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Patent Litigation 2024

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Japan: Trends & Developments

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Trends and Developments

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Chuo Sogo Law Office

Chuo Sogo Law Office 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 insure 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, among a total of 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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JAPAN TRENDS AND DEVELOPMENTS

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Patent Litigation Before the Japan Intellectual Property Courts

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 have a significant impact on business activities and industrial economy, the Grand Panel, which is made up of five judges of IP High Court, is formed ad hoc to render its decisions. The following Grand Panel decisions were issued in 2022 and 2023.

DWANGO Co., Ltd. v FC2, Inc. and Homepage System, Inc., Case No 2020 (Ne) 10024 (decision rendered on 26 May 2023)

The plaintiff, DWANGO, had the patent right for an invention titled “Comment Delivery System”. The issue in the case was whether the defendant FC2’s act of distributing its files from a server in the USA to user terminals in Japan, through FC2’s systems for online video delivery services with commentary (“FC2’s act”), falls under the definition of “production” in Article 2, paragraph 3, item 1 of the Patent Act.

The Grand Panel of the IP High Court first decided that the principle of territorial jurisdiction applies to the Patent Act of Japan. The Court further ruled, however, that with regard to whether or not the act of newly creating a network-type system falls under “production”, even in a case where a server which is a part of the elements constituting the system in question exists outside Japan, if the act can be considered as having been performed within the territory of Japan, by comprehensively taking into consideration factors such as the specific manner of the act, the function and role played by the

elements which exist in Japan, the place where the effect of an invention can be obtained from the use of the system, and the effect of such use on the economic interests of the patentee, then the act falls under “production.”

In this case, the court considered the following circumstances:

- FC2’s files are sent by a server in the United States to the user terminals in Japan, and the user terminals in Japan receive the files;
- the transmission and receipt are performed as a package;
- if it is considered that FC2’s system is completed when the user terminals in Japan receive the files, it can be said that the transmission and receipt are performed in Japan;
- the user terminals in Japan perform the main functions of the invention;
- FC2’s system can be accessed from Japan via a user terminal, so that the effect of the invention, which is to use commentary in communication to make the invention more entertaining, is manifested in Japan; and
- the use in Japan may affect the economic interests which can be obtained by the plaintiff by using the system which pertains to the invention in Japan.

FC2’s act was therefore regarded as taking place in the territory of Japan by the Court, so it concluded that FC2’s act falls under “production” and constituted infringement of the patent right.

In a related case of DWANGO v FC2, Case No 2018 (Ne) 10077 (decision rendered on 20 July 2022), the issue was whether the distribution of FC2’s program constituted “provision through a telecommunication line” under the Patent Act. The IP High Court held that even if a part of the working of the patented invention is formally

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performed outside Japan, if the act of provision can be regarded as substantially and totally performed in the territory of Japan, it constitutes “provision through a telecommunication line”.

The above cases are significant in that the Grand Panel set forth the criteria for determining whether the “production” of a network system invention can be evaluated as having taken place in Japan. Both cases have been appealed to the Supreme Court and a petition for acceptance of appeal has been filed, but the decision has not (as of February 2024) been issued. Unless the conclusion reached by the Grand Panel is changed by the Supreme Court, the criteria set in the decisions will be referred to in future practice.

FUJI MEDICAL INSTRUMENTS MFG. CO., LTD. v Family Inada Co. Ltd., Case No 2022 (Ne) 10046 (decision rendered on 20 October 2022)

I) Compensation for damages in Japan

When filing a patent infringement claim for damages, the patentee must prove the value of damages caused by the infringing act. However, because it is difficult to prove the specific extent of damages, Article 102, paragraphs 1–3 of the Patent Act provide for presumption of the damages.

Under Article 102, paragraph 2, the profit earned by the infringer is presumed to be the value of damages incurred by the patentee. However, if (i) the infringer’s production capacity or sales efforts exceed the patentee’s implementation capabilities, (ii) the patented technology is used only in part of the infringing product, or (iii) the market where the patentee’s products are sold and the market where the infringing products are sold are different, it may not be reasonable to presume that the full amount of the profits

earned by the infringer represent damages of the patentee. Therefore, if the circumstances outlined above exist, the damages presumed under Article 102, paragraph 2 will be overturned. This is called the “overturning the presumption”.

