Patent Right	Date	July 22, 2020	Court	Tokyo District Court, 40th Civil Division
	Case number	2019 (Wa) 1409		
- A case in which the court ruled that the clinical trial of a regenerative medicine product that falls within the technical scope of a patented invention constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.				

Summary of the Judgment

In this case, the Plaintiff, the holder of the patent right for an invention titled "Viruses and their use in therapy" (Patent No. 4212897) (hereinafter referred to as the "Patent Right"), alleged that the clinical trial conducted by the Defendant in Japan using the virus in question constitutes the exercise of the Patent Right, and claimed an injunction against the Defendant'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 the same Article.

The Plaintiff's patented invention (the "Invention") relates to a "herpes simplex virus comprising a deletion within the BstEII-EcoNI fragment of the BamHI x fragment of the virus." Based on this invention, the Plaintiff's research group is conducting a clinical trial of a virus named G47Δ (the Plaintiff's virus) with the aim of achieving its commercialization, targeting glioblastomas, a type of malignant brain tumor, as an indication. In this virus, modifications are made to three genes, ICP34.5 (γ34.5), ICP6, and ICP47. On the other hand, the virus for which the Defendant conducts a clinical trial, targeting malignant melanoma as an indication, talimogene laherparepvec [generic name] (hereinafter this clinical trial and virus are referred to as the "Clinical Trial" and the "Defendant's virus"), is a herpes simplex virus-type 1 (HSV-1) which is weakened by functionally deleting two genes, ICP34.5 (γ34.5) and ICP47. The Defendant's virus falls within the technical scope of the Invention. The Defendant's parent company (a US company) has already obtained approval for the Defendant's virus from the foreign drug regulatory authorities including the FDA (US Food and Drug Administration) in the United States. In the Clinical Trial, a bridging study is being conducted as a study performed to provide pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in the new region. The Defendant's virus falls within the scope of regenerative medicine products prescribed in Article 2, paragraph (9) of the Pharmaceuticals and Medical Devices Act. Provisions of this Act concerning

regenerative medicine products in terms of marketing approval are basically identical to the provisions concerning pharmaceuticals.

The Defendant refuted the Plaintiff's claims, alleging that: [1] 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; and [2] the Defendant holds a non-exclusive license for the Invention.

In this judgment, the court cited 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"), which ruled that: if a third party intends to manufacture and sell a generic drug that has the same active components, etc. as those of the pharmaceuticals that are relevant to the patented invention after the term of the patent right expires, and if, in order to apply for manufacturing approval as prescribed in Article 14 of the Pharmaceutical Affairs Act (effective at that time), the third party, during the term of the patent right, produces chemical substances or pharmaceuticals that fall within the technical scope of the patented invention and conducts necessary tests by using those chemical substances or pharmaceuticals for obtaining data to be attached to the written application, such act of conducting necessary tests constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act, and does not constitute infringement of the patent right. The Defendant's virus, which is subject to the Clinical Trial, is a pioneer drug for which manufacturing approvals have already been granted by the drug regulatory authorities of foreign countries and bridging study has been conducted in Japan. The court ruled that the purport of the Supreme Court Judgment in 1999 is valid for the Clinical Trial as well for the following reasons. [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 Supreme Court Judgment in 1999 points out that in order to apply for manufacturing approval for a generic drug, it is necessary, as in the case of other drugs, to conduct in advance prescribed tests which require a certain amount of time, and in order to conduct such tests, it is necessary to produce and use certain chemical substances or pharmaceuticals which fall within the technical scope of a patentee's patented invention. In order to apply for marketing approval for the Defendant's virus as well, it is necessary to conduct a clinical study which requires a certain amount of time by administering the Defendant's virus in Japanese subjects, and in order to conduct such study, it is necessary to produce and use the Defendant's virus which falls within the technical scope of the Invention. [2] The

Supreme Court Judgment in 1999 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 a patented invention during the term of a 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 a patent right expires, thereby widely benefiting society. In order to apply for marketing approval for the Defendant's virus as well, it is necessary to conduct in advance prescribed 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. Such consequence is contrary to the foundation of the patent system. [3] The Supreme Court Judgment in 1999 ruled that if a third party, during the term of a patent right, produces and uses any chemical substances involved in a patented invention beyond the extent necessary for conducting tests for the purpose of obtaining manufacturing 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 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. With regard to the Clinical Trial, there is no evidence suggesting that the Defendant performs or is likely to perform the production, etc. of the Defendant's virus 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 the Defendant's virus after the expiration of the term of the Patent Right. Accordingly, an opportunity for the Plaintiff, 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 the Defendant's virus, this could lead to the same consequence as extending the term of the Patent Right for a considerable period of time. Such consequence goes beyond the bounds of the benefit assumed under the Patent Act as a benefit to be granted to the patentee. The court ruled that for these reasons, the purport of the Supreme Court Judgment in 1999 is valid for the Clinical Trial as well, and hence, 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, and dismissed the Plaintiff's claims.

