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Date of the judgement

1999.10.22

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Case Number

1998(Gyo-Hi)43

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Title

Judgment upon the case concerning 'the period in which the patented invention could not be worked' due to the necessity of obtaining approval of production, etc., as provided by the Law on Pharmaceutical Business, which serves as a ground for the registration of extension of the period of subsistence of the patent

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Result

Judgment of the Second Petty Bench, October 22, 1999

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Court of the Second Instance

Tokyo High Court, Judgment of March 12, 1998

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Summary of the judgement

'The period in which the patented invention could not be worked' due to the necessity of obtaining approval of production etc. as provided by the Law on Pharmaceutical Business, which serves as a ground for the registration of extension of the period of subsistence of the patent is the period between the date of the beginning of the test which is required for the approval, or the date of patent registration, whichever is later, and the day before the date when the above approval took effect by reaching the applicant.

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References

Article 67, para.3 Patent Law (before the amendment by Law No.26, 1993)

1 The period of subsistence of a patent can be extended up to five years by application for the registration of extension, if the patent could not be worked due to the necessity of obtaining an approval or other decisions based upon a provision of a law purpose of which is to ensure safety in relation to the patented invention and is listed in the cabinet order as a decision which requires a substantial period in order to make it accurately in the light of the purpose, procedure etc. of the decision.

Article 67-3, para.1 Patent Law (before the amendment by Law No.26, 1993)

The patent examiner shall render a decision of refusal of the application for the registration of an extension of the period of subsistence for patents, if the application falls within one of the following:

1) it is not acknowledged that for the working of the patented invention, the decision as provided by the cabinet order in Art.67, para.3 was necessary
2) the patent holder, a person who has an exclusive licence to work the patent, or registered non-exclusive licence has not obtained the decision as provided by the cabinet order in Art.67, para.3
3) the period in which the patented invention could not be worked was less than 2 years
4) the period for which the extension is applied exceeds the period in which the patent could not be worked
5) the applicant is not the patent holder
6) the application does not fulfil the requirements as provided in paragraph 4 of the preceding provision

Article 14, Law on Pharmaceutical Business

1. The Minister of Public Health shall give approval for production of pharmaceutical products (except for pharmaceutical products which the Minister designates by setting a criteria), quasi-pharmaceutical products (except for quasi-pharmaceutical products which the Minister designates by setting criteria), and cosmetics and medical devicess which contain ingredients designated by the Minister, upon application of those who intend to produce them.

2. The approval as provided by the preceding paragraph shall be granted on the basis of the examination of the name, ingredients, amount, structure, use, dosage, means of use, intended

effect, effect, function, side-effects etc. of the pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devicess upon application; approval shall not be given in the following cases:

1. pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devices upon application cannot be acknowledged to have the intended effect, effect, or function as indicated in the application.
1. pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devices upon application have a substantially harmful effect in comparison with the intended effect, effect, and function and therefore, has no value of use as a pharmaceutical product, quasi-pharmaceutical product, or cosmetic or medical devices
1. in addition to the instances as provided in the preceding two subparagraphs, falls within the category of pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devices designated by the ordinance of the Ministry of Public Health

3. Those who intend to obtain the approval as provided by paragraph 1 shall apply for approval with the materials concerning the result of the clinical test and other materials in accordance with the ordinance of the Ministry of Public Health attached to he application. In such cases, if the pharmaceutical product upon application is a pharmaceutical product as provided by the ordinance of the Ministry of Public Health, the materials must be compiled and prepared in accordance with the criteria set by the Minister of Public Health.

4. In the examination as provided by paragraph 2, the quality, effectiveness, safety of the product shall be investigated on the basis of the content of the application concerning the product upon application and the materials as provided in the first half of the preceding paragraph (including investigation on the differences from products whose production or import has already been approved in relation to the ingredients, amount, structure, use, dosage, means of use, intended effect, effect, function etc.). In such cases, if the given product falls within the category of products designated by the ordinance of the Ministry of Public Health as provided in the second half of the said paragraph, investigation by documents or experiment as to the compatibility of the materials regarding the said product with the provision of the second half of the said paragraph shall be conducted.

