Legal 500
Country Comparative Guides 2025

Japan
Patent Litigation

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This country-specific Q&A provides an overview of patent litigation laws and regulations applicable in Japan.

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Japan: Patent Litigation

1. What is the forum for the conduct of patent litigation?

Only two courts, the Tokyo District Court and Osaka District Court, have jurisdiction of first instance to handle patent infringement litigation. The Tokyo District Court covers the eastern part of Japan and the Osaka District Court covers the western part of Japan. Only one court, the Intellectual Property High Court ("IPHC") has jurisdiction of second instance to handle patent infringement litigation.

Invalidation of a patent and opposition to a patent are handled by the Trial and Appeal Department of the Japan Patent Office ("JPO") at first. Appeals seeking to revoke decisions rendered by JPO in invalidation proceedings or opposition proceedings, known as "revocation litigation," are handled by IPHC.

The Tokyo District Court has four intellectual property divisions; the Osaka District Court has two. IPHC has four divisions. As of August 2024, the intellectual property divisions of Tokyo District Court have 15 judges. As of August 2024, the intellectual property divisions of Osaka District Court have five judges. As of August 2024, IPHC has 12 judges. There are no technical judges in any of these courts. Some of these judges have a great deal of experience in patent litigation, but none were appointed as a "patent judge," that is, a judge who specifically handles patent litigation. All the judges are subject to occasional transfer to other courts in accordance with the decision of the Supreme Court of Japan. The Trial and Appeal Department of JPO has 33 divisions. Trial Examiners of JPO, who handle invalidation proceedings and opposition proceedings, all have technical background.

When filing a patent infringement action, the choice of court depends mainly on (i) the defendant's residence, and (ii) the place where the act of infringement took place. If both courts have jurisdiction, the plaintiff can choose the more convenient court.

2. What is the typical timeline and form of first instance patent litigation proceedings?

With respect to patent infringement litigation, the first hearing is held around six weeks after the filing of a complaint. The following hearings are held around once every two months. The parties are expected to submit briefs and evidence before the hearings. At the hearings, the court may question the parties in relation to the briefs and evidence submitted before the hearings, and asks the parties how they want to proceed (whether they want to rebut the other party's arguments or to submit further evidence). A hearing generally lasts around 15 minutes. The defendant can raise an invalidity defence separately from invalidation proceedings or opposition proceedings, and the court handles the issues of infringement and invalidity in parallel. Issues of claim construction are only considered as a part of issues of infringement. The court hears issues of damages after issues of liability, and only when the court finds that the patent is infringed and should not be invalidated. Where the plaintiff seeks both injunction and compensation of damages, when the parties have submitted all the arguments and evidence in relation to infringement and invalidity, the court proceeds to the deliberation. Where the court finds that the patent is not infringed or should be invalidated, the court closes the hearing. Several months later, the court will render a judgment. If the court finds that the patent is infringed and should not be invalidated, the court informally notify the parties of the preliminary conclusion on infringement/invalidity and proceeds to issues of damages. When the parties have submitted all the arguments and evidence in relation to damages, the court closes the hearing. Several months later, the court will render a judgment. The average length of intellectual property litigation before district courts in the first instance (from the filing of the complaint through the rendition of the first instance judgment) is 14.5 months (FY2024). Note that this is the average length of all intellectual property cases, and the average length of patent cases is not published. In comparison to other intellectual property cases, patent cases tend to take longer, and it takes 18–24 months from the filing of the complaint through the rendition of the first instance judgment, or the informal notice of the preliminary conclusion on infringement/invalidity, whichever comes first, on average. It additionally takes 6-12 months if issues of damages are heard.

With respect to invalidation proceedings before JPO, when a person ("Demandant") files a Request for Invalidation Trial, it is served to the patentee ("Demandee"). The Demandee files an Answer, and can file a Request for Correction at the same time. In most

cases, one oral hearing is held. If the Board of Trial Examiners does not find reasonable grounds for the Request for Invalidation Trial, the Board issues a Trial Decision dismissing the Request for Invalidation Trial. If the Board of Trial Examiners does find reasonable grounds for the Request for Invalidation Trial, on the other hand, the Board issues a Pre-notice of Trial Decision, in which the Board describe the reasons that the patent is to be invalidated. The Demandee has an opportunity to file a Request for Correction within a certain designated period after issuance of the Pre-notice of Trial Decision. After that period, the Board considers the matter and issues a Trial Decision invalidating the patent or dismissing the Request for Invalidation Trial. The average length of invalidation proceedings (from the filing of a Request for Invalidation Trial through the issue of a Trial Decision or a Pre-notice of Trial Decision, whichever comes first) is 15.1 months (FY2024).

