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Japan: Trends & Developments

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Trends and Developments

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Chuo Sogo LPC is an international business law firm founded in 1968. Within the scope of its corporate, commercial and litigation practices, the firm assists clients with intellectual property matters, including patent, trade mark, copyright, and unfair competition matters, as well as related litigation and dispute resolution. The firm has offices in Osaka, Tokyo and Kyoto. The protection of investment in intellectual property is essential to ensure the sustained success of many companies, and Chuo Sogo handles a range of litigation, negotiation and contract drafting related to intellectual property law, unfair competition prevention law and copyright law. With over ten lawyers in its IP group and 80 lawyers at the firm, its experienced IP attorneys offer guidance to protect IP rights in a wide array of commercial sectors. With the co-operation of its affiliated patent firms, the firm is part of a strong global legal network, allowing it to cater to clients' international IP needs with an innovative and cost-effective approach.

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Intellectual Property High Court Grand Panel Decisions

The rulings of the Intellectual Property High Court (the "IP High Court") have a major impact on the interpretation of intellectual property rights in Japan. In cases involving particularly important legal issues and where decisions could significantly impact business activities and the industrial economy, the Grand Panel, which is made up of five judges of the IP High Court, is formed ad hoc to render its decisions. However, there is no pending case at the Grand Panel of the IP High Court at this moment (December 2024).

Life sciences

In 2024, several significant rulings by Japanese Courts, including the IP High Court, have been made in the field of life sciences. The first case below shows the criteria for determining the inventive step with regard to a patent relating to a vaccine adjuvant, which enhances a vaccine's effectiveness. The second case showcases another interesting discussion regarding the patent linkage system in Japan.

KM Biologics Co, Ltd. v Seqirus UK Limited, Case No 2023 (Gyo-Ke) 10056, Intellectual Property High Court (decision rendered on 25 March 2024)

In a recent case concerning a patented invention titled "Hydrophilic Filtration During the Manufacture of Vaccine Adjuvants," the IP High Court rescinded the decision of the Japan Patent Office (JPO) that the request for a trial for patent invalidation for the patent owned by the defendant (the "Invention") is groundless, stating that, at the time of the priority date, a person skilled in the art could have easily conceived the structure of the Invention based on the cited invention and well-known techniques. Furthermore, the Court noted that the effects achieved by the Invention were neither unpredictable by a person skilled in the art based on the structure of the Invention nor demonstrated to exceed the scope of effects reasonably expected from the structure. As a result, the decision of the JPO to invalidate the patent was overturned.

The Invention in question provided a method for manufacturing a squalene-containing oil-in-water emulsion, and this method comprised of:

- a process to provide a first emulsion having a first average oil droplet size;
- a process to microfluidize said first emulsion to form a second emulsion having a second average oil droplet size that is smaller than said first average oil droplet size; and
- a process to filter said second emulsion using a hydrophilic double-layer polyethersulfone membrane comprised of a first layer having a pore size of 0.3 μm or greater and a second layer having a pore size of less than 0.3 μm, thereby providing a squalene-containing oil-in-water emulsion.

In Japan, the concept of an inventive step is defined in Article 29(2) of the Patent Act. This article states that a patent cannot be granted for an invention if it could have been easily created, prior to the filing of the patent application, by someone with ordinary skill in the relevant field based on existing prior art.

The patent examiner determines whether the claimed invention is novel by comparing it with the prior art cited to identify the differences between them. Where there is no difference, the claimed invention lacks novelty. If there is any difference, the examiner determines whether the claimed invention has an inventive step. If there is an invention-specific feature in the claimed invention that is not described in the prior cited

invention, that feature will be recognised as a difference. If a person skilled in the art can easily think of that difference based on the state of the art at the time of filing, the claimed invention will be judged to lack an inventive step based on the cited invention.

In its inventive step analysis, the Court first determined that the technique related to the structure of filtration using a membrane of a commercially available product listed in a product catalogue was a well-known technique at the time of the priority date. This commercially available product had a hydrophilic heterogenous bilayer polyethersulfone membrane that combined a polyethersulfone prefiltration membrane with a pore size of 0.45 µm and a polyethersulfone final filtration membrane with a pore size of 0.2 µm, and the product catalogue state that the product was designed to filter a wide range of pharmaceutical products. Therefore, the Court noted that this product could naturally be applied to the manufacturing of a vaccine adjuvant emulsion, and thus, the technical field to which the Invention and this product belong are the same. The Court reasoned that the difference between the filtration process of the Invention and that in cited inventions could have easily been conceived by a person ordinarily skilled in the art by applying this well-known technique.

