

WINDS FROM JAPAN

The Licensing Executives Society Japan

Patent Linkage in Japan Vol.1: Fundamentals

By Yasuko TANAKA *

Patent linkage generally refers to the procedure of verifying the relationship between a generic drug and the patents of the corresponding originator drug during regulatory review. It is not stipulated in the TRIPS Agreement, and was first established globally in 1984 under the U.S. Hatch-Waxman Act. Japan has no statute explicitly providing for patent linkage, but since around 2009 it has been implemented de facto through

notifications issued by the Ministry of Health, Labour and Welfare (MHLW).

Beginning with this piece, I'll be introducing Japan's patent linkage system across several volumes.

In Japan, as shown in the chart below, the process from a generic drug application (GDA) to market launch, proceeds through the following steps: GDA, generic drug review (GD Review), marketing approval (MA), request for drug price listing (Request for DPL), DPL, and Launch.



Generic drugs are approved twice a year (February and August), and the DPL occurs also twice a year (June and December), so that a generic drug approved in February can be priced in June of the same year at the earliest, or in December if approved in August.

Patent linkage in Japan constitutes two stages: the First Stage is held in the GD Review, and the Second Stage is held after MA, but before the Request for DPL between the originator and generic maker and it is so-called "Prior Negotiation." The details of the two stages are as follows:

First stage

Once a GDA is submitted to the MHLW, it is reviewed by the Pharmaceuticals and Medical Devices Agency (PMDA), which is an organization under the MHLW and performs GD Review, and approved in about one year. During the review process, it is confirmed that the submitted generic

drug does not conflict with the originator patents at the time of the expected MA date. The originator patents refer to substance/use patents described in "Pharma Patent Information Sheet."

The **Pharma Patent Information Sheet (Info-Sheet)** is one of the submission documents upon a new drug application and includes the patents relating to the new drug. The Info-Sheet is equivalent to the US "Orange Book." While the Orange Book is publicly available, the Info-Sheet is not. The patents listed in the Info-Sheet can be revised or added up to the end of the reexamination period. The **Reexamination period** is the Japanese version of the data-protection period, a period of eight years for new drugs. Even after the reexamination period, newly registered patents can be additionally recorded.

The First Stage is to confirm conflicts with the originator substance/use patents listed in the Info-Sheet, and other patents such as formulation and

manufacturing process patents are not referenced even if they are listed in it. There are no sanctions for listing patents other than substance/use. The First Stage takes place behind closed doors at the PMDA. Specialists such as lawyers and patent attorneys haven't really been part of the process. However, beginning on November 14, 2025, a new system was introduced that allows the PMDA to consult specialists whenever decisions become difficult.

After the GD review, if the authority concludes that there is no possibility of infringement, the generic drug is approved. If the possibility of infringement remains, however, the process simply comes to a halt. This kind of standstill has been seen as a problem since there is no clear way to deal with such situations. There have been some court cases arising from this problem. I will share them in future volumes.

Second Stage (Prior Negotiation)

If a generic maker wishes to request drug pricing for an approved generic drug that may be subject to a patent dispute, it must conduct negotiations with the originator prior to the DPL and submit the results to the MHLW by the specified deadline. When a generic drug is approved, its MA details are posted on the MHLW website. The

originator company, upon discovering a generic drug that may infringe its patents, contacts the generic maker to initiate negotiations.

Substance and use patents are reviewed during the First Stage, while the Second Stage examines possible infringement of other patents such as formulation and manufacturing process patents. Although reporting to the MHLW is mandatory, the parties are not required to reach an agreement, since only submission of a report is necessary. Therefore, even if the drug price is listed following negotiations before the DLP, this does not preclude patent infringement or litigation. A patent lawsuit may arise after the DPL, or it may be initiated before the DPL to prevent potential infringement.

Please note that in the case of an additional MA, such as a new indication or a change in dose and dosage, for a generic drug that has already been initially approved and priced, the drug may be sold immediately after the MA. In such cases, there will be no Second Stage of patent linkage.