With respect to opposition proceedings before JPO, a Notice of Opposition is filed by the Opponent and is served to the patentee. In most cases, no oral hearing is held. If the Board of Trial Examiners does not find reasonable grounds for the Opposition, the Board issues a Decision maintaining the patent. If the Board of Trial Examiners finds reasonable grounds for the Opposition, on the other hand, the Board issues a Notice of Reasons for Cancellation and gives the patentee an opportunity to file an Opinion within a certain designated period after the Notice is issued. The patentee has an opportunity to file a Request for Correction within the said period. After that period, the Board considers the matter and issues a Decision canceling the patent or maintaining a patent. The average length of opposition proceedings (from the filing of the Notice of Opposition through the issue of a Decision or a Notice of Reasons of Cancellation, whichever comes first) is 7.9 months (FY2024).

A losing party in invalidation proceedings can file a complaint seeking revocation of Trial Decision with IPHC. The patentee in opposition proceedings, if the Board cancelled the patent, can file a complaint seeking revocation of Decision with IPHC. IPHC handles revocation litigation as the court of first instance. The Plaintiff files a brief in which the reasons of revocation are described, and the Defendant files a brief to rebut the reasons of revocation. After holding one or two hearings, the court closes the hearing. Several months later, the court will render a judgment. The average length of revocation litigation before IPHC in the first instance (from the filing of the complaint through the rendition of the first instance judgment) is 8.3 months (FY2024).

3. Can interim and final decisions in patent cases be appealed?

A final decision rendered by the court of first instance in patent infringement litigation can be appealed. Any party losing in the first instance has a right of appeal, which right entails a right to contest all aspects of the judgment. Generally, a judgment becomes enforceable when it becomes final and binding. Thus, if there is a pending appellate proceeding to a judgment, it is not enforceable. If there is a declaration of provisional enforcement with respect to all or part of a judgment, that judgment is provisionally enforceable in whole or in part even before it becomes final and binding. In such case, the defendant can request the court to stay the enforcement of the judgment by providing security. The average length of intellectual property litigation before IPHC in the second instance (from the filing of the Notice of Appeal through the rendition of the second instance judgment) is 7.4 months (FY2024). This is the average length of all intellectual property cases; the average length of patent cases is not published. As noted above, in comparison to other intellectual property cases, patent cases tend to take longer, and it takes around nine months from the filing of the Notice of Appeal through the rendition of the second instance judgment on average.

A party that loses in the second instance in patent infringement litigation may file a petition to take the case to the Supreme Court as the final appellate court, as may a party that loses in the first instance in revocation litigation. The Supreme Court has discretion as to whether or not to take a case as the final appellate court. Generally, the Supreme Court takes a case as the final appellate court only when it finds that the case involves material matters on the interpretation of laws or regulations. It takes from six months to three years for the Supreme Court to make a decision on whether to take the case as the final appellate court. If the Supreme Court takes the case as the final appellate court, it additionally takes around two to four months to render a judgment.

Interim decisions cannot be appealed.

4. Which acts constitute direct patent infringement?

Under the Patent Act of Japan, inventions are classified into three categories: an “invention of a product,” an “invention of a method” and an “invention of a method for producing a product." In the case of an invention of a product, to act in such a way as to constitute direct patent infringement is to produce, to use, to “Assign, etc.” (i.e. to assign or to lease, including, in the case where the

product is a computer program, to provide through electrical communication line), to export, to import, or to offer to "Assign, etc." the product as part of one's business. For an invention of a method, on the other hand, to act in such a way as to constitute direct patent infringement is to use the method as part of one's business. In the case of an invention of a method for producing a product, to act in such a way as to constitute direct patent infringement is to use the method as part of one's business or to use, to "Assign, etc.," to export, to import, or to offer to "Assign, etc." the product produced by the method as part of one's business.

5. Do the concepts of indirect patent infringement or contributory infringement exist? If, so what are the elements of such forms of infringement?

Yes, the concept of indirect patent infringement exists. Typically, an act of indirect infringement can be found to have occurred where (i) a party produces, sells, imports, or offers to sell a product as part of its business, (ii) the product is used for the production of the patented product, (iii) the product is essential for the resolution of the problem that was solved by the patented invention, and (iv) the party is aware that the invention is a patented invention and that the subject product is used for the implementation of the patented invention.