Furthermore, regarding the effect of the Invention, the Court referred to data from the description in the specification and determined that, only based on such data, it is not proved that the significant recovery rate is achieved thanks to the effect of the hydrophilic double layer polyethersulfone membrane related to the Invention. The Court noted that according to the evidence, it is reasonable to find that a person ordinarily skilled in the art at the time of the priority date could have easily understood that if approximately 50 litres of emulsion is filtered using the commercially available product, the clogging degree of the membrane is reduced and a high recovery rate (as stated in the description of the specification) can be achieved.

Based on its analysis, the Court denied the inventive step of the Invention and set aside the decision of the JPO that the invalidation trial was not successful. The Court concluded that a person ordinarily skilled in the art at the time of the priority date could have conceived of the configuration of Invention based on the cited invention and well-known art above. Furthermore, the Court did not find that:

- the effect of the Invention could not have been predicted by a person of ordinary skill in the art; or
- the effect is significant beyond the scope that a person ordinarily skilled in the art could have predicted.

A skilled individual in the field would have easily recognised the well-established filtration technology using a membrane made from a commercially available product. Furthermore, based on the comparison presented in the specifications, the Invention did not produce any significant effect. The impact of the Invention was predictable, considering the information contained in the catalogue listing the commercially available product.

Samsung Bioepis Co., Ltd. v Bayer Healthcare LLC., Case No 2024 (Yo) 30029, Tokyo District Court (decision rendered on 28 October 2024)

Patent linkage system in Japan

The patent linkage system refers to a mechanism in which regulatory authorities consider the infringement of patent rights related to the

original drugs in the procedures for the approval of generics. The purpose of patent linkage is to ensure a stable supply of generics by considering the patent rights related to the original drugs. The implementation of the system and its contents differ from country to country.

In Japan, the patent linkage system has no clear legal basis, and it is handled as an administrative practice under the guidance of the Ministry of Health, Labour and Welfare (MHLW) based on two administrative notifications (both are notifications by a section chief and are thus collectively referred to as the "Two Section Chief Notifications"). The details of the practice are as follows.

- If a patent exists on the active ingredient of the original drug and the manufacturing of that active ingredient is not possible, the generic will not be approved.
- If a patent exists for part of the indications, dosage and administration ("indications, effects, etc") of the original drug, and if it is possible to manufacture a drug adopting other indications, effects, etc, the generic drug will be approved. However, the indications, effects, etc, for which a patent exists are not approved.
- The existence or non-existence of a patent shall be determined on the scheduled approval date of the generic.

In the procedure of the National Health Insurance (NHI) price listing of generic drugs, the Two Section Chief Notifications require that matters with patent-related concerns be adjusted between the parties in advance and that listing procedures be taken only for items considered capable of stable supply. However, this preliminary adjustment between the parties is to be made during the NHI price listing after obtaining approval for the generic, and the actual practice is that, even if discussions or adjustments between the parties are unsuccessful, the MHLW permits the NHI price listing of the generic if there is an application from a generic drug manufacturer. Also, as mentioned above, although the MHLW is responsible for determining whether the generic drug infringes the patents of the original drug, there is no mechanism in place for the MHLW to rely on any judicial judgment.

Rulings

Bayer Yakuhin Co., Ltd., a Japanese subsidiary of the defendant, manufactured and sold an anti-VEGF agent using the recombinant fusion protein Aflibercept (the "Defendant's Original Drug") for indications such as age-related macular degeneration (AMD).

After the launch of the Defendant's Original Drug, the defendant obtained a patent for a specific use aimed at treating a particular subgroup of wet age-related macular degeneration (AMD) patients who meet certain inclusion and exclusion criteria (the "Defendant Patent"). The Defendant Patent is characterisedcharacterised as a use invention, based on the discovery of a previously unknown property of Aflibercept—a known substance—showing superior therapeutic effects in patients meeting specific criteria, and creating a novel use with remarkable effectiveness.