Judgment rendered on July 22, 2020
Original received on the same date by the court clerk
2019 (Wa) 1409 Case of seeking injunction against patent infringement, etc.
Date of conclusion of oral argument: March 24, 2020

Judgment

Plaintiff: X

Defendant: Amgen Inc.
(Former trade name: Amgen Astellas BioPharma K.K.)

Main text

1. All of the Plaintiff's claims shall be dismissed.
2. The Plaintiff shall bear the court costs.

Facts and reasons

No. 1 Claims

1. The Defendant must not use the virus specified in the list of articles attached hereto.
2. The Defendant shall destroy the virus specified in the list of articles attached hereto which is in its possession.
3. Declaration of provisional execution

No. 2 Outline of the case

1. In this case, the Plaintiff alleges that the clinical trial conducted by the Defendant in Japan using the virus specified in the attached list of articles constitutes the exercise of the patent right held by the Plaintiff and infringes that patent right. Based on this allegation, the Plaintiff claims an injunction against the Defendant's use of the virus under Article 100, paragraph (1) of the Patent Act, and also claims the disposal of the virus under paragraph (2) of the same Article.
2. Basic facts (facts not disputed between the parties or facts found from evidence cited herein and the entire import of oral arguments; unless otherwise indicated, evidence with a number that has branch numbers includes all articles of evidence with these branch numbers)

(1) Parties, etc.

A. The Plaintiff is a researcher who serves as a professor at the Division of Innovative

Cancer Therapy, the Institute of Medical Science, University A, and a professor at the Department of Surgical Neuro-Oncology of the hospital affiliated to that institute.
B. The Defendant is a subsidiary of a U.S. company, Amgen Inc. (hereinafter referred to as "US Amgen"), and it is a stock company primarily engaging in research, development, manufacturing, sale, import, etc. of pharmaceuticals, quasi-pharmaceutical products, and medical devices.
(2) Patent right held by the Plaintiff
A. Patent right held by the Plaintiff

The Plaintiff holds the patent right specified below (hereinafter this patent right is referred to as the "Patent Right" and the patent pertaining to it is referred to as the "Patent") (Exhibit Ko 1).

Title of the invention: Viruses and their use in therapy
Patent No.: 4212897
Filing date: March 27, 2002 (Patent Application No. 2002-574742)
Priority date: March 27, 2001
Country of priority claim: United States
Registration date: November 7, 2008

B. Circumstances of the filing of the application for the Patent

The Plaintiff is one of the inventors of the Patent. The Plaintiff was registered as the patentee of the Patent Right under the following circumstances.
(A) On March 27, 2002, MediGene, Inc. and the General Hospital Corporation, both of which are US corporations (hereinafter referred to as "MediGene" and "Hospital Corp.," respectively), and Georgetown University, filed an application for the Patent in Japan (Exhibit Ko 1; the entire import of oral arguments).
(B) On July 15, 2005, MediGene transferred its interest in the right to obtain a patent regarding the Patent to Hospital Corp. On the same day, Hospital Corp. concluded an agreement with MediGene and its affiliated company for granting a license for rights that would be vested in the patent application filed and a patent to be granted in Japan, on condition of a non-exclusive, royalty-free license subject to prohibition on sublicensing (hereinafter this agreement and this license are referred to as the "Licensing Agreement" and the "License," respectively) (Exhibit Otsu 3).
(C) On September 30, 2005, Georgetown University transferred its interest in the right to obtain a patent regarding the Patent to Hospital Corp. (Exhibit Otsu 6).
(D) On October 26, 2006, Hospital Corp. transferred its right to obtain a patent regarding the Patent to the Plaintiff (hereinafter referred to as the "Transfer Agreement"). After that, following the procedure for changing the name of the registered applicant to register the

Plaintiff as the applicant for the Patent, the Plaintiff became the applicant of the application for the Patent (Exhibit Otsu 1).

C. Claims of the Patent

Claim 1 of the Patent is as described below (hereinafter the invention based on this claim is referred to as the "Invention" and the description and drawings of the Patent are referred to as the "Description, etc.").

"A herpes simplex virus comprising a deletion within the BstEII-EcoNI fragment of the BamHI x fragment of the virus."

