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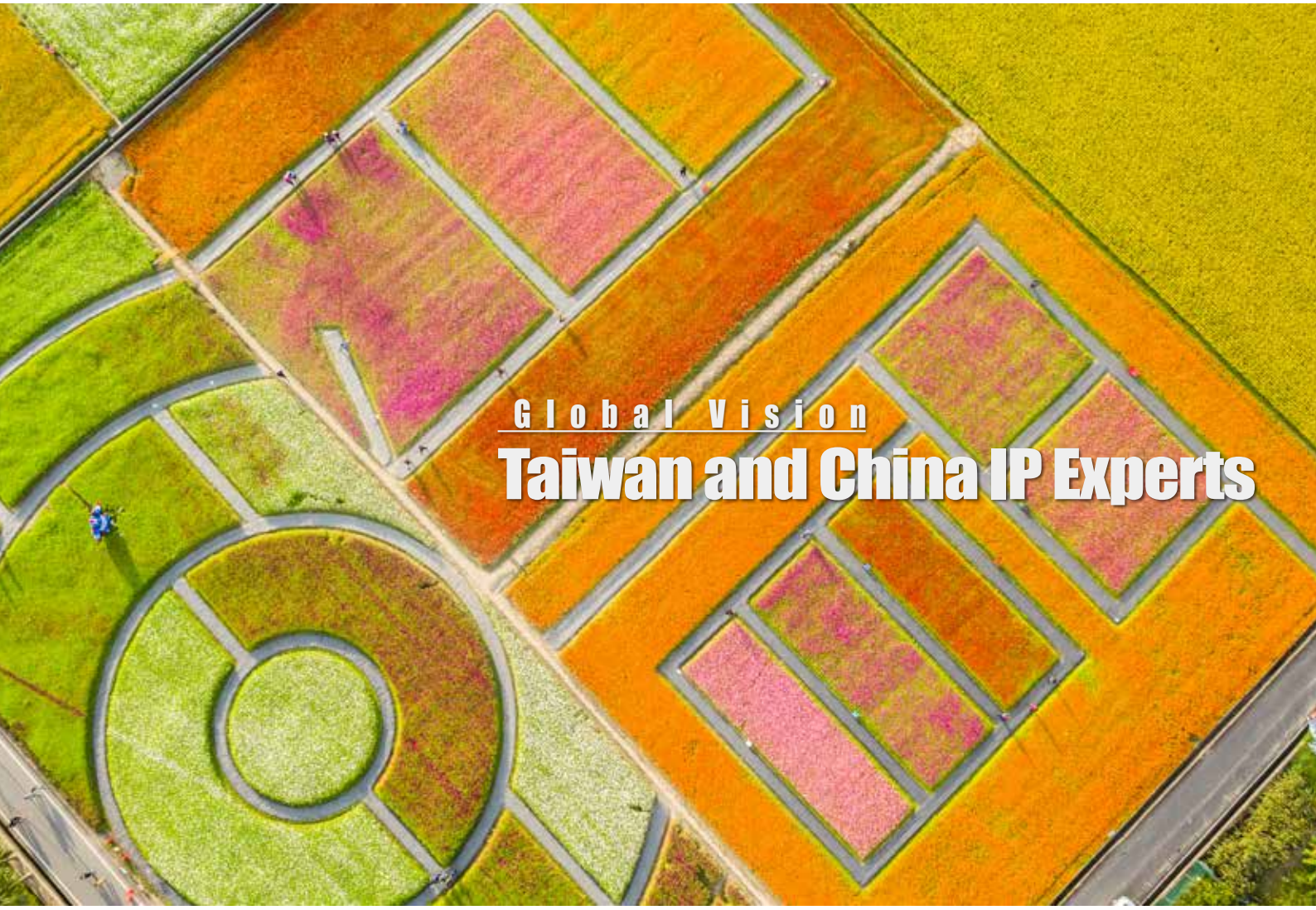

Global Vision

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First judicial judgment and first administrative decision for pharmaceutical patent linkage released in April

The new 2021 Patent Law of China provides a system connecting the patent and the pharmaceutical regulatory authorities in order to clear potential infringement disputes over a patented drug at an earlier stage before issuing market approval to a generic copy. To this end, the patentee or an interested party—the exclusive licensee, for example—has two ways of resolving such a dispute. Firstly, they may choose to file a lawsuit with the court for a judicial judgment, where the Beijing IP Court possesses the exclusive jurisdiction over the subject matter. Alternatively, they may file a complaint with the China National IP Administration (CNIPA) in pursuance of an administrative decision. Recently, in April 2022, both forums made decisions regarding the first cases they docketed at the end of 2021.

