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- News about Sonoda & Kobayashi -

1. Sonoda & Kobayashi holds webinar on Chinese patent law implementation rule amendments

On the 29th of February, Sonoda & Kobayashi held a webinar on the theme "News about China's Patent Term Extension, Open Permissions System, and more! Points to note on the revised Implementing Regulations of the Patent Law of China." presented by <u>Mr. Ma</u> (Chinese Patent Attorney, Sonoda & Kobayashi Beijing IP Group). We extend our thanks to the attendees of this online event.

2. Sonoda & Kobayashi participates in the Global IP Exchange 2024 in Dusseldorf

Sonoda & Kobayashi attended the Global IP Exchange, in Dusseldorf, Germany on the 11th and 12th of March. Dr. Yoshitaka Sonoda (Founder), Mr. Munenori Sakurai (Japanese Patent Attorney), and Ms. Debora Cheng (New Zealand Lawyer, International Affairs) represented our firm at our booth, and Dr. Sonoda gave a presentation on "Strategic use of Advisory Opinions of the JPO" as an official speaker. We would like to thank everyone who interacted with us during the event.

- JPO and CNIPA News -

1. JPO publishes additional examples on the examination of AI-related technologies

On the 13th of March, the JPO published new additional examples on its website on the examination of Al-related technologies.

As technologies that relate to artificial intelligence continue to develop further and patent applications for these technological fields continue to increase, the JPO continues to add new types of examples that were not covered by existing cases.

Further information can be found <u>here</u> in the presentation describing the new cases, as well as <u>here</u> in the updated examination handbook that contains these 10 cases.

2. JPO's Trial and Appeal study group publishes annual report

On March 22nd, the Trial and Appeal Study Group of the JPO published its annual report for the 2023 financial year.

In this study group, participants came together to study trial and appeal decisions as well as court decisions. Participants included corporate IP professionals, patent attorneys, and attorneys at law, as well as professionals from the public sectors such as chief administrative judges and administrative judges.

For 2023, the group studied 4 fields of patent applications (Machinery, Chemistry 1 and Chemistry 2, and Electricity) as well as general issues related to designs and trademarks. The study group had in-depth discussions on specific cases in the above fields and shared their perspectives from their different positions.

The results of the group's discussions were based on "a multifaceted consideration of issues and points of contention that are important in practice and lead to concrete understanding or clarification of the criteria for determination" (can be found in part two of the report linked below). These results were then used by the JPO's administrative judges, examiners, and other officials at the JPO.

An English summary of this year's report is available here.

3. CNIPA issues notice on the handling patent open licensing system

From January 20, 2024, the CNIPA has started examining the patent open license declaration submitted by the patentee in accordance with Article 50 of the Chinese Patent Law and Articles 85 to 88 of the Detailed Rules for the Implementation of the Patent Law and Chapter 11 of Part V of the Patent Examination Guidelines.

1. Timing of submission After the publication announcement of the grant of the patent right.

2. Submission method In electronic form.

3. Submission of materials

Including signed or sealed declaration of the patent open license, a brief explanation of the basis and method of calculating royalties, etc (Section 3.3 of Chapter 11 of Part V of the Patent Examination Guidelines).

4. Fees

If the patentee submits a request for the filing of a patent open license exploitation contract in accordance with the provisions of Article 51, Paragraph 2 of the Patent Law and Article 87 of the Detailed Rules for the Implementation of the Patent Law, and is granted permission for filing, the CNIPA shall, after the implementation of the patent fee standards and payment reduction policies issued by the development and reform department of the State Council, the finance department and the CNIPA, implement a reduction in the payment of the patent annuity fee that has not expired from the date of filing of the contract during the implementation period of the patent open license in accordance with Section 8 of Chapter 11 of Part V of the Patent Examination Guidelines.

5. Review and notification

If the patent open license statement meets the requirements after examination, the CNIPA shall issue a notice of approval of the announcement of the patent open license statement.

