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SONODA & KOBAYASHI
INTELLECTUAL PROPERTY LAW

Japan IP News Bulletin



September 2021

Contents

- **News about Sonoda & Kobayashi**

1. Sonoda & Kobayashi presents its China-focused newsletter
2. Story of the month

- **JPO News**

1. JPO strengthens cooperation with ASEAN
2. JPO releases guide to support trademark applications
3. CNIPA held a regular press conference for the third quarter

- **Latest IP News in Japan**

1. Toyota leads in Electric vehicle patents, but not in sales
2. Japanese city of Matsuyama trademarks name of a local dance

- **Latest IP News in China**

1. ZTE, one of China's 5G leaders, has more than 40000 global granted patents

2. Statistical analysis report on patent cases which were declared invalidation in China

- **IP Law Updates in China: Insights from Sonoda & Kobayashi**

1. Drug Patent Linkage System in China

- News about Sonoda & Kobayashi -

1. Sonoda & Kobayashi presents its China focused newsletter

Welcome to the September edition of Sonoda & Kobayashi's bi-monthly newsletter. As the picture on the first page of this document may have shown you, this edition is not only about Japanese IP news, but also features Chinese IP-related issues and a written contribution by our Chinese patent attorney.

Perhaps you may remember our recent e-mail or maybe you saw the posting on our website.

Since this year, Sonoda & Kobayashi has opened [an office in Beijing, China](#).

We hope to expand Sonoda & Kobayashi's reliable and high-quality services to China.

We are able to help prosecute patents, utility models, trademarks and designs, and stand ready to protect your intellectual property in China. We hope you will enjoy this special newsletter edition in which we update you on China-specific IP news.

Feel free to reach out to us with any questions about IP protection in the middle kingdom.

2. Story of the Month

After graduating from university, Yanhui Wang worked at a major patent office in China for six and a half years. She was responsible for all patent operations in the field of chemistry pertaining to Japan and China. Ms. Wang then gained employment with a Japanese patent office for two years. She joined our office after qualifying as a Chinese patent attorney in 2011 and as a Chinese lawyer in 2013.

Q1 : What brought you to Sonoda & Kobayashi?

A colleague who used to work in Sonoda & Kobayashi highly recommend it as an international IP law firm which is very friendly to foreigners. So I joined here about four years ago.

Q2: What do you enjoy about working at here?

We can express our views freely, and my colleagues are coming from different countries. I find it very interesting to experience different cultures.

Q3: Tell us one thing about yourself many people do not know?

I used to drive through vast grasslands, wild road, etc. for many days.

Q4: What is your most memorable moment here?

On the 20th anniversary of our firm, many colleagues invited their families to the party. We could meet our colleagues' families and learn interesting stories about them. Now because of the pandemic, we can't see each other face-to-face. That scene is what I miss most and won't ever forget

Q5: Pick a Japanese word to describe the office and explain why.

信頼感、安心感 “Shinraikan”, “Anshinkan” meaning “feeling of trust” and “sense of safety”
As a foreigner, I am given considerable trust and support to develop the business. We have no social pressure in the firm, so we can focus on our work in a relaxed way.

JPO and CNIPO News

1. JPO strengthens cooperation with ASEAN

On the 3rd of August, the JPO and ASEAN held the 11th ASEAN-Japan Patent Office Commissioners' meeting. In this edition, they approved the action plan for IP cooperation in 2021, and also discussed the results of a survey on patent examination for AI-related invention in the ASEAN countries.

The meetings have been held regularly in the framework of the ASEAN's IP action plan 2016 – 2025 where they aim to improve the IP environment in the region. The JPO has been working with the ASEAN countries in various ways to deepen cooperation.