In the next volume, I'll talk about the reform of Japan's patent linkage in 2025. Stay tuned!

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\* *Editor / Patent Attorney, S-Cube Corporation/S-Cube International Patent Firm*

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## **Supreme Court Decisions on Cross-Border Webservice Related Inventions: Dwango v. FC2 Patent Infringement Litigation Cases**

**By Mitsuo KARIYA\***

On March 3, 2025, the supreme court rendered decisions on two cases for the cross-border webservice related inventions finding that Japanese patents could be infringed even if some claim elements are located outside Japan in certain circumstances.

### **Background and lower courts' decisions**

Dwango Co., Ltd., a Japanese company providing web services, owns Japanese patents, JP Nos. 4,734,471 which has display device claims and program claims as well as Japanese patents, JP No.6,526,304 which has comment streaming system claims. Dwango sued FC2, Inc., a US company, providing web services and Home Page System, Inc., (HPS), a Japanese company

developing web services for patent infringement before the Tokyo district court (Case 1 for the 471 patent; Case 2 for the 304 patent). FC2, Inc., and HPS will be collectively referred as the "defendant", hereinafter. Dwango's patented inventions relate to movie streaming services in which users can add comments to the movies and view the movies together with the added comments. The streaming system includes servers for streaming movies and comments, user terminals and telecommunication lines connecting therebetween.

In Case 1, the Tokyo district court denied patent infringement by finding that at least one element of the asserted patent claim is not satisfied in the defendant's devices and programs. The IP high court found that the defendant's programs infringe the patent and ordered injunctions and damage awards although the defendant's server is located in the US. The district court decision and the

IP high court decision for Case 1 were reported in the WINDS #75.

In Case 2, the Tokyo district court denied infringement because the server is located in the US. The IP high court grand panel found that the defendant's programs infringe the patent and ordered injunctions and damage awards although the defendant's server is located in the US. For Case 2, the district court decision was reported in the WINDS #75 and the IP high court grand panel decision was reported in the WINDS #78.

The defendant appealed to the supreme court for Cases 1 and 2.

## **Supreme court decisions**

### **Supreme court decision on Case 1:**

The issue is whether the action of delivering a program to the territory of Japan through the internet from outside Japan corresponds to the "provision through the telecommunication lines" in Patent Act, Article 2(3)(i) and the "transfer, etc." in Patent Act, Article 101(i), and therefore infringes the Japanese patent.

The defendant delivers the program which falls in the scope of the present patent claim to the user terminals located in Japan from the server located in the US through the internet for providing the present services. In the present streaming, when the user accesses the webpages for viewing the movies related to the present services by using the terminals located in Japan, the program is transmitted from the server located in the US and downloaded in the user terminal.

When the present program is downloaded at the user terminal, the present program becomes executable and it becomes possible for the user to view the movies with the comments.

Although Japanese patents have effect only in Japan, in the current circumstance where it is extremely easy to distribute information across the border through the telecommunication lines, it is not in line with the purpose of patent law if the transmission of the program from outside Japan is always considered not to correspond to the "provision through the telecommunication lines" only because of the transmission from outside Japan when the program is provided to the territory of Japan by transmitting from outside Japan through the telecommunication lines.

There is no reason to prevent Japanese patents from having effect to such actions when it is considered to substantially correspond to the "provision through the telecommunication lines" in Japan by considering the actions in question as a

whole. This logic should also apply to the "transfer, etc." in Patent Act, Article 101(i).

As the present streaming is performed by transmitting the present program from the server located outside Japan and having the user terminal located in Japan receive it, a part of the action is conducted outside Japan if it is observed formally. However, if it is observed as a whole, the streaming is performed naturally in order for the users using the terminal located in Japan to receive the services. The services are to have the users view the movies with comments at the user terminal located in Japan. Based on this fact, the streaming is performed during the information processing procedure at the time of providing the services in Japan, it naturally causes the effect of the program invention to perform, and there is no particular meaning of the location of the server being outside Japan in connection with performing the effect of the invention. It is also not considered that there is no economic effect on the respondent (the patent owner) by the present streaming.