6. How is the scope of protection of patent claims construed?

The language used in the claims themselves determines the scope of protection of patent claims. In determining the meaning of the terms used in the claims, courts may refer to the specification or the prosecution history. There is no strict prosecution history estoppel, but the patentee's arguments in patent infringement litigation that are contrary to what was stated in the course of the prosecution are oftentimes denied. Even when a part of a patent claim does not correspond to the allegedly infringing product and the product does not literally fall within a patent claim, the scope of protection of the patent claim extends to the product under the doctrine of equivalents if (i) the non-corresponding part is not the essential part of the patented invention, (ii) the purpose of the patented invention can be achieved by replacing this part with a part in the product and an identical function and effect can be obtained, (iii) a person skilled in the art could easily come up with the idea of such replacement at the time of the production of the product, (iv) the product is not identical to the technology in the public domain at the time of the patent application or could have been easily conceived at that time by a person skilled in the art, and (v) there were no special circumstances such as the fact that the product had been intentionally excluded from the scope of the patent claim in the course of the prosecution.

7. What are the key defences to patent infringement?

The most commonly raised defence to patent infringement is the invalidity defence. In addition, the prior use defence and exhaustion are sometimes raised.

8. What are the key grounds of patent invalidity?

Grounds of patent invalidity are the same as the grounds of refusal of patent application. Popular grounds of patent invalidity are (i) lack of novelty, (ii) lack of an inventive step, (iii) the patent not meeting the support requirement and (iv) the patent not meeting the enablement requirement.

9. How is prior art considered in the context of an invalidity action?

Prior art includes (i) an invention that was publicly known prior to the filing of the patent application within Japan or in a foreign country, (ii) an invention that was publicly used prior to the filing of the patent application within Japan or in a foreign country, and (iii) an invention that was described in a distributed publication within Japan or in a foreign country. When the claimed invention and the prior art are compared and no difference is found, the claimed invention lacks novelty. In determining whether the claimed invention involves an inventive step, the claimed invention and the primary prior art are compared and the differences between them are identified. Then, whether a person skilled in the art could have applied other prior art or common technical knowledge to close the gap between the invention and the primary prior art is considered. Whether a person skilled in the art could have applied other prior art or common technical knowledge to the primary prior art is determined based on (a) the relevance of technical fields, (b) the similarity of problems to be solved, (c) the similarity of operations or functions, and (d) the suggestions shown in the content of the prior art. Even when one or more of those factors is found, it can be determined that a person skilled in the art could not have applied other prior art or common technical knowledge to the primary prior art when there are any obstructive factors obstructing the application of other

prior art or common technical knowledge to the primary prior art. If it is determined that a person skilled in the art could not have applied other prior art or common technical knowledge to the primary prior art, the claimed invention is determined to involve an inventive step. Further, even when it is determined that a person skilled in the art could have applied other prior art or common technical knowledge to the primary prior art, the claimed invention is determined to involve an inventive step if it has an outstanding effect that goes beyond the effect that a person skilled in the art could have predicted based on the structures of the claimed invention. There are no circumstances under which a prior art citation can be used for asserting certain grounds of invalidity but not others.

10. Can a patentee seek to amend a patent that is in the midst of patent litigation?

A patentee can seek to amend a patent regardless of pending patent infringement litigation, but an amendment of a patent can be sought only in a limited time period. A patentee can seek to amend a patent by filing (a) a Request for Correction Trial with JPO, or (b) a Request for Correction with JPO. A Request for Correction Trial is a request to initiate an independent proceeding to determine whether the correction is acceptable or not. A Request for Correction Trial cannot be filed from the time when an Opposition or a Request for Invalitation Trial is filed until a Decision to the Opposition or a Trial Decision to the Request for Invalitation Trial becomes final and binding. Third parties cannot oppose a Request for Correction Trial. A Request for Correction is a request to determine whether the correction is acceptable or not in the course of the pending opposition proceedings or invalidation proceedings. A Request for Correction can be filed within a limited time period during the pending opposition proceedings or invalidation proceedings. Third parties cannot oppose a Request for Correction. Thus, it is often the case that a patentee cannot seek to amend a patent when patent invalidation litigation is pending before a court. A correction is limited to the following: (i) restriction of the claims, (ii) correction of errors or mistranslations, (iii) clarification of an ambiguous statement, or (iv) rewriting a claim that cites another claim into a claim that does not cite that other claim. A correction must also remain within the scope of the matters disclosed in the initial specification. Further, a correction must not substantially enlarge or alter the claims.