In the meeting it was decided to (further) cooperate on:

- Organizing a second expert meeting to share knowledge on the development of patent examination standards for advanced technologies
- A study will be conducted on the status and challenges of using of patent information
- A study on will be conducted for each country on their patent examination operations in the field of advanced technologies
- Promote accession to the Madrid and The Hague agreements
- Promotion of cooperation on Human resource development and prosecution management
- Promotion of cooperation on commercialization of IP and IP awareness

During the meeting, the parties also discussed the results of a survey on patent examination on AI-related inventions. The study looked at how certain example cases listed in the JPO's handbook are judged based on the practice in ASEAN countries. The contents will be used for the 2nd expert meeting later this year.

For more information, please click [here](#) (in Japanese).

2. JPO releases guide to support trademark applications

On the 5th of August, the JPO published its guide to support trademark application called “How to apply for a trademark” (Shohyou shutsugan tte dou yaru no?). The point of this guide is to provide easy-to-understand pointers to improve the quality of trademark

application and prevent rejections.

In recent years, the number of trademark applications in Japan has risen, and particularly so those submitted by SMEs. Small- and medium-sized businesses now make up 60% of all domestic trademark applications. The guide aims to support these businesses and help them avoid common stumbling blocks.

The full guide can be found in Japanese [on this page](#).

3. CNIPA held a regular press conference for the third quarter

On July 14, 2021, CNIPA held a press conference that included two parts. The first part released the semi-annual statistical data of patents, trademarks, geographical indications and integrated circuit layout-designs, and analyzed the main characteristics of the statistical data in the first half of 2021. The second part answered reporters' questions regarding relevant issues.

In the first part, in addition to the semi-annual statistical data of patents, trademarks, geographical indications and integrated circuit layout-designs, data on the protection and application of intellectual property rights were also released. For example, in the first half of 2021, 339,000 patents were authorized and 3,724,000 trademarks were registered. The number of administrative adjudication cases of patent infringement disputes in various provinces (regions and cities) across China is 13,800. The amount of pledge financing of patents and trademarks in the whole country was 107.4 billion yuan, a year-on-year increase of 25.9%; the number of pledged projects was 6195, a year-on-year increase of 32.4%. The other section focused on the main characteristics of the statistical data in the first half of 2021. Among them, by the end of June, the average examination cycle of invention patents in China had been reduced to 19.4 months, the examination cycle of high-value patents had been reduced to 13.4 months, and the average examination cycle of trademark registration was unchanged at within 4 months. In addition, the data also showed that the grant and registration of intellectual property rights for foreign applicants continued to grow in China.

In the second part, CNIPA answered reporters' questions, regarding, for example, the situations of the introduction and implementation about "the early resolution mechanism of drug patent disputes (trial)" and "Measures for administrative adjudication of major patent infringement disputes" issued by CNIPA.

More information can be found [here](#) (in Chinese)

- Latest IP News in Japan -

1. Toyota leads in Electric vehicle patents, but not in sales

Nikkei Asia, 2 September 2021

On the 2nd of September, Nikkei Asia reported on Electric Vehicle (EV) technology and sales.

In particular, the newspaper teamed up with a research firm to investigate global companies and their competitiveness regarding EVs.

While Tesla and Volkswagen are ahead of Japanese automakers when it comes to EV sales, Japanese car makers do hold important EV-related patents. In the competitiveness ranking, based on EV-related patents in the U.S., factors such as how often patents are cited or disputed were used to determine a score.

Toyota came out on top in the number 1 spot, and a grand total of 21 Japanese companies made it into the top 50. Among these are parts maker Denso, Honda Motor and Nissan Motor.

Also in the top 50 are 13 American companies, such as Ford, General Motors and Tesla, and several South Korean and German companies, namely Hyundai and Robert Bosch. Chinese companies BYD and Nio ranked 32nd and 47th respectively.

The analysis looked at patents for EV parts such as motors and batteries, but also at infrastructure pieces like charging stations. An analysis of the EV-related patents in the EU reinforced the picture of Japan's lead in the field.

