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Life Sciences & Pharma IP Litigation 2024

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Japan: Trends & Developments

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Trends and Developments

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Recent Cases in Life Sciences & Pharma IP Litigation in Japan

Overview

Japan has frequently (almost every year) amended its intellectual property (IP) laws in recent years and, in 2023, significant amendments were made mainly regarding the Trademark Act and the Unfair Competition Prevention Act. However, these amendments are likely to have little impact on IP litigation in the life sciences and pharma field in Japan, and thus, it can be said that there have been no acts or amendments regarding intellectual property laws in this field that are noteworthy and expected to influence the practice thereof in the past couple of years.

Several notable IP litigation judgments in the life sciences and pharma field were issued in Japan from late 2022 to 2023. Among those judgments, the following judgments of the Intellectual Property High Court (IPHC) should be noted in particular.

- Chugai v Sawai et al (IPHC Judgment, 13 December 2022, Case Number: 2022 (Ne) 10065).
- Regeneron v Amgen (IPHC Judgment, 26 January 2023, Case Number: 2021 (Gyo-ke) 10093 and 10094).
- Nipro v Eisai et al (IPHC Judgment, 10 May 2023, Case Number: 2022 (Ne) 10093).

Overviews of the cases and some of the key points in the IPHC's judgments are provided below.

Chugai v Sawai et al

Introduction

In recent years, among pharmaceutical use inventions, there appear to be not only "inventions regarding the specific use of a substance in the treatment of a specific disease" but also inventions where the subject disease to be treated is specified in more detail or a group of target patients is specified in addition to the disease. Regarding such use inventions, the relevant issues are whether or not an invention is novel and involves an inventive step over prior art where the subject disease is specified in a regular manner and a group of target patients is not specified. While there had been a few cases in which this issue was the main disputed issue, it was the main disputed issue in this case.

Facts

Chugai Pharmaceutical Co, Ltd (Chugai) and Taisho Pharmaceutical Holdings Co, Ltd are the joint patentees for JP 5,969,161 entitled "agent

for preventing forearm bone fractures comprising eldecalcitol" (the "Patent"). Each of Sawai Pharmaceutical Co, Ltd (Sawai) and Nichi-Iko Pharmaceutical Co, Ltd (Nichi-Iko) respectively obtained marketing authorisation for a drug comprising eldecalcitol as an active ingredient for the treatment of osteoporosis on 17 February 2020 and began selling the drug in the market.

Sawai and Nichi-Iko jointly filed an action for invalidation against the Patent with the Japan Patent Office (JPO) on 23 December 2019. During the action, Chugai filed a request for correction to correct claims 3 and 4 into corrected claims 3 to 8 on 30 November 2020. Though Chugai's request for correction was accepted, the JPO rendered a trial decision invalidating claims 1 to 8. Chugai filed an appeal against the decision with the IPHC on 21 May 2021.

Chugai filed a patent infringement action with the Tokyo District Court against Sawai and Nichi-Iko seeking an injunction and argued that Sawai and Nichi-Iko infringed the Patent. The court dismissed Chugai's claim on the ground that the patented inventions in claims 1, 2 and 4 lacked novelty over the invention described in a prior art document B1 ("Invention B1") and the correction in claim 4 did not resolve the ground for the invalidation. Chugai filed an appeal with the IPHC.

While claim 1 is: "A pharmaceutical composition for inhibiting non-traumatic forearm fractures comprising eldecalcitol", Invention B1 is: "A drug that comprises ED-71, which has the following chemical structure (1α,25-dihydroxy-2β-(3-hydroxypropoxy)vitaminD3) and is administered orally at a dose of 0.75 μg/day for the treatment of patients with primary osteoporosis." The difference between claim 1 and Invention B1 ("Difference 1") is that, while Invention B1 is a drug for the treatment of osteoporosis, claim 1 is a pharmaceutical composition for inhibiting non-traumatic forearm fractures. Please note that the difference between the subject claims (not only claim 1 but also claim 2 and claim 4 before the correction) (collectively, the "Patented Invention") and Invention B1 is Difference 1.

Chugai argued that the Patented Invention is novel and involves an inventive step. Also, Chugai argued that the ground for the invalidation regarding claim 4 was overcome by the correction.

Among others, the following were the key disputed issues:

- Does the Patented Invention lack novelty over Invention B1 (Disputed Issue 1)?
- Is the ground for the invalidation regarding claim 4 resolved by the correction (Disputed Issue 2)?

Decision of the IPHC

Regarding Disputed Issue 1

Regarding the novelty requirement for use inventions, the IPHC held that, "As a general rule, a product that is publicly known lacks novelty according to Article 29(1) of the Patent Act. However, if it can be said that the invention at issue is an invention that discovers an unknown attribute of the product and finds that the product is suitable for a new use, the invention is distinguished from the publicly known product by the existence of the use and therefore is considered to be novel as a use invention."

