Patent Right	Date	February 9, 2021	Court	Intellectual Property High Court, Second Division
	Case number	2020 (Ne) 10051		
- A case in which the court found that conducting necessary tests for filing an application as prescribed in Article 14, paragraph (1), etc. of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices with regard to what is generally referred to as a pioneer drug constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.				

Case type: Injunction
Result: Appeal dismissed
References: Article 69, paragraph (1) of the Patent Act
Related rights, etc.: Patent No. 4212897
Judgment of the prior instance: Tokyo District Court, 2019 (Wa) 1409, rendered on July 22, 2020

Summary of the Judgment

1. T-VEC is a pioneer drug that falls within the technical scope of the invention covered by the patent held by the Appellant for the invention titled "Viruses and their use in therapy." The Appellee aims to obtain approval of the Minister of Health, Labor and Welfare for drug marketing (under Article 14, paragraph (1), etc. of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act")) using T-VEC, for which marketing approvals have already been granted by the drug regulatory authorities of foreign countries, and with this aim, it conducts a clinical trial (hereinafter referred to as the "Clinical Trial") for the purpose of obtaining clinical data or pharmacodynamic data regarding the efficacy, safety, dosage and dose of this drug in Japan.
2. Article 69, paragraph (1) of the Patent Act provides that a patent right is not effective against the "working of the patented invention for experimental or research purposes." The purport of this provision is interpreted as follows: in order to achieve the purpose of the Patent Act prescribed in Article 1, i.e., "encourage inventions through promoting the protection and utilization of inventions, and thereby contribute to the development of industry," it is necessary to protect the interest of a patentee who has made an invention; however, if a patent right is made effective against the working of the

patented invention for experimental or research purposes as well, this could rather result in impeding the development of industry; therefore, from the perspective of industrial policy, it is provided that a patent right is not effective against the working of the patented invention for experimental or research purposes, with a view to achieving the balance between the interest of the patentee and the interest of the general public.

It is appropriate to determine whether the Clinical Trial constitutes the "working of the patented invention for experimental or research purposes" as referred to in that paragraph, in light of factors such as the purpose of the Patent Act prescribed in Article 1, the abovementioned legislative purpose of Article 69, paragraph (1) of that Act, the purpose of and regulations under the Pharmaceuticals and Medical Devices Act, the purpose and content of the Clinical Trial, the characteristics of the drug, etc. used in the clinical trial, and the consistency with the system for extension of the term of a patent right, and from the perspective of achieving the balance between the interest of the patentee which should be protected, and the interest of the general public.

3. (1) With regard to why a generic drug constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act, the judicial precedent of the Supreme Court, 1998 (Ju) No. 153, the judgment of the Second Petty Bench of the Supreme Court of April 16, 1999, Minshu Vol. 53, No. 4, at 627 (hereinafter referred to as the "Supreme Court judgment in 1999"), points out that in order to apply for marketing approval for a generic drug, it is necessary, as in the case of other drugs, to conduct prescribed trials or tests, which require a certain amount of time, and in order to conduct such trials or tests, it is necessary to produce and use chemical substances or pharmaceuticals which fall within the technical scope of the patentee's patented invention. It further explains that if a third party is not allowed to produce or otherwise handle such chemical substances or pharmaceuticals which fall within the technical scope of the patentee's patented invention during the term of the patent right, the third party would be unable to use the patented invention freely for a considerable period of time even after the term of the patent right expires, and such consequence is contrary to the foundation of the patent system, which is designed to enable any person to use a patented invention freely after the term of the patent right expires, thereby widely benefiting society.

T-VEC, which is subject to the Clinical Trial, is a pioneer drug for which marketing approvals have already been granted by the drug regulatory authorities of foreign countries and bridging study has been conducted in Japan. In order to apply for marketing approval for this drug, it is necessary, as in the case of a generic drug, to conduct prescribed trials or tests, which require a certain amount of time. If a third party

is unable to produce or otherwise handle any pharmaceuticals which fall within the technical scope of the Invention during the term of the Patent Right, the third party would also be unable to use the Invention freely for a considerable period of time even after the term of the Patent Right expires. As stated in the Supreme Court judgment in 1999, such consequence is contrary to the foundation of the patent system.

