# Intellectual Property High Court Judgment regarding the Description Requirement and Correction Requirement for a Use Limitation in Pharmaceutical Inventions (2020 (Gyo-Ke) 10135; "Pregabalin Case")

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Case at bar:
Lawsuit against Trial Decision rendered by the Japan Patent Office (JPO)
Judgment of the Intellectual Property High Court, Second Division
March 7, 2022 (2020 (Gyo-Ke) 10135)
Plaintiff: Warner-Lambert Co. LLC
Defendants: Sawai Pharmaceutical Co., Ltd. and 15 other defendants

## 1. Case Background

Recently, development of original drugs has become far more difficult than before and, in Japan, the further dissemination of generics has been required as a national policy. [1] Under these circumstances, it is not uncommon to find severe patent disputes between originator drug pharmaceutical companies and generic drug pharmaceutical companies.

The case introduced here is such a case, in which Warner-Lambert Co LLC[2] ("Plaintiff / Patentee Warner-Lambert") sought rescission (the "Lawsuit") against the decision rendered by the Japan Patent Office ("JPO") in the invalidation trial of Patent No. JP 3693258 (the "Patent"; its description referred to as "Description"; and the invention claimed therein referred to as the "Invention") directed to the analgesic drug LYRICA® (general name: pregabalin), which is manufactured and sold by Pfizer.

Pregabalin is an analgesic drug that has a mechanism of action different from steroid and nonsteroidal anti-inflammatory drugs (NSAIDs) that are generally used for nociceptive pain, such as "inflammatory pain," etc. Pregabalin is approved for indications of "neuropathic pain" and "pain associated with fibromyalgia." [3] While there were numerous drugs approved for "nociceptive pain," such as inflammatory pain, etc., at the time the application for the Patent was filed, drugs and treatment methods for "neuropathic pain" and "pain associated with fibromyalgia" were limited. In fact, pregabalin was the first drug approved in Japan for the pain associated with fibromyalgia.[4] As a result, it is extremely difficult to substitute pregabalin in the treatment for these types of pain and, therefore, Lyrica has become a blockbuster with annual sales of over 100 bil-

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lion yen in Japan.

As disclosed in the Description, the use of GABA analogues, including pregabalin, for the treatment of epilepsy, etc. was well known.[5] Thus, the Patent is directed to a new indication (pain inhibition) of a known compound.

One of the leading generic drug pharmaceutical companies in Japan,[6] Sawai Pharmaceutical Co., Ltd. (the "Defendant/Petitioner Sawai Pharmaceutical"), requested a trial for invalidation of the Patent, alleging violation of the enablement requirement and the support requirement on the grounds that the Description disclosed animal experiment data for therapeutic effects for "nociceptive pain," such as inflammatory pain, but did not provide support for efficacy as to "neuropathic pain" and "pain associated with fibromyalgia" (the indications for Lyrica).

An additional 15 generic drug pharmaceutical companies that have an interest in the patent's validity intervened to join the invalidation trial (pursuant to Article 148, paragraph (1) of the Patent Act). At first, the trial decision invalidated all claims (Claims 1 through 4) of the Patent, whereupon the Patentee Warner-Lambert requested corrections to the claims. The outcome was the JPO approved Claims 3 and 4 in which the indications are limited to "nociceptive pain (inflammatory pain and postoperative pain)"; however, it did not approve the corrections to, and invalidated Claims 1 and 2, which included "neuropathic pain" and "pain associated with fibromyalgia" as important indications covered by the claims.[7]

In response to the JPO decision on Claims 1 and 2, Patentee Warner-Lambert filed a lawsuit seeking rescission of the JPO decision (the Lawsuit discussed herein). However, because the JPO ruled that Claims 1 and 2 were invalid, the manufacture of generic drugs by the petitioners (intervenors) was approved.[8] Patentee Warner-Lambert then filed a lawsuit in Tokyo District Court for an injunction (and provisional disposition) against more than 20 generic drug pharmaceutical companies that were manufacturers and distributors or distributors of pharmaceuticals related to said manufacturing approval, seeking discontinuation, etc. of their manufacturing and selling.

All of these infringement lawsuits were litigated up to the Intellectual Property High Court and, therefore, they developed into unprecedented set of cases, wherein all Intellectual Property Divisions (29th, 40th, 46th, and 47th) of the Tokyo District Court and all Divisions (1st through 4th) of the Intellectual Property High Court and were involved.

In this article, the details of the aforementioned contentious cases, mainly the Judgment, and the issues of the Judgment, etc. are examined in the sections that follow. LYRICA® has been approved for manufacture in at least 120 countries and regions around the world. There are other countries where patent disputes arose in the same way as in Japan. Their issues and the conclusions of judgments vary.[9] Among these, similar issues to those in the Lawsuit were disputed in the Supreme Court of the United Kingdom,[10] so that ruling is compared with the Judgment and commented upon as appropriate.

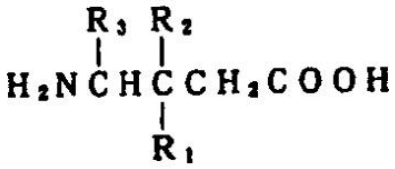
## 2. Introduction to the Judgment

### 2-1. Outline of the trial for patent invalidation and background of this lawsuit

The Patent was originally granted with the following Claims 1 through 4:

[Claim 1]

Formula I



An analgesic drug for pain treatment comprising a compound as described in Formula I (wherein $R_1$ is a straight or branched alkyl of 1 to 6 carbon atoms, $R_2$ is hydrogen or methyl, $R_3$ is hydrogen, methyl, or carboxyl) or a pharmaceutically acceptable salt, diastereomer, or enantiomer thereof.