11. Is some form of patent term extension available?

There are two types of patent term extensions. The first is a patent term extension for pharmaceutical drugs. When there is a “period during which the patented invention cannot be implemented because the marketing authorisation is necessary to implement the patented invention,” the patent term extension is available. A “period during which the patented invention cannot be implemented because the marketing authorisation is necessary to implement the patented invention" is the period from the date of the beginning of the test required for the marketing authorisation or the date of the patent application, whichever is later, to the date on which the marketing authorisation becomes effective. The period of the extension shall not exceed the “period during which the patented invention cannot be implemented because the marketing authorisation is necessary to implement the patented invention," which period cannot exceed five years. Another type is a patent term extension as compensation for the curtailment of the term due to the examination of the patent application by the JPO. In order to calculate the available length of the extension, the “reference date" needs to be determined. The reference date is the later of the date five years after the filing of the patent application and the date three years after the filing of a request for the examination of the application. The maximum permissible length of the extension period is calculated by extracting, in brief, the period attributed to the patent applicant and the period for the appeal proceedings and litigation from the length of the period starting from the reference date and ending on the registration date of the patent. Patent term extensions can be challenged by filing a Request for Invalidation Trial of Patent Term Extension with JPO. A Request for Invalidation Trial of Patent Term Extension is not, however, commonly used.

12. How are technical matters considered in patent litigation proceedings?

Courts handle technical matters by letting parties submit technical documents, including prior art documents, technical articles, textbooks, reference books, and expert reports, as evidence. Courts do not generally take testimonies or any other oral statements from technical experts, or appoint technical experts, nor do they generally give an opportunity to cross-examine the technical experts whose expert reports are submitted as evidence. Courts examine the technical documents submitted by the parties and consider the parties' arguments. Judges are assisted by technical assistants, who have a technical background. Most of these

assistants, who work full-time at courts, are seconded by JPO and the others are former patent attorneys (benrishi).

13. Is some form of discovery/disclosure and/or court-mandated evidence seizure/protection (e.g. saisie-contrefaçon) available, either before the commencement of or during patent litigation proceedings?

During patent litigation proceedings, a party can request the court to order a person who possesses a document to submit the document to the court. The court considers whether the document is relevant and necessary to prove the relevant fact and whether the person who possesses the document is obligated to submit same. The possessor thereof is required to submit a document (i) if such document has been cited in litigation by the party possessing the document, (ii) if a party who requests the document as evidence has a right to request the possessor to deliver it or to have it inspected, (iii) if the document has been prepared in the interest of the requesting party as evidence or with regard to the legal relationship between the requesting party and the possessor, or (iv) in cases other than (i) through (iii) above, if the document does not fall under any of the following: (a) a document detailing a matter for which the possessor or a person related to the possessor would likely be subject to criminal prosecution or conviction, or a matter that would harm the reputation of such persons, (b) a document concerning confidential information in connection with a public officer's duties, which, if submitted, would likely harm the public interest or substantially hinder the performance of a public duty, (c) a document detailing a fact which was learned by a person who owes a duty of confidentiality under the law, or a matter that involves a technical or professional secret, neither of which are exempt from the duty of silence, (d) a document prepared exclusively for the use of the possessor thereof, or (e) a document related to the litigation of a criminal case, the case record in a juvenile proceedings, or a document seized in any such case or proceeding. If the party ordered by the court does not submit the document in accordance with the order, the court can deem the fact to be proved based on the document as true at its own discretion. If a third party ordered by the court does not submit the document in accordance with the order, the court can impose the third party an administrative monetary penalty. Further, a party can request the court to order the other party to submit documents that are needed to prove the infringement or to calculate the damage caused by the infringement. The court can issue an order unless the party who possesses the document has legitimate grounds for refusing to submit the documents. Before commencing proceedings, if a party who intends to file an action has provided advance notice to the other party, each party can request the court to commission the other party to send certain documents to the court. However, even if the party who has received the instruction from the court does not send the requested documents to the court, there is no sanction. Further, a party can request the court to appoint a technical expert as an inspector and order the inspector to inspect plants and other sites of the alleged infringer when there are adequate grounds to suspect that the alleged infringer has infringed the patent and the requesting party cannot collect relevant evidence by themselves or through other means (such inspection, an "On-site Inspection").

14. Are there procedures available which would assist a patentee to determine infringement of a process patent?

When the Defendant denies the Plaintiff's arguments with respect to the specific process that the Defendant uses, the Defendant shall specifically disclose its own process. However, even when the Defendant does not comply with this, there is no sanction. In the case where the infringement of a patent of an invention of a method for producing a product is asserted, if the product was not publicly known in Japan prior to the filing of the patent application, any article identical to that product is presumed to have been produced using the patented method. The On-site Inspection referred to in the answer to Question 13 can be useful in obtaining evidence to demonstrate infringement of a process patent.

15. Are there established mechanisms to protect confidential information required to be disclosed/exchanged in the course of patent litigation (e.g. confidentiality clubs)?

In order to protect confidential information from disclosure to third parties, the court can issue an order to restrict third parties' inspection of any part of the case record that includes trade secrets.