6. Registration and announcement

Matters related to the declaration of patent open license shall be registered in the patent register and published in the patent gazette, including main classification number, patent number, open license declaration number, patentee, title of invention, filing date, date of grant announcement, payment method and standard of patent license royalties, patent license term, contact information of the patentee, effective date of the declaration of open license, etc.

7. Remedies

If the patentee is not satisfied with the decision on whether to reduce the annual fee during the implementation period of the patent open license, the patentee may make a statement to the CNIPA, consult by telephone, or apply for administrative reconsideration.

Further information can be found <u>here</u>. (Chinese)

4. CNIPA introduces progress of intellectual property work in 2023 in press conference

On January 16, 2024, the CNIPA introduced the progress of intellectual property work in 2023.

1. Patents

921,000 invention patents, 2.09 million utility model patents and 638,000 design patents were authorized throughout 2023. 65,000 patent re-examination cases were concluded, and 7,700 invalidation cases were concluded. 74,000 PCT international patent applications were received. Chinese applicants filed 1,814 international Hague design applications.

2. Trademarks

There were 4,383,000 registered trademarks throughout the year of 2023. The examination of 153,000 trademark opposition cases was completed, as well as the trial of 373,000 trademark review cases. 6,196 Madrid applications for international trademark registration were received from Chinese applicants.

By the end of 2023, the number of valid trademark registrations in China will be at 46,146,000.

3. Geographical indications

During the year, thirteen geographical indication products were granted, and 201 geographical indications were granted for registration as collective trademarks and certification trademarks. 5,842 business entities have been granted to use special geographical indications.

By the end of 2023, China had granted a total of 2,508 geographical indication products, granted 7,277 geographical indications as collective trademarks and certification trademarks, and the total number of business entities for geographical indications has

reached 26,000, with an annual output value of more than 800 billion yuan.

4. Layout design of integrated circuits

In the whole year, 11,000 integrated circuit layout design certificates were registered and issued.

By the end of 2023, a total of 72,000 integrated circuit layout designs have been issued in China.

5. The enforcement of intellectual property rights

The registered amount of patent and trademark pledge financing was 853.99 billion yuan, benefiting 37,000 enterprises. Statistics show that in 2022, the added value of China's patent-intensive industries will be 15.3 trillion yuan, an increase of 7.1% over the previous year (before deducting price factors), and the proportion of GDP will rise to 12.7%.

Further information can be found here. (Chinese)

- Latest IP News in Japan -

1. Behind the Curve: Japan's Struggle with University Patents

Nikkei Asia, March 9, 2024

On the 9th of March, Nikkei Asia reported on the struggle of Japanese universities to commercialize their researched intellectual property, despite having a comparable number of patents to American universities.

According to the article, Japanese universities struggle to effectively utilize their intellectual property due to a lack of support systems connecting research outcomes to businesses. This deficiency is highlighted by the fact that top Japanese universities earn only 2% as much from patents as their U.S. counterparts.

Unlike some overseas universities, where experts assist in identifying commercial potential in research, Japanese institutions face staffing shortages and limited funding for patent strategies and commercialization. Despite having a comparable number of patents to American universities, Japanese institutions generate significantly less revenue from them.

Few Japanese universities offer support programs for researchers looking to start businesses, and only a small percentage have patent attorneys. This disparity in support infrastructure hampers researchers' ability to engage in both research and business development. In contrast, leading U.S. and European universities benefit from robust support systems for patents and business strategies, contributing to the success of startups and the proliferation of unicorns in those regions.

The Japanese government's focus on research programs leaves a gap in funding for mechanisms linking research outcomes to revenue generation. Experts emphasize the need to bolster support for commercializing research findings and to cultivate individuals

with expertise in both technology and business to drive innovation and entrepreneurship in Japan.

Further information can be found here. (English)

2. Conveyor Belt Conflict: Sushi Chains Clash Over Alleged Unfair Competition *NHK, March 12, 2024*

On the 12th of March, NHK reported on a conflict between two conveyer belt sushi chains, stemming from a potential violation of the Unfair Competition Prevention Act.

