturing of Ingredient A	Approval of manufacturing and distribution of pharmaceutical product	○
Case 10	Method for manufacturing of Ingredient A	Approval of manufacturing and distribution of pharmaceutical product	○
Case 11	Insecticide	Registration of manufacturing of agricultural chemical	○
Case 12	Insecticide	Registration of manufacturing of agricultural chemical	○
Case 13	Fungicide and Insecticide	Registration of manufacturing of agricultural chemical	×
Case 14	Anticancer	Approval of manufacturing and distribution of pharmaceutical product	○

[Case 1] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Analgesics

Patented Invention pertaining to an application for registration for extension

[Claim 1] Analgesics comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, pain relief as efficiency and effect, and 5 mg/dose as dosage and administration (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a2 as an active ingredient, pain relief as efficiency and effect, and 5 mg/dose as dosage and administration (a2 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and pain relief as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in active ingredient, i.e., in “ingredient” which is an examination matter related directly to substantial identity. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to fall under the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 2] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Analgesics

Patented Invention pertaining to an application for registration of extension

[Claim 1] Analgesics comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, pain relief as efficiency and effect, and 5 mg/dose as dosage and administration (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, liver cancer as efficiency and effect, and 5 mg/dose as dosage and administration (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and pain relief as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

The prior disposition is made on a pharmaceutical product comprising liver cancer as efficiency and effect, whereas the patented invention pertaining to an application for registration of extension is an invention of analgesics. More specifically, the pharmaceutical product in the prior disposition does not fall under the working of the patented invention. Therefore, it is impossible to say that the present application shall fall under 3.1.1(1)(ii) over the prior disposition.

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 3] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Analgesics

Patented Invention pertaining to an application for registration of extension

[Claim 1] Analgesics comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, pain relief as efficiency and effect, and 30 mg/dose as dosage and administration (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, pain relief as efficiency and effect, and 3 mg/dose as dosage and administration (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and pain relief as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in dosage and administration, i.e., in “dosage” and “administration” which are examination matters related directly to substantial identity. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to fall under the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 4] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Injection for Pain Relief

Patented Invention pertaining to an application for registration of extension

[Claim 1] Injection for pain relief comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “30 mg of a1 as an active ingredient, pain relief as efficiency and effect, and injection as a dosage form (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “3 mg of a1 as an active ingredient, pain relief as efficiency and effect, and injection as a dosage form (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and pain relief as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in dose of the active ingredient, i.e., in “dose” which is an examination matter related directly to substantial identity. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to fall under the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 5] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Injection for Pain Relief

Patented Invention pertaining to an application for registration of extension

[Claim 1] An injection for pain relief comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “10 mg of a1 as an active ingredient, pain relief as efficiency and effect, and injection as a dosage form (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “10 mg of a1 as an active ingredient, pain relief as efficiency and effect, and a tablet as a dosage form (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and pain relief as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

The prior disposition is made on a pharmaceutical product comprising a tablet as a dosage form, whereas the patented invention pertaining to an application for registration of extension is an invention of injection. The pharmaceutical product in the prior disposition does not fall under the working of the patented invention. Therefore, it is impossible to say that the present application shall fall under 3.1.1(1)(ii) over the prior disposition.

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 6] (Application that shall be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Anticancer

Patented Invention pertaining to an application for registration of extension

[Claim 1] Anticancer comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “10 mg of a1 as an active ingredient,  $\alpha$ -gene positive stomach cancer as efficiency and effect, and a tablet as a dosage form (a1 is more specific concept of A)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “10 mg of a1 as an active ingredient, stomach cancer as efficiency and effect, and a tablet as a dosage form (a1 is more specific concept of A)”.

[Conclusion]

It is not admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Summary of Reasons for Refusal]

The present disposition is made on an approval of manufacturing and distribution of pharmaceutical product, whereas the patented invention pertaining to an application for registration of extension is an invention of product. Therefore, examination matters related directly to substantial identity comprise “ingredient, dose, dosage, administration efficiency, and effect”.

When the present disposition is compared with the prior disposition, the prior disposition includes the present disposition in “efficiency” and “effect” which are examination matters related directly to substantial identity as a pharmaceutical product, and there is no other difference between the both. In view of the above, it is admitted that the act of the manufacturing and distribution of the pharmaceutical product of the prior disposition includes the act of the manufacturing and distribution of the pharmaceutical product of the present disposition. Therefore, the present application shall fall under 3.1.1(1)(ii).

As a result, it is not admitted that obtaining of present disposition was essential in working the patented invention. This application shall be refused pursuant to Article 67ter (1) (i) of Patent Act.

[Explanation]



The present disposition is made on a pharmaceutical product comprising 10 mg of al as an active ingredient and  $\alpha$ -gene positive stomach cancer as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i). However, the present application shall fall under 3.1.1(1)(ii) for the reason as set forth in the [Summary of Reasons for Refusal].

[Measures of the applicant]

Normally, it is impossible to overcome this Reasons for Refusal.