[Claim 2]

The analgesic drug according to Claim 1, wherein the compound is the (R), (S), or (R, S) isomer of the compound wherein $R_3$ and $R_2$ are both hydrogen and $R_1$ is - $(CH_2)_{0-2}$ - $iC_4H_9$ in Formula I.

[Claim 3]

The analgesic drug according to Claim 1, wherein the compound is (S)-3-(aminomethyl)-5-methylhexanoic acid or 3-aminomethyl-5-methylhexanoic acid.

[Claim 4]

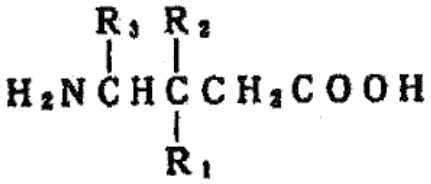
The analgesic drug according to Claim 1, wherein the pain is inflammatory pain, pain from neurological disorders, pain from cancer, postoperative pain, phantom limb pain, burn pain, gout pain, osteoarthritis pain, trigeminal neuralgia, pain from acute herpes and post-herpetic pain, causalgia, idiopathic pain, or fibromyalgia.

The "(S)-3-(aminomethyl)-5-methylhexanoic acid" as recited in Claim 3, which depends from Claim 1, is pregabalin, the active ingredient of LYRICA®, and the structural formula described in Formula I of Claim 1 is a genus structure that encompasses GABA analogues. In Claim 1 through Claim 3, the type of pain that is the indication is not specified; however, in Claim 4, which depends from Claim 1, various pains, such as inflammatory pain, pain from neurological disorders, postoperative pain, fibromyalgia, and other pains are expressly recited.

In view of the above, Petitioner Sawai Pharmaceutical filed for an invalidation trial of the Patent and alleged as follows: the pain, which is an indication of the Invention, includes pain from neurological disorders and fibromyalgia; however, according to the three animal experiments (formalin test, carrageenan test, and postoperative test) described in the Description, the analgesic effects for said pains were not identified; such effects were not in the common general technical knowledge as of the filing date of the application for the Patent; and, therefore, the Patent does not fulfill the enablement requirement and support requirement and so is invalid.

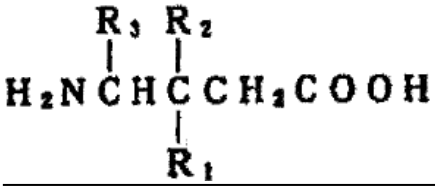
The JPO approved of the petitioner's allegations and gave an advance notice that the trial decision would find that Claim 1 through Claim 4 were all invalid. In response to the notice, Patentee Warner-Lambert attempted to correct (the "Correction") Claims 1 through 4 as follows (corrections are underlined).

[Claim 1]
Formula I



An analgesic drug for treatment of pain from hyperalgesia or tactile allodynia, comprising a compound as described in Formula I (wherein $R_1$ is a straight or branched alkyl of 1 to 6 carbon atoms, $R_2$ is hydrogen or methyl, $R_3$ is hydrogen, methyl, or carboxyl) or a pharmaceutically acceptable salt, diastereomer, or enantiomer thereof.

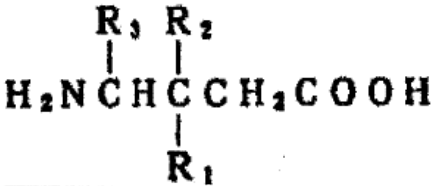
[Claim 2]
Formula I



An analgesic drug for treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia, including compounds (R), (S), or (R, S) isomer in Formula I (wherein $R_3$ and $R_2$ are both hydrogen and $R_1$ is - $(CH_2)_{0-2}$ - $iC_4H_9$).

[Claim 3]
An analgesic drug for treatment of pain due to inflammation or pain due to surgery, comprising (S)-3-(aminomethyl)-5-methylhexanoic acid or 3-aminomethyl-5-methylhexanoic acid.

[Claim 4]
Formula I



An analgesic drug for treatment of pain from hyperalgesia due to inflammatory pain or pain from hyperalgesia or tactile allodynia due to postoperative pain, comprising a compound as described in Formula I (wherein $R_1$ is a straight or branched alkyl of 1 to 6 carbon atoms, $R_2$ is hydrogen or methyl, $R_3$ is hydrogen, methyl, or carboxyl) or a pharmaceutically acceptable salt, diastereomer, or enantiomer thereof.

As seen above, in Claims 3 and 4 the causes of the pain are limited to inflammatory pain and postoperative pain, for which the cause of the plain is nociceptive pain, and, therefore, their importance in the argument related to invalidation decreased.[11] On the other hand, the types of pain recited in Claims 1 and 2 were limited to "pain from hyperalgesia or tactile allodynia," though the source being pains from neurological disorders or fibromyalgia were included in Claim 2. Therefore, whether the Correction related to Claims 1 and 2 fulfills the correction requirements was an issue, as well as the enablement requirement and support requirement.

In this regard, Patentee Warner-Lambert alleged that as of the application filing date, it was known as common general technical knowledge that pains from hyperalgesia or tactile allodynia were caused by nerve cell sensitization regardless of the cause of the pain, and

that the formalin test described in the Description is related to central sensitization, thus corrected Claims 1 and 2 fulfill all of the correction requirements, enablement requirements, etc.

