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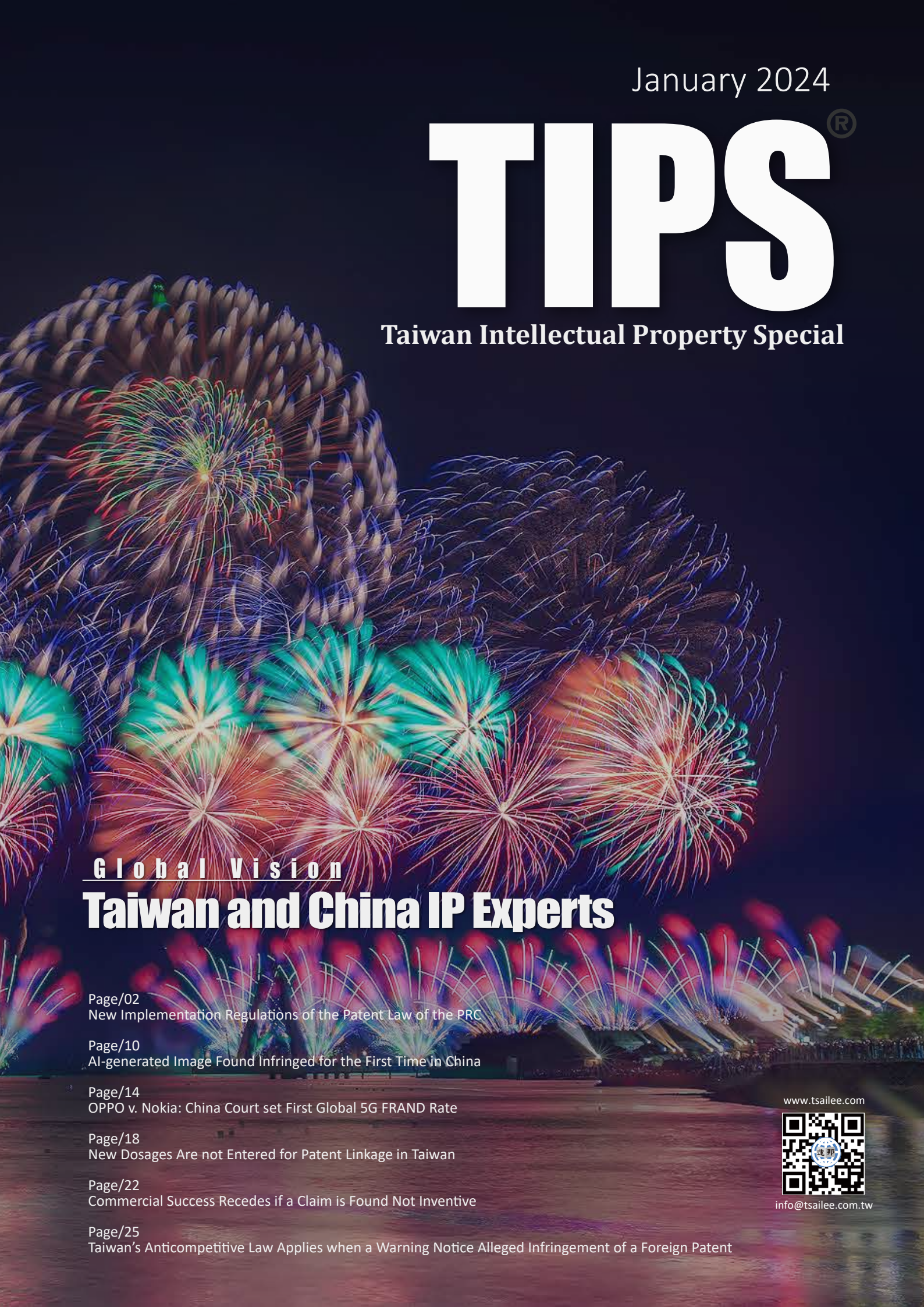

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New Implementation Regulations of the Patent Law of the PRC

On December 11 – before the end of the year 2023 – the State Council of China approved the new Implementation Regulations ("IR") of the Patent Law. The entire text was released several days later along with the new Patent Examination Guidelines. The new IR has come into effect on January 2, 2024.

Good faith as one of the fundamental disciplines was again emphasized in the new IR. Combatting abnormal filings has been one of the most important tasks on the CNIPA' s working agenda in recent years. It is now stipulated in the new IR that the patent prosecution shall be carried out in good faith and must originate from true and genuine activities of invention and creation without the occurrence of any fraudulent events.[1] Violation of the good faith obligation will be subject to a fine.[2] Furthermore, the delayed examination for invention patent applications was officially established in the new IR, followed by the lower-hierarchy operative document – the Invention Patent Delayed Examination Guidelines – which was released a few months ago.[3]

Other important highlights are set forth below.

Removal of mailing buffer time

According to the old rule, the time of delivery of the CNIPA' s document was presumed to be 15 days from the sending date, regardless of whether it was sent by mail or electronically. Under the new IR, this 15-day buffer time period does not apply if the documents are sent electronically. For example, if the first Office action is sent electronically to the applicant's patent attorney, the applicant needs to respond within the prescribed time window (usually four months) without the addition of a further 15 days.