5. The Minister of Public Health may conduct the examination of the pharmaceutical product or medical devices as provided by para.2 ahead of other pharmaceutical products or medical devices, if the pharmaceutical product or medical device upon application is a rare

pharmaceutical product or medical devices, or especially needed on medical grounds.

6. Those who obtained approval as provided by para.1 may apply for the alteration of approval if he intends to alter the approved matters in part. In such cases, paras. 1 to 5 are applicable with modification.

Art.23 Law on Pharmaceutical Business

Arts. 13 to 19, paras.1 and 2 of Art.20, and Art.21 are applicable with modification to the business of importing pharmaceutical products, quasi-pharmaceutical products, cosmetics and medical devices. In such cases, 'in cases where the approval of the Minister of Public Health has not been obtained' shall be read as 'in cases where the approval of the Minister of Public Health has not been obtained (except in cases where a person who produces the said product in a foreign country has obtained the approval of the Minister of Public Health as provided by Art.19-2)'. 'May not grant approval' in para.2 of the said article shall be read as 'May not grant approval (the same applies to cases where a person who produces the said product in a foreign country (if this person is a juridical person, then directors of this juridical persons are included) is a person as provided by Art.19-2)'. 'The person has not obtained approval of the Minister of Public Health in relation to the said product as provided in the n ext provision (including cases where the next provision is applied with modification by Art.23; the same applies to the next paragraph)' in Art.13-2, para.1, main text, shall be read as 'the person or a person who produces the said product in a foreign country has not obtained approval of the Minister of Public Health in relation to the said product as provided in the next provision (including cases where the next provision is applied with modification by Art.23; the same applies to the next paragraph) and Art.19-2'. 'Next provision' as provided in para.2 of the same provision shall be read as 'next provision (the same applies to the next paragraph) or Art.19-2'.

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Main text of the judgement

The judgment of the original instance court shall be quashed.

The award of the Patent Agency of October 31, 1996 on the adjudication case No.5909 of 1993 shall be revoked.

The cost of litigation shall be borne by the appellee.

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Reasons

On Item 1 of the grounds of appeal by the representative of the appellant, Tamotsu Aoyama and Shoji Nakajima

1. Facts lawfully ascertained by the original instance court are as follows:

P holds a patent on an invention called 'new group of polypeptides, its method of production, pharmaceutical product containing this group of polypeptide and its means of use' (registered on June 28, 1989, patent No.1501778, hereinafter, 'the Patented Invention' and 'the Patent' respectively).

Joint Stock Company Q Pharmaceutical, which was licensed by P to work the Patented Invention, obtained approval of partial alteration of the matters subject to import approval as provided by the Law on Pharmaceutical Business on June 28, 1991 (approval (01AMYu) No.0040 (partial alteration), hereinafter, 'the Approval'). P applied for the registration of the extension of the period of subsistence for the Patent for 2 years and 12 days on the ground that the company received the certificate of Approval on June 28, 1991, and therefore, the period in which the Patented Invention could not be worked was between the date of registration and the day before the date of the receiving of the certificate, but the application was rejected.

Upon the request of P, the Patent Agency considered the case as adjudication case No.5509 and rejected this application on the ground that this the period for which the extension is applied exceeds the period in which the patent could not be worked as provided by subpara.4, para.1 of Article 67-3 of the Patent Law before the amendment by Law No.26, 1993 on October 31, 1996 (hereinafter, 'the Adjudication').

The appellant succeeded the rights of P in December 20, 1996 by merger.

2. The present case involves a claim by the appellant for the revocation of the Adjudication on the ground that the calculation of the period in which the patent could not be worked was wrong.
The original instance court dismissed the claim of the appellant on the ground that:

1 'the period in which the patented invention could not be worked' as provided by Art.67-3, para.1, subpara.4 of the Patent Law before the amendment is the period the between the date of the beginning of the test which is required for the approval as provided by the cabinet order on the basis of Art.67, para.3, or the date of patent registration, whichever is later, and the day

before the date when the above approval as provided by the above cabinet order was given

1 in the present case, this period shall be calculated from the date of patent registration, which is June 28, 1989

1 the day before the date of the approval as provided by the above cabinet order is June 27, 1991, and thus, the period in which the Patented Invention could not be worked was one year 364 days. Therefore, the present Application for the extension of two years 12 days coincides with Art.67-3, para.1, subpara.4 of the Patent Law before the amendment.