Also under Article 102, paragraph 3, if the amount of damages should be an amount equivalent to the royalty that the patentee would receive for the exploitation of the patented invention, then the amount of that royalty will be presumed to be damages of the patentee.

II) Outline and significance of the case

The Grand Panel of the IP High Court first determined that in cases where the patentee had exported or sold a competing product of the same type that shares the same consumer as the infringing product in the market, the infringing act has caused a decrease in the sales of the patentee’s products, thus Article 102, paragraph 2 applies.

Where Article 102, paragraph 2 applies and if there are circumstances that overturn the presumption, the entire amount of profits earned by the infringer will not be fully considered as damages granted to the patentee. For example, if the profit earned by the infringer is determined to be JPY100 million and the overturned presumption rate is 30%, damages granted to the patentee will be JPY70 million. The issue here is whether Article 102, paragraph 3 (the amount equivalent to the royalty) applies to this overturned JPY30 million portion.

The Court stated that damages suffered by the patentee due to the infringing act can be considered to be (i) a decrease in the sales of products that the patentee could have sold if there had not been the infringing act (where Article 102, paragraph 2 applies); and (ii) profits that could have

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been gained due to loss of licensing opportunity, regardless of whether the patentee is actually working the patented invention or has the ability to work the patented invention (where Article 102, paragraph 3 applies). Therefore, in a case where the presumption under Article 102, paragraph 2 is partially overturned and such overturned portion can be considered to be “the portion where the patentee could have been able to grant a licence”, Article 102, paragraph 3 applies to the overturned portion.

The Court further stated that, if the presumption is overturned due to (i) it being beyond the ability of the patentee to carry out sales, etc; or (ii) the market for the patentee’s product and the market for the infringer’s products being different, such overturned portion is considered to fall under “the portion where the patentee could have been able to grant a licence”, thus Article 102, paragraph 3 does apply to the overturned portion. On the other hand, if the presumption is overturned due to the patented invention being practiced only in part of the infringing product, then Article 102, paragraph 3 does not apply.

This decision by the Grand Panel provides an important concept regarding the “damages” of the patent infringement.

Life sciences

In 2023, there have been several significant rulings by the IP High Court in the field of life sciences. The first case below shows the criteria for determining the support requirement with regard to a patent relating to antibody drugs, which have been attracting particular attention in the pharmaceutical industry in recent years. The second case showcases an interesting discussions regarding the patent linkage system in Japan.

Regeneron Pharmaceuticals, Inc. v Amgen, Inc., Case No 2021 (Gyo-Ke) 10093 (decision rendered on 26 January 2023)

The plaintiff, Regeneron Pharmaceuticals, Inc., had filed with the Japan Patent Office a request for a trial for invalidation of the patent owned by the defendant, Amgen Inc. The invention in question is titled “ANTIGEN BINDING PROTEIN TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)”. The Japan Patent Office dismissed the request by the plaintiff with the opinion that the said patent was valid. Accordingly, the plaintiff filed a suit to seek rescission of such decision by the Patent Office.

Under the case brought before the IP High Court, the issue was whether the said antibody patent satisfied the support requirement. The IP High Court first presented the same framework to determine the support requirement in line with prior precedents, then rendered its decision that the said patent did not satisfy the support requirement based on the functional characteristics of the antibody patent.

The support requirement of the patent means that the invention for which the patent is sought must be stated in the detailed explanation of the invention (Article 36, paragraph 6, item 1 of the Patent Act). This is because, if an invention that is not stated in the detailed explanation were to be claimed in the scope of claims, it would create an exclusive right for an unpublished invention.

The framework to determine the satisfaction of the support requirement is:

- to first make a comparison between the statement of the scope of claims and the statement of the detailed explanation of the invention; then

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- to examine whether or not the invention stated in the scope of claims is materially the invention stated in the detailed explanation of the invention, by examining whether or not the invention stated in the scope of claims falls within the scope where a person of ordinary skill in the art can recognise that the “problem of the invention” can be solved by the statement of the detailed explanation of the invention.