Therefore, it should be said that the present streaming corresponds to the "provision through the telecommunication lines" in Patent Act, Article 2(3)(i).

The present device is produced by installing the program to the user terminal and the effect of the device invention is naturally performed at the user terminal in Japan. Therefore, it is reasonable to consider that the defendant performs the "transfer etc." as the provision of the present program through the telecommunication lines which is used only for production of the present device in Japan substantially.

It should be said that the present streaming corresponds to the "transfer etc." in Patent Act Article 101(i). The original judgment can be approved as legitimate.

### **Supreme court decision on Case 2**

The issue is whether the action of building the system including the server located outside Japan and the user terminal located in Japan corresponds to the "production" in Patent Act, Article 2(3)(i) and therefore infringes the Japanese patent.

When the present streaming is performed, the user terminal requests data files of movies and comments to the server through the internet and performs the process of displaying the movies and comments so that the comments do not overlap each other, and then the present system including the user terminal and the server is built.

In the current circumstance where it is extremely easy to distribute information across the border through the telecommunication lines, although Japanese patents have effect only in Japan, it is not in line with the purpose of patent law if the “action of building the system “ is always considered not to correspond to the “production” only because there is an action or a configuration located outside Japan when a part of the action of building the system including the server and the user terminal is performed from outside Japan through the telecommunication lines and the server as a part of the system configuration is located outside Japan.

There is no reason to prevent Japanese patents from having effect to such actions when it is considered to substantially correspond to the “production” in Japan by considering the action of building the system and the built system in question as a whole.

As the present streaming is performed by transmitting a program file from the server located outside Japan and having the user terminal located in Japan receive it, it can be formally said that a part of the action of building the present system is conducted outside Japan and the server as a part of the present system which is built as a result of the present streaming is located outside Japan. However, if the present system and the action of building the present system are observed as a whole, the building of the present system by the present streaming is naturally performed when the user using the terminal located in Japan accesses the server for receiving the present service. As a result, the process is performed by the present system so that the comments do not overlap each other and the result of the process is displayed at the user terminal located in Japan.

Accordingly, it can be said that there is no particular meaning of the location of the server being outside Japan in connection with the effect of the present invention, because the building of the present system by the streaming is performed as an information processing procedure for providing the present service in Japan, and naturally causes the effect of the present invention to perform at the user terminal located in Japan by building the present system including the user terminal located in Japan. There should be no circumstance where the present streaming and the resultant present system has no economic influence to Dwango. It is reasonable to consider that the defendant produces the present system substantially in Japan by the present streaming and the building of the resultant present system.

Therefore, it should be said that the building of the present system by the present streaming corresponds to the “production” in Patent Act, Article 2(3)(i). The original judgment can be approved as legitimate.

### **Consideration**

The two supreme court decisions confirmed that Japanese patents could be infringed in a certain situation even if a part of the system is located outside Japan or a part of the action is performed outside Japan while maintaining the territorial principle. It can be said that Japanese patents are protected more appropriately in the circumstance where the information services are provided across the border.

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* *Editor / Patent Attorney, Kariya IP Office/Tokyo-Hirakawa Law Office*

The first Joint Meeting between EPLAW and LES Japan

By Koichiro YAMASHITA *

It is with great pleasure that EPLAW and LES Japan held the first joint meeting on November 17. The first meeting was hosted by Mr. Koichiro Yamashita, leader of European Issues Working Group in LES Japan, with full support of Ms. Marleen van den Horst (Vice-Chair Japan EPLAW Outreach Committee). EPLAW Delegates consisted of 14 members from SE, NL, DE,

BE, UK, FR, ES, IT. The joint meeting was carried out in accordance with the following program:

1. Introduction of LES Japan and European Issues Working Group *Presented by* Ms. Chikako Hashimoto (President of LES Japan, Sakai International Patent Office)
2. Introduction of EPLAW and Outreach Group *Presented by* Mr. Alex Wilson (EPLAW Chair Japan Outreach Committee, Powell Gilbert)

and Ms. Marleen van den Horst (EPLAW Vice-Chair Japan Outreach Committee, La Gro)