The IPHC then held that, "A person skilled in the art would NOT recognise that the pathology of bones in the forearm and the resulting risk of fracture in osteoporosis patients is different from the pathology of bones in other parts of

the body and the risk of fracture, NOR would he/she recognise that the purpose of administering eldecalcitol as 'a drug for the treatment of osteoporosis' and its effect in Invention B1 is different between the forearm and other parts of the body" based on the following common technical knowledge.

- A person skilled in the art would recognise that Invention B1's "drug for the treatment of osteoporosis" is an agent administered to patients who have lost bone mass and bone strength in their bones throughout the body, including the vertebral column, forearm, thigh, and upper arm, due to the deterioration of bone microstructure, in order to reduce the risk of fractures at each site.
- A person skilled in the art would expect that the effects of eldecalcitol would extend to both the trabecular and cortical bone and would recognise that the effects would extend to the forearm bone, which is composed of the trabecular and cortical bone.
- A person skilled in the art would recognise that in osteoporosis, any part of the body can be fractured by external forces, and that the risk of fracture in the forearm is similar to that in other parts of the body prone to fracture due to osteoporosis, in that the risk increases as bone strength decreases.

The IPHC, considering the foregoing and others, held that, "by specifying the use of eldecalcitol as 'for inhibiting non-traumatic forearm fractures', a person skilled in the art would NOT recognise that eldecalcitol has an unknown action or effect or that it can treat a condition different from that treated by eldecalcitol administered as a drug for the treatment of osteoporosis. As such, it cannot be found that the Patented Invention is a use invention that discovered an unknown attribute of eldecalcitol, which is a publicly known substance and found that eldecalcitol is suitable for use in a new application due to said attribute, and therefore, the use pertaining to Difference 1 is not distinct from the use of 'a drug for the treatment of osteoporosis' of Invention B1. Therefore, the use of eldecalcitol for inhibiting non-traumatic forearm fractures is not distinguishable from the use of 'a drug for the treatment of osteoporosis' of Invention B1."

Regarding Disputed Issue 2

The IPHC held that neither the difference between the corrected claim 4 and Invention B1 nor the difference between the corrected claim 5 and Invention B1 was substantive and concluded that the ground for the invalidation of claim 4 was not resolved by the correction.

Conclusion

The IPHC held that the Patented Invention lacked novelty and the ground for invalidation was not resolved by the correction and affirmed the judgment of the Tokyo District Court that dismissed Chugai's claim. The IPHC also dismissed Chugai's appeal of the trial decision of the JPO that invalidated the Patent.

Comments

This judgment determined that use "for inhibiting non-traumatic forearm fractures" and use "for the treatment of osteoporosis" were not distinguished based on common technical knowledge and, thus, would be helpful. As a result of this judgment, the JPO decision invalidating the Patent became final and binding.

Regeneron v Amgen

Background

This case concerns litigation over patents regarding an anti-PCSK9 antibody that are also being disputed in the US and Europe. An anti-PCSK9 antibody is used as an active ingredient of

drugs for the treatment of hypercholesterolemia. Amgen Inc. ("Amgen") is marketing Repatha, its drug for hypercholesterolemia whose active ingredient is an anti-PCSK9 antibody, and Sanofi K K was marketing Praluent, its drug for hypercholesterolemia whose active ingredient is an anti-PCSK9 antibody.

In Amgen v Sanofi K K (Amgen's patent infringement action) and Sanofi v Amgen (Sanofi's action for invalidation) (eg, Amgen v Sanofi K K (IPHC Judgment, 30 October 2019)), it was found that Amgen's JP 5,705,288 and JP 5,906,333, entitled "Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9)", conformed to the support requirement. In Regeneron v Amgen, however, the IPHC held that the patented inventions pertaining to the patents did not satisfy the support requirement.

Amgen v Sanofi K K and Sanofi v Amgen (2016–2020)

In the patent litigation cases between Amgen and Sanofi/Sanofi K K in Japan from 2016 to 2020, ie, Sanofi's action for invalidation of Amgen's patents and Amgen's patent infringement action against Sanofi K K seeking an injunction on the grounds that Sanofi K K's sales of Praluent, comprising alirocumab as an active ingredient, constituted patent infringement, Amgen's patents were maintained based on the reasoning that they conformed to the support requirement, etc, and it was concluded that Sanofi K K infringed Amgen's patents, and, therefore, an injunction was issued.

