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Date of the judgement

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1999.07.16

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Case Number

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1998(O)604

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Title

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Judgment upon case concerning the availability of an injunction against the production and sale of products whose quality standard was confirmed by using a method which is patented as an invention of method

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Result

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Judgment of the Second Petty Bench, quashed and decided by the Supreme Court

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Court of the Second Instance

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Osaka High Court, Judgment of November 18, 1997

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Summary of the judgement

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(1) It is not allowed to seek an injunction against the production and sale of products whose quality standard was measured by using a method which is patented as an invention of method

(1) 'Acts needed for the prevention of infringement' as provided by Art.100, para.2 of the Patent Law shall be measures to ensure the effectiveness of an injunction in the light of the content of the patented invention, the form of infringement which is being carried out or is likely to be carried out in the future, specific contents of the injunction which the patent holder seeks etc., and should be limited to the scope necessary for the realisation of the claim for injunction.

(1) Under the circumstances where the infringement of a patent of method comprises the use of the method for confirming the quality standard of a pharmaceutical product and the claim for

injunction is limited to the use of this method, the abandonment of the pharmaceutical product and the withdrawal of the application for the listing for the pricing standards of pharmaceutical products are not 'acts needed for the prevention of infringement' as provided by Art.100, para.2 of the Patent Law.

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## References

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On item 1

Art.2, para.3 of the Patent Law

In this Law, 'working' of an invention means the following acts.

in invention of things, the production, use, assignment, rental, or export, or offering of assignment or rental (including the displaying for the purpose of rental or assignment)

in invention of method, the use of the method

in invention of the method of production, in addition to subpara.2, the use, assignment, rental, or export, or offering of assignment or rental of things produced by this method

Art.68, *ibid.*

The patent holder has a right to work the patented invention in an exclusive manner as a business. 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.100, para.1, *ibid.*

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.

On items 2 and 3

Art.100, para.2, *ibid.*

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 object which effected the infringement (in patented invention on the method of producing a thing, this includes the thing which constituted the 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.

On item 3

Art.43-9, para.2 of the Law on Health Insurance

The amount of the cost of medical treatment as provided in the preceding paragraph shall be calculated on the basis of the standard set by the Minister of Public Health

Notification of the Ministry of Public Health No.30, 1998

(the purchase price of the pharmaceutical products (pricing standards of pharmaceutical products))

the purchase price of the pharmaceutical products shall be the price of pharmaceutical products determined in the attached list (inclusive of consumption tax and local consumption tax).

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Main text of the judgement

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The part of the judgment of the original instance court in which the appellant has lost shall be quashed.

In relation to this part, the jokoku appeal of the appellee is dismissed.

The cost of koso and jokoku appeal shall be borne by the appellee.

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Reasons

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On items 1 to 4 of the grounds of appeal by representatives Akira Kamisaka, Shuji Kitamoto, assistant to the appellant, Takeo Ito

The ruling of the original instance court on the above points can be acknowledged as justifiable

in the light of the evidence listed in the original judgment, nor is there any breach of law in the process as argued by the appellant. The argument merely criticises the adoption of evidence and ascertaining of facts which belong to the exclusive power of the original instance court and cannot be accepted.

On items 5 and 6

1 The facts lawfully ascertained by the original instance court are as follows:

The appellee has a patent called 'method of measurement of physiological activating substance' (Patent No.1725747, hereinafter, 'the Patent').

The entry of item 1 of the scope of the patent claim in the specification attached to the application of the Patent is 'a method of measuring the capability of preventing the generating of kalikrein of the tested substance by mixing and causing reaction of animal blood plasma, blood coagulation XII factor activating substance, electrolyte, and the substance which is tested, and adding, within the time in which a direct relationship can be established between the generation of kalkrein and the time of reaction, of preventing substance which does not affect the activated kalikrein which has been generated, but has an effect on the blood coagulation XII factor activating substance selectively in order to prevent the generating of kalikrein in this reaction, and then measure the amount of the generated kalikrein.

The appellant has obtained the approval for the production of the fluid as indicated in list (1) attached to the judgment of the original instance court (hereinafter, 'fluid of the appellant') and the product which contains this fluid as indicated in the same list (commercial name, Rosemorgen, hereinafter, 'product of the appellant', together with the fluid of the appellant, 'pharmaceutical product of the appellant') based upon the Law on Pharmaceutical Business and produces and sells the pharmaceutical product of the appellant. The product of the appellant is listed in the pricing standards list on the basis of the Law on Health Insurance.

The appellant uses the method as indicated in list (3) attached to the judgment of the original instance court (hereinafter, 'the Method') for a confirmation test for the capability of preventing the generation of kalikrein for the examination of the quality standard in the process of producing the appellant's pharmaceutical product.

1 The appellee claims that the production and sale of the appellant's pharmaceutical product by

using the Method is an infringement of the Patent and seeks (1) the injunction of the production of the appellants fluid, the production and sale of the appellant's pharmaceutical products, and the advertisement of the fluid and products, (2) abandonment of the appellant's pharmaceutical products, (3) withdrawal of the application for the listing for the pricing standards of pharmaceutical products, (4) withdrawal of the application for the approval for the production obtained in accordance with the Law on Pharmaceutical Products and prohibition of the succession and assignment of the status obtained by the above approval to a third party.