(2) The Supreme Court judgment in 1999 states that if a third party, during the term of a patent right, produces and uses chemical substances involved in the patented invention beyond the extent necessary for conducting tests for the purpose of obtaining marketing approval under the Pharmaceutical Affairs Act (effective at that time) in order to produce a generic drug that is to be transferred after the expiration of that term or to use those substances as components of such generic drug, such an act of the third party infringes the patent right and therefore it is impermissible.

There is no evidence suggesting that the Appellee performs or is likely to perform the production, etc. of T-VEC during the term of the Patent Right beyond the extent necessary for conducting tests for the purpose of obtaining marketing approval under the Pharmaceuticals and Medical Devices Act, with the expectation to perform the transfer, etc. of T-VEC after the expiration of the term of the Patent Right. An opportunity for the Appellant, as the patentee, to gain profit by exclusively working the Invention during the term of the Patent Right can be secured, and if, nevertheless, it is considered to be also permissible to exclude the production, etc. performed during the term of the Patent Right for conducting necessary tests for applying for marketing approval for T-VEC, this could lead to the same consequence as extending the term of the Patent Right for a considerable period of time. As indicated in the Supreme Court judgment in 1999, such consequence goes beyond the bounds of the benefit assumed under the Patent Act as a benefit to be granted to the patentee.

(3) For the reasons stated above, the purport of the Supreme Court judgment in 1999 is valid for the Clinical Trial as well, and therefore the Clinical Trial constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.

udgment rendered on February 9, 2021
2020 (Ne) 10051 Appeal case of seeking injunction against patent infringement
(Court of prior instance: Tokyo District Court, 2019 (Wa) 1409)
Date of conclusion of oral argument: December 16, 2020

Judgment

Appellant: X

Appellee: Amgen Inc.

Main text

1. The appeal shall be dismissed.
2. Both of the claims additionally filed by the Appellant in this instance shall be dismissed.
3. The Appellant shall bear the cost of the appeal.

Facts and reasons

The abbreviations of the terms used herein and the meanings of the abbreviations shall be as prescribed in the judgment in prior instance, and the term "attachment" that appears in each part cited from the judgment in prior instance shall be replaced with "attachment of the judgment in prior instance." Unless otherwise indicated, documentary evidence with a number that has branch numbers shall include all articles of evidence with these branch numbers.

No. 1 Object of the appeal

1. The judgment in prior instance shall be revoked.
2. The Appellee must not perform the production, use, transfer, etc. (meaning transfer and lending), import, export, or offer of transfer, etc. of the virus specified in the list of articles, the attachment of the judgment in prior instance.
3. The Appellee must not apply for marketing approval regarding the virus specified in the list of articles, the attachment of the judgment in prior instance under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.
4. The Appellee shall dispose of the virus specified in the list of articles, the attachment of the judgment in prior instance, which is in its possession.
5. The Appellee shall pay to the Appellant 1,000,000 yen with an amount accrued thereon at the rate of 5% per annum from October 8, 2020, until the completion of the payment.

6. The Appellee shall bear the court costs for both the first and second instances.
7. Declaration of provisional execution
No. 2 Outline of the case
1. In this case, the Appellant, who is a patentee of the Patent for the invention titled "Viruses and their use in therapy," alleged that the Appellee conducts the Clinical Trial using the virus (T-VEC) specified in the list of articles, the attachment of the judgment in prior instance, in Japan in the course of trade and that such conduct of the Appellee constitutes the working of the Invention and infringes the Patent Right. Based on this allegation, the Appellant claimed an injunction against the Appellee's use of the virus under Article 100, paragraph (1) of the Patent Act, and also claimed the disposal of the virus under paragraph (2) of that Article.

