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Infringement of Extended Patent Right by Generic Drug Not Found

Recent actions at the Japanese Courts may impact the strategies and activities of generic drug manufacturers in Japan. Debiopharm Group, a Swiss-based biopharmaceutical company, filed a lawsuit seeking an injunction against Towa Pharmaceutical Co., Ltd. on the manufacturing and sales of Towa’s generic anti-cancer drug comprising Oxaliplatin on the grounds that the drug infringes Debiopharm’s patent, Japanese Patent No. 3547755. The Tokyo District Court ruled that the generic drug produced by Towa is out of the scope of the patent right that had been extended. Debiopharm appealed against the decision at the Intellectual Property (IP) High Court. However, the IP High Court upheld the decision leading Debiopharm to file an appeal at the Supreme Court. The Third Petty Bench of the Supreme Court dismissed Debiopharm’s appeal on May 8, 2018, thus affirming the IP High Court decision. The point at issue in this case was how the scope of a patent right for which a patent term extension has been granted should be recognized. If time is required to get approval for the manufacturing and sales of a medical drug and the patented invention cannot be worked during that period, the patent term for the medical drug may be extended up to five years after the original patent term if the Japanese Patent Office (JPO) grants the extension. However, the scope of the extended patent right and the effects thereof will be limited to the implementation of the approved object for the approved use only for the extended term. It was not clear what drugs would be covered by the extended patent right. The scope of the patent right during the extended term was the main topic in this case.

In January 2017, the Grand Panel of the IP High Court established a judging standard stating that if generic drugs have only slight differences in their components, quantities, or methods of use in comparison with the original (patented) drugs, then the generic drugs should be deemed to be substantially identical to the original drugs, but the differences in the technical features and functional effects between the original drugs and the generic drugs should be considered when making a judgment on infringement. Based on this principle, the Judges handed down a decision stating that Towa’s product is not “practically the same” as the original drug since it contains an additive as a stabilizer which the original drug does not comprise, and concluded that the patent right during the extended term does not cover Towa’s product. This decision made by the IP High Court is in line with the Tokyo District Court decision. Debiopharm filed a request for appeal at the Supreme Court which was dismissed, finalizing the decision made by the IP High Court.

If generic drug manufacturers intend to produce and sell generic drugs during the period when the extended patent right of the original drugs is valid, it is necessary to design the generic products such that they will not be deemed to be practically the same as the approved original drugs. Doing so will help avoid the situation where the generic drugs are recognized as infringing the extended patent right for the original drugs. Therefore, it is believed to be important that generic drugs be objectively deemed to have technical features and functional effects that the original drugs do not have. In other words, in order to not infringe an extended patent right, it is better for generic drugs to have new technical features and functional effects that would not be easily conceived of by a person skilled in the art and that the original drugs do not provide.

“Declaration of Design Management” Compiled by JPO Expert Panel Suggests Revisions to Japanese Design Law

In May 2018, a Japanese Patent Office (JPO) expert panel—known as the Study Group on the Relation between Industrial Competitiveness and Designs—held a discussion on challenges to be addressed and measures to be taken with the aim of enhancing industrial competitiveness through designs in Japan. We herein introduce a report titled “Declaration of Design Management” compiled by the study group. According to this report, in recent years, overseas companies have been successful in developing new products by implementing “design-oriented” policies that lead to enhancements in technical innovation and competitive strength. The report suggests that Japanese companies have shifted their focus towards “Design Management” which bolsters their competitive strength and brand value.

Proposals for revisions to Japanese Design Law

In this report, the study group proposes that the JPO take action by revising the Japanese Design Law. Problems surrounding the current design system and proposed solutions are listed in “Ideal State of Future Design System Contributing to Enhanced Industrial Competitiveness”, an annex to the main report. Please refer to the partial translation of the annex as follows.

Subjects of Design Protection

Protection of Graphic Images (GI)

Point at issue

With the rapid advancement of technical innovation, products and services utilizing cutting-edge technology have recently served as a source of newly-emerging industrial competitiveness. Companies in such burgeoning technical fields face a dilemma in that, as their technology improves, their services and products become more and more complicated. In order to tackle this issue, the user interface (UI) and user experience (UX) have taken on a drastically more significant role. In addition, since consumers tend to place greater value on “experience”, there is a dire need to protect both UI and UX which are directly connected to consumers. Furthermore, some companies provide their customers with novel experiences by offering services and products utilizing virtual reality (VR), augmented reality (AR), and various projection technologies to differentiate themselves from their competitors. However, the current design law system cannot sufficiently protect design rights related to these cutting-edge technologies. Expert Panel’s Proposal/Recommendation to Promote “Design Management”

The JPO should consider reviewing the subjects of design protection as well as the definition of “design” itself under the Japanese Design Law. It is necessary to sufficiently protect designs related to services and products that leverage new technologies, such as GIs. Figure 1 shows an example of a design which cannot be protected under the current Japanese Design Law.