However, the JPO did not find support for the existence of such common general technical knowledge, instead finding that it was common general technical knowledge as of the application filing date that the causes and pathophysiology of pains vary. Then, the JPO found that there is no explicit statement in the Description that the compound of the Invention is used as an analgesic drug for treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia; said effects cannot be read in the animal experiments stated in the Description; and, therefore, it is not stated that the compound is effective for treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia. The JPO did not approve the Correction of Claims 1 and 2. And the JPO decided based on almost the same grounds as above that Claims 1 and 2 before correction violate the enablement requirement and support requirement and, therefore, these claims are invalid.

Dissatisfied with these decisions, Patentee Warner-Lambert filed an appeal before the Intellectual Property High Court seeking rescission of the JPO decision on Claims 1 and 2.

### 2-2. Outline of procedural act in the Lawsuit

In the Lawsuit, both parties submitted many new items into evidence in addition to the evidence that had been submitted at the JPO trial. In this regard, concerning common general technical knowledge of pain categories and mechanisms, evidence submitted by the Defendants included much textbook literature that was published before the application filing date. However, many items of evidence submitted by Plaintiff Warner-Lambert were academic articles[12] published before the priority date in question (hereinafter referred to as the "Priority Date"), but did not include textbook literature in the field of pain.

In the Lawsuit, the common general technical knowledge that was assumed in the Description was a big issue. As support for the common general technical knowledge alleged by the Plaintiff, the Plaintiff's side submitted the written opinions of experts who are considered to be authorities in the field of pain study, including Professor Woolf of Harvard University (advocated a hypothesis on central sensitization), Professor Dickenson of the University of London, (internationally famous in the field of neuropathic pain), Professor Clauw of the University of Michigan (an authority on fibromyalgia), Professor Masako Iseki of Juntendo University, Faculty of Medicine (the chairperson of the Japanese Association for the Study of Pain), and other experts. On the other hand, the Defendant's side submitted the written opinion of Professor Tatsuro Kohno of the International University of Health and Welfare, Faculty of Medicine, who engaged in the pain research under Professor Woolf of Harvard University. Therefore, the Lawsuit also attracted attention as to how these opinions were determined.

In addition, in the Lawsuit, a technical briefing was held after the procedures of written allegations. In concrete terms, in the presence of a panel

and three expert advisers, both parties gave presentations particularly on the point of common general technical knowledge, and then judgment was rendered after oral arguments.

**2-3. Outline of the Judgment**

In the Judgment, first, the court ruled as follows as to whether the Correction of Claims 1 and 2 (the court judgment refers to "Inventions 1 and 2") fulfilled the correction requirements (whether new matters were added) (underlined by the author; the same applies hereinafter).

> "B. The correction in a trial for patent invalidation must 'remain within the scope of the matters disclosed in the description, claims, or drawings attached to a written application' (Article 126, paragraph (5) of the Patent Act as applied mutatis mutandis pursuant to Article 134-2, paragraph (9) of said Act). Said matters refer to technical matters directed by a person skilled in the art by taking all indications of the Description or drawings together. If the correction does not introduce new technical matters in the relationship with technical matters that are introduced as described above, said correction is not considered to be an addition of new matters and will 'remain within the scope of the matters disclosed in the description, claims, or drawings attached to a written application' (see the judgment of the Intellectual Property High Court on May 30, 2008, 2006 (Gyo-Ke) 10563).
>
> Invention 2 is a so-called pharmaceutical-use invention where the pharmaceutical-use was discovered with Compound 2, which is a well-known substance, as an analgesic drug. The Correction related to Corrected Matter 2-2 is to correct the indication '請求項１記載の（鎮痛剤）[(analgesic drug) as stated in Claim 1]' to '神経障害又は線維筋痛症による、痛覚過敏又は接触異痛の痛みの処置における（鎮痛剤）[(analgesic drug) for treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia]' and demands to particularly specify its use as an analgesic drug. In addition, in order for 'an analgesic drug for pain treatment' to be a pharmaceutical-use invention, it is naturally required that the analgesic drug is effective for said pain treatment. Based on the aforementioned fact, in order to say that the correction related to Corrected Matter 2-2 does not fall under the addition of a new matter, the fact that Compound 2 'has effects' as an analgesic drug for the treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia is required as a technical matter that is led by a person skilled in the art in consideration of common general technical knowledge at the time of the Application Filing Date by taking all indications of the Description (including the scope of the patent claim before the Correction; the same applies hereinafter) or drawings together."
>
> "C. In this regard, the Plaintiff alleged that when making a decision on whether the correction falls under an addition of new matters, it is only necessary for a person skilled in the art to examine whether the corrected matters fall under technical matters as directed by taking all indications of the description or drawings together, and, therefore, there is a mistake with the JPO

Decision. However, in light of the details of Invention 2 and details of Corrected Matter 2-2 as described above, if it is not possible to conclude from the indications of the Description or drawings that Compound 2 'has effects' as an analgesic drug for the treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia, Corrected Matter 2-2 is not a technical matter directed by a person skilled in the art by taking all indications of the Description or drawings together. Consequently, even based on the aforementioned allegation of the Plaintiff, in order to say that the Correction related to Corrected Matter 2-2 does not fall under the addition of a new matter, it must be possible to say that a person skilled in the art understands that the fact that Compound 2 'has effects' as an analgesic drug for the treatment of pain from hyperalgesia or tactile allodynia due to neurological disorders or fibromyalgia is indicated or equivalent to being indicated in the Description or drawings."

"(i) According to the statements in the literature described in (b) through (h) above, at the time of the Application Filing Date, it seems there was knowledge to understand that the late phase of the formalin test reflects the sensitization of central nerve cells (central sensitization). However, it is found, furthermore, that the late phase of the formalin test is considered to be a useful model for studying the acceptance of continued noxious stimuli. Therefore, even according to said literature, it cannot be found that a person skilled in the art at the time of the Application Filing Date would recognize that the late phase of formalin test reflected only the central sensitization, which was alleged by the Plaintiff.