The invention in the case is an isolated monoclonal antibody which can neutralise binding between PCSK9 and LDLR protein, because it competes for binding to PCSK9 with the 21B12 antibody (the “reference antibody”). The Japan Patent Office determined that:

- the problem solved by the invention is to provide a novel antibody and to produce a pharmaceutical composition which neutralises binding between PCSK9 and LDLR and increases the amount of LDLR, thereby achieving an effect of causing a decrease in serum cholesterol in a subject, treating or preventing diseases related to elevated cholesterol levels, and reducing the risk of such diseases;
- a person ordinarily skilled in the art can understand from the statement of the present detailed explanation that the antibody of the present invention can solve the above problem, thus the present invention can be deemed to be stated in the detailed explanation; and
- the said patent therefore satisfies the support requirement.

However, the IP High Court reversed the decision by the Patent Office, giving the following reasoning.

- The technical significance of the said invention is that it is specified that an antibody which competes with the 21B12 antibody interferes with, blocks, reduces, or modulates the interaction between PCSK9 and LDLR protein by directly blocking a binding site of LDLR protein by a mechanism similar to that of the 21B12 antibody; however, this point was not disclosed in the detailed explanation, therefore the said invention does not satisfy the support requirement.
- The range of antibodies having characteristics that mean they compete for binding to PCSK9 with the reference antibody includes a very wide variety of antibodies; furthermore, such a range would include antibodies which prevent or reduce specific binding of the reference antibody to PCSK9 in various degrees; however, the detailed explanation does not state anything about such a mechanism, thus this also means that the said invention does not satisfy the support requirement.

This judgment is considered to be appropriate as the scope of claims in the case would result in granting exclusivity to inventions based on characteristics that are different from the functional characteristics described in the detailed explanation of the invention.

NIPRO CORPORATION v Eisai Co., Ltd., Case No 2022 (Ne) 10093 (decision rendered on 10 May 2023)

I) Patent linkage system in Japan

The patent linkage system refers to a mechanism in which the regulatory authorities take into account the infringement of patent rights related to the original drugs in the procedures for the approval of generics. The purpose of the patent linkage is to realise the stable supply of generics by considering the patent right related to the

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original drugs. The implementation of the system and its contents differ from country to country.

In Japan, the patent linkage system has no clear basis under the law, and it is handled as an administrative practice under the guidance of the Ministry of Health, Labour and Welfare 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 those items that are considered to be 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 Ministry of Health, Labour

and Welfare permits the NHI price listing of the generic if there is an application from a generic drug manufacturer. Also, as mentioned above, although the Ministry of Health, Labour and Welfare is responsible for determining whether the generic drug infringes the patents of the original drug, there is no mechanism in place for the Ministry of Health, Labour and Welfare to rely on any judicial judgment.

2) Rulings

The plaintiff, NIPRO CORPORATION, was a generic drug manufacturer, and it had filed an application for approval for the manufacture and sale of its generic drug.

The plaintiff asked the Court to confirm that (i) the defendants, Eisai Co., Ltd., the manufacturer and seller of the original drug, and EISAI R&D MANAGEMENT CO., LTD., the holder of the patent for the original drug, did not have the right to demand an injunction based on patent infringement with respect to the manufacture and sale of its generic drug, and (ii) that they did not have the right to claim damages. The issue was whether or not the plaintiff would have standing for a declaratory judgement in relation to Japan’s patent linkage system.

The plaintiff’ arguments were as follows:

- The fact that the patent linkage system was actually being disputed in the case meant that there was a legal dispute over the existence or non-existence of patent infringement, and thus the plaintiff’s legal status (that its “own generic drug would not be approved by the Ministry of Health, Labour and Welfare”) was in danger, and if the Court determined whether there was a patent infringement, such danger would be eliminated.

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- Japan ratified the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (the “TPP11 Agreement”), and in order for the Japanese practice of patent linkage based on the Two Section Chief Notifications to comply with TPP11 Agreement, and if there is any doubt as to whether the generic drug infringes the patent of the original drug, it is necessary that the Court render its judgment by approving its standing for a declaratory judgement.
- In the present practice based on the Two Section Chief Notifications, the generic drug manufacturer had no choice but to file a request at the Patent Office for a trial for invalidation for the patent of the original drug; however, this would only determine the validity of the patent, not the existence or non-existence of infringement, thus the current practice under the Patent Linkage, in which the Ministry of Health, Labour and Welfare is in charge of the patent infringement determination, is inconsistent with the doctrine of law where the patent infringement is clearly a matter that should only be determined by the Court.