Kappa Sushi and Hama Sushi are two competing sushi restaurant chains in Japan. The parent company of Hama Sushi, Zensho Holdings Co., filed a suit in the Tokyo District Court against Kappa Sushi's parent company, Kappa Create Co., its former president Koki Tanabe (47) and another entity.

Zensho alleges that Tanabe, formerly an executive at Zensho prior to working for Kappa, illegally took trade secrets such as cost data and an earnings statement of Hama Sushi and shared them within Kappa. Zensho claims that this has caused them a loss of over 6.3 billion yen and is seeking 500 million yen in damages from Kappa Sushi, Tanabe and the other party, and also demands the destruction of the information allegedly taken.

If Kappa Sushi did violate the Unfair Competition Prevention Act, this unauthorized acquisition and use of sensitive business information could provide Kappa Sushi with an unfair advantage in the market by potentially allowing them to gain insights into Hama Sushi's strategies, pricing, or operations. Such actions could undermine fair competition in the sushi restaurant industry by giving Kappa Sushi an unfair edge over its competitors, including Hama Sushi.

The potential violation of the Unfair Competition Prevention Act, for which Kappa Create was fined, underscores the legal repercussions of engaging in practices that distort competition by unlawfully accessing and exploiting confidential business information from competitors. The legal action taken by Hama Sushi's parent company, seeking compensation for damages resulting from this alleged unfair competition, reflects the seriousness with which such breaches are regarded and the efforts made to protect fair competition within the industry.

Further information can be found here. (Japanese)

- Latest IP News in China -

1. Huawei and Amazon enter into global patent licensing agreement

Reuters, March 5, 2024

Reuters reported that on March 5th, Huawei Technologies of China and the U.S. tech giant Amazon have announced the signing of a multi-year agreement for patent licensing, marking the resolution of their ongoing litigation. While specific terms of the deal remain

undisclosed, Alan Fan, who heads Huawei's intellectual property rights department, revealed that the Chinese company has withdrawn its lawsuits against Amazon in Germany concerning patented technology related to Wi-Fi and video playback.

The backdrop of strained relations between the United States and Chinese telecom companies, such as Huawei and ZTE, has been marked by regulatory actions, including the barring of Chinese firms from the U.S. market over data security concerns. This has necessitated the removal of Huawei and ZTE equipment from U.S. networks by American carriers, further exacerbated by restrictions on U.S. firms supplying components to Huawei, impacting its smartphone business.

Nevertheless, Fan emphasized that the patent licensing agreement signifies a noteworthy collaboration between American, Chinese, and other global companies in standards and patent licensing, despite geopolitical tensions.

Additionally, Huawei announced another cross-licensing patent agreement with the Chinese smartphone manufacturer Vivo, covering communication technologies, particularly 5G. This move echoes Huawei's existing patent arrangements with other Chinese smartphone giants such as Xiaomi and Oppo.

Further information can be found here. (English)

2. Oppo ends long-standing legal dispute with Nokia, will pay 5G royalties *South China Morning Post, February 16, 2024*

On February 16th, The South China Morning Post reported that Oppo and Nokia have resolved their global patent dispute with a licensing agreement, ending years of legal battles over cellular patent rates. The disagreement, spanning 12 countries since 2021, resulted in bans on Oppo's smartphone sales in some markets where courts ruled in favor of Nokia. Following a recent ruling in China, Oppo petitioned for lower royalty rates for Nokia's patents, which was supported by a Chinese court.

Under the newly announced agreement, Oppo will pay royalties to Nokia for using its 5G and other cellular technology patents. Both companies will drop pending litigation worldwide. However, specific terms and fees of the deal remain confidential.

This agreement is crucial for Oppo, the fourth-largest smartphone brand globally, as it aims to resolve legal challenges and boost sales amidst tough competition. Meanwhile, Nokia has also struck similar licensing deals with other smartphone makers, including Honor, to safeguard its intellectual property rights.