In addition, as explained in a. above, the common general technical knowledge, where pains from hyperalgesia or tactile allodynia are caused by the neurologic dysfunction, which is caused by sensitization of peripheral and central nerve cells in common regardless of their causes, did not exist at the time of the Application Filing Date. Therefore, even if an aspect to reflect central sensitization is seen at the late phase of formalin test, it cannot be found that the formalin test was a test to confirm efficacy of drugs for all pains from hyperalgesia or tactile allodynia, for which causes are different, at the time of the Application Filing Date, based on the aforementioned fact.

As described above, it cannot be found to be the common general technical knowledge of a person skilled in the art that the late phase of the formalin test reflected central sensitization exclusively and the formalin test was a test to confirm the efficacy of drugs for pains from hyperalgesia or tactile allodynia at the time of the Application Filing Date. And there was no other accurate evidence to find said common general technical knowledge."

"C. As described above, it cannot be found that the Correction related to Corrected Matter 2-2 remains within the scope of matters described in the description or drawings attached to the application. Consequently, the Correction related to Corrected Matter 2-2 violates Article 126, paragraph (5) of

the Patent Act as applied mutatis mutandis in Article 134-2, paragraph (9) of said Act and, therefore, it is not allowed.

(3) The Correction related to Corrected Matter 2

The Correction related to Corrected Matter 2-2 is not allowed as explained in (2) above. Therefore, the Correction related to Corrected Matter 2, which includes Corrected Matter 2-2, also violates Article 126, paragraph (5) of the Patent Act as applied mutatis mutandis in Article 134-2, paragraph (9) of said Act and, therefore, it is not allowed. There is no error in the JPO Decision, for which the purport is the same as the above.

(4) The Correction related to Corrected Matter 1

Concerning Claims 1 and 2 before the Correction, Claim 2 cites the statement in Claim 1. The Correction related to Claims 1 and 2 (the Correction related to Corrected Matters 1 and 2) is implemented with Claims 1 and 2, which are grouped. As explained in (3) above, the Correction related to Corrected Matter 2 is not allowed, and, therefore, the Correction related to Claim 1, which comprises a group of claims along with Claim 2 (the Correction related to Corrected Matter 1) is not approved as well."

As described above, in the Judgment, the court determined that the fact of "having effects" related to the corrected matter must be directed by the statements in the Description or drawings; since said effects cannot be read, the correction of Claim 2 falls under the addition of a new matter; and since Claim 1 constitutes a group of claims along with Claim 2, the Correction is not allowed as a whole. Based on the above, the enablement requirement for Claims before the Correction 1 and 2 are determined as follows (the court also made a decision on the support requirement; however, it is substantially the same as the enablement requirement and, therefore, it is omitted in this article).

"(1) Article 36, paragraph (4) of the Patent Act before amendment by Act No. 24 of 2002 stipulates that the detailed explanation of the invention in the description must be clearly and fully stated to the extent that a person who has normal knowledge in the technical field to which the invention belongs can work the invention. The term "work" as used in this provision refers to the act of using, etc. an article in the case of the invention of an article (Article 2, paragraph (3), item (i) of the Patent Act). Therefore, in order for an invention of an article to fulfill the enablement requirements, the detailed explanation of the invention in the description must be indicated to the extent where a person skilled in the art can use the article related to the invention based on the statement and common general technical knowledge at the time when the application was filed without implementing excessive trial and error.

In cases of a pharmaceutical-use invention, it is generally difficult to predict the usefulness of the invention only by indicating the name of the substance, chemical structure, and other information; even if the effective dose, administration method, and other information are stated in the detailed explanation of the invention, it is diffi-

cult for a person skilled in the art to predict whether said drug can be actually used for said use based on said information alone; and, therefore, in order to say that there is a statement to the extent that a person skilled in the art can use the article related to the invention without implementing excessive trial and error, it is reasonable to understand that it is necessary to state that pharmacological or other matters that can be deemed to be equivalent thereto concerning that said substance can be used for said usage, and, in light of the common general technical knowledge at the time when the application was filed, to indicate that a person skilled in the art can understand that said substance can be used as drugs for said use.

Applying the above understanding to this case, as indicated in No. 2, 2. above, the Inventions are pharmaceutical-use inventions wherein the Compounds are used for indication of 'an analgesic drug for pain treatment.' Therefore, in order for the statement of the detailed explanation of the invention in the Description to fulfill the enablement requirement for Inventions, the Description must state pharmacological data or other matters that can be deemed to be equivalent thereto concerning that the Compound can be used for an indication of 'an analgesic drug for pain treatment' so that a person skilled in the art can understand that the Compound can be used as a drug for said indication in light of common general technical knowledge at the time of the Application Filing Date."

"A. The Plaintiff alleged that it was known at the time of the Application Filing Date that pains from hyperalgesia or tactile allodynia due to neuropathic pain or fibromyalgia are caused by the sensitization of peripheral and central nerve cells regardless of their causes. However, as explained in 1. (2) B. (A) a. above, that fact cannot be found.

The Plaintiff also alleged concerning idiopathic pain that pain is caused by the sensitization of nerve cells; however, in light of the explanation in 1. (2) B. (A) a. above, that fact cannot be found and there is no other accurate evidence to find that fact."