The original claim 1 of JP 5,705,288 is "an isolated monoclonal antibody capable of neutralising binding between PCSK9 and LDLR proteins, competing, on binding to PCSK9, with an antibody comprising a heavy chain containing CDR 1, 2, and 3, consisting of amino acid sequences of SEQ ID NOs 368, 175, and 180, respectively, and a light chain containing CDR 1, 2, and 3 consisting of SEQ ID NOs 158, 162, and 395, respectively." The corrected claim 1 based on Amgen's request for correction made in the course of the action for invalidation is "an isolated monoclonal antibody that can neutralize the binding of PCSK9 to LDLR protein and that competes with an antibody comprising a heavy chain containing a heavy chain variable region consisting of the amino acid sequence of SEQ ID NO 49 and a light chain containing a light chain variable region consisting of the amino acid sequence of SEQ ID NO 23 for binding to PCSK9."

Regarding the support requirement, based on the descriptions contained in the specifications and common technical knowledge, the IPHC stated, "It can be found, in light of the foregoing, that a person skilled in the art can understand from the descriptions contained in each of the Specifications that: it is possible to obtain isolated monoclonal antibodies that neutralize the binding of PCSK9 to LDLR proteins and that compete with Reference Antibody 1 or 2; therefore, monoclonal antibodies of Inventions 1-1 and 2-1, which are new antibodies, are provided; and with the use of pharmaceutical compositions of Inventions 1-2 and 2-2 that utilise them, it is possible to solve the problem of treating or preventing diseases associated with elevated cholesterol levels (such as hypercholesterolemia, etc) and reducing disease risks", and determined that "it can be found that each of the Inventions conforms to the support requirement."

Regeneron v Amgen

Regeneron Pharmaceuticals, Inc. ("Regeneron") filed an action for invalidation of JP 5,705,288 and JP 5,906,333 with the JPO on 12 February 2020. As the JPO rendered the Trial Decision

maintaining Amgen's patents on 7 April 2021, Regeneron filed an appeal with the IPHC on 13 August 2021. The IPHC rendered a judgment revoking the JPO Trial Decision on 16 January 2023. Since Amgen's final appeal was rejected by the Supreme Court on 14 September 2023, the case was remanded to the JPO.

Decision of the IPHC in Regeneron v Amgen

Regarding the support requirement, the IPHC held, based on the descriptions in the specifications and common technical knowledge, that, "It cannot be deemed that an antibody, if it competes with the 21B12 antibody, directly blocks the site where PCSK9 binds to an LDLR protein by way of binding to the site that interacts with LDLR's EGFa domain; no other mechanism is disclosed, through which any type of antibody, so long as it competes with the 21B12 antibody, becomes an antibody that inhibits the interaction (ie, binding) between PCSK9 and LDLR's EGFa domain (and/or LDLR generally); and in light of the foregoing, it must be deemed difficult for a person skilled in the art to arrive at the understanding that antibodies, which compete with the 21B12 antibody, are binding-neutralising antibodies", and, therefore, determined that Amgen's patented inventions violated the support requirement.

Comments

There have been few cases where, after the IPHC had held that no grounds for invalidation had been found in relation to a certain patent and the judgment became finalised, the IPHC determined that the same patent should be invalidated. In this regard, where the ground for invalidation in a dispute is a lack of an inventive step, it is possible that the court would come to a different determination on the inventive step if a new prior art document was found and submitted to the court. On the other hand, where the ground for invalidation in a dispute is a violation of the enablement requirement or the support requirement, it is unlikely that the court would reach a different determination on the same ground for invalidation. This judgment is interesting, not only because the IPHC made a different decision, but also because the IPHC stated that the circumstance for the determination of the support requirement changed because of new evidence.

Nipro v Eisai, et al

Background

This dispute concerns the patent linkage system in Japan, an overview of which is provided below:

Japan does not have a statutory patent linkage system like that in the US. In other words, there are no statutes requiring the health authority to consider, when an application for marketing authorisation of a generic drug is filed, the existence of a patent that may cover the generic drug in determining whether to issue the marketing authorisation.

However, there is a non-statutory patent linkage system in Japan. Specifically, the Ministry of Health, Labour and Welfare (MHLW) issued a letter (the "MHLW Letter") to prefectures stating that when reviewing an application for marketing authorisation of a generic drug:

- if the manufacture of the active ingredient of the original drug is not possible due to the existence of a patent on the active ingredient, the generic drug will not be approved; and
- in cases where a patent exists for certain indications, dosage and administration of an original drug ("indications, etc") and it is possible to manufacture a drug claiming other indications, etc, a generic drug may be

approved, but not for the indications, etc, for which the patent exists.

Note that the MHLW Letter is an administrative internal letter and not legally binding.