(3) Significance of the Invention and the subjects of the clinical trials by the Plaintiff and the Defendant

A. An oncolytic virus therapy for cancer is a therapeutic method of transmitting a virus that can grow only in cancer cells in order to have the virus directly destroy cancer cells (Exhibit Ko 14). The virus related to the Invention is also a "virus that can be used for therapeutic methods such as the treatment of cancer (paragraph [0015] in the Description, etc.), and it is used in an oncolytic virus therapy for cancer.

B. The Invention relates to a "herpes simplex virus comprising a deletion within the BstEII-EcoNI fragment of the BamHI x fragment of the virus." As stated in paragraph [0016] in the Description, etc., which reads, " Some of the viruses of the invention are herpes simplex viruses (HSV) that contain inactivating mutations in the viral ICP47 locus. This mutation can occur, for example, between the BstEII and EcoNI sites of the BamHI x fragment of HSV-1 and can include, for example, a deletion of the BstEII-ExoNI fragment," the "deletion within the BstEII-EcoNI fragment of the BamHI x fragment" mentioned here contains inactivating mutations in the viral ICP47.

The Description, etc. discloses G47Δ as an example of the virus related to the Invention. This virus "contains a deletion in the γ34.5 gene, an inactivated insertion in the ICP6 gene, and a 312 base pair deletion in the ICP47 gene" (paragraph [0021]). In this virus, in addition to a deletion in the CIP47 gene, modifications are made to the γ34.5 gene and the ICP6 gene. The virus for which the Plaintiff conducts the clinical trial for commercialization is this virus, G47Δ.

C. The virus specified in the attached list of articles for which the Defendant conducts the clinical trial, talimogene laherparepvec [generic name] (trade name: Imlygic or T-VEC; hereinafter referred to as "T-VEC"), is a herpes simplex virus-type 1 (HSV-1) which is weakened by functionally deleting two genes, ICP34.5 (γ34.5) and ICP47 (Exhibit Ko 7), whereas three genes are modified in G47Δ. Thus, T-VEC contains a deletion in the ICP47 gene and falls within the technical scope of the Invention.

(4) Status of the clinical trial of G47Δ by the Plaintiff

Aiming to achieve commercialization of G47Δ, the Plaintiff's research team has been conducting Phase II study in Japan since around 2015, targeting glioblastomas, a type of malignant brain tumor, as an indication. G47Δ is designated as an orphan regenerative medicine product and also designated as the subject item under the SAKIGAKE Designation System (Exhibits Ko 9 and 14).

(5) Status of the clinical trial of T-VEC by the Defendant

In Japan since around March 2017, the Defendant has been conducting a clinical trial of T-VEC, which is a regenerative medicine product, targeting malignant melanoma as an indication (hereinafter referred to as the "Clinical Trial") (Exhibits Ko 2 and 8; the entire import of oral arguments).

US Amgen obtained approval for T-VEC as a therapeutic agent for a specified type of melanoma lesion (malignant melanoma) from the FDA (US Food and Drug Administration) in October 2015, and from the EMA (European Medicines Agency) in December 2015. In the Clinical Trial, a bridging study is conducted using the relevant foreign clinical data.

A bridging study is defined as a study performed in the new region to provide pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in the new region that will allow extrapolation of foreign clinical data to the population in the new region (Exhibit Otsu 15)

For the Clinical Trial, the date of completion of primary evaluation and the date of completion of the Clinical Trial initially scheduled were June 6, 2019, and March 27, 2021, respectively. Later, the date of completion of primary evaluation and the date of completion of the Clinical Trial were changed to March 27, 2020, and April 16, 2021, respectively (Exhibits Ko 8 and 15).

(6) Structure of a clinical trial of an anticancer drug

A clinical trial is a test performed in order to collect data concerning the results of a clinical study for inclusion among data submitted pursuant to the provisions of Article 14, paragraph (3), Article 23-25, paragraph (3), etc. of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (formerly called the "Pharmaceutical Affairs Act" prior to the amendment by Act No. 84 of 2013 (put into effect as of November 25, 2014; hereinafter referred to as the "2013 Amendment Act"); hereinafter basically referred to as the "Pharmaceuticals and Medical Devices Act" throughout the periods before and after the amendment) (Article 2, paragraph (17) of the Pharmaceuticals and Medical Devices Act). It is generally divided into three phases.

In Phase I, clinical pharmacological studies are conducted generally in healthy volunteer subjects, without therapeutic objectives, to determine the tolerability of the dose

range expected to be needed for later clinical studies, determine the nature of adverse reactions that can be expected, and collect information on the absorption, distribution, metabolism, and excretion of the drug. In the case of anticancer pharmaceuticals, studies are generally conducted in patients.

In Phase II, exploratory clinical studies are conducted generally in a group of patients who are selected by relatively narrow criteria, leading to a relatively homogeneous population, with the primary objective of exploring therapeutic efficacy. In this phase, the dose and regimen for Phase III trials are determined, and endpoints (assessment items to demonstrate the efficacy of the therapeutic practice), therapeutic regimens, and target populations are evaluated.