The original instance court found that (I) the Method falls within the technical scope of the Invention, (II) although the Invention is an invention of the method, in the light of the fact that the Method has been incorporated in the production process of the appellant's pharmaceutical products and is used with other production work in an inseparable manner, it can be regarded in substance as being the same as the invention of the method of production of a thing, and therefore, the Patent has the effect of preventing the sale of the products produced by using the Method. The court approved the claim of the appellee on (1) the injunction of the production of the appellants solution, the production and sale of the appellant's pharmaceutical products, and the advertisement of the fluid and products, (2) abandonment of the appellant's pharmaceutical products, (3) withdrawal of the application for the listing for the pricing standards of pharmaceutical products.

1 However, within the ruling of the judgment of the original judgment court, the above (II) cannot be accepted on the following grounds.

(1) Since a patent holder may demand the termination or prevention of infringement vis vis a person who infringes or is likely to infringe his patent (Art.100, Patent Law) and has a right to work the patented invention as business in an exclusive manner (Art.68, main text, *ibid.*), working of a patented invention by a third party as a business is an infringement of the patent. Since the working of a patented invention in an invention of method means the use of the method (Art.2, para.2, subpara.2, *ibid.*), the patent holder is entitled to seek an injunction against the act of using this method vis vis the person who uses the method of the patented invention as a business. In contrast, in an invention of the method of producing an object, the working of the patent means, in addition to the act of using the method, the use, assignment, rental, or export, or offering of assignment or rental of things produced by this method (subpara.3, *ibid.*), and therefore, the patent holder may seek an injunction against the person who effects these acts as a business.

(1) Because invention of method and invention of the method of production of an object are clearly distinguished in the law and the effect of the patent granted is evidently different, it is not possible to regard them as identical, not can a patent on the invention of method be granted the same effect as the patent on the method of production of an object. In which category of invention the given invention belongs shall be determined primarily by the scope of the patent claim as indicated in the patent specification attached to the application (Art.70, para.1, *ibid.*). Since, in the present case, in item 1 of the scope of the patented claim in the patent specification, the method of measuring the capability of preventing the generation of kalikrein, it is evident that the Invention is not an invention of the method of producing an object, but an invention of method. Although the Method is incorporated in the production process of the appellant's pharmaceutical products, it cannot be said that the Invention is an invention on the method of producing a thing, nor is it possible to acknowledge grounds for granting the same effect as the invention on the method of producing an object to the Invention.

(1) Because the Method falls within the technical scope of the Invention, the use of the Method in the production process of the appellant's pharmaceutical products by the appellant is an infringement of the Patent. Therefore, the appellee is entitled to seek an injunction against the use of the Method vis vis the appellant on the basis of Art.100, para.1 of the Patent Law. However, since the Invention is not an invention of a method of producing a thing, even if the appellant uses the Method in the production process of the appellant's pharmaceutical products for the confirmation test of the determination of the quality standard, the production and the subsequent sale cannot be regarded as an infringement of the Patent. Therefore, all the claims for an injunction by the appellee against the production etc. of the appellant's pharmaceutical products by the appellant as indicated in claim (1) cannot be accepted (in addition, in the light of the process of the present litigation, claim (1) cannot be construed to include a claim for the injunction against the use of the Method).

(1) Since Art.100, para.2 of the Patent Law lists the abandonment of the object which constituted the infringement (in a patented invention on the method of producing a thing, this includes the thing which was produced by the infringement) and the destruction of the equipment used for the infringement as measures necessary for the prevention of infringement which the patent holder may claim in the course of seeking an injunction, 'acts necessary for the prevention of infringement' as provided in the said paragraph should be understood as measures to ensure the effectiveness of an injunction in the light of the content of the patented invention, the form of infringement which is being carried out or is likely to be carried out in the future, specific contents of the injunction which the patent holder seeks etc., and should be limited to

the scope necessary for the realisation of a claim for an injunction.

In the present case, the appellant's pharmaceutical products are neither equipment used for the infringement, nor a thing which constituted the infringement. Furthermore, since the Invention is an invention of a method and the act of infringement was the use of the Method, and therefore, injunction is limited to the injunction against the use of the Method; it is evident that the abandonment of the appellant's pharmaceutical products and the withdrawal of the application for the listing for the pricing standards of pharmaceutical products are beyond the scope of measures necessary for the realisation of the right to an injunction. Thus, the claim of the appellee vis vis the appellant (2) and (3) cannot be granted either.

1 The ruling of the original instance court which acknowledged part of claim (1), and claims (2) and (3) of the appellee is against the law in erring in the application and interpretation of the law, and it is evident that this error affects the judgment. The argument on this point has a ground and the part of the judgment of the original instance court in which the appellant has lost cannot but be quashed. In the light of the above, the judgment of the first instance court which found that all the claims of the appellee were without grounds is justifiable in conclusion, and therefore, the koso appeal of the appellee against this part of the judgment shall be dismissed. Therefore, the justices unanimously rule as the main text of the judgment.

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Presiding judge

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Justice FUKUDA Hiroshi

Justice KAWAI Shinichi

Justice KITAGAWA Hiroharu

Justice KAMEYAMA Tsugio

Justice KAJITANI Gen

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