Figure 1: Graphic image projected onto a wall



Simplification of Formality Requirements for Design Registration

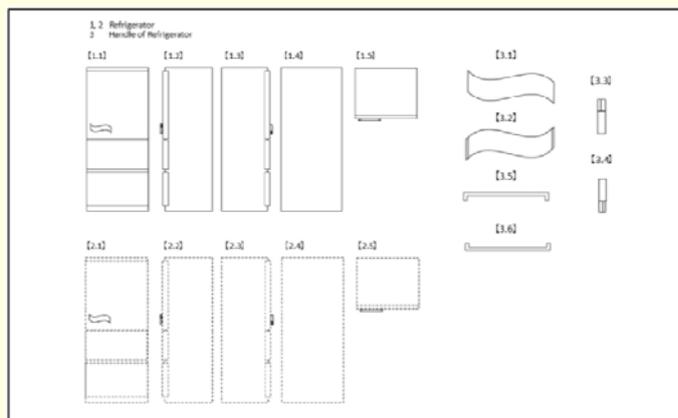
One Application per Design

Point at issue

When attempting to broadly protect design rights, it would be effective for an applicant to create a group of designs and file them together in a single design application from the standpoint of facilitating the enforcement of design rights pluralistically. In addition, there are cases where multiple design applications are simultaneously filed when designs associated with a mutual concept covering multiple articles are derived from a single design concept. However, the current Japanese Design Law does not allow a single design application to cover multiple designs. Applicants have been requesting revisions to the current system to ensure that multiple designs can be protected by one design application, thus allowing applicants to reduce the financial burden and time associated with filing design applications.

Expert Panel’s Proposal/Recommendation to Promote “Design Management”

The JPO should consider a revision that would allow an applicant to file a single design application including multiple designs.



Hypothetical Case (illustrated by the JPO): International design application for multiple designs via a single design application (whole design and partial designs).

Article of the Design

Point at issue

Recent technological developments enable the integration of conventional technologies with different functions and create new articles equipped with novel and versatile functions. In particular, the arrival of artificial intelligence (AI) and the Internet of Things (IoT) has accelerated the creation of new articles that go beyond the boundaries of conventional products. Under the current design law system, applicants have to describe the "article of the design" in the design application in accordance with certain requirements. This prosecution procedure puts a burden on applicants.

Expert Panel's Proposal/Recommendation to Promote "Design Management"

The JPO should consider a revision to the description requirements for the "article of the design".

Description Requirements for Figures, etc.

Point at issue

Under the current design law system, applicants are, in principle, required to disclose the whole figure of the article with respect to the design when filing the design application. The current requirements are more rigorous than those in other countries. There have been many requests from applicants seeking relaxation of the description requirements for figures to reduce the burden of drafting figures.

Expert Panel's Proposal/Recommendation to Promote "Design Management"

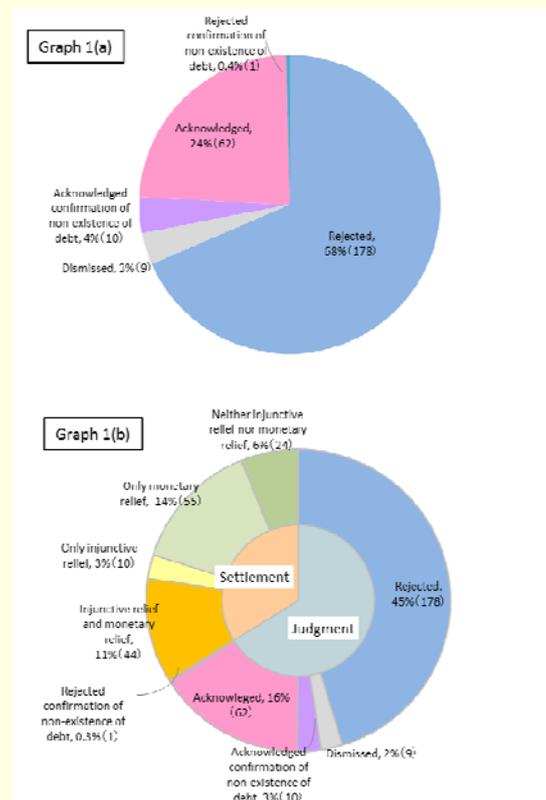
The JPO should consider easing the description requirements for figures in harmony with the international design registration system and the design systems of other countries.