The Beijing IP Court made the nation's first-ever judgment for a patent linkage lawsuit on April 15th.[1]

Chugai Pharmaceutical Co., Ltd. from Japan (Chugai) is the owner of the patent no. 200580009877.6, which is associated with the drug Eldecalcitol (traded as Edirol) for the treatment of osteoporosis. Chugai listed the information of this patent and Eldecalcitol on the Patent Information Registration Platform (PIRP). The domestic company Wenzhou Haihe Pharmaceutical Industry (Haihe) attempted to apply for marketing approval for a generic version of Eldecalcitol and also certified that its generic copy did not infringe the registered patent. However, Chugai sued Haihe for patent infringement.

The court found that Haihe's generic drug did not fall within the literal scope defined by the patent claims, nor did it match the patent's claimed elements by equivalence. Therefore, the court ruled in favor of the defendant Haihe. It is reported that Chugai has appealed the judgment to the Beijing High People's Court.

In giving its reasoning for this judgment, the court highlighted the legislative background of the patent linkage system introduced in the new Patent Law effective from mid-2021. Firstly, patent linkage stimulates investments in the innovation and development of new drugs, and secondly, it encourages the creation of cheaper generic versions available in the market. With this mechanism in place, patients as consumers will benefit by having more affordable access to high-quality medicines.

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[1] https://www.court.gov.cn/zixun-xiangqing-355061.html

Only a few days later, on April 25th, the CNIPA announced the first batch of administrative decisions on the pharmaceutical patent linkage disputes.[2]

Purdue Pharma L.P. (Purdue) from the USA listed on the PIRP three patents—nos. 201210135209.X, 201510599477.0 and 201010151552.4—related to its three different dosages of a sustained-release tablet of oxycodone hydrochloride, which is an opiate analgesic. Purdue requested the CNIPA to determine whether the technical features of a generic copy manufactured by a competitor, Yichang Renfu Pharmaceutical Co., Ltd. (Renfu), were read on by its three listed patents.

In order to examine this case, CNIPA formed a review panel consisting of five examiners with backgrounds specialized in pharmaceutical and chemical science. The panel coordinated with the National Medical Products Administration (NMPA) to retrieve critical documents and organized several rounds of evidence exchange with both parties. Following an oral hearing, the panel found that Renfu's generic copy did not fall within the scope of the patents.

Looking at the results of both the judgment and the administrative decision, the generic drug manufacturers have been victorious in both cases. A winning patentee or original drug manufacturer is yet to be seen. Furthermore, following a review, it was decided that both the judicial judgment and the administrative decision had been issued efficiently. The Beijing IP Court took approximately five months (from November to April) to reach a decision, while the CNIPA spent around six months (from October to April) to reach one. They correctly observed the 9-month halting period, in which the NMPA cannot issue approval to the generic copy until a decision for a patent infringement dispute has been reached, either by CNIPA or by Beijing IP Court.

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[2] https://www.cnipa.gov.cn/art/2022/4/25/art_53_175126.html

Air Liquide v. Nippon Sanso Taiwan: IPC Court Provides an Alternative View of Fictitious Novelty[1]

L'Air Liquide Societe Anonyme pour l'Etude et l'Exploitation des Procedes Georges Claude SA, formerly Air Liquide SA, is a France-based gas company (hereinafter "Air Liquide") which accused Nippon Sanso Taiwan, Inc. of infringing its patent no. TW I525210 (the patent at issue), which is an invention regarding the method of forming dielectric films and new precursors. Nippon Sanso Taiwan raised an affirmative defense that the patent right at issue should not be granted and should be revoked due to its lack of novelty based on legal fiction. On February 15, 2022, the IP Court ruled in favor of Nippon Sanso Taiwan and indicated an alternative view regarding the legislative purpose of fictitious novelty which has not previously been put forward by the IP Court.