Through its manufacturing and sales subsidiary in Japan, the plaintiff submitted an application to the MHLW for marketing approval of the plaintiff's product (the "Plaintiff's Biosimilar Drug"), as a biosimilar to the Defendant's Original Drug. The Plaintiff's Biosimilar Drug included wAMD as an indication and adopted the same descrip-

tions as the Defendant's Original Drug in its dosage and administration.

Under the patent linkage system, the defendant notified the MHLW that the generic drug manufacturer's act of manufacturing and selling a biosimilar to the Defendant's Original Drug would infringe the Defendant Patent (the "Notice in Question").

The plaintiff asserted that it was evident that the Plaintiff's Biosimilar Drug did not infringe the Defendant Patent, and therefore the Notice in Question by the defendant constituted a clearly false statement. The plaintiff further argued that this act of the defendant amounted to "the act of disseminating or notifying false facts harmful to the business reputation of a competitor" under Article 2(1)(21) of the Unfair Competition Prevention Act, posing a potential risk of damaging the plaintiff's business interests. Consequently, the plaintiff sought a provisional injunction to stop the defendant from issuing the Notice in Question.

Does the Notice in Question Constitute a False Statement?

A use invention is an invention characterised by the discovery of an unknown property of a known substance and the creation of a novel use with significant effects based on that property. Therefore, "implementing" a use invention refers to acts such as manufacturing or using the known substance for the purpose of the novel use.

The Court recognised that the Defendant Patent was also a use invention and defined its "implementation" as acts such as manufacturing or using a preparation containing the known substance for administration to a specific patient group, among wAMD patients, that satisfies certain inclusion and exclusion criteria defined by the Defendant Patent.

In its assessment, the Court concluded the following:

- The Plaintiff's Biosimilar Drug is a biosimilar to Defendant's Original Drug, its package insert merely includes wAMD as an indication and does not describe the specific patient group meeting the inclusion and exclusion criteria of the Defendant Patent, nor does it mention the significant effects achieved by administering it to such a specific patient group.
- Therefore, the manufacture and sale of the Plaintiff's Biosimilar Drug cannot be regarded as acts of manufacturing or using a preparation containing the known substance for administration to the specific patient group. Accordingly, it does not infringe the Defendant Patent.

The Court addressed the validity of the Defendant's Patent and noted that the Plaintiff's Biosimilar Drug is equivalent and identical to the Defendant's Original Drug. It observed that the Defendant's Original Drug had been manufactured and sold before the filing date of the Defendant's Patent. Additionally, the Defendant's Original Drug was administered to a specific group of patients as part of the general treatment for wAMD. Therefore, the manufacture and sale of the Defendant's Original Drug constituted prior public use, which rendered the Defendant's Patent invalid.

For these reasons above, the Court concluded that the Notice in Question constituted a false statement.

Unfair Conduct

As described, the Court determined that the Notice in Question issued by the defendant constituted a false statement. The Court further examined whether such an act amounts to unfair conduct under the Unfair Competition Prevention Act within the context of the patent linkage system based on the following criteria:

Scope of statements under the patent linkage system

The defendant issued the Notice in Question to the MHLW under the patent linkage system. This system has no specific restrictions on the content of such statements. Patent holders are not prohibited from expressing their opinion regarding the existence or absence of patent conflicts between their patented drug and a follow-on generic drug.

Purpose of the patent linkage system

The patent linkage system aims to confirm the existence or absence of patent conflicts between patented drugs and follow-on generic products during the approval process of generic drugs, ensuring the stable supply of generic drugs. However, this system does not permit patent holders to provide arbitrary or misleading information.

Evaluation of false statements

If a patent holder makes a false statement claiming a patent conflict under the guise of providing information within the patent linkage framework, while the substance of such a statement is to disadvantage the applicant seeking approval for a generic drug and to secure a competitive advantage for themselves, such conduct would disrupt fair competition among businesses.

Determination of unfair conduct

Acts by a patent holder under the patent linkage system that involve providing false information about patent conflicts could amount to unfair competition if "exceptional circumstances exist where such acts are deemed grossly inappropriate in light of the purpose of the patent linkage system."

Application to this Case

The defendant argued that:

- It is now common technical knowledge that administering the Defendant's Original Drug to a specific patient group yields superior therapeutic effects, and such knowledge has evolved since the filing date of the Patent in Question.
- Consequently, the manufacture and sale of Defendant's Original Drug before the filing date does not constitute a prior public use, and the current manufacture and sale of Plaintiff's Bio-Similar Drug infringes Defendant's Patent.