1 Article 11 of the Implementation Regulations
2 Article 100 of the Implementation Regulations
3 Article 56 of the Implementation Regulations

Priority

The 2020 Patent Law opened the door for design applications to claim domestic priority. The new IR further increases the range of applicable priority basis. When a design patent application claims priority to an invention patent or a utility model application, the design(s) disclosed in the drawings of the prior application may serve as a lawful basis for priority. The invention patent or utility model application as the priority basis will not subsequently be deemed withdrawn.[4]

Restoration of priority is now available. Within two months of the expiry of priority, the applicant for an invention patent or a utility model may request for the priority to be restored.[5] Furthermore, for an invention or utility model application with lawfully claimed priority, the applicant is permitted to add or rectify priority claim(s) within 16 months of the priority date or four months of the filing date.[6]

For an invention patent or a utility model application filed with priority right(s), if the claims or description are completely or partially missing or are incorrect, the applicant may correct the error through "incorporation by reference" of the priority application(s) within two months of filing or in a timeframe specified by the CNIPA, in order to preserve the filing date.

Patent Evaluation Report

Designs and utility models are not substantively examined; hence their validity may be vulnerable. The new Patent Law 2020 provides that not only the patentee but also the parties of

4 Article 35 of the Implementation Regulations
5 Article 36 of the Implementation Regulations
6 Article 37 of the Implementation Regulations

interest and the accused infringers can request an Evaluation Report. In accordance with the IR, when the applicant makes such a request in conjunction with the process of patent grant, the CNIPA shall produce and publish the report within two months of the date of grant.[7]

Patent term adjustment (PTA)

To compensate for any unreasonable delay in the course of the examination, a request must be made by the applicant within three months of the patent being granted. An unreasonable delay (in terms of number of days) refers to the time between the date of grant and the date that is four (4) years from the filing date or three (3) years from the date of request for substantive examination, whichever is later, excluding any delay caused by the applicant.[8] Reasonable delays refer to delays caused by re-examination, ownership disputes, and preservation measures during civil litigations, among others. On the contrary, unreasonable delays to be subject to PTA are failure to respond to Office actions, delayed examination, and supplementation of application materials, among others.[9] Moreover, as a special rule, for granted invention patents in the event of parallel filing, PTA is not available.

For PTA requests lawfully made after June 1, 2021, the CNIPA will start to examine these requests as per the Implementation Regulations on January 20, 2024.

7 Article 63 of the Implementation Regulations
8 Article 42(2) of the Patent Law of the PRC
9 Article 79 of the Implementation Regulations

Patent term extension (PTE)

The new Patent Law 2020 stipulates that the compensation term for patents related to new drugs during the examination of Chinese marketing approvals is up to five years.[10] The total remaining patent term after the launch of the new drug for sale shall not exceed fourteen years. The patents of a new drug eligible for PTE are those directing to a new product, preparation method, or medical use.[11] A PTE request must be made within three months of the issuance of the marketing approval.

The definition of a new drug was for some time the subject of debate. Although the new IR does not determine which type of new drugs – either new globally or new in China only – can have their patent term extended, the answer seems to become obvious in conjunction of other reference documents. According to the Chemical Drug Production Registration Work Plan 2016, newly registered medicinal products are partitioned into five categories. Categories 1 and 2 are innovative drugs and modified new drugs, both of which are not yet on sale in China or abroad, while Category 5 refers to drugs that were previously marketed abroad then sold in China. In a further reference to the new Examination Guidelines, new drug eligible for PTE are either innovative drugs or modified drugs according to the regulations of the medical affairs authority.[12] Hence, a new drug qualifying for PTE is one that is new not only in China but globally. This is likely to encourage international drug companies to launch their products in China earlier for the benefit of Chinese patients in need.

10 Article 42(3) of the Patent Law of the PRC

11 Article 80 of the Implementation Regulations

12 Section 3.4, Chapter 9, Part 5 of the Patent Examination Guidelines 2023; Page 546

Compensation of the patent term for drugs is subject to several limitations. When a new drug is covered by multiple patents, only one of these patents can be extended. When a patent involves a new drug' s multiple marketing approvals, only one approval can be used to extend a patent. Furthermore, to qualify for a request for extension, the patent must remain valid and must not have been previously extended.[13]

Only PTE requests lawfully made after June 1, 2021 will be examined. The CNIPA will start to examine these requests on January 20, 2024.[14] If a patent expires before January 20, 2024, the extended term will continue from the time of expiry if the CNIPA awards the extension following a review.

The extendable term is the number of days between the date of patent filing and the date of issuance of marketing approval minus five years. In a form of an equation, extendable term = (Date of marketing approval issuance – Date of patent filing) – 5 years. Lastly, the scope of protection during the extended term is limited to the new drug and the claimed invention in relation to marketing approval's indication(s).

Open License

After the patent is granted, a voluntary announcement of a license open to all can be publicly made, specifying the patent number, patentee name, royalty payment standards and license term, among other things. An open license is not allowed if the patent is preempted by a

13 Article 81 of the Implementation Regulations

14 Article 13(2) of the Transitional Measures for Examination as per Patent Law and Implementation Regulations (2023)

sole or exclusive license, has pending ownership dispute(s), is subject to a preservation order, has unpaid annuity fees outstanding, is under a pledge without the consent of the pledger, or has the full exercise of the patent right otherwise compromised.[15] Besides, any dishonest activities related to the open license in order to obtain an annuity discount will be subject to a fine.[16]

Remuneration for Service Invention

The new IR stipulates new remuneration methods for employee' s inventions during the performance of their duties, echoing the new Patent Law. Rather than just by means of cash, remuneration may be provided in the form of equity, stock options and dividends to the employees; this is intended to motivate them by rewarding a reasonable share of the revenue generated from the company's innovative activities.