In this case, the parties entered into a debate on the question of whether the accused product falls within the literal scope of Claim 29 and Claim 30 of the patent at issue. In addition, the defendant argued that Claim 29 and Claim 30 should be revoked on the grounds of lacking fictitious novelty. According to Article 23 of the Taiwan Patent Act, "[w]here an invention claimed in a patent application for invention is **identical** to an invention or utility model disclosed in the description, claim(s) or drawing(s) of an earlier-filed patent application for invention or utility model which is laid open or published after the filing of the later-filed patent application, an invention patent shall not be granted." With regard to the definition of identical invention, the Examination Guidelines for Patents, published by the Taiwan Intellectual Property Office (TIPO), provide the following criteria for determination: (1) the invention claimed and the technical contents disclosed in a citation are completely identical, (2) the difference only lies in the literal descriptions or in the technical features which can be directly or unambiguously deduced, (3) the difference between the corresponding technical features resides in the generic concepts and specific concepts, or (4) the difference lies only in the technical features which can be directly substituted based on common general knowledge. If any of the above scenarios apply, the two inventions are deemed identical as stipulated in Article 23 of the Patent Act.

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[1] 110-CivilPatTrial-No.32

Nippon Sanso Taiwan provided a cited reference which was filed on November 30, 2006 and published on August 1, 2007. In contrast, the patent at issue was filed on June 1, 2007, later than the filing date of the citation. Also, the priority date of the cited reference, December 6, 2005, is earlier than the priority date of the patent at issue, June 2, 2006. Therefore, the cited reference could be determined as admissible evidence.

Next, the court pointed out that the difference between the cited reference and Claims 29 and 30 of the patent at issue lies only in the metal element contained in the compound. In comparison to Hafnium (Hf) as claimed by the cited reference, Air Liquid specified Zirconium (Zr) as the element recited in Claims 29 and 30. The court found that the two elements are both in group 4 of the periodic table of elements; they have similar characteristics in chemical reactions. Therefore, Hafnium (Hf) and Zirconium (Zr) are interchangeable and people possessing ordinary skill in the art are able to directly replace Hafnium (Hf) with Zirconium. That is, Hafnium and Zirconium are deemed identical according to the Examination Guidelines.

In response to the IP Court' s opinion, Air Liquide argued that the two elements have different electron densities because of the numbers of electron shells. Furthermore, based on common knowledge, the two elements are not completely identical in function, means and purpose in the context of chemical reactions. Unfortunately, the court did not support this argument. The court emphasized that being completely identical in means and purpose is not a requisite for determination of novelty. Neither is it required for fictitious novelty.

The original purpose of fictitious novelty is to avoid the situation in which the invention filed earlier and published after the filing date of the later application may not be the prior art of the later application. As an exception, the invention filed earlier can be used as the prior art of the later application when the two inventions are identical. In addition to consideration of novelty, the spirit of patent laws does not allow two patent rights to the identical invention to be granted.

It is worth noting that the court provides an alternative consideration regarding the legislative purpose of fictitious novelty from the perspective of bona fide third parties, whereby "[i]f two patent rights are granted to two inventions with identical or directly replaceable technical features, the bona fide third party who intends to obtain a patent license may not know whom he or she must consult with. Moreover, granting two patent rights on the same invention will lead to their mutual exclusion from exploitation, which obviously contradicts the purpose of promoting industrial development as proclaimed in Article 1 of the Patent Act."

Chroma v. ITECH, ILOAD & Z-FONE: How to Determine Damages due to the Act of Offering for Sale[1]

Chroma ATE Inc. ("Chroma") is a Taiwan-based manufacturer of precision testing and measurement instruments. Chroma purchased the accused product in China and conducted an infringement analysis, and then accused ITECH Electronic Co., Ltd. (the manufacturer, based in Nanjing, China, hereinafter "ITECH"), ILOAD Electronic Co., Ltd. (the Taiwan-based parent company of ITECH, hereinafter "ILOAD") and Z-FONE Technology Co. Ltd. (the distributor in Taiwan, hereinafter "Z-FONE") of infringing its patent at issue (patent no. TW I488197). While the IP Court stated that the accused product falls within the literal scope of the patent at issue, the IP Court ruled in February 2022 that the damages claimed by the plaintiff should be dismissed because the infringement was merely an act of offering for sale.

When the Court has confirmed that there is an infringement, the next step is to calculate the amount of damages, and the person claiming damages bears the burden of proof as to the damages he or she suffered as a result of the infringement. According to Article 58 of the Taiwan Patent Act, "the patentee of an invention patent has an exclusive right to prevent others from exploiting the invention without the patentee' s consent ("exclusive right clause"); where the invention is a product, exploiting of [that product] means the acts of making, offering for sale, selling, using or importing that product for the aforementioned purposes (definition of exploitation clause)." In cases where an act of exploitation only involves offering for sale, there are divided opinions in precedents over whether damages can be claimed.