[Case 7] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Syringe

Patented Invention pertaining to an application for registration of extension

[Claim 1] A syringe P comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “3 mg of a1 as an active ingredient, diabetes as efficiency and effect, 3 mg/dose twice a day as dosage and administration, and a pen-shaped syringe p1 with pre-filled formulation as a dosage form (a1 is more specific concept of A; and p1 is more specific concept of P)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “3 mg of a1 as an active ingredient, diabetes as efficiency and effect, 3 mg/dose twice a day as dosage and administration, and a kit of vial formulation and a syringe p2 as a dosage form (a1 is more specific concept of A; and p2 is more specific concept of P)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and a pen-shaped syringe p1 with pre-filled formulation as a dosage form. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

Further, the present disposition is made on approval of manufacturing and distribution of pharmaceutical product, and the patented invention pertaining to an application for registration of extension is an invention of a syringe. Therefore, examination matter related directly to substantial identity contain “ingredient, dose, dosage, administration, efficiency, and effect” and, if required, a matter on the syringe.

When the present disposition is compared with the prior disposition as to the examination matter related directly to substantial identity as a pharmaceutical product, the both do not differ from each other in “ingredient, dose, dosage, administration, efficiency, and effect”, however; the both differ from each other in the matter on the syringe. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is

not deemed to include the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 8] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Syringe

Patented Invention pertaining to an application for registration of extension

[Claim 1] A syringe P comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “3 mg of a1 as an active ingredient, diabetes as efficiency and effect, 3 mg/dose three times a day as dosage and administration, and a pen-shaped syringe p1 with pre-filled formulation as a dosage form (a1 is more specific concept of A; and p1 is more specific concept of P)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “3 mg of a1 as an active ingredient, diabetes as efficiency and effect, 3 mg/dose once a day as dosage and administration, and a pen-shaped syringe p1 with pre-filled formulation as a dosage form (a1 is more specific concept of A; and p1 is more specific concept of P)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and a pen-shaped syringe p1 with pre-filled formulation as a dosage form. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in dosage and administration, i.e., in “dose” and “administration” which are examination matters related directly to substantial identity as a pharmaceutical product. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to include the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 9] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Method for Manufacturing of Ingredient A

Patented Invention pertaining to an application for registration of extension

[Claim 1] A method for manufacturing of an ingredient A by a step X.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, antitussive as efficiency and effect, 3 mg/dose as dosage and administration, and a step x1 as a manufacturing method (a1 is more specific concept of A; and x1 is more specific concept of X)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, antitussive as efficiency and effect, 1 mg/dose as dosage and administration, and a step x1 as a manufacturing method (a1 is more specific concept of A; and x1 is more specific concept of X)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and a step x1 as a manufacturing method. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i)

When the present disposition is compared with the prior disposition, the both differ from each other in dosage and administration, i.e., in “dose” and “administration” which are examination matters related directly to substantial identity as a pharmaceutical product. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to include the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 10] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Method for Manufacturing of Ingredient A

Patented Invention pertaining to an application for registration of extension

[Claim 1] A method for manufacturing of an ingredient A by a step X.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, antitussive as efficiency and effect, 3 mg/dose as dosage and administration, and a step x1 as a manufacturing method (a1 is more specific concept of A; and x1 is more specific concept of X)”.

Prior Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, antitussive as efficiency and effect, 3 mg/dose as dosage and administration, and a step x2 as a manufacturing method (a1 is more specific concept of A; and x2 is more specific concept of X)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and a step x1 as a manufacturing method. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

The present disposition is made on an approval of manufacturing and distribution of pharmaceutical product, whereas the patented invention pertaining to an application for registration of extension is an invention of a manufacturing method. Therefore, examination matters related directly to substantial identity contain “ingredient, dose, dosage, administration, efficiency, and effect” and, if required, a matter on the manufacturing method.

When the present disposition is compared with the prior disposition as to the examination matters related directly to substantial identity as a pharmaceutical product, the both do not differ from each other in “ingredient, dose, dosage, administration, efficiency and effect”, however; the both differ from each other in the matter on the manufacturing method. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior

disposition is not deemed to include the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 11] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Insecticide

Patented Invention pertaining to an application for registration for extension

[Claim 1] Insecticide comprising an active ingredient A.

Present Disposition

Registration of manufacturing of an agricultural chemical comprising: “a1 as an active ingredient, a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease, and aqueous suspension as physical and chemical property (a1 is more specific concept of A)”.

Prior Disposition

Registration of manufacturing of an agricultural chemical comprising: “a1 as an active ingredient, a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease, and a granular formulation as physical and chemical property (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on an agricultural chemical comprising a1 as an active ingredient and a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease. The agricultural chemical in the present disposition falls under the working of the patented invention pertaining to an application for registration for extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in physical and chemical property, i.e., in “physical and chemical property” which are examination matters related directly to substantial identity as an agricultural chemical. Therefore, the act of manufacturing of the agricultural chemical in the prior disposition is not deemed to include the act of manufacturing of the agricultural chemical in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.