The Court noted that even though the defendant's view above may be considered its own interpretation, it is a potentially arguable position when alleging patent infringement. Therefore, the mere act of adopting this viewpoint does not immediately render the defendant's argument baseless. Patent infringement disputes require careful deliberation based on expert knowledge, and the limited examination conducted during preliminary injunction proceedings is insufficient to determine that the defendant's argument is entirely unfounded.

Thus, although the defendant's issuance of the Notice in Question may be considered careless, it was not the case that "exceptional circumstances exist where such acts are deemed

grossly inappropriate in light of the purpose of the patent linkage system." Accordingly, the Notice in Question does not amount to an unfair act under the Unfair Competition Prevention Act.

The above ruling is rendered to determine whether the defendant's act constitutes an unfair act under the Unfair Competition Prevention Act. However, as the plaintiff argued, there is a question about the current practice that the MHLW determines the patent infringement, and there is no mechanism for prior co-ordination between the parties at the approval or prior approval stage. Future discussions on the Japanese patent linkage practice are therefore expected.

Technology

The following recent decisions by the Japanese Courts also show important developments in the field of technology. The first case below shows interesting discussions regarding the eligibility of AI as an inventor, which have been attracting particular attention all over the world in recent years. The second case shows how the standard established in the past IP High Court's decision regarding the support requirement is specifically applied.

A v Japanese Government, Case No 2023 (Gyo-U) 5001, Tokyo District Court (decision rendered on 16 May 2024)

In recent years, with the remarkable advancements in artificial intelligence (AI), AI – particularly generative AI – has come to be widely utilised even in creative activities. This case involves a patent application for an invention (titled "Food Container and Devices and Methods for Attracting Enhanced Attention") submitted by the plaintiff who developed the AI known as "DABUS". The application listed "DABUS, The invention was autonomously generated by an artificial intelligence" as an inventor. However, the JPO rejected the patent application on the grounds that it did not include the name of a natural person as an inventor. The plaintiff challenged this decision as unlawful and sought its cancellation at the Tokyo District Court.

In this case, the key issue was whether the interpretation of an "inventor" as defined under Japan's Patent Act could include AI. The Court ruled that AI cannot be considered an "inventor" based on the following findings:

- Intellectual Property Basic Act, Article 2(1): This provision defines "invention" as something created through human creative activity, which reasonably implies that inventions are the products of natural persons.
- Patent Act, Article 36(1)(ii): This article requires the "name" of the inventor to be stated. In contrast, Article 36(1)(i) requires the "name or designation of the applicant. This distinction indicates that "name" refers specifically to the name of a natural person, thereby assuming that inventors are natural persons.
- Patent Act, Article 29(1): This article states that a person who has made an invention is entitled to receive a patent for that invention. However, since AI lacks legal personality, it cannot be the holder of rights to a patent. Therefore, "a person who has made an invention" must reasonably be interpreted as referring to a natural person.
- Lack of statutory basis for determining inventorship in AI-generated inventions: If AI were to be included as an "inventor," there would be no legal framework to determine who among those involved with the AI's creation and operation should be considered the inventor.
- Patent Act, Article 29(2): This provision states that an invention is unpatentable if it could

have been easily conceived by a person skilled in the art (an individual with ordinary knowledge in the relevant technical field) prior to the patent application. Since it is challenging to equate the creative abilities of natural persons with AI's evolving autonomous creative abilities, it is inappropriate to immediately apply the concept of "a person skilled in the art" to AI.

In this case, the invention was filed as a PCT international application. With the exception of South Africa, which conducts only formal examinations, the eligibility of AI as an inventor has been denied in other jurisdictions, including the United States (USPTO), the United Kingdom (UKIPO), and Europe (EPO). Similarly, in this ruling, the Court held that it is reasonable to interpret "inventor" as stipulated in the Patent Act as being limited to natural persons. This marked the first time in Japan that the eligibility of AI as an inventor was explicitly denied.

In this case, the plaintiff argued that despite the emergence of AI-generated inventions in the industrial sector, adhering uncritically to the traditional inventor-centric view – where only natural persons can be inventors – fails to consider the incentives for AI-generated inventions. The plaintiff claimed this approach contradicts the purpose of the Patent Act, which is to "contribute to the development of industry" (Article 1 of the Patent Act).