"As explained in (2) E. above, at the time of the Application Filing Date, there was no common general technical knowledge that pains cannot be distinguished by their causes. Therefore, even though there is a statement that the Compound has an effect in treatment of pain caused in the formalin test, carrageenan test, and postoperative test, it is absolutely impossible that a person skilled in the art could understand that the Compound also has an effect in the treatment of 'pains' with different causes based on said statement. Consequently, it cannot be found that the statement related to the results of the formalin test, carrageenan test, and postoperative test allows to find that, in the detailed explanation of the invention in the Description, there are statements of pharmacological data or other matters that can be deemed to be equivalent thereto concerning that the Compounds can be used for indication of 'an analgesic drug for pain treatment' and that a person skilled in the art at the time of the Application

Filing Date was able to understand that the Compounds were able to be used as a drug for said indications."

As described above, also in the decision on the enablement requirement, the subject compound in the Invention was determined to be violating the enablement requirement on the grounds that they cannot be found to be able to be used as an analgesic drug for pain from hyperalgesia or tactile allodynia due to neuropathic pain or fibromyalgia. In addition, the Plaintiff's requests were dismissed on the grounds that there are no errors, which have no impact on the conclusion, in the JPO decision, where decisions were made with the same purport as above.

## 3. Examination of the Judgment

### 3-1. Finding of the common general technical knowledge that is a major issue in the Judgment

In the Lawsuit, as a major issue common to the correction requirements and enablement requirement (and support requirement), whether there is an integrated mechanism, "central sensitization," common to nociceptive pain, such as inflammatory pain, etc., and pains from different causes, such as neuropathic pain or fibromyalgia, etc., that are the animal models disclosed in the Description (in addition, whether they were common general technical knowledge as of the Application Filing Date) was disputed.

Actually, it is common general technical knowledge that clinical conditions and mechanisms of pain vary greatly due to the cause of the pain and there is no mechanism common to pains with all types of causes. In this regard, there is no change between the time of the Application Filing Date and today. In addition, concerning animal models, they are not classified by symptoms of pain, such as hyperalgesia or tactile allodynia, etc., but they are built by the cause of pain, such as the inflammatory pain model, postoperative pain model, neuropathic pain model, etc. The appropriate analgesic effects of a drug cannot be analyzed unless an appropriate animal model is used for each cause of the pain. This common general technical knowledge can be fully recognized from textbook technical literatures published before the Application Filing Date that were submitted by the Defendants at the stage of JPO trial.

Looking at the Description, it showed the results of the formalin test and carrageenan test and then, stated that "This data indicates that gabapentin and CI-1008 (note by the author: this compound is pregabalin) are effective for the treatment of inflammatory pain." Furthermore, it indicated that "The assay by Bennett G.J. provides an animal model of peripheral mononeuritis with rats that causes pain sensory disorder similar to that found with human beings (Pain, 1988; 33: 87-107)" and "The assay by Kim S.H. et al. provides an experiment model of peripheral neurological disorders caused by ligation of segmented spinal nerves with rats (Pain, 1990; 50: 355-363)." [13] As described above, the statements in the Description were found to suggest that the analgesic effects for pains with different causes, such as neuropathic pain, etc., require animal experiments of the neuropathic pain model in addition to animal model experiments as described in the

Description.

Based on the above, it is appropriate that the Intellectual Property High Court, Second Division did not find "common general technical knowledge" as alleged by the Plaintiff and dismissed the request in question in the Judgment. In this regard, the JPO trial made almost the same decisions and the same decisions were made by all four Intellectual Property Divisions of the Tokyo District Court and all Divisions of the Intellectual Property High Court in the infringement lawsuits.

### 3-2. Evaluation of evidence submitted in the Lawsuit

As stated in 2-2 above, the Plaintiff submitted, as support for the common general technical knowledge it alleged, the written opinions of expert authorities in the field of pain study, including Professor Woolf of Harvard University, Professor Dickenson of the University of London, Professor Clauw of the University of Michigan, Professor Masako Iseki of Juntendo University, Faculty of Medicine, and other experts. These written opinions asserted the common general technical knowledge was consistent with the allegation by the Plaintiff. However, in the Lawsuit, there was essentially no mention of these written opinions and the decision rendered ignored the presence of said written opinions. Pretty much the same treatment occurred in all four Intellectual Property Divisions of the Tokyo District Court and all four Divisions of the Intellectual Property High Court in the infringement lawsuits.

In this regard, courts tend to value highly objective materials that actually existed before the Application Filing Date more so than evidence that is created retroactively, such as written opinions, etc. The written opinions in this case included few technical materials that support the opinions and this is considered to be one of grounds for them not being valued as evidence.[14] Actually, the written opinions of experts are helpful for identifying common general technical knowledge; however, they are created retroactively and usually at the request of one of the parties. Therefore, even though the details are not wrong, it cannot be avoided to have bias to an extent. If said written opinions are valued excessively, the larger the corporations that have abundant financial power and personal connections, the more they become advantageous and the higher the possibility that the court decision is distorted. For this reason, the decision method in the Judgment is appropriate, where it does not value said written opinions so much, but the common general technical knowledge was found based on the textbook technical literature that was issued before the Application Filing Date.

Based on the above, in terms of the lawsuit strategy in Japan, the written opinions of experts to prove common general technical knowledge should be considered as supplementary for objective materials and it is very difficult to prove the common general technical knowledge with written opinions alone without the support of objective materials.