In Phase III, confirmatory studies are conducted in a larger number of subjects to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use, with the primary objective of gaining data that will serve as an adequate basis for approval.

In the case of an anticancer drug, its marketing generally becomes possible if it is approved by the Ministry of Health, Labour and Welfare based on the information collected through the clinical trial, including Phase I and Phase II studies or Phase III studies as well (Exhibit Ko 18; the entire import of oral arguments [General Considerations for Clinical Trials]).

(7) Other provisions of laws and regulations concerning marketing approval for pharmaceuticals, etc.

A. Purpose of the Pharmaceuticals and Medical Devices Act

Article 1 of the Pharmaceuticals and Medical Devices Act provides that its purpose is to improve health and hygiene by providing the control required for securing the quality, efficacy and safety of pharmaceuticals, regenerative medicine products, etc. and for preventing the occurrence or spread of health and hygiene-related hazards caused by the use of those pharmaceuticals, etc. by taking measures against designated substances, and by taking necessary measures for the promotion of research and development of pharmaceuticals, and regenerative medicine products, etc. which fulfill particularly high medical needs.

B. Provisions concerning pharmaceuticals

(A) Application for marketing approval

Article 14, paragraph (1) of the same Act provides that a person who intends to market pharmaceuticals must obtain approval from the Minister of Health, Labour and Welfare for each item, and the first sentence of paragraph (3) of the same Article provides that a person who intends to obtain such approval must make an application by attaching data

concerning the results of clinical studies and other pertinent data to their written applications, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

Furthermore, Article 14, paragraph (2), item (iii) of the same Act provides that the approval is not to be granted in such cases where: as a result of an examination of the matters related to quality, efficacy and safety of the pharmaceuticals pertaining to the application, such as the name, components, quantity, dosage, administration, efficacy, effects, and side effects, the pharmaceuticals are not found to have the efficacy or effects indicated in the written application.

(B) Priority examination

Article 14, paragraph (7) of the same Act provides that when confirming that the pharmaceuticals in applications prescribed in paragraph (1) are orphan drugs or other pharmaceuticals which fulfill particularly high medical needs, the Minister of Health, Labour and Welfare may prioritize an examination under paragraph (2), item (iii) for these pharmaceuticals over an examination, etc. for other pharmaceuticals (priority examination).

(C) Reexamination

Article 14-4, paragraph (1), item (i), (a) of the same Act provides that a person who has received approval prescribed in Article 14 of the same Act for orphan drugs among pharmaceuticals instructed by the Minister of Health, Labour and Welfare upon approval as those that have active components, quantities, directions, dosage, efficacy and effects, etc. which are obviously different from those of pharmaceuticals which have already been approved pursuant to the provisions of the same Article, etc. ("new pharmaceuticals"), must file an application within the application period (a period within three months starting from the day on which the investigation period (a period designated by the Minister of Health, Labour and Welfare of at least six years and not exceeding ten years from the date of the approval) has elapsed) for the pharmaceuticals concerned for reexamination by the Minister of Health, Labour and Welfare.

(D) Orphan drugs

The term "orphan drug" refers to pharmaceuticals designated by the Minister of Health, Labour and Welfare, which fall under both of the following (Article 2, paragraph (16)): the number of subjects pertaining to the usage in Japan does not reach the number specified by Order of the Ministry of Health, Labour and Welfare (50,000 persons in principle (Article 251 of the Regulation for Enforcement of the Pharmaceuticals and Medical Devices Act)); and with marketing approval for the pharmaceuticals in application, the pharmaceuticals will have particularly excellent value for usage.

C. Provisions concerning regenerative medicine products

(A) Meaning of the term "regenerative medicine product"

The term " regenerative medicine product" refers to the following items as specified by Cabinet Order: [i] items intended either for [1] reconstruction, repairing or formation of the structure or function of the bodies of humans or animals or [2] treatment or prevention of disease in humans or animals, which are obtained after culturing or other processes using human or animal cells; or [ii] items intended for use in the treatment of disease in humans or animals which are introduced into cells of humans or animals and contain genes to be expressed in their bodies (Article 2, paragraph (9) of the Pharmaceuticals and Medical Devices Act; while the same Act makes a distinction between "pharmaceuticals" and "regenerative medicine products," in this judgment, G47Δ and T-VEC may be referred to as "pharmaceuticals, etc.").