However, the Court took a conservative stance, emphasising the difficulties of defining inventorship in AI-generated inventions within the framework of the existing Patent Act, which was designed with natural persons in mind. The judgment highlighted that current patent law does not clearly specify who among those associated with an AI invention (such as the AI itself, the rights holders of the AI's source code or software, or those who exclusively control the AI) should be granted inventorship and the right to a patent. This ambiguity made it challenging to create new legal principles through judicial precedent in this domain, given the critical importance of determining the ownership of patent rights.

Given the ongoing advancements in AI, developing intellectual property frameworks and legislation that address these emerging issues will be necessary. The Court also acknowledged the importance of AI-generated inventions in industrial policy and expressed the need for legislative efforts to address the challenges surrounding such inventions. It emphasised the importance of examining AI-generated inventions from a legislative perspective and reaching conclusions on the matter as promptly as possible.

Future legislative developments will be expected to resolve the issues surrounding the recognition of AI as an inventor, ensuring that the intellectual property system evolves in line with technological advancements.

JFE Steel Corporation v Nippon Steel Corporation, Case No 2023 (Gyo-Ke) 10020 and 10021, Intellectual Property High Court (decision rendered on 23 January 2024)

Support requirement under the Patent Act

Article 36(6)(i) of the Patent Act stipulates the so-called support requirement that the invention set out in the claims must not exceed the scope described in the detailed explanation of the invention. This is because, if the claims included an invention not disclosed in the detailed explanation, rights would be conferred on an undisclosed invention. The support requirement is intended to prevent such a situation. Failure to meet the support requirement not only consti-

tutes grounds for refusing a patent application but also provides grounds for cancellation in patent opposition proceedings and for invalidation in patent invalidation trials.

Rulings from past cases

In the past, with respect to the support requirement, there was debate over whether the wording in the specification needed to formally include the language of the claims, or whether a more substantive assessment was permissible. In The Nippon Synthetic Chemical Industry Co., Ltd. v Commissioner, Japan Patent Office, Case No 2005 (Gyo-Ke) 10042 (decision rendered on 11 November 2005), the Intellectual Property High Court, in a decision by its Special Division, held as follows:

- The support requirement should be evaluated by comparing the claims' wording with the invention's detailed description. It's important to determine if the invention outlined in the claims aligns with what is described in the detailed explanation. Additionally, one must assess whether a person skilled in the relevant field, using that description, would recognise that the problems addressed by the invention can be effectively resolved.
- Additionally, the support requirement is satisfied if, even in the absence of explicit description or suggestion, a person skilled in the art, considering the common technical knowledge at the time of filing, would recognise that the problems addressed by the invention can be resolved.
- The burden of proof as to the existence of the support requirement lies with the patent applicant or patentee.

At present, these rulings have become firmly established in practice. JFE Steel Corporation v Nippon Steel Corporation also adopted the same rulings.

Determining whether the support requirement was satisfied in JFE Steel Corporation v Nippon Steel Corporation

The invention in question relates to a steel pipe pile-type jetty constructed by driving multiple steel pipe piles into the seabed and integrating the heads of these piles with a reinforced concrete superstructure. Among such steel pipe pile-type jetties, those designated as seismic reinforcement facilities are required, under port regulations, to have no piles that have reached full plasticity at two or more points (ie, no piles in which the bending moment has reached the full plastic moment).

To ensure that piles located in areas with significant Level 2 seismic activity meet the necessary full plastic performance requirements, one might consider measures such as increasing the wall thickness of the steel pipe piles or enlarging their diameter; however, the effectiveness of such measures is often limited, can sometimes have adverse effects, and leads to increased construction costs, which posed a significant challenge.

There are three claims (Claims 1 to 3) of the invention in question. The IP High Court found that, with respect to the inventions defined by Claims 1 and 2, the specification did not contain any examples directly disclosing them.

The IP High Court recognised, based on common technical knowledge, that the curvature found in the steel pipe piles described in the specifications would yield nearly identical results despite variations among the embodiments. Consequently, the court concluded that a person skilled in the art – upon reviewing the specified

embodiments and taking into account established technical knowledge – would understand that the issue of increased construction costs could be addressed for both inventions claimed in Claims 1 and 2.

As a result, the IP High Court ruled that the invention in question satisfies the support requirements and overturned the invalidation decision by the JPO.

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