In order to protect confidential information from disclosure to officers or employees of the other party or counsel to the other party or from use of confidential information for any purpose other than conducting the pending litigation, the court can order the parties, officers or employees of the parties, and/or counsel to the parties not to disclose the trade secrets included or to be

included in the briefs or evidence to any person other than those to which the order is addressed, and not to use such trade secrets for any purpose other than conducting the pending litigation (any such order, a "Confidentiality Protective Order"). A person who violates a Confidentiality Protective Order is subject to criminal penalty. Since the penalty is significant, the court first instructs a party to consider other means to protect highly confidential information before filing a Request for Confidentiality Protective Order. Generally the court and the parties discuss whether there is any way of submitting briefs or evidence that does not include such information or whether the confidentiality agreement between the parties suffices.

16. Is there a system of post-grant opposition proceedings? If so, how does this system interact with the patent litigation system?

As for invalidation proceedings and opposition proceedings, please see the answers to Questions 1 and 2. Patent infringement litigation and invalidation/opposition proceedings are handled separately. The court handling patent infringement litigation does not stay the proceedings when invalidation/opposition proceedings are pending; conversely, the Board of Trial Examiners of JPO handling invalidation/opposition proceedings does not stay the proceedings when patent infringement litigation is pending. If patent infringement litigation is pending before IPHC as the court of second instance and revocation litigation is pending before IPHC, the same panel handles both litigation.

17. To what extent are decisions from other fora/jurisdictions relevant or influential, and if so, are there any particularly influential fora/jurisdictions?

Parties can submit decisions from other fora/jurisdictions as evidence. The court does not need to consider them, but may study them in practice. Where foreign decisions relates to a relevant issue for which no precedent in national law exists, the court will likely study such decisions. If the court agrees with the legal theories applied by such decisions, it may follow them. Even when there are decisions rendered by foreign tribunals in respect of foreign equivalents of a patent in suit, the court will not likely regard such decisions to be relevant because the facts should be determined based on the evidence submitted in the pending litigation, and will make a determination on its own.

18. How does a court determine whether it has jurisdiction to hear a patent action?

A court has jurisdiction to hear a patent infringement action when (i) the defendant resides in the area (i.e., the eastern or western part of Japan) covered by the court, or (ii) the alleged act of infringement takes place in the area covered by the court. Further, a court has jurisdiction to hear a patent infringement action seeking compensation of damages when the plaintiff resides in the area covered by the court. The court will determine whether it has jurisdiction to hear a patent infringement action based on a foreign patent by considering, for example, (i) the defendant's residence, (ii) the location of the alleged act of infringement, (iii) the location of the relevant evidence, and (iv) any other factors that affect equity or prevent a fair and speedy trial. If the court determines that it has jurisdiction, it can consider questions of infringement and validity in respect of the foreign patent in question. There is no court precedent on anti-suit injunction, but Japanese courts will not grant an anti-suit injunction because Japanese courts will determine that a party does not have a legal right to prevent the other party from filing a legal action in a foreign country or from enforcing a decision of a foreign court in a foreign country.

19. What are the options for alternative dispute resolution (ADR) in patent cases? Are they commonly used? Are there any mandatory ADR provisions in patent cases?

Mediation in patent cases is provided by the Tokyo District Court and Osaka District Court (such mediation, "Intellectual Property Mediation"). Arbitration services are provided by the Japan Intellectual Property Arbitration Center and International Arbitration Center in Tokyo ("IACT"). Disputes with relatively few and straightforward issues are suitable for Intellectual Property Mediation and arbitration provided by the Japan Intellectual Property Arbitration Center. Complex international intellectual property disputes, and in particular disputes related to Standard Essential Patents (SEPs), are suitable for arbitration provided by IACT. These methods are not commonly used, and there is no mandatory ADR provisions in patent cases.

20. What are the key procedural steps that must be satisfied before a patent action can be commenced? Are there any limitation periods for commencing an action?

A Patentee typically sends letters to the alleged infringer

so that the dispute can be amicably resolved without filing a complaint with a court, but pre-litigation negotiation is not required. A claim for compensation of damages caused by patent infringement is extinguished if not exercised within three years. In other words, generally speaking, when claiming compensation of damages caused by patent infringement, a patentee can get compensation of damages caused within three years before the filing of a complaint.

21. Which parties have standing to bring a patent infringement action? Under which circumstances will a patent licensee have standing to bring an action?

A patentee has standing to bring a patent infringement action. A registered exclusive licensee, who is registered in JPO's patent register, also has standing to bring a patent infringement action. A non-registered exclusive licensee can bring a patent infringement action seeking compensation of damages. A non-registered exclusive licensee can bring a patent infringement action seeking an injunction against the infringer on behalf of the patentee in limited circumstances. In general, in the case where the non-registered exclusive licensee has a legal right under the license agreement to request the licensor to exercise its right against the infringer to prevent the act of infringement, and the patentee does not exercise its right against the infringer, the licensee can bring a patent infringement action seeking an injunction against the infringer on behalf of the patentee.