In this case, the IP Court said that the accused product purchased by Chroma in China falls within the literal scope of the patent at issue. However, Chroma could not prove that the same product could be purchased in Taiwan from any of the defendants (although there was an introduction of the accused' s serial products on the homepage of Z-FONE) or that Z-FONE had ever sold other products of ITECH. From the evidence submitted by Chroma, the packaging of the accused product came with a certificate of calibration. The contact information on the certificate at issue showed that ITECH was based in Taiwan; thus, the Court may infer that ITECH had offered for sale in Taiwan. However, while ITECH and ILOAD are from the same business group, it is hard to further prove that ILOAD had ever

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[1] 110-CivilPatTrial-No.20

advertised the accused product on its company webpage, or even sold the accused product. Besides, the defendants argued that the products sold in Taiwan and in China are different because it is common for manufacturers to customize their products according to the availability of raw materials, market orientation, or regulatory compliances in various countries. The IP Court accepted the defendants' argument and ruled that ITECH and Z-FONE' s act of introducing ITECH' s products on their company webpage only constitutes an act of offering for sale in Taiwan.

Nevertheless, according to Article 96(1) of the Patent Act, "[a] patentee of an invention patent may demand a person who infringes or is likely to infringe the patent right to stop or prevent such infringement" ; the court stated that there are justified reasons for considering that ITECH and Z-FONE may exploit the patent in the future in Taiwan as a manufacturer and a distributor, respectively. Therefore, the IP Court ruled that the defendants shall not make, offer for sale, sell, use or import the accused product for the aforementioned purposes in Taiwan.

With regard to the damages claimed by the plaintiff, according to Article 216 of the Civil Code, "the compensation shall be limited to the injury actually suffered and the interests which have been lost." In addition, according to Article 179 of the Civil Code, "[a] person who acquires interests without any legal grounds and prejudice to the other shall be bound to return it." When claiming damages, the claimer should prove not only the infringer's willfulness or negligence but also the damage he or she caused to the claimer. In practice, those who are in support of not awarding damages argue that if the alleged infringers only conduct an act of offering for sale, the patentee has not suffered any damages or loss of profits, so there is no reason to claim for damages. However, it is still possible to demand a person who is likely to infringe the patent right to stop or prevent such infringement.

As a result, there is no justified reason for Chroma to claim damages merely because of the defendants' act of offering for sale in this case.

A New Regulations for the Implementation of the Drug Administration Law will be in place in China

China' s National Medical Products Administration (NMPA) is publicly soliciting comments to a new draft amendment to the Regulations for the Implementation of the Drug Administration Law. Drug Administration Law is the fundamental statutory provisions governing pharmaceutical affairs in China. Its latest version took effect in December 2019. On May 9 of 2022, in order to further reinforce the supervision and management of pharmaceutical products, to safeguard people' s health using medicines, and to encourage the high-quality development in the pharmaceutical industry, NMPA formulated this draft amendment to the Regulations for the Implementation of the Drug Administration Law and published the same to invite general public inputs.

This new draft amendment has 181 articles allotted in a total of 10 chapters, which is way populated than the currently effective version by 101 articles more. Particularly the Section 5 of Chapter 2 is headlined "Intellectual Property Protection for Pharmaceutical Products," including Articles 38 to 40.

Article 38 for "patent linkage" reiterates primarily the same system in the Patent Law and the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes. Where there is patent right dispute during the application for marketing approval of drugs, the relevant parties may file a lawsuit to the court or request for an administration adjudication to the CNIPA. Noteworthily, the examination for the application does not pause during a legal action. For a chemical drug that passed the examination, NMPA will eventually grant a marketing approval or not according to the court' s judgement, verdict, or settlement agreement, or the CNIPA' s administrative adjudication. Having not receive the above documents from the court or CNIPA in lapse of a certain period of time, the NMPA may grant a marketing approval at its own power. Besides, the NMPA is the legal authority to run and supervise a pharmaceutical drug patent information registration platform to disclose patent status associated with a drug, where the marketing approval applicant holder are responsible for the authenticity, accuracy and completeness of the uploaded patent information.

Article 39 for "promoting the development of generic drugs" provides a market exclusivity to the first successful chemical generic drug which wins in a patent linkage dispute, meaning that the NMPA would not grant approval to anther generic copy within 12 months from the date of the first successful generic' s approval. But the market exclusivity term does not exceed beyond the expiry of the challenged patent term.