Statistics on Patent Infringement Litigation

The Japanese Patent Office (JPO) released a report titled "Appropriate Assessment of the Amount of Compensation for Damages regarding Patent Infringement Litigation" in March 2018. The purpose of this report was to prepare materials which will form a useful basis for parties involved in disputes to appropriately assess the amount of compensation for damages. A particular focus was placed on studying the balance between giving incentives for inventions and promoting the utilization of inventions from various perspectives, including law and economics. In this article, we review statistics compiled by the Intellectual Property (IP) High Court on judgments and settlements in patent infringement litigation and introduce some statistics regarding the amount of damages (approved amounts) in judgments that appear in the report.

Statistics on Judgments and Settlements in Patent Infringement Litigation at the District Courts (Statistics from IP High Court)

Graphs 1(a) and 1(b) give breakdowns (percentages) of the judgments and settlements based on IP High Court statistics on patent infringement litigation at the Tokyo District Court and the Osaka District Court from 2014 to 2017. According to Graph 1(a), the percentage of cases in which patent holders' requests were acknowledged was 24% among cases in which judgments were ruled at the District Courts. In contrast, according to Graph 1(b), the percentage of cases which were settled with injunctive benefit provisions and/or monetary benefit provisions was 28% (=11%+3%+14%). If cases that were settled with injunctive benefit provisions and/or monetary benefit provisions are considered as also providing some benefits to patent holders, then the percentage of cases at the District Courts which provided some benefits to patent holders was 44% (=16%+28%). This means that patent holders earned some benefits through litigation from nearly half of the cases.



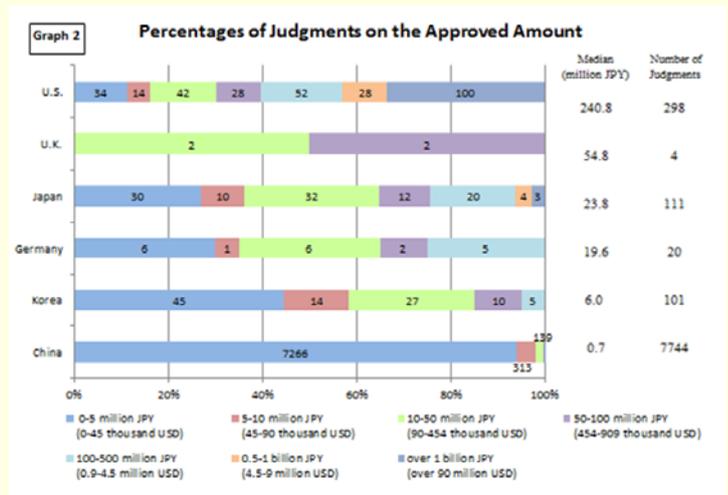
- Numbers shown in parentheses are the number of judgments.
- "Acknowledged" includes partially acknowledged.
- "Rejected confirmation of non-existence of debt" includes partial rejection.
- "Rejected confirmation of non-existence of debt" is the total amount in 2017. Data between 2014 and 2016 is included under "Rejected".

Source: Statistics from IP High Court

http://www.ip.courts.go.jp/vcms/lf/2018_sintoukei_H26-29.pdf (Japanese)

Percentages of Judgments on the Approved Amount

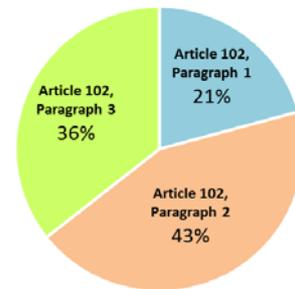
Graph 2 shows the distribution of the amount of damages approved in judgments of patent infringement litigation based on statistics from the Courts in each country over the last decade (from January 2007 to November 2017). According to this graph, the amounts approved in the U.S. stand out from other countries. The median in the U.S. is approximately 240 million JPY (2.2 million USD: 1 USD = 110 JPY) and the percentage of cases in which over 1 billion JPY (9.1 million USD) of damages were approved was approximately 35% (100/298). On the other hand, the median of the damages for patent litigation in Japan was 23.8 million JPY (220,000 USD), showing that there is a huge gap between Japan and the U.S. However, in comparison with other major countries, the median in Japan is not so low and it comes in third after the U.S. and the U.K., exceeding Germany. It should be noted that most cases in Europe and the U.S. conclude with settlements and the number of cases in which judgments are made is relatively small. Especially in Germany and the U.K., some judgments relating to damages are separately made after the conclusion of infringement litigation due to institutional constraints on the courts, and cases for which the amount of damages is disclosed in judgments are rare. Therefore, for such reasons, it is difficult to compare statistics between countries on the damages found in patent infringement litigation.