More notably, without the company' s overriding work rule to govern the remuneration, the statutory minimum according to the new IR has been raised to CNY 4,000 per invention patent granted and CNY 1,500 per utility model or design patent granted.[17] There are no more revenue shares to the employee in a specific percentage when the patented technology is exploited to yield profits, as was the case in the past. Instead, if there is no special agreement regarding the distribution of profits to the employee resulting from the exploitation of patented technology, the provisions of the 2015 Technological and Scientific Achievement Law shall apply.

15 Article 85 of the Implementation Regulations

16 Articles 88 and 100 of the Implementation Regulations

17 Article 93 of the Implementation Regulations

Administrative Enforcement

The CNIPA is empowered to adjudicate in infringement cases with significant nationwide impact at the request of patent holders or parties of interest. The definition of a case of significant nationwide impact is either (1) one where major public interest is involved; (2) one which exerts a major influence on industrial development; (3) any significant case which takes place across geographical jurisdictions (provinces, autonomous regions and municipalities); or (4) any other scenario in which the CNIPA is deemed to have a major impact.[18]

Partial Design

With the new Patent Law 2020, partial design became a patent-eligible subject matter. As an operating rule, the IR provides that the drawings for the entire product submitted shall use a combination of solid lines and dashed lines or other means to indicate the area subject to patent protection. Should the applicant choose not to use solid and dashed lines, the claimed area in the drawing shall be illustrated in detail in the description of the application. In addition to the solid and dashed lines, a semi-transparent layer of single colors can be used to cover the unclaimed area. In order to distinguish claimed areas from those unclaimed, dotted-chain lines shall be used to indicate boundaries.[19]

18 Article 96 of the Implementation Regulations

19 Section 4.4.2, Chapter 3, Part 1 of the Patent Examination Guidelines 2023; Page 83

Hague Agreement

The Hague Agreement became effective on May 5, 2022. As an ancillary provision, the IR affirms that international applications for industrial design registrations which have a registration day and designate China are deemed equally Chinese design applications. The international registration day is equivalent to the Chinese filing date. The CNIPA will conduct an examination after the publication of said international application. Finally, regardless of whether the CNIPA decides to approve or reject the application, the decision will be reported back to the International Bureau. To effect a divisional application(s) in the event of an international application including more than two designs, the applicant shall submit a request to the CNIPA for division within two months of the international publication.[20]

[20] Articles 137, 138, 141 and 143 of the Implementation Regulations

AI-generated Image Found Infringed for the First Time in China

Mr. Li operated Stable Diffusion to produce a picture and then posted it onto his own social media page. Ms. Liu was a blogger who posted an article in which she had inserted Li's picture—titled The Spring Breeze brought Tenderness ("the image")—as an illustration. The picture appeared in Liu' s blog without Li' s consent and with the watermark removed. Li sued Liu for copyright infringement for CNY 5,000 and injunctive relieves at the Beijing Internet Court.[1]

A work subject to copyright protection refers to an intellectual product that is original in the fields of literature, art or science and is expressed in a certain form. This definition of a copyrighted work was instrumental in how the court decided to approach this case. Several main questions were raised: whether the image constitutes a work under the definition of copyright law; whether the Plaintiff Li holds the copyright for the image; and whether the defendant' s use constitutes infringement of copyright with liabilities. The majority of the court' s reasoning focused on question number one. Accordingly, the court proceeded to analyze the respective elements.

Intellectual Production

Intellectual production refers to any product resulting from a human's intellectual activities, the court pinpointed. A work shall faithfully demonstrate the intellectual investment of human beings. Stable Diffusion is a model trained by a

1 (2023) Jing-0491-MinChu-No. 11279 (2023.12.27)

myriad of pictures and corresponding descriptive text which is able to yield an image with corresponding traits that the prompt instructions offer by adopting the homology of the syntax of the prompt and the pixels in the pictures. It does not merely take available pictures straight from online search engines or perform combinations of several factors predetermined by the programmer. Specifically, Stable Diffusion uses accumulated capability to delineate, contour and draw the lines in place of human manual tasks.

In the present case, the Plaintiff prompted Stable Diffusion, set up relevant parameters, added other prompt terms and adjusted further parameters in a first draft, before finally choosing an image to his satisfaction. The court found that throughout the process, from the conception to the decision, the Plaintiff had devoted his intellectual activities to, for instance, the style of the presenting figure, the choice and orders of prompts, the arrangement of parameters and finally the choice of an ideal output image. Therefore, the element of intellectual production was met.

Originality

A work must be independently completed by a producer with the producer' s personalized expression, the court reasoned. On the contrary, a mechanical display of an intellectual product is deemed to be lacking originality, for example, a product completed in a particular order or displaying a distinct formula or structure.