After hearing these arguments, the IP High Court ruled that whether or not the Ministry of Health, Labour and Welfare would approve an application of the plaintiff for the manufacture and sale of a generic drug is a public law dispute between the plaintiff and the Minister of Health, Labour and Welfare, not a legal dispute between the plaintiff and the defendants, and that if the plaintiff is dissatisfied with a dispute under public law, the plaintiff should seek relief by (i) filing an action to confirm the illegality of the non-approval or (ii) filing an appeal against the government. The standing for a declaratory judgement cannot therefore be recognised in the case.

The above ruling of the IP High Court is consistent with the common understanding of the standing for a declaratory judgement. However, as the plaintiff argued, there is a question about the current practice that the Ministry of Health, Labour and Welfare determines the patent infringement, and there is no mechanism for prior co-ordination between the parties at the stage of approval or prior approval. Future discussions on the Japanese patent linkage practice is therefore expected.

Technology

The following recent decisions by the IP High Court also show important developments in the field of technology IP.

Dai Nippon Printing Co., Ltd. v Commissioner, Japan Patent Office Case No 2022 (Gyo-Ke) 10030 (decision rendered on 9 March 2023)

Under the Patent Act, anyone may file an opposition against a patent with the Japan Patent Office within six months after publication of the patent in the patent gazette. In the opposition proceedings, when the administrative judge intends to make a decision to revoke the patent, the judge must give the patentee an opportunity to submit a written opinion, and the patentee may file a request for a correction of the patent to eliminate the grounds for revocation.

In this case, a third party filed an opposition to a patent of Dai Nippon Printing (DNP) titled “LAMINATE OF POLYESTER RESIN COMPOSITION”. During the patent opposition proceedings, DNP filed a request for correction, but the Japan Patent Office refused to allow the correction and revoked the patent.

The said patent had so-called open claims, and when the case was brought before the IP High Court, the issue was whether the correction to

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“exclude” matters not directly disclosed in the claims or the specification or drawings (“excluded claims”) that are made in order to avoid revocation of the patent, can be considered as “reduction of the scope of claims,” which is a requirement for the correction. The Court held that the correction fell within the scope of reduction of the claims and did not introduce any new technical matter, thus the correction was valid, and reversed the revocation decision by the Japan Patent Office.

Specifically, the correction in this case was to add a provision to exclude “the laminate with a vapour-deposited film of inorganic oxide on the laminate and a gas-barrier coating film provided on the said vapour-deposited film”. However, the claims before the correction did not include the words “vapour-deposited film of inorganic oxide” or “gas-barrier coating film.” Also, there was no reference to a configuration in which something was provided “on” the laminate.

The Court found that the claims before the correction simply specified “a laminate having at least two layers,” and therefore, the patent was a so-called open claim that included a laminate consisting of a “first layer,” a “second layer,” also a “vapour-deposited film of inorganic oxide,” and a “gas barrier coating film provided on the vapour-deposited film”. Thus, the Court concluded that the correction was intended to reduce the scope of the claims.

The decision in this case will be helpful in practice as a case decision that judges that a correction of open claims excluding matters not described in the specification or drawings does not substantially introduce new technical matter.

Nanshin Co., Ltd. v Luz Com Co., Ltd. Case No 2022 (Gyo-Ke) 10140 (decision rendered on 16 November 2022)

This case was a lawsuit to seek rescission of a decision made by the Japan Patent Office (the “JPO decision”) to the effect that a request for a trial for invalidation of a patent relating to an invention titled “ELECTROFORMED TUBE MANUFACTURING METHOD AND ELECTROFORMED TUBE” was groundless. The major grounds for seeking rescission included an error in the determination on the clarity requirement.