(B) Provisions that are identical to or different from those concerning pharmaceuticals

Provisions concerning regenerative medicine products in terms of marketing approval (Article 23-25, paragraph (1) and paragraph (2), item (iii) of the same Act), priority examination (paragraph (7) of the same Article), reexamination (Article 23-29, paragraph (1), item (i), (a) of the same Act), and orphan regenerative medicine products (Article 77-2, paragraph (1) of the same Act) are basically identical to the provisions concerning pharmaceuticals.

On the other hand, unlike pharmaceuticals, there is a conditional and time-limited approval system for regenerative medicine products. Under this system, when an item that the applicant for approval intends to market is a regenerative medicine product satisfies certain requirements, approval prescribed in Article 23-25, paragraph (1) may be granted for such item by providing necessary conditions for the appropriate use of the item and the time limit (Article 23-26, paragraph (1) of the same Act).

D. SAKIGAKE Designation System

With the aim of providing the world's most advanced treatment drugs for patients in Japan earlier, the Ministry of Health, Labour and Welfare operates the SAKIGAKE Designation System, under which innovative new drugs, etc. that satisfy the four requirements—i.e., [i] the drug is innovative, [ii] the target disease is of serious nature, [iii] the drug has extremely high efficacy for the target disease, and [iv] the applicant has the intention to develop the drug and apply for approval for it earlier in Japan than in any other parts of the world—are designated as the target items from a relatively early stage of development and are treated preferably in the consultation and examination process for obtaining marketing approval. Drugs, etc. designated under this system are eligible for priority examination (Exhibit Ko 14).

(8) 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")

The Supreme Court Judgment in 1999 stated as follows regarding the relationship between the act of conducting necessary tests for applying for approval as prescribed in Article 14 of the Pharmaceutical Affairs Act and the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.

"It is appropriate to consider that where a person holds a patent right for chemical substances or pharmaceuticals that contains them as active components, if a third party intends to manufacture and sell a drug that has the same active components, etc. as those of the pharmaceuticals that are relevant to the patented invention after the term of the patent right expires (hereinafter referred to as a "generic drug"), and, in order to apply for manufacturing approval as prescribed in Article 14 of the Pharmaceutical Affairs Act, the third party, during the term of the patent right, produces chemical substances or pharmaceuticals that fall within the technical scope of the patented invention and conducts necessary tests by using those chemical substances or pharmaceuticals for obtaining data to be attached to the written application, such act of conducting necessary tests constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act, and does not constitute infringement of the patent right. The reasons for this determination are as follows.

1. The patent system is designed to encourage inventions by granting a person who has disclosed their invention an exclusive right to use the invention for a certain period, and also to provide a third party with the opportunity to use the disclosed invention, thereby contributing to the development of industry. In light of this, it can be said that it is one of the elements of the foundation of the patent system that any person is given the ability to use a patented invention freely after the term of the patent right expires so as to widely benefit the general public.

2. The Pharmaceutical Affairs Act provides that approval of the Minister of Health, Labour and Welfare must be obtained for manufacturing pharmaceuticals in advance in order to secure the safety, etc. of the pharmaceuticals. In order to apply for the approval, the applicant is required to conduct certain types of tests and attach data concerning the test results to the written application. The same applies to generic drugs in that in order to apply for manufacturing approval, it is necessary to conduct in advance prescribed tests which require a certain amount of time, and in order to conduct such tests, it is necessary

to produce and use certain chemical substances or pharmaceuticals which fall within the technical scope of a patentee's patented invention. If such tests are considered not to fall within the scope of "experiment" as referred to in Article 69, paragraph (1) of the Patent Act, and a third party is not allowed to produce or otherwise handle such chemical substances or pharmaceuticals 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 mentioned above.

3. On the other hand, if a third party, during the term of a patent right, produces and uses any chemical substances involved in a patented invention beyond the extent necessary for conducting tests for the purpose of obtaining manufacturing approval under the Pharmaceutical Affairs Act in order to produce a generic drug that is to be transferred after the expiration of that term or produce and use those substances as components of such generic drug, it should be considered that such an act of the third party infringes the patent right and therefore it is impermissible. As long as it is so considered, an opportunity for the patentee to gain profit by exclusively working the patented invention during the term of the patent right can be secured, and if 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 manufacturing approval for the generic drug, this could lead to the same consequence as extending the term of the patent right for a considerable period of time, and such consequence goes beyond the bounds of the benefit assumed under the Patent Act as a benefit to be granted to the patentee."

(Throughout this judgment, the term "generic drug" refers to a drug that has the same components, dosage, effects, etc. as those of the pharmaceuticals relevant to the patented invention.)

3. Issues

(1) Whether 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 (Issue 1)

(2) Whether the Defendant has a non-exclusive license for the Invention (Issue 2)

(omitted)

No. 4 Judgment of this court

1. Issue 1 (whether 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)

(1) 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 the same 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 pharmaceuticals, 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 patentee's interest to be protected and the interest of the general public.