22. Who has standing to bring an invalidity action against a patent? Is any particular connection to the patentee or patent required?

Only an interested person can file a Request for Invalidation Trial with JPO. An interested person is, for example, a person who is implementing, or is planning to implement, the patented invention, or a person to whom the patentee sent a letter arguing that the person infringed the patent. Any person can file a Notice of Opposition with JPO.

23. Are interim injunctions available in patent litigation proceedings?

A patentee may file a request for preliminary injunction against an infringer. A request for preliminary injunction is theoretically available when it is necessary to avoid any substantial loss or imminent danger. When a patentee files a request for preliminary injunction on the ground that an alleged infringer is infringing the patent and the court finds that the patent is infringed, the court usually finds the necessity to avoid any substantial loss or imminent danger and grants a preliminary injunction. A patentee needs to show prima facie evidence that the alleged infringer infringes the patent or is likely to infringe the patent. This means that the burden of proof in a preliminary injunction action is lower than in a regular litigation case in theory, but there is no material difference between the two proceedings in practice. Also, the period from the filing of a request for preliminary injunction to the rendition of the decision is almost the same as the period from the filing of a complaint to the rendition of a judgment in regular litigation where only injunction is sought. Thus, it usually takes more than one year to obtain a preliminary injunction. A preliminary injunction cannot be obtained on an ex-parte basis. The patentee shall provide security before the court issues a preliminary injunction.

24. What final remedies, both monetary and non-monetary, are available for patent infringement? Of these, which are most commonly sought and which are typically ordered?

Injunction and compensation of damages are available for patent infringement. Both are commonly sought and both are typically ordered.

25. On what basis are damages for patent infringement calculated? Is it possible to obtain additional or exemplary damages? Can the successful party elect between different monetary remedies?

In brief, a patentee can get compensation of damages at the amount of (i) the profit per product that the patentee could have earned from the sale of the patent owner's products multiplied by the number of the products sold by the infringer, (ii) the profit gained by the infringer from the act of infringement, or (iii) a reasonable royalty. A patentee may choose its preferred calculation method, or can claim the greatest amount among the amounts obtained from multiple calculation methods. Neither additional nor exemplary damages are available.

26. How readily are final injunctions granted in patent litigation proceedings?

When the court finds that the patent is infringed, it almost automatically grants a permanent injunction. Courts have

never denied injunction by considering public interest factors or proportionality of injunctive relief. When granting a permanent injunction, the court typically orders the defendant not to produce, assign, use, or offer to assign, the products at issue. There are no carve outs or exemptions with respect to a permanent injunction. In the circumstances where a permanent injunction is not ordered, there is no monetary compensation or payment of royalties instead.

27. Are there provisions for obtaining declaratory relief, and if so, what are the legal and procedural requirements for obtaining such relief?

A declaratory proceeding can be brought when obtaining a declaratory judgment is necessary and reasonable in order to eliminate risks or uncertainties that could destabilise the rights or legal status of the plaintiff. Typically, a person to whom the patentee sent a letter arguing that the person infringed the patent can file a complaint requesting a declaratory judgment that declares that the patentee does not have a legal right to request injunction or to get compensation of damages in relation to the plaintiff's product. When the court does not find that the plaintiff's product infringes the patent or the court finds that the patent should be invalidated, the court issues a declaratory judgment. "Arrow" declarations (or equivalent) are not available.

28. What are the costs typically incurred by each party to patent litigation proceedings at first instance? What are the typical costs of an appeal at each appellate level?

The filing fee to be paid to the court for commencement of a patent infringement action depends on the amount or the value of the claim. When the amount of the claim is JPY 100 million, the filing fee to be paid to the court for the first instance is JPY 320,000. The amount of the filing fee to be paid to the court on an appeal from the first instance judgment for a patent infringement action is 1.5 times the amount of the filing fee to be paid to the court for commencement of a patent infringement action. The amount of the filing fee to be paid to the court on a final appeal from the second instance judgment for a patent infringement action is twice the amount of the filing fee to be paid to the court for commencement of a patent infringement action. The attorneys' fees for a patent infringement action largely depend on the number of infringed patents, the number of the allegedly infringing products, the complexity of the invention, and the number of the reasons of invalidity. The typical attorneys' fees for a patent infringement action for the first instance would be around JPY 20–35 million. The typical attorneys' fees for a patent infringement action for the second instance would be around JPY 10–20 million. The typical attorneys' fees for a patent infringement action for a final appeal would be around JPY 5–15 million.