As the court of prior instance dismissed the Appellant's claims, the Appellant filed an appeal with the court of second instance, while amending the claims to seek: [i] under Article 100, paragraph (1) of the Patent Act, an injunction against the production, use, transfer, etc. (meaning transfer and lending), import, export, and offer of transfer, etc. of that virus; [ii] under paragraph (2) of that Article, an injunction against an application for marketing approval regarding that virus under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceuticals and Medical Devices Act"); [iii] under paragraph (2) of that Article, disposal of that virus; [iv] as a claim for the return of unjust enrichment or claim for compensation of damage in tort due to patent infringement, payment of 1,000,000 yen, with delay damages accrued thereon at the rate of 5% per annum as prescribed in the Civil Code prior to the amendment by Act No. 44 of 2017 for the period from October 8, 2020, the day following the date of service of the petition for amendment of claims, until the completion of the payment.
2. Basic facts (facts not disputed between the parties and facts found from evidence and the entire import of oral arguments)

The basic facts are as described in No. 2, 2. in the "Facts and reasons" section of the judgment in prior instance and therefore cited herein, except for correcting the judgment in prior instance as follows:
(1) the phrase "[Exhibit Ko 1-2]" is added following the phrase containing "drawings" in line 24 on page 3 of the judgment in prior instance;
(2) a new line is started following line 6 on page 5 of the judgment in prior instance, and the following sentence is added: "In Japan, there is no product involving the Invention for which drug marketing approval has been granted (Exhibit Ko 32).."; and
(3) the phrase "or a specific type of patients" is added following the phrase "healthy

volunteers" in line 5 on page 6 of the judgment in prior instance.

(omitted)

No. 3 Judgment of this court

1. This court determines that all of the Appellant's claims, including those added in this instance, should be dismissed. The reasons for this determination are as described in No. 4, 1. in the "Facts and reasons" section of the judgment in prior instance and therefore cited herein, except for correcting the judgment in prior instance as follows and making an additional determination on the Appellant's allegations presented in this instance.

(1) The statements in line 17 to line 21 on page 30 of the judgment in prior instance are corrected as follows:

"As the Clinical Trial, the Appellee has been conducting Phase I Clinical Study based on the provisions of the Pharmaceuticals and Medical Devices Act as mentioned above. There is no evidence suggesting that the Appellee performs or is likely to perform the production, etc. of T-VEC during the term of the Patent Right, beyond the extent necessary for conducting tests for the purpose of obtaining marketing approval under that Act."

(2) The statements in line 23 on page 32 to line 44 on page 33 of the judgment in prior instance are corrected as follows:

"According to the Appellant's allegations as the premise, once a third party obtains marketing approval for a drug, etc. used in a clinical trial and becomes able to commence marketing the drug during the term of a patent right, the third party might be deemed to have intended to commence marketing during the term of the patent right even though the party did not have such intention, and could be sued for patent infringement, and hence, the determination on the existence of patent infringement could vary depending on unexpected circumstances. Since the time required for completing the clinical trial or approval procedure is not necessarily known with certainty at the time the third party commences the clinical trial or approval procedure, such a view based on Appellant's allegations should be considered to make the status of the third party conducting the clinical trial unnecessarily unstable."

(3) The phrase "[to complete] examination for approval for regenerative medicine products" in line 25 on page 33 of the judgment in prior instance is corrected as "[to obtain] approval for regenerative medicine products."

(4) The statements in line 13 to line 18 on page 34 of the judgment in prior instance are corrected as follows:

"The reexamination system under the Pharmaceuticals and Medical Devices Act is a system designed for reconfirming the quality, efficacy and safety of a new drug based on the results of investigation of safety information regarding the use in actual medical services after a certain period of time (e.g., eight years for a drug with a new active component, ten years for a drug for a rare disease, or four or six years for a drug with a new efficacy, effect, dosage or dose) has passed since the drug was approved (Article 23-29, paragraphs (1), (3) and (5) of the Pharmaceuticals and Medical Devices Act). If, during the reexamination period, a party other than the party that has obtained marketing approval for a new drug intends to apply for approval for a drug that is found to be identical with that new drug in terms of active components, efficacy, effects, dosage, dose or other elements, it is necessary to submit the same or greater level of data compared to data required for the new drug, and it is impossible to obtain approval by submitting simplified data that is acceptable for generic drugs. Thus, it is found that the reexamination system is considered to substantially restrict market entries of generic drugs during the reexamination period, thereby serving to "protect data" for pioneer drugs (Exhibit Ko 28).