3. Presentation 1: UPC – basics and practical value of UPC & key topics *Presented by* Mr. Luca Pellicciari (EPLAW, Trevisan & Cuonzo)
4. Presentation 2: CJEU decision BSH Hausgeräte/Electrolux *Presented by* Mr. Ludvig Holm (EPLAW, Westerberg & Partners)
5. Panel discussion
Impact of BSH decision on national and UPC patent proceedings

Different strategies (PI/final relief, invalidation actions/ defenses, national/UPC/hybrid)

Precautionary measures for a defendant in anticipation of or in response to UPC/national/longarm attacks

Moderator: Marleen van den Horst

NL: Marleen van den Horst

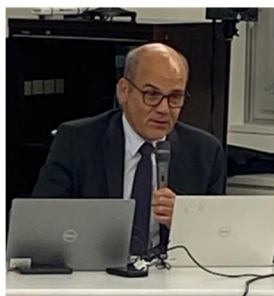
UK: Daniel Lim (Kirkland & Ellis, London)

DE: Michael Rüberg (Boehmert & Boehmert)

ES: Rais Amils Arnal (Gómez-Acebo & Pombo)

IT: Luca Giove (GR Legal)

6. Questions/comments



EPLAW Outreach Committee (from left), Chair Alex Wilson, Vice-Chair Marleen van den Horst, Vice-Chair Luca Pellicciari, Vice-Chair Ludvig Holm

EPLAW presented us with an overview of the current landscape of European patent litigation. The presentation includes a basic introduction to the UPC and the key topics of the CJEU decision in BSH Hausgeräte/Electrolux case. The CJEU decision has a significant impact on European patent litigations, particularly with respect to long-arm jurisdiction. The court in the defendant's domicile does not lose jurisdiction over the infringement cases, even when an invalidity defense is raised. However, the court may stay the infringement proceedings if (i) invalidity case is 'duly brought' in that respective member state, and/or (ii) the court considers it justified, in particular where there is a reasonable, non-

negligible chance that the patent will be declared invalid.

The panel discussion provided us with valuable insights into European patent litigation. The panelists introduced the key features of patent litigation in their respective local courts. In Europe, every country has its own patent litigation system, and it is difficult to comprehend all of them thoroughly. This discussion was highly valuable as it allowed us to exchange perspectives on the distinctive features of each jurisdiction. The discussion covered topics such as the impact of the UPC and the CJEU decision concerning BSH in various jurisdictions.



The member of panel discussion (from left) Mr. Luca Giove, Mr. Daniel Lim, Ms. Marleen van den Horst, Mr. Michael Rüberg, Ms. Rais Amils Arnal

A networking reception was held following the joint meeting, providing an excellent opportunity for participants to exchange opinions and strengthen professional relationships. We greatly appreciated the opportunity to have direct conversations with European patent litigation attorneys from across multiple countries.

I would like to express my sincere gratitude to the EPLAW Delegates, as well as European Issues Working Group members in LES Japan, who worked hard to organize the meeting.

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\* Patent attorney, Innoventier IP Attorney

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## Editors' Note

This issue includes articles " Patent Linkage in Japan Vol.1: Fundamentals" by Ms. Yasuko TANAKA, "Supreme Court Decisions on Cross-Border Webservice Related Inventions: Dwango v. FC2 Patent Infringement Litigation Cases" by Mr. Mitsuo KARIYA and "The first Joint Meeting between EPLAW and LES Japan" by Mr. Koichiro YAMASHITA.

Thank you for supporting "*WINDS from Japan.*" This newsletter will continue to provide you with useful information on activities at LES Japan and up-to-date information on IP and licensing activities in Japan.

If you would like to refer to any back issues of our newsletters, you can access them via the following URL:

<https://www.lesj.org/en/winds/new.php>

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