Types of Calculated Damages

Graph 3 shows the percentages of approved types of damages in Japan. Japanese Patent Law, Article 102, Paragraph 1 allows for damages to be calculated as lost profits using the profit earned by the patent holder per product (unit). This Article was introduced into the Patent Law due to the difficulty in ascertaining the profits of infringers. However, in actuality, the percentage of cases in which damages were approved using Japanese Patent Law, Article 102, Paragraph 2 to calculate the amount of damages based on accused infringers' profits was the greatest (over 40%) because patent holders may not wish to disclose their own profit per product. The next highest percentage of cases, occupying about one third of the graph, is the calculation based on Paragraph 3 in which damages are determined in accordance with the amount of reasonable license fees.

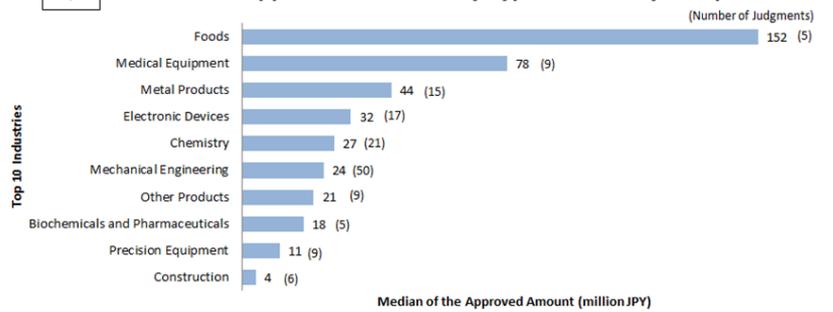
Graph 3 Types of Calculated Damages in Japan



Median of Approved Amounts by Type of Industry

Graph 4 shows the approved amount of damages by type of industry to which patent holders and infringers belong in Japan. Although the number of judgments in Japan is limited and the reliability as statistics is not high overall, the median of the approved amounts related to the food industry and the medical equipment industry in Japan are extremely high.

Graph 4 Median of Approved Amounts by Type of Industry in Japan



Conclusion

Generally speaking, one may be under the impression that the amount of damages approved in patent infringement litigation in Japan is not so high compared with other major foreign countries, and these beliefs may be the cause of the small number of patent infringement litigation cases lodged in Japan. However, according to the JPO report, the approved amounts in Japan are not so small and Japan actually ranks third after the U.S. and the U.K. Furthermore, it was revealed that there are major gaps in the approved amounts based on the type of industry. We hope that this information has contributed to your understanding of the current situation of patent infringement litigation in Japan.

Source: "Appropriate Assessment of the Amount of Compensation for Damages regarding Patent Infringement Litigation" (March 2018) https://www.jpo.go.jp/shiryou/toushin/chousa/pdf/zaisanken/2017_11_zentai.pdf (Japanese)

Guide to Licensing Negotiations Involving Standard Essential Patents

On June 5, 2018, the Japanese Patent Office (JPO) published “Guide to Licensing Negotiations Involving Standard Essential Patents” (hereinafter referred to as “Guide”) concerning the licensing of standard essential patents (“SEPs”), which are patents essential in the implementation of standards in technical fields such as wireless communications. The aim of this Guide is to enhance transparency and predictability, facilitate negotiations between rights holders and implementers, and help prevent or quickly resolve disputes. The SEPs addressed in this Guide are those which the current or original rights holders have presented to standards setting organizations (“SSOs”) as FRAND*-encumbered SEPs.

[*FRAND: Fair, Reasonable and Non-Discriminatory]

With companies from a broad spectrum of industries now finding themselves involved in SEP licensing negotiations, there is a call for appropriate information to be provided to enable businesses unfamiliar with such negotiations to feel confident when taking a seat at the negotiating table. While the legal basis for placing limits on injunctions concerning FRAND-encumbered SEPs varies from country to country, in many cases, it seems that different factual situations have led courts in different countries to reach different conclusions. Recent years have seen an increasing cross-border convergence in case law regarding how parties should behave in SEP licensing negotiations based on a thorough factual inquiry into whether good faith negotiations have been conducted. In circumstances such as these, the Guide aims to offer an explanation of what actions companies can take to increase the likelihood that they will be recognized as “negotiating in good faith”, thus helping implementers to avoid injunctions and rights holders to secure appropriate compensation. The Guide includes notes pointing out what rights holders and implementers should be aware of during each step of the SEP licensing negotiation process shown below. It also presents several royalty calculation methods.

[SEP Licensing Negotiation Process]

Step 1: Licensing Negotiation Offer from Rights Holder

Step 2: Expression from Implementer of Willingness to Obtain a License

Step 3: Specific Offer from Rights Holder on FRAND Terms

Step 4: Specific Counteroffer from Implementer on FRAND Terms

Step 5: Rejection by Rights Holder of Counteroffer/Settlement of Dispute in Court or through ADR (Alternative Dispute Resolution)

The above article is excerpted from the JPO’s Guidelines. For more detailed information, please refer to the JPO website below.

<http://www.meti.go.jp/press/2018/06/20180605003/20180605003-2.pdf>