Further information can be found here. (English)

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

1. Patent Term Extensions (PTE) in China

Yanhui Wang (Chief Attorney (Chinese Law), Sonoda & Kobayashi Beijing IP Group)

The fourth amendment to Chinese patent law (Article 42) introduced PTE into China for the first time in 2021, and 2 years later, China revised the Implementing Regulations of the Patent Law and the Guidelines for Patent Term Extensions (PTE) which entered into force on January 20, 2024.

CNIPA has yet to publish the official fees for PTE. Examinations will begin once the official fees are published.

This article will describe an extensive overview of PTE applications, including our recommendations.

Deadline for filing PTE application

Within three months from the (drug) approval date. Please note that drugs are limited to those approved after June 1, 2021. The issue date of the patent must be earlier than the drug approval date in China.

Applicant eligibility

Only patentees can file the PTE application.

If the patentee is not the holder of the marketing approval, then written consent from the holder of the marketing approval shall be requested by CNIPA.

Allowable types of drugs

PTEs are available for drugs in China on <u>new drugs and improved new drugs</u> that have been approved for the first time in China according to Article 42(3) of the Chinese Patent Law.

However, neither the Patent Law nor the Implementing Rules gives a specific definition for "new drugs". Following the provisions of the Measures for the Administration of Drug Registration (2020), **"new drug"** refers to innovative drugs. This refers to new drugs that have not been approved in China or **abroad**, meaning Class 1 drugs of drug registration classification, which are "new globally", not just new in China.

"Improved new drugs" will be eligible if the classes listed on the drug certificates issued by NMPA fall into one of the following categories (Guideline Part 5, Chapter 9, Section 3.4).

- Chemical drugs of class 2.1 that perform esterification or salification on known active ingredients
- Chemical drugs of class 2.4 (i.e. drugs containing known active ingredients for new indications)
- Preventive biological products of class 2.2 that are vaccines improved against bacterial or viral strains
- Therapeutic biological products of class 2.2 for new indications
- Traditional Chinese medicine of class 2.3 (i.e., traditional Chinese medicine with increased indications).

The simplest way to know if the drug is eligible for PTE or not is to check the drug certificates issued by NMPA. If the classes that have been approved by NMPA belong to these five classes, then the drug is eligible for PTE in China.

It can be understood that medical devices/instruments/equipment cannot be the subject matter for a PTE application.

Moreover, drugs eligible for PTE are those covering an active pharmaceutical ingredient that is approved for marketing for the first time in China ("new API").

Allowable Patents

PTE is available to patents related to products, preparation methods, or medical uses of new drugs (Art. 42(3), Reg. 80).

Patents can claim a product (including compound, formulation, crystal, composition etc.), medical uses (including both first and second medical uses), or a preparation method (including method of manufacture)

Moreover, although this is not explicitly described in the CNIPA Examination Guidelines, starting material, intermediate patents, and administration methods are not eligible for PTE in China.

We note that the medical use must be in the form of Swiss-type claims, as treatment and diagnosis methods are not patent-eligible in China.

For example, the recommended format for medical uses by CNIPA is:

"A use of substance A in the manufacturing of a medicament for treating indication X."

While the recommended format for medical uses by JPO is:

"A medicament for treating indication X, the medicament comprising substance(s?) A."

Scopes of Patents to be Extended (Guideline Part 5, Chapter 9, Section 3.5)

The protection scope during the compensation period does not directly extend to the original patent rights.

The protection scope of claims related to new drugs shall be based on the structure, composition, and content of the new drugs approved by NMPA, as well as the approved production process and indications.

- The protection scope of product claims is limited to the approved new drugs for the approved indications.
- The protection scope of medical use claims is limited to the approved indications of the approved new drugs.
- The protection scope of preparation method claims is limited to production processes filed with the NMPA for the approved new drugs for the approved indications.