In the use of Stable Diffusion, the more distinctive the input prompt procedure is and the more clearly defined the description of element layouts is, the more an output demonstrates personalized expression. It is to some degree correct to deduce that the image was drawn by Stable Diffusion; however, the Plaintiff by himself designed the female figure and its presentation via his choice of prompts and rearranged the image' s layout through parameters, notwithstanding his further modification of the image with further prompts and other parameters. All of these

activities were a reflection of the Plaintiff' s aesthetic judgments and personal choices in creating the final image. In the court' s hearing, the Plaintiff operated the same generative AI model on-site to produce different images by inputting different prompts and parameters. That is, clearly the image in dispute was not a mere mechanical display of an intellectual product; it was one displaying originality.

Work in artisticfield

A generative AI model which has no free will is not a subject at law, the court emphasized. When a person uses a model to produce an image, this is essentially no different from using a tool to make creations. In other words, it was the human who dedicated intellectual investments rather than the model. Encouragement of creation is the core policy purpose of copyright law. So long as an image—despite being generated by a machine—can present a person' s original intellectual investments, the image shall be considered a work protectable by copyright law.

Besides, the image in dispute was a piece of planar creation made up of lines and color and with aesthetic implications. Hence, it is considered an artistic work.

Ownership

In principle, the copyright of a work belongs to the author. Stable Diffusion was merely a tool that the Plaintiff used to create an image, as forementioned. The designers of Stable Diffusion did not pre-determine the output of the model, nor were they involved in the steps of image generation. Furthermore, the designers of Stable

Diffusion disclaimed any rights in association with the outputs. In view of the above, neither the Stable Diffusion model nor the designers were the authors of the image in dispute.

On the contrary, the Plaintiff was the person who gave direct prompts, set parameters and chose the image. The image was produced as a result of the Plaintiff' s intellectual input and thus demonstrated the Plaintiff' s personalized expression. The Plaintiff authored the image and therefore was the owner of the image.

The image in dispute was a protectable work as per copyright law. The court continued to the infringement determination.

The court found the Defendant to have infringed the Plaintiff' s right of paternity and the right of information network dissemination through their use of the image and removal of the watermark on the same. As a result, the court awarded light damages amounting to CNY 500 and also ruled the defendant to issue a public apology in her blog.

From a comparative perspective, notably, this trial decision turned out to be in marked contrast to the stance of the US Copyright Office ("USCO") in February 2023. In the Zarya of the Dawn Letter of the USCO, it is quoted that "[A] person who provides text prompts to Midjourney does not 'actually form' the generated images and is not the 'master mind' behind them." "The information in the prompt may 'influence' the generated image, but prompt text does not dictate a specific result." The USCO emphasized that there is a huge difference between a user' s prompts and the images that an AI model actually produces. Thus, the user, lacking meaningful control of the nature of the outputs, is not the output's creator.

Returning to the present case, it was apparent that the scientific theories of an AI model' s generation of outputs were not sufficiently reasoned so as to offer a convincing analytical basis. This could form the basis of one of several arguments in a further challenge from the defendant. However, up until the deadline of appeal no parties filed for an appeal. The case is therefore finalized and turned effective.

OPPO v. Nokia: China Court set First Global 5G FRAND Rate

On November 28, 2023, the Chongqing First Intermediate People' s Court ("Court") made a trial judgment in the dispute between OPPO and Nokia over the Standard Essential Patent royalty rate for 5G and 4G handheld devices (See Table 1). This judgment marked the first decision by a Chinese court regarding the global royalty rate of SEP licensing. The Court also fixed the global industrial cumulative rate for the 5G standard at 4.341%-5.273% and the intergenerational value ratio from 5G to 2G for 5G multimode mobile phone at 5G:4G:3G:2G = 50:40:5:5. The calculation and methodology used to decide the rate and royalty fee formed the nucleus of the judgment.

Nokia and OPPO entered into a licensing agreement in 2018 ("2018OPPO agreement") with a license covering 4G to 2G SEPs. Three years later, they failed to renew the deal, leading Nokia to file lawsuits for infringement on SEPs and non-SEPs in more than ten countries or regions worldwide.[1] In return, OPPO sued Nokia in China for an adjudication on new licensing terms. Nokia had moved to challenge the competence of geographical jurisdiction of the Chinese court. But the Court dismissed the motion and continued on with the substantive issues of the case.

Regarding the fundamental elements of the licensing terms, the Court decided that the duration of the license should be three years to cover the OPPO, Realme and Oneplus smartphone brands. Both the 2018OPPO agreement and an agreement between Xiaomi and Nokia ("Xiaomi agreement") were accepted as the comparable references. Furthermore, the Court took the net selling price (nsp) of a mobile phone as the unit pricing basis (to time the royalty rate to generate the royalty fee) rather than the average selling price (asp) since the latter, being a higher figure, would unreasonably include the costs of packaging, insurance and shipping, among other things. With these elements set, the Court proceeded to analyze the royalty fees for 4G and 5G multimode mobile phones. They are set forth as the following.

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1 Germany, the UK, Spain, France, China, India, Indonesia, the Netherlands, Finland, Sweden, and Russia.