29. Can the successful party to a patent litigation action recover its costs?

The winning party can recover the filing fee from the losing party. In a patent infringement action, the patentee can include a certain amount of attorneys' fees in the damages incurred by patent infringement. The court often awards as attorneys' fees around 10% of the amount of other damages awarded as compensation.

30. What are the biggest patent litigation growth areas in your jurisdiction in terms of industry sector?

Pharmaceuticals continue to be the most popular technological area in patent litigation practice.

31. What do you predict will be the most contentious patent litigation issues in your jurisdiction over the next twelve months?

The scope of a patent during its extended term will be the most contentious issue. Two recent judgments address this point directly: one by the Tokyo District Court on May 15, 2025, and another by the IPHC on May 27, 2025. Article 68-2 of the Patent Act provides that the scope of the patent during its extended term is limited to the drug that was the subject of the marketing authorization on which the extension was based, and only for the use specified in that authorization. This means that, in order to exercise rights under a patent during its extended term, the patentee must prove that (i) the alleged infringing drug falls within the technical scope of the patented invention, (ii) the alleged infringing drug is the same as the drug that was the subject of the marketing authorization on which the PTE was based, and (iii) the alleged infringing drug is used for the use specified in that authorization. On January 20, 2017, the IPHC addressed the interpretation of Article 68-2 for the first time in a patent infringement case, in Debiopharm International SA v. Towa Pharmaceutical Co., Ltd. The IPHC held that the effect of the patent during the extended term covers not only a "product" (drug) specified by the "ingredients, quantity, dosage, administration, indication, and usage" stipulated in the

marketing authorization, but also those considered substantially identical as pharmaceuticals. Even when the allegedly infringing drug differs from the configuration set out in the marketing authorization, if such differences are merely minor or insignificant as a whole, the allegedly infringing drug is considered substantially identical to the drug subject to the marketing authorization and falls within the scope of the patent during its extended term. In Debiopharm, the IPHC further identified four categories of drugs that may be considered "substantially identical." Among them, the first category refers to cases in which the patented invention is characterized solely by the active ingredient of a drug, and where some inactive ingredients are added or modified using techniques that were well-known and conventional at the time of the marketing authorization application. However, it should be noted that in Debiopharm, the IPHC ultimately held that the allegedly infringing drug did not fall within the technical scope of the patented invention, without even considering the limitation under Article 68-2. Therefore, the court's statements regarding Article 68-2 in Debiopharm should still be regarded as obiter dicta. Thus, prior to the Tokyo District Court's judgment on May 15, 2025, there had been no judicial precedent addressing the interpretation of Article 68-2 in a case where the court determines that, or the alleged infringer admits that, an allegedly infringing drug fell within the technical scope of a patent for which a patent term extension was granted. On May 15, 2025, the Tokyo District Court addressed this issue in Sawai Pharmaceutical Co., Ltd. v. Bristol-Myers Squibb, a case involving a claim asserted by Bristol-Myers Squibb Company ("BMS") against Sawai Pharmaceutical Co., Ltd. ("Sawai") alleging that a generic drug ("Sawai's Product") sold by Sawai infringed a patent owned by BMS during the patent's extended term. The patent owned by BMS claims a compound and the patent term extensions were granted based on the marketing authorizations and the partial change approvals thereof for "Sprycel® Tablets 20mg" and "Sprycel® Tablets 50mg" (collectively, "Sprycel® Tablets"), respectively. The generic name of Sprycel® Tablets is dasatinib hydrate. There was no dispute between the parties as to the fact that Sawai's Product comprises a compound falling within the technical scope of the Invention. Therefore, the key issue in dispute was whether the scope of the patent during its extended term covers Sawai's Product. The Court pointed out that (i) the patented invention is an invention characterized solely by the active ingredient of a drug, (ii) while the active ingredient of Sprycel® Tablets is dasatinib hydrate, the active ingredient of Sawai's Product is dasatinib anhydride, (iii) Sawai's Product contains different excipients from those of Sprycel® Tablets, (iv) dasatinib hydrate and dasatinib anhydrite have different properties in equilibrium solubility, dissolution, and stability and Sawai selected different excipients so that the drug product would present dissolution behavior and stability similar to Sprycel® Tablets. Consequently, the Court found that Sawai's Product involved the addition and modification of excipients to address challenges arising from differences in the active ingredients between Sprycel® Tablets (dasatinib hydrate) and Sawai's Product (dasatinib anhydride). The Court further determined that there was no adequate evidence to recognize that such addition and modification of excipients were based on well-known or conventional techniques. Rather, the Court found that these additions and modifications were made by Sawai based on its own techniques. Accordingly, the Court concluded that Sawai's Product cannot be considered substantially identical to Sprycel® Tablets as a pharmaceutical, which means that the scope of the patent during its extended term does not cover Sawai's Product and it does not infringe the patent owned by BMS. About two weeks later, on May 27, 2025, the IPHC addressed this issue in another case, Toray Industries, Inc. v. Sawai Pharmaceutical Co., Ltd., et al., a case involving a claim asserted by Toray Industries, Inc. ("Toray") against Sawai and Fuso Pharmaceutical Industries, Ltd. ("Fuso") alleging that generic drugs ("Defendants' Drugs") sold by Sawai and Fuso infringed a patent owned by Toray during the patent's extended term. The patent owned by Toray claims an antipruritic agent comprising a compound and the patent term extensions were granted based on the marketing authorization for "Remitch® OD Tablets 2.5 μg" ("Toray's Drug"). The Court first determined that the Defendants' Drugs fall within the technical scope of the patented invention. Then the Court proceeded to the determination on whether the scope of the patent during its extended term covers the Defendants' Drugs. The Court noted that the patented invention is a medicinal use invention whose technical feature lies in that it provides a new medicinal use as an antipruritic agent based on the "κ receptor agonistic activity of compounds represented by general formula (I)," which was the unknown property, and that it does not specify any excipients to be contained in the antipruritic agent. The Court noted that the patented invention is a medicinal use invention whose technical feature lies in that it provides a new medicinal use as an antipruritic agent based on the "κ receptor agonistic activity of compounds represented by general formula (I)," which was the unknown property, and that it does not specify any excipients to be contained in the antipruritic agent. Then, the Court noted that: (i) both Toray's Drug and the Defendants' Drugs are antipruritic agents whose active ingredient is nalfurafine, a κ receptor agonist represented by general formula (I), and are drugs for which bioequivalence with Remitch® Capsule 2.5 μg has been