For example:

The approved new drug: Class 2.1 of chemical drugs The active pharmaceutical ingredient: A1 The medical use approved: The treatment of asthma The patent claims involve compound A1 of the general formula.

In this case, during the compensation period, the scope of protection of this patent is limited to "the use of the treatment of asthma of compound A1" or "compound A1 for the treatment of asthma."

So generic drug companies may only need to remove the first indication in the label to overcome the possibility of infringement and the limitation of compound patents.

Term of Extension

PTE = (China marketing approval date – the filing date of the Chinese patent) – 5 years The term is extendable up to a maximum of 5 years, and less than 14 years after marketing approval.

Requirements

Here are the requirements for PTE in China. Failure to observe these may be a reason for rejection of the application.

- 1. The patent term must not have expired.
- 2. The new drug must fall within the scope of the patent.
- 3. The patent must not have been previously granted one PTE, which means each patent can only be extended once (Reg. 81)
- If one patent covers multiple drugs, a PTE request can be based on one drug only (Reg. 81);
- 5. If the drug is protected by multiple patents in China, PTE is granted for only one of the patents in the patent family covering the drug (Reg. 81).

For example, if a drug A1 involves multiple patents B1, B2... Bn, the patentee can only choose one of the patents (such as B1) for the PTE application. If these patents B1, B2... Bn, belong to different patent owners, then it is completely unclear and unknown which patent owner the PTE should be granted to. However, according to the consultation window of CNIPA, these patent owners need to negotiate which one should be chosen for PTE application. Otherwise, the PTE may be granted to the patentee who filed the earliest application.

On the other hand, if a patent, such as B2, covers more than one drug (such as a combination formula A1, A2... An with different claims involving different compounds), and all of these drugs have been approved by the NMPA, the patentee of patent B2 can only choose one of the drugs (such as A2) for the PTE application.

Documents Needed for PTE Application

- 1. Request letter: the approval information and the patent information.
- 2. A copy of the approval certificate.
- 3. Written statement: if the patentee is not the same as the holder of the drug marketing license.
- 4. A part of the approval application documents proof materials including relevant materials such as description, production processes, quality standards, etc.
- 5. Explanation of compensation reasons based on supporting materials, such as:

- Identifying the claims related to drugs and provide specific explanations of the claims including drug-related technologies based on the proof.
- Calculating the basis for requesting PTE.
- Clarifying the scope to be protected during the compensation period.

The required materials may vary depending on the approved new drugs for marketing and the types of patent claims for compensation requested. The CNIPA has published formats for reference, and we are also happy to assist with this if needed.

Examination and remedy

The CNIPA will give at least one opportunity for the applicant to make remarks and amendments. If there is any disagreement between a patentee and CNIPA regarding the eligibility or length of a term extension, the patentee or interested parties can apply for administrative reconsideration by the CNIPA.

Subsequently, any party dissatisfied with the reconsideration decision can file a lawsuit with a court within fifteen days of receiving the reconsideration decision.

Access to PTE Application Documents by a Third Party

After PTE is granted, the CNIPA will publish the relevant matters in the patent bulletin and patent publication documents, including the IPC code, application date, patent number, grant date, drug name, approved indications, the original patent term, and the new patent term after extension.

The documents filed for the PTE application (for example, filed Remarks, issued Office Actions and records of interviews with the Examiner) are not available so far.

If a third party wishes to access the PTE application documents, they can access the CNIPA system <u>here</u> to check it.

If the materials involve trade secrets, the relevant content may be redacted, but this shall not affect the judgment of whether the specified claims include new drug-related technical solutions according to the request of guidelines.

PTE in China is a new system, and many things are not clear yet, even for the CNIPA. We will continue to monitor the new changes very closely and check for new updates.

If you have any questions, please feel free to contact us at <u>mailbox@china.patents.jp</u>.

About

SONODA & KOBAYASHI is a law firm offering dependable legal services for intellectual property. Our multinational team of about 100 experts in technology, law, languages and international communication has served companies worldwide and gained a reputation for thoroughness and reliability.

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