4G multimode mobile phone

In order to determine the 4G royalty, the Court primarily looked into the 2018OPPO agreement. The Court extracted Nokia' s unilateral license royalty fee and the expectable sales volume from the 2018OPPO agreement taking into account the negotiation status and regular business norms at that time. The Court further evaluated the change in Nokia' s 4G market strength between the times of the 2018OPPO and the 2021OPPO agreements so an adjustment factor returned. Combining the foregoing factors, the Court concluded the 4G royalty fees under the 2021OPPO agreement in corresponding zones (as in Table 1).

5G multimode mobile phone

The Court firstly recognized both the top-down approach and the comparable agreements approach as being acceptable methodologies for establishing a license royalty. Since both of these approaches have been adopted in Chinese and foreign jurisprudences, one was not superior over the other.

❶ Top-down approach

The basic formula to determine Nokia' s 5G multimode mobile phone royalty rate is as follows:

(5G global cumulative rate x Nokia' s patent market strength in 5G network x Contribution weights of 5G network' s value) + (4G global cumulative rate x Nokia' s patent market strength in 4G network x Contribution weights of 4G network' s value) + (3G global cumulative rate x Nokia' s patent market strength in 3G network x Contribution weights of 3G network' s value) + (2G global cumulative rate x Nokia' s patent market strength in 2G network x Contribution weights of 2G network's value).

Firstly, from knowledge in the industry, precedent judgments, third-party institutional research reports and Nokia' s own declarations regarding its 4G market strength, the cumulative royalty rates for 4G and previous generation networks are found to be 6-8% for 4G, 5% for 3G, and 5% for 2G. Secondly, considering that the agreement in dispute covers only the earlier time of implementation of the 5G network in smartphones and also that there is no strong evidence to demonstrate that 5G contributes significantly more than 4G, 5G technology is found to account for approximately 50% of the value of smartphone communication. Hence, the intergenerational contribution weights of the networks' values from 5G to 2G are 50%: 40%: 5%: and 5%, respectively. As for the global cumulative licensing rate for the 5G standard, OPPO' s experts have used an economic model to derive a figure of 4.341%-5.273% for a three-year term.

It is interesting to note that the Court evaluated the market strength of Nokia' s 5G to 2G SEP based on the "number" of Nokia' s declared patents and pending applications in the totality of the SEPs in a given generation network rather than the "validity" or vulnerability of patents or applications in the pool. As the Court stressed, taking quantity over quality is acceptable in the present case because the size of the SEP sample pool was so great. Nevertheless, the Court noted that if Nokia were able to submit evidence of a significantly higher or lower quality of its patents in the pool, such evidence may be factored into the evaluation.

❷ **Comparable agreement approach (in conjunction with the partial conclusion from the top-down approach)**

Based on the 4G multimode mobile phone royalty rate in the 2018OPPO agreements (as previously explained) and the fact that the value contribution weights of 5G mono-mode mobile phones and 4G multimode mobile phones are 50% each, the formula for a 5G multimode mobile phone is as follows:
5G multimode mobile phone' s royalty rate for the duration of a new license = 5G mono-mode royalty rate x 5G contribution ratio (50%) + 4G multi-mode royalty rate x 4G contribution ratio (50%).

Although Nokia argued for the resolution of terms and conditions in the Xiaomi agreement to be used as an additional example for comparison, the Court found this unnecessary since the way in which Nokia had resolved the Xiaomi agreement did not comply with the Court' s intermediate conclusions. The Xiaomi agreement was somehow ambiguous in its contractual language. Nokia as the defendant bore the burden of proof, but it failed in this regard meaning that what presented to the Court were only assumptions rather provable facts. The Court could not come to a solid evaluation on the basis of Nokia' s allegations.

Finally, for the 5G multimode mobile phone royalty fee, the Court made its calculations using both the top-down and comparable agreement approaches. Since the figures are lower, and therefore supposedly more favorable to Nokia, as a result of the comparable agreement method, the Court determined the fees accordingly (see Table 1).

Table 1 SEP Global Royalty Rate set by the Chongqing Court	4G multimode mobile phone		5G multimode mobile phone	
	Royalty Rate	Royalty Fee (USD/unit)	Royalty Rate	Royalty Fee (USD/unit)
Zone 1*	N/A	0.777	N/A	1.151
Zone 2		0.477		0.707
Zone 3		0.477		0.707

*Zone 1 refers to the countries or regions with GDP equal to or greater than USD 20,000; Zone 2 refers to Mainland China; and Zone 3 refers to all other countries or regions.

New Dosages Are *not* Entered for Patent Linkage in Taiwan

That how many types of new drugs are eligible for listing in the Patent Linkage Registration Platform ("the Platform") has been like a see saw going up and down since the system was established in Taiwan in 2019. The Ministry of Health and Welfare ("MHW"), as the authority governing the Platform have been holding in a conservative stance to narrowly define that only the drugs of *new compositions, new therapeutic compounds and new methods of administration* (hereinafter referred to collectively as "category 1"). In December 2022, two trial court' s decisions shed a different light with the opposite opinion and seemly opened the door for more drug types. To some' s regret, however, the Supreme Administrative Court ("SAC") being the appellate court recently rendered two judgements in November 2023 on the other two cases dictating that drug types other than category 1 are not registrable onto the Platform.[1]

MSD is the owner for ISENTRESS 600 mg table, an integrase inhibitor in HIV treatments, and Allergan is the developer for LUMIGAN ophthalmic solution 0.01%, an eye drop that helps reduce eye pressure due to glaucoma and other eye diseases. MSD and Allergan (collectively referred to as the "Plaintiffs") logged in the Platform to register the patents of their respective products. Later in the input review by the maintaining staff of the MHW, it was discovered that the medical product authorization by which the Plaintiffs upload the associated patents directed not to any kind of category 1 but a drug in "new administered dose." MHW deleted the registrations. In reaction, the Plaintiffs sued for restoration of their registrations by canceling the take-down.