confirmed; (ii) both Toray's Drug and the Defendants' Drugs were developed as orally administered drugs to be OD tablets having no difference in efficacy and safety from Remitch® Capsule 2.5 µg; (iii) it can be understood that the use of the Defendants' Drugs is aligned with that of Toray's Drug; and (iv) Toray's Drug and the Defendants' Drugs are identical in their "active ingredient and quantity" and "dosage, administration, indications and usage," and they differ only in the excipients. Furthermore, the Court noted that excipients are generally substances that do not exhibit pharmacological effects at the dosage of the drug, are harmless, and are added as substances not impairing the therapeutic effects of the active ingredient, and that in light of the description in the Specification and the development history of the Defendants' Drugs, the excipients used in Toray's Drug and the Defendants' Drugs do not have any other technical significance. Based on the above, the Court determined that because the technical features and effects of Toray's Drug and the Defendants' Drugs are identical in that they are both antipruritic agents whose active ingredient is nalfurafine, and their specific dosage form as a pharmaceutical is identical, in light of the significance of excipients, the differences in excipients between Toray's Drug and the Defendants' Drugs are regarded as minor or insignificant as a whole, and the Defendants' Drugs are substantially identical to Toray's Drug as pharmaceuticals, which means that the scope of the patent during its extended term does cover the Defendants' Drugs and they infringe the patent owned by Toray. Because the Tokyo District Court' decision and the IPHC's decision diverge in their application of Article 68-2, the outcomes on appeal will be closely watched. While it is presently unclear whether an appeal has been filed from the Tokyo District Court' May 15, 2025 judgment, a final appeal and a petition for acceptance of final appeal have reportedly been filed from the IPHC's May 27, 2025 judgment. The appeal court's treatment of Article 68-2 in these cases —potentially within the next twelve months—will be of considerable interest.

32. What are the biggest challenges and opportunities confronting the international patent system?

Due to the recent development on various devices connected to the internet, whether there should be any changes in the theory of exhaustion is discussed. It has been understood that if a licensee of a patent of a module sells a module implementing the patented invention, the patent is exhausted and the patentee cannot exercise the patent against the products comprising the module. This is because (i) if the license is needed every time the patented product is assigned, the smooth transaction of patented products in the market would be harmed, and (ii) the patentee already has an opportunity to obtain the royalty by the time the patented product is sold the first time. Where the price of the device comprising the patented product is much higher than the price of the patented product, however, some argue that the patentee does not have an opportunity to obtain sufficient royalty, because the appropriate amount of royalty varies depending on the price of the device comprising the patented product. This discussion will also be influenced by the positions taken by foreign laws from the perspective of international harmonisation. Since this is a recent discussion, it will take some time before a court makes any determination on this issue.

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