However, the reexamination system is a system designed for reconfirming the quality, efficacy and safety of a new drug based on the results of investigation of safety information regarding the use in actual medical services after a certain period of time has passed since the drug was approved, and even if market entries of generic drugs are substantially restricted during the reexamination period, this is nothing more than a de facto benefit that can be enjoyed as a reflection of the regulations under that Act.

It is inappropriate to adopt the interpretation that could result in the same effect as extending the term of the patent right for a considerable period of time in consideration of such de facto, reflexive benefit."

3. Determination on the Appellant's allegations presented in this instance

(1) The Appellant alleges that: a necessary test for obtaining marketing approval for a new drug is outside the scope of applicability of the Supreme Court judgment in 1999 as a judicial precedent. Whether such a test constitutes the "experiment or research" referred to in Article 69, paragraph (1) of the Patent Act is an issue that should be answered by closely examining the interest of the patentee and the interest of a third party, and the Clinical Trial does not constitute "experiment or research" under that paragraph.

However, as stated in No. 4, 1. (2) in the "Facts and reasons" section of the judgment in prior instance, the Clinical Trial that is necessary for obtaining marketing approval for a new drug constitutes the "experiment or research" referred to in Article 69, paragraph (1) of the Patent Act.

The Appellant alleges that a test conducted for the purpose of obtaining marketing approval for a new drug differs in content from a test conducted for the purpose of obtaining marketing approval for a generic drug. However, as stated in No. 4, 1. (2) in the "Facts and reasons" section of the judgment in prior instance, the purport of the Supreme Court judgment in 1999 is valid for the Clinical Trial as well, and this may not be affected depending on the content of a test conducted for obtaining marketing approval.

(2) The Appellant alleges that even if a third party that is not the patentee obtains marketing approval for a new drug during the term of the patent right, the third party is unable to market the new drug until the term of the patent right expires, and for this reason, there arises a period in the reexamination period of the new drug during which the third party cannot market the new drug. However, investigation of safety information regarding the use in actual medical services can be commenced after the patent term expires, and it is not true that, in this manner, the purpose of investigation of safety information regarding the use in actual medical services cannot be fully achieved.

(3) The Appellant alleges that: if a patent right is not effective against a clinical trial conducted by a third party that is not the patentee in which a patented invention is applied to a new drug, it would be possible for the third party to obtain marketing approval ahead of the patentee, which could make it virtually impossible for the patentee to conduct a clinical trial of the product involving his or her patented invention even during the term of his or her patent right; in that case, filing a patent application would not bring any benefit but would only result in a considerable disadvantage in the form of disclosure of an invention, and therefore inventors of pharmaceuticals would hesitate to file patent applications, which would seriously hinder the development of the pharmaceutical industry, contrary to the purpose of the Patent Act.

However, although the Patent Act ensures an opportunity for the patentee to gain profit by working the patented invention exclusively during the term of the patent right, it does not go so far as to guarantee that the patentee can actually gain profit. Therefore, even though a third party may obtain marketing approval ahead of the patentee, or it may become difficult in actuality for the patentee to conduct a clinical trial of the product involving his or her patented invention, such situations cannot be found to be contrary to the purpose of the Patent Act, and hence, the Appellant's allegation mentioned above cannot affect the determination that the Clinical Trial constitutes an "experiment" referred to in Article 69, paragraph (1) of the Patent Act.

(4) The Appellant alleges that since particularly, biopharmaceuticals among regenerative medicine products, are subject to regulations and restrictions that are different from those imposed on ordinary pharmaceuticals, and it takes a long period of time to develop

biopharmaceuticals, it is unavoidable that the patentee can obtain marketing approval and commence marketing only at a time shortly before the expiration of the term of the patent right, and thus, if a third party is allowed to conduct a clinical trial (clinical study) for the purpose of applying for approval during the term of the patent right, this would bring about a considerable disadvantage to the patentee.

However, as stated in No. 4, 1. (3) C. of the "Facts and reasons" section of the judgment in prior instance, the Appellant's allegation on this point is unacceptable.