The definition of a new drug eligible for linkage system was the core of the trial court's opinion. Patent linkage connects the marketing approval of a new drug and the disclosure of the legal information of its associated patents. It also connects the examination process for generic applications and the resolution of disputes of whether the new drug' s associated patents are infringed. Under the Pharmaceutical Affairs Act,

1 SAC-111-Appeal-No. 531 (Allergan case) and SAC-111-Appeal-No. 532 (MSD case)

a new drug refers to a medical preparation having *new compositions, new therapeutic compounds or new method of administration*.[2] The MHW is the competent authority to determine whether a product sent for marketing approval examination is in one of the types in category 1. As for the preparations of *new dosage forms, new administered doses and new unit strengths* (collectively hereinafter referred to "category 2"), the Regulations for Registration of Medicinal Products only provide that their examination for marketing approval applies in the same process as category 1. No more preferences were endowed to category 2 drugs to afford them the same legal status identical to category 1 drugs. In view of such, category 2 was not new drugs as per the statutes. The Plaintiffs' attempts to register products of no new drugs were therefore not lawful. Therefore, deleting the registrations of the Plaintiffs' authorizations for new doses was correct, opined by the trial court.

With the unfavorable decisions, the Plaintiffs appealed.

In the appellate judgement, the SAC sided with the trial decision to affirm that the authorizations for new administered dosages are not eligible for the linkage regime. More elaborations were added.

Investigating the policy goal of the legislation by the time of introducing the linkage system in 2018, the SAC reasoned that the term "drug" clearly referred to the definition of category 1 when the statute was amended in 1993. That is, the legislators in 2018 knew what new drugs in the statute have been since 1993. They intentionally limited the scope of new drug eligible for the linkage system to category 1 only when they enacted the same.

Being reluctant to yield, the Plaintiffs persisted that the statutes further provided that the definition to a new drug should be resorted to the dedicated Chapter for Patent Linkage where it stipulated only *substance*, *composition* or formulation, *medical use*

2 Article 7, Pharmaceutical Affairs Act

being registerable on the Platform. The SAC found such argument erroneous. To correctly interpret the law, not only did a patent direct to a *substance*, a *composition or formulation*, or a *medical use* but also its associated marketing authorization must be a product of category 1, SAC analyzed. In other words, the product authorizations and the associated patents have their respective requirement to be met before they can be listed onto the Platform. Thus, a product able to enter the linkage system remained to be a category-1 drug indeed.

The SAC explained, what kinds of drugs are eligible is determined up to choice of the parliament. Each step of the linkage system, including a patented drug' s listing, a generic challenger' s declaration, the notification to the IP office, the suspension of generic approval issuance, sale exclusivity privilege, etc., hinges on the public welfare, supply and demand, competition strength, and the product prices. Each country has its own sets of conditions and policy goals. Taiwan' s rules and regulations in the linkage system do not have to be consistent in all aspects with other nations. The statute that defined what a new drug is was previously enacted by the parliament in the rule of democracy. For any future changes to the definition or scope of subject matters is ought to be resorted to the reserved power of the legislative branch.

Lastly, the Plaintiffs argued that the application for registration of patent onto the Platform was automatically received and then post publically on the Platform' s webpage. The statute only endowed the third parties in the general public to challenge any errors rather than the MHW to take down a registration. The SAC opined to the otherwise. The MHW was the head authority for medical and pharmaceutical affairs. It possessed the dictating jurisdiction to regulate the Platform under the law. The MHW is entitled to exercise its discretionary power to validate the lawfulness of a registration. That is to ensure that a listing would not be illegally post and published, despite the public vetting mechanism available.

To short conclude, the Plaintiffs' argument in seek of a broader scope of new drug to enter the linkage system was not valid. The SAC affirmed the lower court' s decision and the MHW's take-down was lawful. The MSD and Allergan's cases were final.

The series of litigation histories for the drug type disputes is briefly illustrated in the below table. Note following in later November and early December 2023, there have been two other appellate judgements (CIMA Labs and Novartis) on the same issue were made by the SAC to keep in constancy ruling new dosage not registerable.