Thus, the court found the ruling of the Adjudication to be justifiable and dismissed the claim of the appellant.

3. However, within the judgment of the original instance court, item (3) cannot be upheld on the following grounds:

1) While the system of patent acknowledges the exclusive right to work the patented invention as a business to the patent holder and provides for the period of subsistence of patents, Art.67, para.3 of the previous Patent Law provides that the period of subsistence of a patent can be extended up to five years by application for the registration of extension, if the patent could not be worked due to the necessity of obtaining an approval based upon a provision of a law the purpose of which is to ensure safety in relation to the working of the patented invention.
Decisions which serve as a ground for application for extension as provided in the said paragraph are limited to those determined by a cabinet order. Approval and partial alteration of matters subject to approval of production and importation of pharmaceutical products as provided by the Law on Pharmaceutical Business (hereinafter, 'Approvals') fall within the category of these decisions (Art.1-3, Enforcement Order of Patent Law).

1) In order to produce or import pharmaceutical products as a business, a licence based on the Law on Pharmaceutical Business is required (arts.11 and 12, Law on Pharmaceutical Business); this licence is not available, if the applicant for the approval has not obtained approval for the product which he intends to produce or import (arts.13, para.1, 23, Law on Pharmaceutical Business). Approvals are acts of an administrative agency to publicly confirm the effectiveness and safety of pharmaceutical products; by these Approvals, the applicant is granted a status to obtain licence of producing the products as a business and therefore, the Approvals can be regarded as administrative acts in relation to the applicant. Thus, the effect of Approvals

emerges when they reach the applicant, i.e. when the applicant actually becomes aware of the approval or is in a situation where he should be aware of the approval unless there is a special provision to the contrary.
By examining relevant legislation, there is no provision which provides for the means of notification of Approvals, but in the light of the wording of arts.14, para.1, 13, para.1 of the Law on Pharmaceutical Business, the absence of the provision on notification cannot be interpreted as denying the necessity of notification to the applicant; there is no provision from which it can be surmised that the Approvals take effect without reaching the applicant.
Furthermore, provisions of the Patent Law on the extension of the period of subsistence (arts.67, para.3, 67-2, para.3 etc.) are understood to presuppose that decisions which serve as the basis of registration of extension take effect when they reach the relevant party.
Therefore, Approvals which serve as the basis of registration of extension should be understood to take effect when they reach the applicant.

1) Since, as mentioned above, the situation of being unable to work the patented invention ceases when the approval as provided by the Law on Pharmaceutical Business which serves as the basis of registration of extension takes effect when it reaches the applicant and thus takes effect, the date when the approval has taken effect is not included in the period in which the patented invention could not be worked because of the necessity of obtaining the decision as provided by arts.67, para.3, 67-3, para.1, subpara.4 of the Patent Law before the amendment, and the end of the above period is the day before the approval reached the applicant.

1) Thus, 'the period in which the patented invention could not be worked' due to the necessity of obtaining approval of production etc. as provided by Art.67-3, para.1, subpara.4 of the Law on Pharmaceutical Business before the amendment should be understood as the period between the date of the beginning of the test which is required for the approval, or the date of patent registration, whichever is later, and the day before the date when the above approval took effect by reaching the applicant.

1) Therefore, the award of adjudication which found the day before June 28, 1991, the date as indicated in the Certificate, to be the end of the period in which the Patented Invention could not be worked without ascertaining the date of the arrival of the Approval to Joint Stock Company Q Pharmaceutical and rejected the Application on the ground that it coincides with Art.67-3, para.1, subpara.4 of the Law before the amendment, is against the law and should be revoked.

1 The judgment of the original instance court which dismissed the claim of the appellant for the revocation of the Award of Adjudication based upon a view different from the above contains a breach of law which evidently affects the judgment. The argument of the appellant coincides with the above and therefore, has a ground, and the judgment of the original instance court cannot but be quashed. Based upon the above, the claim for the revocation of the Adjudication Award should be acknowledged. Therefore, the justices unanimously rule as the main text of the judgment.

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Presiding judge

Justice Shinichi Kawai

Justice FUKUDA Hiroshi

Justice KITAGAWA Hiroharu

Justice KAMEYAMA Tsugio

Justice KAJITANI Gen