By the way, in the Lawsuit, as literature supporting the common general technical knowledge, such as the enablement requirement, etc., the Plaintiff considered the Priority Date as a standard and submitted mainly technical literature that was disclosed before the Priority

Date (before July 24, 1996), while the Defendants considered the Application Filing Date as a standard and submitted mainly technical literature that was disclosed before the Application Filing Date (before July 16, 1997). In this regard, the Judgment clearly indicated that the application filing date is a standard and the same decision was made by the JPO and all four Intellectual Property Divisions of the Tokyo District Court and all four Divisions of the Intellectual Property High Court in the infringement lawsuits. Therefore, at least in practice in Japan, the standard time of common general technical knowledge related to the enablement requirement (the same applies to the correction requirements and support requirement) is considered to be the application filing date. In this regard, for example, also in the judgment of the Supreme Court of the United Kingdom[15], there are court precedents which ruled that the priority date is used as a standard. Therefore, a globally unified standard is not always used and the presence of technical literature disclosed within one year at a maximum may have an impact on the judgment. Attention should be paid to this point.

### 3-3. Comparison with the judgment of the Supreme Court of the United Kingdom ([2018] UKSC 56)

As described at the beginning of this article, there are countries where patent disputes arose in the same way as Japan and their issues and conclusions of the judgment vary. In particular, in the Supreme Court of the United Kingdom, the issue similar to the Lawsuit is disputed as an argument of plausibility that is a requirement of the enablement. In particular, concerning "central sensitization" as described in 2-1. above, Patentee Warner-Lambert made the same allegations as described above in the United Kingdom, and this point was a big issue in the case.

These judgments are examined below. First, both in the Judgment and the judgment in the United Kingdom, it is a natural assumption that, for pharmaceutical-use inventions concerning well-known compounds (as is the case here), support for its efficacy is necessary with respect to all therapeutic uses encompassed by the claims.

However, in the judgment by the Court of Appeal in the U.K. (the court of prior instance to the Supreme Court), neuropathic pain was examined by distinguishing between pain from central nervous system disorders and pain from peripheral nervous system disorders. Although plausibility was not found with the neuropathic pain, it was found concerning pain from peripheral nervous system disorders that there is a "central sensitization," which is a common principle of mechanisms between inflammatory pain and pain from peripheral nervous system disorders.

On the other hand, in the judgment of the Supreme Court, the presence of a "central sensitization," which is a common principle of mechanisms for both the pain from central nervous system disorders and the pain from peripheral nervous system disorders, was denied. Since the experimental data disclosed in the Description was only related to inflammatory pain, the court did not find plausibility with neuropathic pain. However, in relation to the decision, opinions were divided by 3 to 2 among five Supreme Court justices, and the two justices in the minority opposed the majority opinion, stating that it will impose a very high bar

on patentees and it is not appropriate.

As described in 2-1. above, the Plaintiff alleged in the Lawsuit that the "central sensitization" is a common principle of mechanisms for all pain (pain from hyperalgesia or tactile allodynia), including pain from neuropathic pain and fibromyalgia. However, all courts in Japan and the United Kingdom and the JPO decided that there is no such common principle. However, concerning only the pain from peripheral nervous system disorders, it is clearly different from the decisions of Japanese courts and the JPO that completely denied the common mechanism, "central sensitization," that the judgment of the Court of Appeal clearly affirmed the existence of the common mechanism. It is interesting that this issue was very difficult to be settled in the judgment. As the cause of said difference, there are differences in the legal system and statement of claims, as well as, as described in 3-2. above, the differences in the type of evidence, such as prior art literature and written opinions submitted by both parties, and their assessment method also had a big impact.

### 3-4. Other issues in the Lawsuit and the Judgment

As described above, the Judgment is more a judgment on a specific case than on a legal thesis. However, there are decisions that serve as a reference for general terms related to other cases, as described below.

In this case, as described above, the actions and effects (efficacy of a drug using the compound related to the Patent) for the pain from neurological disorders and fibromyalgia (hyperalgesia or tactile allodynia) are issues. If support for said actions and effects are not found, even though the Correction is found, the correction is considered to be invalid due to violation of the correction requirements (the enablement requirement and support requirement). Consequently, whether the existence of the actions and effects can be a problem of the correction requirements is not directly related to the effectiveness of the patent rights related to Claims 1 and 2. For example, however, in cases where there is no support for the treatment effects for the pain from neurological disorders and fibromyalgia (hyperalgesia or tactile allodynia) related to the subject compound, such as pregabalin, etc., but it is stated formally in the Description, there is a question of how the correction requirements were determined. In this regard, in the decision on the correction requirements (whether the correction falls under the addition of a new matter), concerning whether the existence of actions and effects and the enablement, which are originally determined in the decision on the description requirement, can be considered, there are precedents of the Intellectual Property High Court that held that the argument on actions and effects, which is examined in the decision on the support requirement, should be considered in the decision on the correction requirements.[16]

For this reason, the Judgment apparently seems to be inconsistent with said decisions; however, attention must be paid that the usefulness for all pains (hyperalgesia or tactile allodynia) including the pain from hyperalgesia or tactile allodynia that is a question in this case is not stated just as the actions and effects of an invention, but as a pharmaceutical-use invention that is stated as the structure requirements of the invention. In fact, for example, in the judgment of the Intel-

lectual Property High Court on July 28, 2016 (case number: 2016 (Ne) 10023; the judgment on the Meniere's Disease Therapeutic Agent Case), it was determined that "A use invention is characterized by discovering the unknown nature of a known substance and creating a new use with significant effects based on that nature. Therefore, it is reasonable to understand that the term 'work' as used in Article 2, paragraph (3) of the Patent Act in cases of use invention is limited to acts of producing, using, transferring, etc. known substances in order to use them for a new use." In order for an invention to be found to be a use invention, it is essential to discover an unknown nature and to create a new use with significant effect based on the discovery. In consideration of the particularity of use inventions, it may not be particularly disadvantageous to right holders to request support for actions and effects when determining on the correction requirements.

