Contents & Abstracts

Note: These abstracts have been written in Japanese and the National Center for Industrial Property Information and Training (INPIT) translated into English for reference. INPIT is entirely responsible for any errors in expressions or descriptions of the translation. In the event of any discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

Substantial consideration is based on the essence and reality of matters, and thus in many cases is considered as offering more reasonable solutions than formal thinking. However, the expression "substantial consideration" could also be so-called magic words, obscuring logical thinking processes and leading to considerations that are outside the purpose of judgment. In such cases, the substantial consideration is inappropriate.

Regarding the patent term extension system, there are conflicting interests that are difficult to reconcile in the requirement for a patent term extension and the scope of a patent right after the term extension. Recently, two lawsuits on a single patent were decided: a decision for the cancellation of rejection for an application for a patent term extension; and another for infringement of the patent that was deemed effective by the application for term extension. Concerning the requirement for the registration of term extension that the pharmaceutical agent which is the subject of the disposition should be covered by the patent, the decision for the cancellation of the rejection ruled that what the pharmaceutical agent is should be determined substantially. Meanwhile, the decision for the infringement ruled otherwise for the scope of the pharmaceutical agents protected by the patent. This is not just a technical issue of what a pharmaceutical agent is. It brings up an issue of interpretation of the patent term extension system, or even the Patent Act concerning how the pharmaceutical agent which is the subject of the disposition stipulated in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices should be interpreted in the patent system.

The patent term extension system purports to restore the patent term eroded because the pharmaceutical agent that is within the scope of the patent cannot be launched until the disposition is granted. Accordingly, the prerequisite is that the pharmaceutical agent which is the subject of the disposition is covered by the patent. In determining what the pharmaceutical agent the subject of the disposition is, it is important that it must be a pharmaceutical agent that can be manufactured and sold after the disposition is granted, and that the pharmaceutical agent must be within the technical scope of the patent. A substantial consideration without reflection on these factors must be deemed as losing sight of the purport of the judgment. Substantial identicalness needs to be considered both in the requirements for registration of extension and in the scope of the extended patent too, and thus substantial consideration must be reflected in each of the purports.

■ **Practices and Issues of Counter-Allegation (“Re-Defense of Correction”) in Patent Infringement Suit** ……26

TAKAMI Ken

Recently, in patent infringement suits, the number of cases has been increasing where, against the claim of invalidity by the alleged infringer (defendant), the patentee (plaintiff) makes the “counter-allegation” that, by correction, the ground for invalidity of the patent is dissolved (“re-defense of correction”). The discussions on the particulars of the counter-allegation have also been getting deeper following the judgment of the Intellectual Property High Court on the Confocal Spectroscopic Analysis Case in 2014 and that of the Supreme Court on the Sheet Cutter Case in 2017.

This article summarizes requirements for counter-allegation based on accumulated court decisions, etc. Further, although arguments on requirements for counter-allegation tended to be focused on whether a request for correction, etc. is necessary to make the counter-allegation, this article reviews other requirements as well.

In addition, arguments on counter-allegation to date have mainly been from the viewpoint of patentees, including those mentioned above, but this article focuses on issues that the alleged infringers face, as the author has practical experience representing both patentees and alleged infringers.

The first issue is that, although details of correction in relation to the counter-allegation are not publicly announced and are thus difficult to foresee, when the counter-allegation is found to be valid, the amount of damages is assessed as if there were no grounds for invalidity. To address this issue, the author proposes that, as a solution, the provision of presumption of negligence (Article 103 of the Patent Act) not be applied and only claims for unjust enrichment be allowed, or that the amount of damages be reduced by a certain degree by means of consideration of absence of intent or gross negligence (application by analogy of the latter sentence of Article 102 Clause 5 of the Patent Act), etc.

The second issue is repetition of the counter-allegation. Once a trial for patent invalidation is pending at the Patent Office, opportunities for a request for correction may be provided to the patentee regardless of the proceedings of the patent infringement suit, who, taking advantage of the opportunities, may repeatedly make counter-allegations, leading to lack of equitability between the two parties. To address this issue, the author proposes that excessive repetition be practically restricted in consideration of the intent of Article 104-3 Clause 2 of the Patent Act or by means of dismissal of allegations or evidence presented after its time without prejudice (Article 157 Clause 1 of the Code of Civil Procedure).