(2) As mentioned in No. 2, 2. (8) above, the Supreme Court Judgment in 1999 ruled that if a third party intends to manufacture and sell a generic drug that has the same active components, etc. as those of the pharmaceuticals that are relevant to the patented invention after the term of the patent right expires, and, in order to apply for manufacturing approval as prescribed in Article 14 of the Pharmaceutical Affairs Act (effective at that time), the third party, during the term of the patent right, produces chemical substances or pharmaceuticals that fall within the technical scope of the patented invention and conducts necessary tests by using those chemical substances or pharmaceuticals for obtaining data to be attached to the written application, such act of conducting necessary tests constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act, and does not constitute infringement of the patent right.

As mentioned in No. 2, 2. (5) above, T-VEC, which is subject to the Clinical Trial, is a pioneer drug for which manufacturing approvals have already been granted by the drug

regulatory authorities of foreign countries and bridging study has been conducted in Japan. The purport of the Supreme Court Judgment in 1999 is considered to be valid for the Clinical Trial as well for the following reasons.

A. 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 Supreme Court Judgment in 1999 points out that in order to apply for manufacturing approval for a generic drug, it is necessary, as in the case of other drugs, to conduct in advance prescribed tests which require a certain amount of time, and in order to conduct such tests, it is necessary to produce and use certain chemical substances or pharmaceuticals which fall within the technical scope of a patentee's patented invention.

In the Clinical Trial, a bridging study is conducted based on the manufacturing approvals granted by the drug regulatory authorities of foreign countries. According to evidence (Exhibit Otsu 15), a bridging study is defined as a study performed in the new region to provide pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in the new region that will allow extrapolation of foreign clinical data to the population in the new region. It is found that although foreign clinical data that conform to certain conditions is acceptable as data to be attached to a written application for manufacturing approval, etc. for pharmaceuticals, it is necessary in principle to also submit data concerning the results of a clinical study conducted in Japan in order to evaluate the efficacy and safety of the pharmaceuticals in Japanese people.

It is found that the Clinical Trial is the "Study to Evaluate the Safety/Efficacy of T-VEC in Japanese Subjects" (Exhibit Ko 8-1, page 2, "Official Title" section), and that the antitumor activity of T-VEC as evaluated by the durable response rate (DRR) using the Modified World Health Organization (WHO) response criteria is the primary outcome (Exhibit Ko 8-1, page 4, "Primary Outcome Measures" section, 2). According to the paper submitted as Exhibit Otsu 14, the DRR is defined as a rate of complete response [CR: the complete disappearance of a tumor] and partial response [PR: a decrease in the size of a tumor at least at a certain rate]) beginning in the first 12 months of treatment and lasting 6 months or longer. Therefore, in order to apply for marketing approval for T-VEC, it is necessary to conduct a clinical study which requires a certain amount of time by administering T-VEC in Japanese subjects.

Accordingly, in order to apply for marketing approval for T-VEC, which is a pioneer drug, it is necessary, as in the case of a generic drug, to conduct in advance prescribed tests which require a certain amount of time, and in order to conduct such tests, it is necessary to produce and use certain pharmaceuticals, etc. which fall within the technical scope of the Invention.

B. The Supreme Court Judgment in 1999 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 a patented invention during the term of a 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 a patent right expires, thereby widely benefiting society.

In order to apply for marketing approval for T-VEC as well, it is necessary to conduct in advance prescribed 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. Such consequence is contrary to the foundation of the patent system. This is as stated in the Supreme Court Judgment in 1999.

C. The Supreme Court Judgment in 1999 ruled that if a third party, during the term of a patent right, produces and uses any chemical substances involved in the patented invention beyond the extent necessary for conducting tests for the purpose of obtaining manufacturing 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 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.

As mentioned above, in the Clinical Trial, Phase I clinical study is being conducted based on the provisions of the Pharmaceuticals and Medical Devices Act, and there is no evidence suggesting that the Defendant 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.