Looking at decisions in infringement lawsuits in the Intellectual Property High Court, the 2nd Division of the Intellectual Property High Court that rendered the Judgment, and 3rd Division and 4th Division also determined that the correction requirements are not fulfilled (therefore, the counterdefense of the correction against the defense of patent invalidation is not established) on the same grounds as the above. In the judgment of the 1st Division of the Intellectual Property High Court[17], it did not mention the correction requirements, but examined the argument on invalidation concerning Claims after Correction 1 and 2 and rejected the counterdefense of the correction on the grounds that the grounds for invalidation, violation of the support requirement, was also not resolved in the structure after the correction. This is the point that drew attention. For this reason, concerning whether the actions and effects (usefulness) of a use invention should be considered when considering the correction requirements, the Intellectual Property High Court, First Division alone may have adopted a different opinion than other divisions and this is also interesting.

In addition, there are some unresolved issues with regard to the parties to the Lawsuit and the lawsuit form. In other words, as described at the beginning of this article, in the patent invalidation trial case in question, after the Petitioner Sawai Pharmaceutical requested a trial for patent invalidation, 15 generic drug pharmaceutical companies that are stakeholders joined the suit via a petitioner intervention (Article 148, paragraph (1) of the Patent Act).[18] In a lawsuit seeking rescission of a trial decision filed by a patentee, there is a question whether the defendants are limited to original petitioner(s) or whether petitioner intervenors also are a proper defendants. In this regard, for a period of time, even in court precedents of the Intellectual Property High Court, there are both cases where the first petitioner alone is treated as the defendant and where petitioners, including petitioner intervenors, are treated as codefendants. Recently, including the Lawsuit, it has become established that both petitioners and petitioner intervenors are treated as codefendants.

Consequently, in the Lawsuit, there are multiple lawsuits for each codefendant. There are opinions that understand the relationship as a necessary joint-action.[19] Today, there is strong opinion to understand it as a regular joint-action.[20] The Lawsuit is also considered to follow the idea.[21] As a result, at the stage where

a patentee files a lawsuit for rescinding a JPO decision, if only one person is not included in the Defendants from among petitioners and petitioner intervenors and the statute of limitations for filing an action elapses under the situation, the trial for invalidation becomes final and binding in the relationship with the party and the patent lapses retroactively. In this case, since the trial decision that invalidates a patent is also effective for a third party, concerning a lawsuit with other parties (who were regarded as defendants in the lawsuit to rescind the JPO decision), the request will be dismissed since it lacks benefits for legal action. In addition, if the period for filing a lawsuit rescinding the JPO decision has elapsed, it is understood that said defect cannot be resolved by the correction of adding parties, such as correction of a complaint.[22] Consequently, when filing a lawsuit to rescind the JPO decision against a decision of a trial involving multiple parties, such as this case, it is necessary to pay careful attention to who should be the defendant.

## 4. Closing

The Judgment was made for a typical case where an original drug pharmaceutical company and generic drug pharmaceutical companies were in dispute. Current disputes related to pharmaceuticals have become more complicated. For example, there are patent disputes between original drug pharmaceutical companies (for example, in cases where, since a broad range of compounds are specified in a Markush claim, pharmaceutical compounds of other generic drug pharmaceutical companies that are not worked by themselves are included in the claim) and patent disputes between generic drug pharmaceutical companies (for example, with the new entry of a generic, a patent is obtained in order to add value and other generic drugs come into conflict with the new generic drug). As described above, regardless of whether it is an original drug pharmaceutical company or a generic drug pharmaceutical company, it is difficult for companies engaging in the development of ethical drugs to predict when and how they are involved in a patent dispute. Therefore, it is important to study trends in decisions made by the courts and the JPO on a routine basis through cases like this one.

In addition, all the judgments of the Intellectual Property High Court in the infringement lawsuits introduced here became final and binding since the final appeal or a petition for the acceptance of a final appeal was not made[23]. On the other hand, concerning the Lawsuit, while a final appeal and a petition for the acceptance of a final appeal were made by the Patentee, the Supreme Court dismissed (did not accept) both of them. As the result, the Judgement has also become final and binding.

**(Notes)**

1 Website of the Ministry of Health, Labour and Welfare, “後発医薬品のさらなる使用促進のためのロードマップ[Roadmap for further promotion of the use of generic drugs]” URL: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/kouhatu-iyaku/index.html

2 The Plaintiff, Warner-Lambert, was acquired by Pfizer in 2000 and is under the control of Pfizer. Pfizer Japan Inc. is the exclusive licensee of the Patent.

3 In the Lawsuit and other infringement lawsuits related thereto, the Plaintiff alleged a different pain classification than that stated here; however, in this article we have adopted the

findings as stated in the Judgment and other infringement lawsuit decisions.

[4] Fibromyalgia is considered to be a kind of psychogenic pain and anti-depressants had been used for the treatment; however, the effects were considered to be limited.

[5] First of all, Pfizer marketed LYRICA® with the indication for epilepsy in Europe. But the patent covering this indication expired in 2013.

[6] In this article, companies engaging in the manufacturing and/or selling of generic drugs are referred to as "generic drug pharmaceutical companies" for the sake of convenience, regardless of whether they engage in other businesses.

[7] The claims (Claims 1 through 4) originally formed a group of claims and the requirements for their correction were judged integrally. Since it is requested for Claims 3 and 4 to be independent claims and a different claim unit, corrections related thereto were approved. No petitioners (intervenors) filed a lawsuit to rescind the JPO decision concerning Claims 3 and 4. Therefore, the JPO decision became final and binding as to claims 3 and 4 at that time.

[8] Under this situation, Pfizer also took action, and manufacturing approval for authorized generics for Lyrica was given at the same time as the aforementioned actions by Warner-Lambert.