The health authority can decide whether to issue marketing authorisation at its own discretion, and, based on the MHLW Letter, when a generic company applies for marketing authorisation for a generic product, the authority informally takes into account the relevant patents of the innovator, and if the health authority believes that the generic drug would infringe the patents, the authority denies the application in respect of the generic. The authority does not, however, reveal its reason for this decision. In light of this, generic companies have come to the idea that, if the relevant company were to obtain a declaratory judgment confirming that the drug does not infringe the relevant patent of the innovator, the company would obtain marketing authorisation pursuant to the judgment. This case may have been brought for such purpose.

Facts

Eisai R&D Management Co, Ltd (Eisai RD) owns JP 6,466,339 and JP 6,678,783 entitled "use of eribulin in the treatment of breast cancer" (collectively the "Patents"). On 19 July 2011, Eisai Co, Ltd (Eisai) started selling its drug comprising eribulin as an active ingredient for "inoperable or recurrent breast cancer", and in February 2016 added "malignant soft-tissue tumor" to its indication.

On 25 February 2022, Nipro Corporation (Nipro) applied for marketing authorisation regarding its generic drug comprising eribulin as an active ingredient. Nipro filed with the Tokyo District Court a declaratory judgment action against Eisai seeking the following declaratory judgment.

Main claims:

- declaration that Eisai RD does not have a right to seek an injunction against Nipro's product based on the Patents; and
- declaration that Eisai and Eisai RD do not have a right to seek compensation for damage caused by manufacture and sale of Nipro's product based on the infringement of the Patents.

First auxiliary claim:

- declaration that Eisai RD does not have a right to seek an injunction against Nipro's product based on the Patents, on condition that Nipro's product is listed in the NHI drug price standard; and
- declaration that Eisai and Eisai RD do not have a right to seek compensation for damage caused by manufacture and sale of Nipro's product, based on infringement of the Patents, under the condition that Nipro's product is listed in the NHI drug price standard.

Second auxiliary claim:

- As between Nipro, Eisai and Eisai RD, a declaration that Nipro's product does not fall within the technical scope of the Patents.

The court dismissed all of Nipro's claims because of the lack of standing to seek a declaratory judgment, and Nipro filed an appeal with the IPHC.

Decision of the IPHC

The IPHC articulated, as the criterion regarding standing to seek a declaratory judgment, that

"standing to seek a declaratory judgment exists only when there is an interest for immediate finality; that is, when it is necessary and appropriate to obtain a declaratory judgment against the defendant in order to resolve a legal dispute concerning the legal relationship, etc, and to eliminate the danger or uncertainty that exists in relation to the plaintiff's rights or legal status."

While Nipro stated that the health authority would not issue marketing authorisation for Nipro's product based on the MHLW Letter and relevant facts, the IPHC held that it was not sufficient to find that there was a high probability that the health authority would issue marketing authorisation for Nipro's product in the near future, and that Nipro's product would be listed in the NHI drug price standard; and the IPHC further held that there was not a high probability that Nipro would manufacture and sell its product in the near future.

Regarding Nipro's argument that marketing authorisation for Nipro's drug would not be granted based on the MHLW Letter and the Patents, the IPHC stated to the effect that whether or not marketing authorisation for Nipro's drug would be granted implicated a legal dispute between Nipro and the government, not between Nipro, Eisai, and Eisai R&D; and that the IPHC did not find it necessary and appropriate that a declaratory judgment be obtained against Eisai and Eisai R&D in order to resolve the said legal dispute between Nipro and the government, because the necessary and appropriate legal actions should be pursued, such as filing a lawsuit to seek confirmation of the illegality of the non-action in relation to the application for marketing authorisation, or filing an appeal to the MHLW.

Therefore, it could not be found that there was actually a dispute between the parties and that there was any danger or uncertainty in relation to Nipro's rights or legal status, with respect to Eisai RD's right to seek an injunction based on the Patents and Eisai's and Eisai RD's right to seek damages based on the infringement of the Patents. The IPHC affirmed the first instance decision and dismissed all of Nipro's claims.

Comments

The IPHC's ruling is consistent with the general understanding in respect of standing to seek a declaratory judgment. According to this ruling, even where a generic company, which is willing to manufacture and sell its generic drug and believes that the generic drug does not infringe any patents of an original drug, files for marketing authorisation for the generic drug, the generic company cannot obtain a declaratory judgment that there is no patent infringement in relation to its generic drug, before the health authority makes the decision on the marketing authorisation for which an application was made. If the generic company believes that the health authority's decision is wrong and ill-founded, it can only be said that there is a dispute between the generic company and the authority, even though it would be difficult in practice to file a lawsuit against the authority.

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