According to the article, the high ranking for competitiveness stems from Japan's success with Hybrid vehicles that use many of the same components as EVs. Yet the main challenge for Japanese companies is a familiar one, also faced by companies in the consumer electronics sectors from the country: the need to translate strength in hardware into marketable products. Without a leading market position when it comes to selling EVs, the technological advantage of Japanese companies may be lost.

In 2020, Tesla sold more EVs than any other company in the world, while BYD and several other Chinese manufacturers accounted for about 20% of unit sales. Japanese car manufacturers Nissan and Toyota however do come close enough.

In terms of relative technological advantage, Tesla is ahead in thermal management technology, which is important in stopping batteries from wearing out quickly. Ford, meanwhile, has efficient air conditioning technology, and is aiming to make EVs 40% of its sales by 2030.

The picture for Chinese EV companies is a little bit harder to interpret, but the expectation is that they will become a bigger force internationally.

The article ends with a warning that if Japanese technologies cannot connect their technology with the business side, car makers could wind up in a similar global position as the Japanese electronics industry.

More info can be found [here](#).

2. Japanese city of Matsuyama trademark's name of a local dance

NHK, 6 September 2021

On the 6th of September, NHK published an article on the city of Matsuyama in Ehime prefecture. The city had applied for a trademark for a locally originated dance, and its application has recently been approved by the Japanese Patent Office.

The name of the dance “Yakyuken Odori” means “baseball fist dance” and was born in the city during the Taisho era (1912 -1926). It is a dance during which participants play rock-paper-scissors, and was first performed after a baseball game.

While it is not unusual for local government to trademark names of agricultural products and specialties, it is rare for this to happen to a name of a dance.

The article mentions that the local government of Matsuyama likely aims to enhance its brand image thereby making the city more well-known around the country.

More information can be found [here](#) (in Japanese).

- Latest IP News in China -

1. ZTE, one of China's 5G leaders, has more than 40000 global granted patents

Sina, September 4, 2021

On August 31, 2021, Sina reported on the World 5G Convention held in Beijing, during which more than 1500 industry experts and enterprise elites at home and abroad participated in the convention forum in the form of Online + Offline.

In the convention, ZTE, a well-known domestic ICT listed enterprise, also disclosed that they had developed 5G ATG Aviation Internet. In addition to the research on 5G Network, ZTE has already planned another unique strategic layout mode - intellectual property rights layout in the field of information and communications.

In terms of quantity, ZTE's patent layout is indeed at the forefront of the industry. In February this year, the report "Who is leading the 5G patent race" released by IPLytics, an international well-known patent data company, showed that ZTE disclosed to ETSI (European Telecommunications Standardization Association) that the total number of declared standard-essential patents for 5G ranked third in the world.

In fact, according to the semi-annual report recently disclosed by ZTE, ZTE has more than 80000 global patent applications, and more than 40000 global granted patents over the years. On the issue of patent layout, ZTE has also adopted the "cross-border + closed-loop" mode. It is reported that ZTE will reach a patent cross-licensing with mainstream enterprises in the industry, and realize rapid iteration from new technologies to new products through commercial interaction, so as to promote the expansion of the technologies of communications industry to vertical industries. At the same time, ZTE will also manage and recover reasonable R&D investment through transfers, licenses, etc., so as to achieve a closed loop of sustainable development of innovation, management and re-innovation.

More information can be found [here](#) (in Chinese).

2. Statistical analysis report on patent cases which were declared invalidation in China

Patent Reexamination, August 25, 2021

“Patent Reexamination”, published a data statistical analysis report on August 25th regarding patent cases which were declared invalid in China in June 2021.

In concrete terms, in June 2021, CNIPA issued 601 examination decisions of the request for invalidation, and “Patent Reexamination” collected and analyzed the data thereof.

-01. Patent types

Among 601 examination decisions of the request for invalidation, the largest group was patents for design, followed by patents of utility model, and the number of patents for invention was the smallest, comprising 273 patents for design, 242 patents for utility model and 86 patents for invention.