The claim of the invention was in the form of a product-by-process claim. The Court ruled that the invention did not satisfy the clarity requirement for the following reasons:

- Under the precedents, when a claim is a product-by-process claim, the statement of the claim should meet the clarity requirement only if there are circumstances where it was impossible or utterly impractical to directly define the product of the invention by means of its structure or characteristics at the time of the application (2012 (Ju) 1204, the Second Petty Bench of the Supreme Court, 5 June 2015).
- However, even in a case where the claim of a product recites the manufacturing process, if the structure or characteristics of the product to be manufactured by that manufacturing process are unambiguously clear at the time of the application based on the statements of the claim, the description and drawings and common general technical knowledge, the interests of third parties would not be unjustly harmed; therefore, in such a case, the invention would not be considered to be in violation of the clarity requirement even when there were no circumstances making it impossible or impractical to directly define

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the product by means of its structure or characteristics.

The IP High Court has here limited the scope of the Supreme Court decision and established a standard to function in practice. This case is instructive as a specific case in which such standard was applied.

United Precision Technologies Co., Ltd. v Commissioner, Japan Patent Office Case No 2022 (Gyo-Ke) 10164 (decision rendered on 16 November 2022)

The case is a suit against a decision dismissing the request for appeal against an examiner's decision of refusal of an invention titled "CONDUCTIVE MEMBER USING COPPER-SILVER ALLOY, CONTACT PIN, AND DEVICE". One of the issues is the procedural violation during the determination of the inventive step by the Japan Patent Office.

The Court first determined that differences between the invention in question and the cited prior art were easily conceivable by those skilled in the art from the cited prior inventions, or only related to a design matter which those skilled in the art should have performed on the basis of the common general technical knowledge, thus it lacked the inventive step.

However, as to the issue of the procedural violation, the Court ruled that, the Japan Patent Office's decision that determined that the invention with "Cited Invention 5" as an additional primary cited reference lacked an inventive step seemed to be reasonable, but since Cited Invention 5 is a document that had not been pointed out in advance in the examination stage or even in the appeal procedure but was pointed out for the first time in the Japan Patent Office's decision, and the plaintiff disputed by concentrating

the assertion exclusively on the point that a difference related to the material of the alloy is present in other cited document in view of the specific history of the examination procedure and the appeal procedure, it should be considered that, if Cited Document 5 were presented in the notice of reasons for refusal, the strategy of the plaintiff would have been seriously affected, and thus determination on the inventive step of the invention with Cited Document 5 as the primary cited reference should not be allowed, from the viewpoint of the plaintiff's procedure guarantee.

This ruling suggests that if it is found that an applicant's opportunity to defend is not substantially guaranteed, it should be considered that non-service of the notice of reasons for refusal can be found to be illegal for violation of procedures.

Recent law reforms

The 2023 Patent Act Amendments made the following reforms from the perspective of (i) strengthening the protection of brands and designs in light of diversification of business activities due to digitalisation, and (ii) developing intellectual property procedures in response to the coronavirus pandemic and digitalisation.

Strengthening the protection of trade secrets (Article 186 of the Patent Act)

The award system in Japan is that, if certain requirements are met, the Commissioner of the Japan Patent Office may grant a compulsory licence. The 2023 Patent Act Amendments made it possible to restrict the viewing of documents relating to the award system that contain trade secrets. It is now expected that documents containing trade secrets will be submitted for the award and the reasonable award judgments be made.

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Reform of the public notice and service system (Article 191 of the Patent Act)

When delivering patent examination results, etc, to persons residing outside Japan, if a situation in which it is difficult to send documents persists for six months, the notification shall be published in the official gazette, etc, and documents will be deemed to have been served. Furthermore, a new system for delivery via the internet will be established.

Reform of document procedures for digitalisation, etc (Article 43 of the Patent Act)

In the procedure for claiming priority under the Paris Convention, it will now be possible to submit the priority certificate online, and it will also be acceptable to submit a copy of the certificate. Thus it is no longer necessary to submit the original document via mail, making the procedure under the Paris Convention much simpler.

Reform of the examination fee reduction/ exemption system (Article 195-2, etc, of the Patent Law)

In Japan, certain small and medium-sized enterprises are exempted from fees for patent examination requests in order to encourage inventions by persons with high potential but limited financial or human resources. However, due to the fact that the system was in some cases being wrongly used, there will be restrictions on the number of applications for which fees can be reduced or exempted.

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