[Case 12] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Insecticide

Patented Invention pertaining to an application for registration for extension

[Claim 1] Insecticide comprising an active ingredient A.

Present Disposition

Registration of manufacturing of an agricultural chemical comprising: “a1 as an active ingredient, a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease, and aqueous suspension as physical and chemical property (a1 is more specific concept of A)”.

Prior Disposition

Registration of manufacturing of an agricultural chemical comprising: “a2 as an active ingredient, a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease, and aqueous suspension as physical and chemical property (a2 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on an agricultural chemical comprising a1 as an active ingredient and a Chinese cabbage and a cabbageworm as a name of crop and a name of applicable disease. The agricultural chemical in the present disposition falls under the working of the patented invention pertaining to an application for registration for extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in active ingredient, i.e., in “types of each component” which is an examination matter related directly to substantial identity as an agricultural chemical. Further, the act of manufacturing of the agricultural chemical in the prior disposition is not deemed to include the act of manufacturing of the agricultural chemical in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.

[Case 13] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Fungicide and Insecticide

Patented Invention pertaining to an application for registration of extension

[Claim 1] Fungicide and insecticide comprising an active ingredient A.

Present Disposition

Registration of manufacturing of an agricultural chemical comprising: “a1 as an active ingredient, a Rice plant as a name of crop (box growing), a rice leaf beetle and damping-off as a name of applicable disease and insects pests (a1 is more specific concept of A)”.

Prior Disposition

Registration of manufacturing of an agricultural chemical comprising: “a1 as an active ingredient, a Rice plant as a name of crop (box growing), damping-off as a name of applicable disease and insects pests (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Summary of Reasons for Refusal]

The present disposition is made on a registration of manufacturing of agricultural chemicals, whereas the patented invention pertaining to an application for registration of extension is an invention of product. Therefore, examination matters related directly to substantial identity comprise “type of agricultural chemicals, physical and chemical property, types and contents of each component, a range of applicable diseases and insects pests, and methods of use”.

When the present disposition is compared with the prior disposition, the prior disposition includes the present disposition in “a range of applicable diseases and insects pests” which is an examination matter related directly to substantial identity as agricultural chemicals, and there is no other difference between the both. In view of the above, it is admitted that the act of the manufacturing of the agricultural chemicals of the prior disposition includes the act of the manufacturing of the agricultural chemicals of the present disposition. Therefore, the present application shall fall under 3.1.1(1)(ii).

As a result, it is not admitted that obtaining of present disposition was essential in working the patented invention. This application shall be refused pursuant to Article 67ter (1) (i) of Patent Act.

[Explanation]

The present disposition is made on an agricultural chemical comprising al as an active ingredient. The agricultural chemical in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i). However, the present application shall fall under 3.1.1(1)(ii) for the reason as set forth in the [Summary of Reasons for Refusal].

[Measures of the applicant]

This Reason for Refusal can be overcome when an applicant removes “damping-off” from the description in a request of the application and materials stating a reason for extension, and show that the act of manufacturing of the agricultural chemical in the prior disposition is not deemed to include the act of manufacturing of the agricultural chemical in the present disposition.

[Case 14] (Application that shall not be refused pursuant to Article 67ter(1) (i) of Patent Act)

Title of Invention

Anticancer

Patented Invention pertaining to an application for registration for extension

[Claim 1] Anticancer comprising an active ingredient A.

Present Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, colon cancer/rectal cancer as efficiency and effect, and ‘administration of 7.5 mg/kg (weight) per dose as an active ingredient a1 with a administration interval of at least 3 weeks’ (a1 is more specific concept of A)”.

Previous Disposition

Approval of manufacturing and distribution of pharmaceutical product comprising: “a1 as an active ingredient, colon cancer/rectal cancer as efficiency and effect, and ‘administration of 5 mg/kg (weight) per dose or 10 mg/kg (weight) per dose as an active ingredient a1 with a administration interval of at least 2 weeks’ (a1 is more specific concept of A)”.

[Conclusion]

It is admitted that the disposition designated by Cabinet Order under Article 67(2) is necessary to obtain for the working of the patented invention.

[Explanation]

The present disposition is made on a pharmaceutical product comprising a1 as an active ingredient and colon cancer/rectal cancer as efficiency and effect. The pharmaceutical product in the present disposition falls under the working of the patented invention pertaining to an application for registration of extension and, therefore, the present application shall not fall under 3.1.1(1)(i).

When the present disposition is compared with the prior disposition, the both differ from each other in dosage and administration, i.e., in “dosage” and “administration” which are examination matters related directly to substantial identity as a pharmaceutical product. Further, the act of manufacturing and distribution of the pharmaceutical product in the prior disposition is not deemed to include the act of manufacturing and distribution of the pharmaceutical product in the present disposition. Therefore, the present application shall not fall under 3.1.1(1)(ii).

As a result, it is admitted that obtaining of present disposition was essential in working the patented invention.