-02. Technical fields

The technical fields of patent for invention and patent for utility model mainly include medicine, architecture, transportation, electricity, etc.

-03. Invalidation petitioner and patentee

There is a situation in which the same petitioner for invalidation made a request for invalidation of multiple patent rights of the same patentee.

-04. The origin of petitioner for invalidation and patentee

The overwhelming majority of the petitioners for invalidation are companies registered in China or natural persons of Chinese origin. Among them, the request for invalidation in the name of natural persons accounts for more than 1/3.

Most of the patentees are companies registered in China or natural persons of Chinese origin, involving 567 cases. 34 cases of patents from foreign patentees had been requested for invalidation. Among them, the highest number of cases is 10 cases from Japanese patentees, followed by 7 cases from American patentees, 5 cases each from German and Swedish patentees, and 1 case from the patentee of another country.

-05. Trial cycle

The trial cycle is calculated from the "date of request for invalidation" to the "date of issuance of invalidation decision". The trial cycle of invalidation cases by CNIPA is mostly 5 ~ 8 months. From the statistical results, the trial cycle is not necessarily related to the types of patents.

-06. Maintenance period of patent right

Among the 307 cases which had declared a patent right completely invalid the maintenance period of patent right (from the “date of announcement of granting the patent right” to the “date of issuance of invalidation decision”) is mostly 1-3 years, and the patents with a longer maintenance period are fewer in number.

-07. The ratio of different invalidation types

Declaring a patent right completely invalid: 51.1%, declaring a patent right partially valid in part: 12%, and maintaining the validity of a patent right: 36.9%.

-08. Causes of request for invalidation

Among the 153 cases of patent for design in which a patent right was declared completely invalid, the main legal basis is Article 23, paragraph 1 (novelty) and Article 23, paragraph 2 (no obvious difference) of the patent law. Among the 126 cases of patent for utility model in which a patent right was declared completely invalid, the main legal basis is Article 22, Paragraph 3 (inventiveness) of the Patent Law, and a small number of cases were declared completely invalid only based on the drafting forms. Among the 28 cases of patent for invention in which a patent right was declared completely invalid, the main legal basis is Article 22, Paragraph 3 (inventiveness) of the Patent Law.

More information can be found [here](#) (in Chinese) .

- IP Law Updates in China : Insights from Sonoda & Kobayashi -

• Drug Patent Linkage System in China

September 10, 2021

Author: [Yanhui Wang](#)

1. Background

China has tried to establish a drug patent linkage system since 2019. After several years, the patent linkage system was finally officially implemented this year. The purpose of the system is to protect the legitimate rights and interests of drug patentees, reduce the risk of patent infringement after generic drugs are listed, and ensure the early settlement of patent disputes before generic drugs are listed. The implementation of this system involves the revision and promulgation of a series of relevant laws and regulations, which has taken a long time to realize and is still being improved.

2. Relevant laws and regulations

(1) On October 17, 2020, CNIPA issued the fourth amendment to Chinese Patent Law^[1], which came into effect as of June 1, 2021. Article 76 of the newly amended Patent Law introduces the drug patent linkage system for the first time, clarifying the cause of action and routes of patent linkage litigation. The cause of action includes confirming whether the drug of the approval application falls within the scope of a relevant patent, and disputes shall be resolved through judicial or administrative means.

(2) On July 4, 2021, the National Medical Products Administration (NMPA) and CNIPA jointly issued the Measures for the Implementation of Early Resolution Mechanisms of Drug Patent Disputes (Trial) (hereinafter referred to as "Trial Measures")^[2], which was effective from the issue date and includes the following:

-Patent registration system

The Drug marketing authorization holders shall register the patent information related to drugs on the "China listed drug patent information registration platform (CDE)" (<https://zldj.cde.org.cn/home>) within 30 days of receiving the drug registration certificate as well as update their registrations within 30 days of any change, which will be the basis for the generic drug applicant to make a patent declaration. At present, the types of patents allowed to be registered for chemical drugs and biological drugs include: compound patents for active ingredients of chemical drugs, combination patents containing active ingredients of chemical drugs, and patents for pharmaceutical uses of chemical drugs; traditional Chinese medicine composition patents, Chinese medicine extract patents, and pharmaceutical use patents of traditional Chinese medicine; patents for sequence structure of active ingredients of biological products, patents for pharmaceutical uses of biological products. Please note that relevant patents do not include: patents for intermediates, crystal forms, metabolites, preparation methods, and detection methods.