■ **Study on One Application per Design Rule and Design for a Set of Articles** ……38

AOKI Hiroya

Articles 7 and 8 of the Design Act are said to have set the one application per design rule and design for a set of articles, respectively. Experts, however, have different views of these Articles. This article focuses on these two Articles and a single design under the Design Act, and tries to summarize the issues of these stipulations in consideration of the ruling of the Intellectual Property High Court No. 2341 Page 127 dated September 21, 2016: “Frozen Dessert with Container;” and revision of the Design Act in 2019.

Based on the legislative history, past interpretations, and arguments at the time of the Revision of various stipulations including the definition of design set out in Article 2 Paragraph 1 of the Design Act, the conclusion of the author is that the traditional and rather restricted practice of treating a design that can be assessed as one article and one form as a single design, as indicated by the “Frozen Dessert with Container” case, is not necessarily required to be changed fundamentally at present. This is also construed from the stipulations

of Article 7 of the Enforcement Regulations of the Design Act, which corresponds to Article 7 of the Act.

The conclusion above, however, is not definitive: there is room for an understanding of a single design that is different from a traditional one depending on the interpretation or lawmaking. To prepare for such a case, this article reviews the possible requirement of clarity of the particulars of a single design that should be placed on the applicant in consideration of the impact on third parties, and possible necessity to take some measures for application fees, etc. for a design with an excessively wide scope. In addition, this article also reviews the tools for supporting the convenience of the applicant, such as possible needs for change in practices regarding Article 10-2 of the Act (division of applications for design registration), which is currently considered solely as a practical leniency provision for applications that are in violation of the principle of one application per design rule.

MARIYAMA Naoko

When a patent dispute arises between an original drug manufacturer and a generic drug manufacturer that the latter is infringing the patent of the former, the former sometimes pays a large amount of money to the latter so that the latter delays its launch of the generic drug. This type of amiable settlement is called "reverse payment" or "pay for delay," and has raised concerns in the global antitrust community. On the other hand, such an agreement has never been taken up as a violation in Japan. The author believes, however, that there is a possibility that such an agreement may be taken up as a violation in Japan as well.

This article reviews how such a reverse payment agreement is assessed in the context of the Antimonopoly Act based on court rulings in the US and in the EU. The conclusions are as follows. Firstly, the reverse payment agreement that the original drug manufacturer pays money to the generic drug manufacturer so that the latter delays launch of the generic drug is subject to the Antimonopoly Act. Certainly, the reverse payment agreement is normally to delay the launch of the generic drug until the expiration of the patent under dispute and thus is within the scope of the exclusive rights of the patent, and some believe that, because of this nature, the agreement is outside the scope of the Antimonopoly Act. However, the reverse payment agreement cannot be viewed as an "exercise of rights" stipulated in Article 21 of the Antimonopoly Act, and thus is considered as within the scope of the Act. Secondly, there are reverse payment agreements for which there are legitimate grounds for the payment, and therefore not all reverse payment agreements are in violation of the Act. Thirdly, in the event that the original drug manufacturer cannot demonstrate the grounds for the payment to the generic drug manufacturer other than for the purpose of postponement of the launch, such agreements are considered to be in violation of the Act.

YAMASHITA Hirotsuna

The Appointment Clause of the US Constitution stipulates that the principal officers are appointed by the President with the advice and consent of the Senate, while the inferior officers may be appointed by the head of a department. The administrative patent judges of the Patent Trial and Appeal Board of the US Patent and Trademark Office are appointed by the Secretary of Commerce; and the inter partes review is judged by a panel mainly consisting of three administrative patent judges. In the case under review, the question was

whether the authority of the administrative patent judges during the inter partes review is compatible with the Appointment Clause of the Constitution; in other words, whether the authority of the administrative patent judge, appointed by the Secretary of Commerce as inferior officer, is compatible with the authority of the administrative patent judge to make decisions on the inter partes review on behalf of the US Patent and Trademark Office.

The US Supreme Court explained that, in consideration of precedent, the inferior officer must be directed and supervised by a principal officer, and then concluded that the authority wielded by the administrative patent judge during the inter partes review is unreviewable within the Patent and Trademark Office, which is incompatible with their appointment by the Secretary of Commerce as inferior officer. The Supreme Court also concluded that, as remedy for the violation of the Constitution, the Director of the Patent and Trademark Office may review the final decisions by the Patent Trial and Appeal Board and, upon review, may then make the decisions himself on behalf of the Board.

Depending on the ruling of the Supreme Court, the case under review could have invalidated the inter partes review system, which could have had a huge impact. However, in its ruling, the US Supreme Court maintained the current inter partes review system as much as possible. After the Supreme Court's ruling, the US Patent and Trademark Office implemented an interim process for Director review.