Table 1: Disputes over Drug Type Eligible for the Linkage System (update until December 2023)

Case	Plaintiff New Drup Type	1st Instance Decision	Appellate Decision	Final
TaipeiHighAdmin-110-Trial-No. 1048	Allergan New Dosage	TaipeiHighAdmin-110-Trial-No. 1048 (2022/5/12); Not Registrable	SAC-111-Appeal-No. 531 (2023/11/23); Not Registrable	YES
TaipeiHighAdmin-110-Trial-No. 824	MSD New Dosage	TaipeiHighAdmin-110-Trial-No. 824 (2022/5/12); Not Registrable	SAC-111-Appeal-No. 532 (2023/11/23); Not Registrable	YES
TaipeiHighAdmin-110-Trial-No. 844	CIMA Labs New Dosage	TaipeiHighAdmin-110-Trial-No. 844 (2022/12/29); Registrable	SAC-112-Appeal-No. 165 (2023/11/30); Not Registrable	YES
TaipeiHighAdmin-110-Trial-No. 1060	Novartis New Dosage	TaipeiHighAdmin-110-Trial-No. 1060 (2022/12/29); Registrable	SAC-112-Appeal-No. 110 (2023/12/07); Not Registrable	YES

Commercial Success Recedes if a Claim is Found Not Inventive

Mr. Lam ("Plaintiff") is the owner of Taiwanese patent 420783 ("'783 patent") titled "Commandless programmable controller", granted in 2001. The Plaintiff complained that Nyquest Technology had implemented the Plaintiff's patented technology in a particular software tool product without consent or a license. Nyquest Technology had allegedly infringed five claims in the '783 patent.

The IPC Court as both the trial and the appellate court held that the '783 patent was invalid and Nyquest Technology had therefore not infringed. The Plaintiff further appealed to the Supreme Court, which vacated and remanded the IPC Court's appellate judgment. In November 2023, the IPC Court reviewed the case and again ruled in favor of Nyquest Technology, finding the '783 patent invalid and that therefore no infringement had occurred.[1]

For all five claims—Claims 21, 27, 28, 36 and 37—in the '783 patent, the court found that they were not inventive under either reference one (document "State Machine Design" published by AMD company, 1993) combined with reference three (user's manual for IC W528X published by Winbond company, 1995) or reference one combined with reference two (research paper "VFSM Executable Specification" by F. Wagner, 1992). All three references were disclosed before the filing day of the '783 patent and they were technical related in the same field, namely the digital circuit controlling method. They correlated to share commonality in technical functions and effect by teaching the modification of output signal via changing the state or mode of a device. Therefore, a person having ordinary skill in the art has the motivation to combine them. In view of the above, although not all of the technical elements in the five claims were anticipated by reference one, either references two or three disclosed the remainder of the elements. Therefore, all five claims were found to be lacking inventiveness and as a result were deemed invalid.

1 IPC-1111-CivilPatentAppealRemandOne-No.11

The Plaintiff, being reluctant to concede, added that the wider acceptance of the claimed invention of the patented technology constituted solid proof of attainment of significant success in business. Such success should be attributed to the technical advancements of the '783 patent. Presenting copies of license agreements as evidence, the Plaintiff argued that many third-party IC companies had implemented the patented technology in their products and that these licenses were an indicator of commercial success.

When the commercial success of an invention applied for a patent was attributed specifically to the outstanding technical features of the invention rather than factors such as sales skills or promotion through advertising, this would indeed contribute to the inventiveness. The Plaintiff alleged that the invention had been licensed to many companies and utilized in several products. However, the fact that the Plaintiff had previously been employed in the globally-renowned toy manufacturing company Mattel Inc. means that the possibility cannot be ruled out that it was his past employment which had equipped him with the necessary negotiating power in the course of IC procurement projects. Taking this personal factor into account, some questions remained as to whether the licensing contracts had been reached entirely due to the outstanding technical achievements, which were obviously non-personal factors. Moreover, the signing of a license contract is a business deal in conjunction with a number of other complex factors. Being no more than essentially a covenant not to sue, a patent license can be agreed, for example, as a result of a pragmatic cost-effect evaluation, where the expenditures of the dispute resolution amount to more than the royalty payments. Entering into a license does not necessarily imply the contribution of an invention's technical features.

Furthermore, the Plaintiff was seemingly unable to produce enough compelling evidence in connection between the commercial success and popularity of the invention in the market. According to the Plaintiff' s evidence, both the size and reputation of the third-party IC companies were considerable. They designed and produced a myriad of IC models. The Plaintiff did not present any evidence demonstrating what percentage was accounted for by the invented technology in those models. Even if some microcontroller unit products on the market were embedded with the invented technology, some skepticism remained as to whether this equated to commercial success.

Most decisively, commercial success is only a secondary factor in determining inventiveness. Inventiveness hinges primarily on the technical quality of a claimed invention and an enquiry as to whether the claimed invention is different yet not easily accomplished in view of the prior art. That is, the question of whether the inventiveness requirement is met is firstly based on a comparison of the claimed invention with a combination of prior art references. As the court emphasized, when the invention is found lacking inventiveness in light of the prior art, an investigation into the secondary factors is deemed no longer necessary.[2] In the present case, since the claimed invention was found not to be inventive in view of two combinations of prior art references, the issue of whether the claimed invention is successful in commercial terms did not play a determinative role in the finding of inventiveness.

The Plaintiff's appeal was subsequently dismissed.

[2] SAC-102-Judgement-No. 205; SAC-109-Appeal-No. 575

Taiwan's Anticompetitive Law Applies when a Warning Notice Alleged Infringement of a Foreign Patent

Inergy and Force Mos are both Taiwanese manufacturers of chips, their key business focus being the research, scientific development and sales of metal-oxide-semiconductor field-effect transistors (MOSFET). Force Mos was the owner of two US patents—US 7,812,409 and US 7,629,634. On November 19, 2018, the US' 409 patent was declared invalid owing to non-payment of annuities. Although it was later revived, the patent was unenforceable during the period between October 12, 2018 and May 24, 2023 since the intervening right arose.