Accordingly, an opportunity for the Plaintiff, 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.
D. As explained above, the purport of the Supreme Court Judgment in 1999 is valid for the Clinical Trial as well, and hence, 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.
(3) Concerning the Plaintiff's allegations
A. The Plaintiff understands that in order for a clinical trial of pharmaceuticals, etc. to constitute the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act, the clinical trial must be intended for advancement of technology, and alleges that the Clinical Trial is not intended for advancement of technology because it is conducted only for the purpose of enabling the sale in Japan of T-VEC, which has already been approved in the United States and Europe.
(A) However, as mentioned above, whether a clinical trial falls under Article 69, paragraph (1) of the Patent Act should be determined from the perspective of the balance between the interest of the patentee and the interest of the general public, while taking into consideration the purpose of the Patent Act and the regulation under the Pharmaceuticals and Medical Devices Act. Given that "experiment or research" that contributes to the public interest may have various purposes and contents, there is no reason to limit the scope of "experiment or research" as referred to in Article 69, paragraph (1) of the Patent Act to those that are intended for advancement of technology, but it is sufficient to make comparison with the interest of the patentee, while taking into consideration the purpose and content of the relevant experiment or research for each case.
(B) The Plaintiff further alleges that the Clinical Trial is intended only for the purpose of enabling the sale in Japan of T-VEC, which has already been approved in the United States and Europe. However, as mentioned above, it is found that the Clinical Trial is not a trial for obtaining marketing approval in Japan by accepting foreign clinical data as it is without conducting any new clinical study, but a trial for evaluating the efficacy and safety of T-VEC in Japanese subjects by conducting a clinical study, which requires a certain amount of time.

Accordingly, even if the view that the "experiment or research" as referred to in Article 69, paragraph (1) of the Patent Act must be intended for advancement of technology is adopted, it should be said that the Clinical Trial is regarded as a trial intended for advancement of technology and that it constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.

B.(A) The Plaintiff alleges that the Clinical Trial is conducted for the purpose of commencing marketing of the test drug during the term of the patent right and therefore it does not constitute the "experiment or research" as referred to in Article 69, paragraph (1) of the Patent Act.

However, the Defendant alleges that it has no plan to put T-VEC on the market during the term of the Patent Right, and as mentioned above, there is no evidence suggesting that the Defendant intends to market T-VEC beyond the extent necessary for conducting tests for the purpose of obtaining marketing approval under the Pharmaceuticals and Medical Devices Act during the term of the Patent Right.

(B) The Plaintiff further alleges that it is possible to commence marketing of T-VEC with the marketing approval obtained during the term of the Patent Right, and that in such case, the Clinical Trial is deemed to be intended for commencing marketing during the term of the Patent Right.

However, even where during the term of a patent right, a third party obtains marketing approval for a drug, etc. which falls within the technical scope of the patented invention, this does not necessarily lead to the third party conducting marketing of the drug, etc. during the term of the patent right, but it is sufficiently possible that the third party would conduct marketing after the term of the patent right expires. Therefore, even though it is objectively possible for a third party to obtain marketing approval during the term of a patent right, it is impossible to immediately deem that because of this a clinical trial of a drug, etc. is intended for marketing during the term of the patent right.

In addition, considering the Plaintiff's allegations as the premise, if a third party obtains marketing approval for a drug, etc. used in a clinical trial and becomes able to commence marketing the drug, etc. during the term of a patent right, the clinical trial by the third party would constitute infringement of the patent right, whereas, if a clinical trial or approval procedure takes more time than expected due to unforeseeable circumstances that occur after the commencement of the clinical trial, and the marketing of the drug, etc. commences after the term of the patent right expires, the clinical trial by the third party would not infringe the patent right. Given the view based on the Plaintiff's allegations, infringement of a patent right would eventually depend on unforeseeable circumstances. Also, in light of the fact that a clinical trial and approval procedure generally require a certain amount of time, such view should be considered to make the status of a third party conducting a clinical trial unnecessarily unstable.

C. The Plaintiff alleges that: in the case of bio-pharmaceuticals, it takes a long period of time from the filing of a patent application until commercialization, and among these, in the case of genetically engineered oncolytic viruses, the timing of commercialization

based on the marketing approval obtained should inevitably be just before the expiration of the term of the patent right; therefore, if a person other than the patentee is allowed to develop (conduct a clinical trial of) a product similar to the patented invention, this could unreasonably undermine the interest of the patentee of innovative bio-pharmaceuticals.

However, as mentioned in No. 2, 2. (7) C. above, regenerative medicine products are subject to almost the same regulations as those for pharmaceuticals except that the conditional and time-limited approval system is put in place for regenerative medicine products, and priority examination applies to regenerative medicine products as well; moreover, regenerative medicine products are also covered by the SAKIGAKE Designation System. In light of these factors, it cannot be said that it is institutionally anticipated that examination of regenerative medicine products would be particularly prolonged.

Furthermore, if a third party is not allowed to conduct a clinical trial of a regenerative medicine product, etc. which falls within the technical scope of a patented invention during the term of a patent right, the third party would have to commence a clinical trial after the term of the patent right expires, and would be unable to use the patented invention freely for a long period of time until it obtains marketing approval. As pointed out in the Supreme Court Judgment in 1999, 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 a patent right expires, thereby widely benefiting society.