-Generic drug patent declaration system

When submitting the approval application, the generic drug applicant shall make a declaration on each relevant drug patent. The declaratory statement should fall under one of the four categories: 1. there is no patent information related to the generic drug in the "China Listed Drug Patent Information Registration CDE "; 2. the relevant patents of CDE have been terminated or declared invalid; 3. the CDE contains relevant patents, and the generic drug applicant promises not to be listed before the expiration of the patent period; 4. the relevant patent rights included in the CDE should be deemed invalid, or the generic drug does not fall within the scope of the patent.

Only when the generic drug applicant makes the fourth declaration and the patentee or interested party has an objection, it is possible to file a lawsuit or apply for administrative adjudication within 45 days from the publication date of the application on the CDE platform.

-Judicial or administrative linkage system

According to Article 7 of the Trial Measures, if the patentee or interested party raises an objection, he/she can choose to take action through either a judicial or administrative route. If an administrative ruling from CNIPA is sought, it will still be possible to bring a lawsuit to the Beijing Intellectual Property Court. On the contrary, according to Articles 4 and 10 of the Trial Measures, if the case has been brought before the court, CNIPA will no longer accept it. After the generic drug applicant makes the fourth declaration, the patentee may file a confirmation lawsuit or apply for confirmation administrative adjudication in accordance with Article 76 of the Patent Law and Article 7 of the Trial Measures. Then the patentee shall notify the generic drug applicant within 15 working days from the date of acceptance of the confirmation lawsuit or confirmation administrative adjudication. Accordingly, the NMPA will suspend the approval procedure of the generic drug and set a nine-month waiting period for administrative approval.

On the other hand, if the patentee fails to file a confirmation lawsuit or apply for confirmation administrative adjudication within 45 days, the waiting period for administrative approval will not be triggered, and the generic drug will smoothly enter the administrative approval procedure. The patentee also has no right to raise any objection to the approval decision of the generic drug marketing license issued by NMPA.

-Approval waiting period system

As mentioned above, from the date of filing or acceptance by the court or the CNIPA for the confirmation lawsuit or confirmation administrative adjudication, NMPA shall set a waiting period of nine months for the approval application of the chemical generic drug. During the waiting period, the National Drug Review Institution shall not stop the examination.

It should be noted that the "waiting period" only applies to chemical drugs. There is no waiting period for biological drugs.

-Classification system for drug approval

If a judicial or administrative ruling is received within nine months, NMPA shall handle the application as follows: I) if it is confirmed that the generic drug falls within the scope of patent protection, the approval procedure of the chemical generic drug application will be suspended until 20 working days before the expiration of the patent; II) if it is confirmed that the generic drug does not fall within the scope of patent protection, if a settlement has been reached between the two parties, or if the patent is declared invalid, the application for the chemical generic drug shall be transferred to administrative examination for approval.

-First generic drug market monopoly system

For the chemical generic drug that is the first to have successfully challenged the relevant patent and the first approved for listing, a market monopoly period shall be given. NMPA shall no longer approve the listing of generic drugs of the same variety within 12 months from the date of approval of the drug, and the market monopoly period shall not exceed the patent period of the challenged drug.

(3) On July 5, 2021, the Supreme People's Court and CNIPA respectively issued the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drug Registration Applications (hereinafter as the "Civil Provisions")^[3] and the Administrative Adjudication of the Early Settlement Mechanism of Drug Patent Disputes (hereinafter as the "Administrative Adjudication Measures")^[4], which came into force as of the date of promulgation.