[9] For example, in Korea, in the final appellate instance in the lawsuit for patent registration invalidation filed by a generic drug pharmaceutical company, the Supreme Court of Korea dismissed the final appeal of the Plaintiff, and thus Pfizer Pharmaceuticals Korea Co., Ltd. won the case.

[10] [2018] UKSC 56. The judgment of the Supreme Court of the United Kingdom is explained in detail in AIPPI (2019) Vol. 64, No.7, pp.570-577.

[11] In the infringement lawsuit, Plaintiff Warner-Lambert alleged that the generic drugs of Defendant companies infringe Claims 3 and 4 after correction. However, because the Defendants' generic drugs are only for "neuropathic pain" and "pain in association with fibromyalgia" and not for pain under a different category, such as inflammatory pain, postoperative pain, etc., and the Plaintiff stated when correcting Claims 3 and 4 that other categories that had been recited in the former claims were now deleted, all courts rejected said infringement allegations.

[12] However, it is not clear whether [all?] the articles underwent the peer-review process.

[13] The Plaintiffs conducted these animal experiments of the neuropathic pain model after the Application Filing Date and thus they are not included in the Description; however, this data was used to support the analgesic effects for neuropathic pain in the application for manufacturing approval for LYRICA. The marketing approval dossiers indicate the results of three animal experiments that were indicated in the Description; however, all of them are treated as references, but not as the basis for supporting the analgesic effects for neuropathic pain and fibromyalgia.

[14] In this regard, in the judgment (rendered on November 30, 2021) of the case at the Tokyo District Court, 47th Division, which is one of infringement lawsuits related to the Lawsuit (case number: 2020 (Wa) 19918 / 2020 (Wa) 22291), none of the written opinions submitted by the Plaintiff were accepted; however, since the written opinion of Professor Tatsuro Kohno, which was submitted by the Defendants, was consistent with other objective materials, it was accepted as evidence that serves as a basis for finding the common general technical knowledge at the time of the Application Filing Date.

[15] [2020] UKSC 27. The judgment of the Supreme Court of the United Kingdom is explained in detail in AIPPI (2021) Vol. 66, No.4, pp.2-10.

[16] For example, in the judgment of the Intellectual Property High Court on June 8, 2017 (case number: 2016 (Gyo-Ke) 10147; the judgment on Ito-en Tomato Juice Case), it was determined as follows: "The Plaintiff alleged that it is clear based on the statement in the Description that the combination of sugar content, sugar acid rate, and numerical range of content of glutamic acid, etc. after the Correction has no effect on the Invention. However, the aforementioned matters alleged by the Plaintiff should be questioned when considering the description requirements of claims (Article 36, paragraph (6) of the Patent Act) and do not have an impact on the decision described in (2) above." In addition, also in the judgment of the Intellectual Property High Court on July 19, 2017 (case number: 2016 (Gyo-Ke) 10157; the judgment on the Acid Taste Masking Method Case), it is determined that "the fact that the presence of acid taste masking effects related to the allegation of the Defendant is questioned when considering the

description requirements of claims (the support requirements as described in Article 36, paragraph (6), item (i) of the Patent Act) does not have an impact particularly on the appropriateness of the decision related to the correction requirements."

[17] The judgment of the Intellectual Property High Court on July 7, 2022 (case number: 2022 (Ne) 10021).

[18] In a patent invalidation trial in practice, the petitioner and patentee enter into a settlement and the request for trial is often withdrawn. In order to avoid such situations, other generic pharmaceutical companies often join in trials for patent invalidation by means of petitioner intervention.

[19] See the judgment of the Tokyo High Court on July 21, 1976 (1973 (Gyo-Ke) 95). In addition, in the Japan Patent Office edited, Chikujo Kaisetsu [Explanation of Provisions], (21st edition, p. 481), concerning Article 132, paragraph (1) of the Patent Act, it is stated that "Paragraph (1) falls under a similar and necessary joint-action as described in the Code of Civil Procedure."

[20] See the judgment of the Tokyo High Court on July 18, 2002 (2001 (Gyo-Ke) 79). In the explanation of judicial research official (Saihan Kaisetsu Minji Hen [Explanation of the Judgment of the Supreme Court, Civil Cases] FY2000 (First volume) p. 45) of the judgment of the First Petty Bench of the Supreme Court of January 27, 2000 (Minshu Vol. 54, No. 1, p. 69), it is indicated that "If a trial is requested jointly from the beginning, trial procedures must be integrated; however, it is not necessary to establish a trial decision uniformly. Therefore, if multiple trial decisions that were requested individually at the beginning are integrated, it should be interpreted to not be necessary to establish the trial decision uniformly in the same way as above."

[21] Actually, in the final oral arguments in the Lawsuit, the court confirmed with all co-defendants to invoke procedural acts of other codefendants and the court gave consideration of the fact that the judgment does not vary by each defendant.

[22] In fact, in the judgment of the Intellectual Property High Court on December 18, 2018 (case number: 2018 (Gyo-Ke) 10057; the judgment on the Two-dimensional Code Case), concerning the similar cases, since the statute of limitations for filing an action elapsed without a lawsuit for rescinding the JPO decision against non-party companies being filed by the Plaintiffs, the patent invalidation decision became final and binding, and as a result, the patent right of the Patent is deemed to have not existed from the beginning (main clause of Article 125 of the Patent Act). Therefore, it determined that the request should be rejected since it lacks the benefits of a lawsuit and it is unlawful.

[23] The main reason for this is that the Patent expired after July 16, 2022, even if the maximum term extension is considered, so there was no benefit to an appeal seeking injunction, etc. against the generic drugs.