On May 23, 2023, Force Mos served a warning letter (1st warning notice) to Inergy and ASUS, who sold in the US market the PC products containing MOSFET chips which were packaged by Panjit after being original design and manufacture by Inergy. In the 1st warning letter, Force Mos accused the MOSFET chips of having infringed the US' 409 patent, albeit with no infringement analytical report attached. Then, on September 14, 2022 and October 21, 2022, Force Mos served two subsequent warning letters (2nd and 3rd warning notice) to ASUS' s US subsidiary alleging infringement of the US' 634 patent. As the supplier of ASUS and Panjit, Inergy filed a lawsuit against Force Mos complaining that the warning notices to Inergy' s clients constituted injuries to Inergy' s commercial reputation by disseminating untruthful statements with bad faith intent. Inergy accused Force Mos of having breached a directive of the Fair Trade Commission which requires a number of precautionary measures to be taken before such a letter is sent to a non-manufacturer[1]; Force Mos was therefore deemed to be in violation of the Fair Trade Act for undertaking false statement dissemination and deceptive or obviously unfair conduct in order to undermine competition.[2]

1 Principles on Cases Involving Warning Letters for Infringement of Copyrights, Trademarks or Patents by Enterprises

2 Articles 24 and 25 of the Fair Trade Act

In review of this case, the main inquiries presented before the court were: (1) Whether the Fair Trade Act of Taiwan applies in this case where the subject matter in dispute was not a Taiwanese patent; and (2) Whether the three warning notices were false statements and deceptive or obviously unfair conducts against the Fair Trade Act.

Taiwanese anticompetitive law applies in a pending dispute only if a party' s accused activities have had a negative impact on the Taiwanese market by attenuating competition. That is, Taiwan must be a relevant market, or a circle of economic competition, in which Force Mos' s activities have caused or have potentially caused injury. The Court explained that a relevant market, defined by the availability of substituting goods and services and the difference in the geo-extent of the sales area, is an integrative combination of the product market and the geographic market. The product market refers to the scope of goods and services with a higher degree of demand or replaceability of supply in terms of functions, characteristics, purpose of use or prices, whereas the geographic market, as the name suggests, intuitively means the area within which an individual making a transaction can easily opt for or switch to another counterparty for a specific good or service. In addition to the above two market concepts, the time is another important element to factor in when defining a relevant market.

In the present case, Inergy manufactured the chip to be delivered to Panjit for assembly. The modules assembled by Panjit containing Inergy' s chips would then be delivered to ASUS and others for installation in the final electronic products. There being no transactional barriers between the countries, Inergy' s chips may actually end up in the US where ASUS sells its laptops. Therefore, the US and Taiwan should be

deemed to be a single relevant market. Moreover, the MOSFET-related business accounts for 63-80% and 79-92% of Inergy and Force Mos' s revenues, respectively. Their businesses overlap significantly and the geographic range of the semiconductor supply chain extends beyond national borders. The warning notices could have resulted in the substitution of one' s products with the other when the buyers chose to do so, meaning that such a warning notice to ASUS' s US and/or Taiwan entity could have an impact on the procurement decision making with Inergy in Taiwan. From the analysis, it was decided that the Taiwan market had been affected negatively. The Court briefly concluded that Taiwan' s anticompetitive law should be applied in the case at issue.

Any exercise of IP rights must be carried out in a legitimate fashion, the Court emphasized. If the IP holder abuses the rights or acts against the good faith requirement in the course of exercising the IP in order to undermine the order of competition, it is not acting legitimately.

In this dispute, Force Mos's US'409 patent had been invalid since November 19, 2018, due to the failure of annuity payments. Before its restoration on May 25, 2023, Force Mos would not be able to exercise any rights with the US' 409 patent. As a large-scale listed company with a considerable quantity of registered capital, Force Mos should have borne the duty of verifying the validity of legal rights before exercising them. Although Force Mos continued to argue that it had delegated the management capacity of the US patents to its US lawyers who did not timely notify it of upcoming renewals, the Court denied its arguments by again underlining that the latest information on patent validity can be readily and swiftly accessed at the USPTO' s

public portal. The cost for an immediate check-up was minimal, suggesting that the cost of preventing injury was far less than the expectable damages from injury.[3] Serving a warning letter accusing the receiver of infringing an invalid patent was apparently an act lacking good faith. At the very least, Force Mos had acted negligently without fulfilling the duty of care as a good manager.

In summary, the 1st warning notice prompted ASUS to question Panjit as to whether Inergy had been involved in infringing activities. It compromised ASUS' s trust in Panjit' s and Inergy' s businesses. Inergy' s commercial goodwill was therefore undermined. Considering that goodwill is essentially an intangible asset, the Court evaluated all available factors to rule with discretion two damages awards, each of which another respective managerial figure was jointly liable for. As for the non-asset or moral damages claimed by Inergy, the Court rejected it on the grounds that only a natural person is entitled to this whereas Inergy was an organization.[4]

The case remained appealable within 20 days of January 3, 2024.

3 Learned Hand formula of Negligence (B<<PxL)

4 IPC-112-CivilPublicPros-No.1 (12.26.2023)

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