The Patent Act specifies the term of a patent right as 20 years from the filing date of the patent application uniformly, irrespective of the type or technical value of the patented invention (Article 67, paragraph (1) of the Patent Act). Even if it may actually take a long period of time to conduct examination for granting approval for a regenerative medicine product, etc., it is inappropriate to adopt a view that could bring about the same consequence as extending the term of the patent right for a considerable period of time by prohibiting a clinical trial of a regenerative medicine product, etc. that falls within the technical scope of a patented invention during the term of a patent right.

D. The Plaintiff alleges that the Supreme Court Judgment in 1999 is based on the premise that the patentee is able to secure a profit by exclusively working the patented invention during the term of the patent right, but in the case of bio-pharmaceuticals, unlike the case of generic drugs, it is difficult for a patentee to secure a profit by exclusively working the patented invention during the term of the patent right, and therefore that judicial precedent is not applicable to bio-pharmaceuticals.

(A) As the basis for this allegation, the Plaintiff argues that it should be taken into consideration that a third party is unable to obtain marketing approval without conducting

basic research or clinical study during the reexamination period in the case of generic drugs, and the pioneer drug manufacturer is in effect able to gain a profit exclusively during that period; but this does not apply to bio-pharmaceuticals (regenerative medicine products).

However, in the case of generic drugs, even if a pioneer drug manufacturer is able to gain a profit exclusively during the reexamination period of a new drug, this is nothing more than a de facto benefit that can be enjoyed as a reflection of the regulations under the Pharmaceuticals and Medical Devices Act. The Supreme Court Judgment in 1999 pointed out that a patentee is in effect able to gain a profit exclusively during the reexamination period but it did not mention this point as a factor to be taken into consideration when determining the applicability of Article 69, paragraph (1) of the Patent Act.

Accordingly, it should be said that even if a patentee is in effect unable to gain a profit exclusively from the regenerative medicine product during the reexamination period, this does not affect the determination as to whether a clinical trial by a third party constitutes the "working of the patented invention for experimental or research purposes" as referred to in Article 69, paragraph (1) of the Patent Act.

(B) The Plaintiff alleges that even if the term of the Patent Right is extended, it is highly likely that the extended Patent Right would not be effective against T-VEC, and in such case, the Defendant would be able to market T-VEC immediately after the expiration of the Patent Right, which would unreasonably benefit the Defendant.

In this respect, there is a court ruling to the effect that, , with regard to pharmaceuticals, the patented invention pertaining to the extended patent right is effective only against the "product" (pharmaceuticals) specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a disposition specified by Cabinet Order under Article 67, paragraph (2) of the Patent Act and products that are substantially identical with that product as pharmaceuticals (see the Grand Panel judgment on the Oxaliplatin Case). In light of this, it can be said that if the term of the Patent Right is extended, the extended patent right would not necessarily be effective against the scope of genetically engineered genes or the working of T-VEC for different indications.

However, if, as alleged by the Plaintiff, the Patent Right as extended is not effective against T-VEC, it would rather serve the purpose of the patent system to enable any person to use the patented invention freely after the term of the patent right expires, thereby widely benefiting society, as stated in the Supreme Court Judgment in 1999.

Accordingly, even if the Defendant is able to market T-VEC immediately after the expiration of the term of the Patent Right, this cannot be regarded as unreasonably

benefiting the Defendant.
(C) The Plaintiff alleges that it should be taken into consideration in this case that the Plaintiff has not yet obtained marketing approval for G47Δ and has not gained any profit at all from exclusively marketing that drug.

However, whether a patentee for a drug, etc. is able to exercise the patent right during the term of the patent right and actually gain a profit depends on circumstances such as the content and nature of the patented invention, whether approval has been obtained under the Pharmaceuticals and Medical Devices Act and the period until it is obtained, the indications of the drug, the market size, and whether there is any competing drug, etc. The Patent Act ensures an opportunity for a patentee to gain a profit by exclusively working the patented invention during the term of the patent right, but it does not guarantee that the patentee would actually gain a profit.

Accordingly, in this case, even if the Plaintiff does not actually gain a profit, this does not affect the conclusion as to whether 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.
E. Consequently, all of the Plaintiff's allegations are unacceptable.
(4) For the reasons stated above, it should be said that 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.
2. Hence, without the need to make a determination on other points, all of the Plaintiff's claims are groundless and therefore they are dismissed, and the judgment is rendered as indicated in the main text.

Tokyo District Court, 40th Civil Division
Presiding Judge: SATO Tatsubumi
Judge: MITSUI Tomonao
Judge KONNO Tomoki is unable to sign and seal due to transfer.
Presiding Judge SATO Tatsubumi

Attachment
List of articles
Generic name: Talimogene laherparepvec