According to Article 1 of the Civil Provisions, a case of first instance brought by a party to confirm whether a drug falls within the scope of patent protection shall be under the jurisdiction of the Beijing Intellectual Property Court. In terms of acceptance conditions, in addition to the general acceptance conditions for civil litigation, the following materials shall be submitted: (1) relevant patent information registered in the CDE, including the title, number, relevant claims, etc. of relevant patents; (2) relevant information of the drug, including the drug name, drug type, registration category, and the corresponding relationship between the drug of the registration application and relevant listed drugs;(3) the fourth declaratory statement made by the applicant and the basis of the statement. However, if the applicant is not satisfied with the judgement of first instance, he/she may appeal to the Supreme Court.

The Administrative Adjudication Measures stipulate that CNIPA shall establish an administrative adjudication committee, and organize and carry out the work related to the administrative adjudication.

3. Conclusion

Sine the new patent linkage system has just come into force, there are some points worthy of attention.

(1) To register or not?

The first step is information disclosure/patent registration. The holder of a drug marketing license shall register all relevant patents within 30 days after obtaining the drug registration certificate. At this time, since registration is not mandatory according to existing legal documents, whether to register or not depends on the commercial consideration of the drug marketing license holder. Without registration, it is impossible to use the drug patent link system to solve disputes early, or to prevent or delay the listing of generic drugs.

(2) When a relevant patent has been invalidated, the administrative waiting period ends and the generic drug enters the approval procedure. An invalidation decision often goes through litigation procedures of first and second instances, and the effective cycle of the invalidation decision is much longer than the nine-month waiting period, so it is doubtful whether a valid judgment can be obtained within nine months.

In addition, administrative rulings are not final. If a party is not satisfied with an administrative ruling, the party can bring an administrative lawsuit to the court. According to the Measures for Patent Administrative Law Enforcement, the trial time limit of a patent administrative ruling is three months and can be extended by one month if the case is complex. That is, the results of administrative adjudication can be obtained in three to four months, which has the advantage of rapidity. In contrast, according to the Civil Procedure Law, the trial time limit of civil cases of first instance is six months and that of second instance is three months. Moreover, in view of the current backlog of cases at the Beijing Intellectual Property Court, it is basically impossible to receive a judgment within the nine-month waiting period. To sum up, under the current situation, the administrative route will likely be the first choice in most cases.

(3) Under the "first generic drug market monopoly system" for the generic drug applicant, NMPA will no longer approve the listing of generic drugs of the same variety within 12 months from the date of approval of the "first generic." Generic drug companies may have greater motivation to challenge the patents of original drugs.

(4) At present, China's patent linkage system does not have any provisions similar to the "data protection period" in other countries. For example, the time interval between the approval of a small molecule new drug and the submission of Abbreviated New Drug Applications (ANDA) for generic drugs in the United States is at least 4 years; and in Japan and nearly 30 EU countries, this period is at least 8 years. However, at present, the time between the approval of a new drug application (NDA) and ANDA is legally "zero interval" in China.

As can be seen from the foregoing, there remain many problems that need to be addressed, especially with respect to the balance between the interests of innovative drug developers and generic drug manufacturers. The evolution of this new patent linkage

system will no doubt be the focus of attention of many drug developers and manufacturers in years to come.

[1] https://www.cnipa.gov.cn/art/2020/11/23/art_97_155167.html

[2] https://www.cnipa.gov.cn/art/2021/7/5/art_546_160571.html

[3] https://www.cnipa.gov.cn/art/2021/7/5/art_546_160569.html?xxgkhide=1

[4] <http://www.court.gov.cn/fabu-xiangqing-311791.html>

About

SONODA & KOBAYASHI is a law firm offering dependable legal services for intellectual property. Our multinational team of about 90 experts in technology, law, languages and international communication has served companies worldwide and gained a reputation for thoroughness and reliability.

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