The Appellant alleges that if a third party is allowed to conduct a clinical trial (clinical study) for the purpose of applying for approval during the term of the patent right, this would have an adverse influence on the research and development of innovative pharmaceuticals or cause considerable confusion to pharmaceutical industries in and outside Japan. However, such circumstances cannot be found on the basis of the Appellant's written statement (Exhibit Ko 32) alone, and there is no other sufficient evidence to find such circumstances.

(5) The Appellant alleges that if a third party is allowed to conduct a clinical trial for the purpose of applying for approval for a new drug without a license during the term of the patent right, such treatment would be contrary to the treatment in foreign countries.

However, since Japan and foreign countries have different legal systems, it cannot be said that Japan must treat such a clinical trial in the same manner as in foreign countries. In addition, according to evidence (Exhibit Ko 41) and the entire import of oral arguments, it is found that European countries, under their respective national laws, provide for the scope of applicability of what is generally called the Bolar provision, which exempts procedures for obtaining drug approval from patent infringement, and that France, Italy, Spain and the United Kingdom do not limit the applicability of this provision only to trials conducted for the purpose of obtaining approval for generic drugs.

The Appellant alleges that Amgen conducts clinical studies on T-VEC after concluding licensing agreements in the United States and Europe with regard to the patents held by Massachusetts General Hospital (the US patent and European patent corresponding to the Patent). However, since it is likely that a third party concludes a licensing agreement with the patentee in order to conduct a clinical trial of a new drug even when such trial is exempt from patent infringement, no findings can be made regarding the systems in foreign countries based on the Appellant's allegation mentioned above.

The Appellant alleges in his or her written statement (Exhibit Ko 32) that unlike the case of a generic drug, it is an established view that a clinical trial of a new drug conducted while the patent involved in the new drug exists constitutes infringement of the patent if

it is conducted without obtaining a license from the holder of the patent. However, according to the aforementioned findings regarding the systems in foreign countries, the Appellant's allegation in the written statement cannot be accepted.

As explained above, since clinical trials of new drugs are exempt from patent infringement in multiple countries, even if there are also countries that do not adopt such exemption, it cannot be deemed to be contrary to the systems in foreign countries to determine in Japan that the Clinical Trial constitutes an "experiment or research" under Article 69, paragraph (1) of the Patent Act.

(6) The Appellant alleges that the Clinical Trial is intended for sale "before" the expiration of the term of the Patent Right.

However, as stated in No. 4, 1. (3) B. of the "Facts and reasons" section of the judgment in prior instance, the Clinical Trial cannot be found to have been intended for marketing during the term of the Patent Right, and this finding is not affected depending on whether the Appellee is likely to obtain approval for T-VEC before the expiration of the term of the Patent Right or whether the Appellee commenced the Clinical Trial at the time when such likelihood existed.

The Appellant alleges that if the logic indicated in the judgment in prior instance is accepted, no clinical trials conducted during the terms of patent rights would ever be found to be intended for marketing during the terms of the patent rights, and hence, that logic completely deviates from the purport of the Supreme Court judgment in 1999, which presented a requirement based on the purpose. However, it is obvious that even when the logic indicated in the judgment in prior instance is relied on, it cannot be said that no clinical trials conducted during the terms of patent rights would ever be found to be intended for marketing during the terms of the patent rights.

(7) All of the other allegations of the Appellant are obviously unacceptable in light of what has been stated above.

(8) For the reasons mentioned above, conducting the Clinical Trial does not infringe the Patent Right.

4. Claims additionally filed by the Appellant in this instance

As stated in 3. (8) above, the Appellee is not found to infringe the Patent Right, and therefore both of the claims additionally filed by the Appellant are groundless.

No. 4 Conclusion

For the reasons stated above, all of the Appellant's claims are groundless. Therefore, the appeal is dismissed, both of the claims additionally filed in this instance are dismissed, and the judgment is rendered as indicated in the main text.

Intellectual Property High Court, Second Division
Presiding Judge: MORI Yoshiyuki
Judge: MANABE Mihoko
Judge: KUMAGAI Daisuke