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Date of the judgement

1999.04.16

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Case Number

1998(Ju)153

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Title

Judgment upon case concerning the conducting of a test needed for the application of so-called following pharmaceutical products for the approval provided by Art.14 of the Law on Pharmaceutical Business and "working of a patented invention for testing or research" as provided by Art.69, para.1 of the Patent Law

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Result

Judgment of the Second Petty Bench, dismissed

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Court of the Second Instance

Osaka High Court, Judgment of May 13, 1998

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Summary of the judgement

Producing a chemical substance or pharmaceutical product which falls within the technical scope of a patented invention and using it for conducting a test needed for obtaining materials to be attached to the application form for the approval of the production in order to apply for the approval of production as provided by Art.14 of the Law on Pharmaceutical Business with the aim of producing and marketing so-called following products which have the same ingredients as the pharmaceutical product resulting from the patented invention after the expiration of the period of subsistence of the patent are 'working of a patented invention for testing or research' as provided by Art.69, para.1 of the Patent Law

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References

Art.67, Patent Law

The period of subsistence of a patent ends after 20 years of the patent application.

2. 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 whose purpose 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.

Art.68, ibid.

The patent holder has a right to work the patented invention as a business in an exclusive manner. However, this does not apply, if an exclusive right to work the patent has been established in relation to the given patent, within the scope of the exclusive right of the holder of such a right to work the patented invention.

Art.69, para.1, ibid.

The effect of the patent right does not extend to the working of a patented invention for testing or research.

Art.100, ibid.

1 A patent holder or the holder of an exclusive right to work the patented invention may demand the termination or prevention of infringement vis vis a person who infringes or is likely to infringe his patent or exclusive right to work the patented invention.

2 The patent holder or the holder of an exclusive right to work the patented invention, when making a claim as provided by the preceding paragraph, may also demand abandonment of the product which constituted the infringement (in patented invention on the method of producing a thing, this includes the thing which was produced by infringement; the same applies in Art.102, para.1), destruction of the equipment provided for the infringement, and other measures necessary for the prevention of infringement.

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 the criteria), quasi-pharmaceutical products (except for quasi-pharmaceutical products which the Minister designates by setting the criteria), and cosmetics and medical devices 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 devices upon application; approval shall not be given in the following cases:

1) pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devices upon application which cannot be acknowledged to have the intended effect, effects, or function as indicated in the application

2) pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical devices upon application which have a substantially harmful effect in comparison to the intended effect, effects, and function and therefore, have no value of use as a pharmaceutical product, quasi-pharmaceutical product, or cosmetic or medical device

3) in addition to the instances provided in the preceding two subparagraphs, falls within the category of pharmaceutical products, quasi-pharmaceutical products, and cosmetics and medical device designated by the ordinance of the Ministry of Public Health

3 Those who intend to obtain the approval provided by paragraph 1 shall apply for approval with the materials resulting from 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 and 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, effects, 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 on 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 device 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 device, 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.

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Main text of the judgement

The appeal is dismissed.

The cost of appeal shall be borne by the appellant.

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Reasons

On the Grounds of petition for certiorari by representatives Keizo Kosaka, Yoichiro Natsuzumi, Hanroku Toriyama, Yasuaki Iwamoto, Hirobumi Ata, Yoichi Tanabe

(1) The present case involves a claim for injunction of the sale of the pharmaceutical product of the defendant (hereinafter, 'the defendant's product') and damages by the appellant who had a patent on a chemical substance and pharmaceutical product which has this substance as a component on the basis of an alleged infringement on the part of the appellee by producing and using the defendant's product within the period of subsistence of the patent for the purpose of conducting a test needed for obtaining materials to be attached to the application form for the approval of the production in order to apply for the approval of production as provided by

Art.14 of the Law on Pharmaceutical Business in relation to a pharmaceutical product which is identical with the above pharmaceutical product resulting from the patented invention in ingredients, amount, usage, dose, purpose, and effect. Against this claim, the appellee argues that the above act is a 'working of a patented invention for testing or research' provided by Art.69, para.1 of the Patent Law, and therefore, did not constitute infringement of the appellant's patent.

(1) In cases where a person has a patent on a chemical substance and a pharmaceutical product which has this substance as a component, if a third party produces a chemical substance or a pharmaceutical product which falls within the technical scope of a patented invention and uses it for conducting a test needed for obtaining materials to be attached to the application form for the approval of the production in order to apply for the approval of production as provided by Art.14 of the Law on Pharmaceutical Business with the aim of producing and marketing so-called following products (hereinafter, 'following products') which have the same ingredients as the pharmaceutical product resulting from the patented invention after the expiration of the period of subsistence of the patent are 'working of a patented invention for testing or research' as provided by Art.69, para.1 of the Patent Law and should be considered not to be an infringement. The reasons are as follows:

The system of patent is intended to contribute to the development of industry by encouraging invention through granting an exclusive right to work the invention for a fixed period to the person who publicised the invention, and at the same time, give an opportunity to use this publicised invention to third parties. One of the basic principles of the patent system is to let any person use the invention freely, once the period of subsistence of the patent has expired, and thus benefit society as a whole.

The Law on Pharmaceutical Business requires the approval of the Minister of Public Health for the production of pharmaceutical products in order to ensure their safety. For this application, various tests are required and the materials on the result of these tests have to be attached to the application. The same applies also for the following products; it is required to conduct designated tests for a certain period. In order to conduct such tests, it is necessary to produce and use the chemical substance or pharmaceutical product which falls within the technical scope of the patented invention of the patent holder. If it is understood that such tests are not the 'test' as provided by Art.69, para.1 of the Patent Law and that within the period of subsistence of the patent, such production is not allowed, third parties will be unable to freely use the invention for a substantial period even after the expiry of the period of subsistence. This outcome should be

regarded to be against the above-mentioned basic principle of the patent system.

On the other hand, if a third party produces the following pharmaceutical products which are to be sold after the expiry of the period of subsistence or produces or uses the chemical substance resulting from the patented invention during the period of subsistence in excess of the scope necessary for the tests in order to apply for approval of production, it is not allowed since it is an infringement of the patent. Insofar as this is acknowledged, the profit earned by the exclusive working of the patented invention during the period of subsistence of the patent is ensured. If it is possible to exclude the above-mentioned production for the tests necessary for the application for the approval of production, it will have the same effect as the extension of the period of subsistence of the patent for a substantial period. This exceeds the profit of the patent holder which the Patent Law presupposes.

3. Thus, under the circumstances lawfully ascertained by the original instance court, the act of the appellee as discussed should be regarded as 'working of a patented invention for testing or research' as provided by Art.69, para.1 of the Patent Law and cannot be considered as an infringement of the patent of the appellant. The judgment of the original instance court is justifiable in its conclusion. The argument criticises the judgment of the original instance court based upon a unique view and cannot be accepted.
Therefore, the justices unanimously rule as the main text of the judgment.

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Presiding judge

Justice KAWAI Shinichi Kawai
Justice FUKUDA Hiroshi
Justice KITAGAWA Hiroharu
Justice KAMEYAMA Tsugio

(Translated by Sir Ernest Satow Chair of Japanese Law, University College, University of London)