Article 40 for "data exclusivity" protects market approval holder' s submitted undisclosed experimental data or other data for some drugs from unfair commercial use by others. Within six (6) years from the grant of a market approval to either a chemical drug or a biologic, the NMPA does not grant approval to another application which cites the same data of the previous market approval. Except the necessity of public interests or when measures safeguarding said data against unfair commercial exploitations were adopted, the NMPA shall not make public the undisclosed experimental data as described in the first sentence.

More prominently, for the first time ever, China is about to award market exclusivities to both pediatric drugs and orphan drugs.

As per Article 28, a market exclusivity of no longer than 12 months will be awarded to the first approved drug of new variety, dosage form, and strength specifically designed for children, to an existing drug with newly added indications or administration routes or doses for children. During said market exclusivity no other drugs of the same variety will be approved. To encourage the research and innovation of pediatric drugs, development of pediatric drugs of new variety, new dosage form, and new strength that match the physiological characteristics of children will be supported. The review process for the applications for market approvals of pediatric drugs will be prioritized.

Furthermore, as per Article 29, a market exclusivity of no longer than seven (7) years will be awarded to an approved orphan drug to treat a rare disease, should the marketing approval holder promise an uninterrupted supply of the drug. In failure to keep the

promise of supply, the market exclusive will be terminated. Likewise, to encourage the research and innovation of orphan drugs, studies for drugs that treat rare diseases will be supported and developments for treating new indications of rare diseases by the already marketed drugs will be fostered. Besides, the review process for the applications for market approvals of orphan drugs in urgent needs for clinical uses will be prioritized.

Rare diseases suggest a small market for a medicine product whereas the cost in time and money to develop a new drug remains overwhelmingly high. Pharmaceutical companies engaging in orphan drugs development would start by applications for compound patents for them to better solicit more funding or financing opportunities in order to advance the projects to the next phases. But the lifecycles of an original drug are usually very long that the patent term would almost reach expiry by the time a new medicine is about to debut. And then a generic drug can follow to launch quickly. The result is that the original drug maker could not break even from the enormous cost ever spent. In lack of economic incentives, this vicious cycle devastatingly dissuades additional investment in innovative activities in orphan drugs. A market exclusivity for orphan drugs as now proposed in the draft amendment seems to be an extra segment of time compensable to the original patent term.

Article 178 prescribes the penalty for data leakage to provide that where the NMPA and its staff reveals any undisclosed experimental data or other data to cause losses of the applicant, the NMPA is liable for the applicant's damages.

Last but not the least, as Article 121 provides, for the sake of public health or national emergent status, the relevant authority of the State Council may propose a compulsory license of a patent based on the necessity of disease diagnosis and treatments. Enterprises who is competent of required capacity may hence submit a request to the CNIPA who would eventually determine whether to grant such a compulsory license. The NMPA shall prioritize the review process for the drug for which a patent compulsory license is granted.

Presicarre & Test Rite v. Itoya: Standard of Care in IP Infringement Cases[1]

Both Presicarre Co., Ltd. ("Presicarre") and Test Rite Retail Co., Ltd ("Test Rite") are renowned retailers and have several stores in Taiwan. Both retail stores sold a poster depicting five gods of wealth; the poster is popular with households and companies as part of their Chinese New Year celebrations.

Itoya Publishing Co., Ltd. ("Itoya") claimed that it is the copyright owner of the work of the five gods of wealth (the copyright at issue). Itoya accused Chi Fu Kae Industrial Co., Ltd. (the manufacturer, hereinafter "Chi Fu Kae"), RT Mart International Co., Ltd. (the retailer, hereinafter "RT Mart"), Presicarre and Test Rite of infringing Itoya' s copyright at issue, for which a judgment was issued on March 19, 2018. Presicarre and Test Rite appealed against the judgment.

Both Presicarre and Test Rite claimed that they had not breached their duty of care as retailers, despite the fact that the IP Court had stated in the first instance judgment that the retailers were held liable for negligence for failure to check the infringing products.

According to Article 184(1) of the Taiwan Civil Code, "[a] person who, intentionally or negligently, has wrongfully damaged the rights of another is bound to compensate him for any injury arising therefrom" ; that person shall exercise the due care of a good administrator. Furthermore, according to Article 88 of the Copyright Act, "[a] person who unlawfully infringes on another person's economic rights or plate rights out of intention or negligence shall be liable for damages. Where multiple persons engage in unlawful infringement, they shall bear joint and several liability for damages."

In cases where retailers have sold products which have infringed the intellectual property rights of others, it is arguable whether the retailers should be jointly and severally liable for the tort of a manufacturer.

In this case, the IP Court stated that the image of the five gods of wealth on the accused product manufactured by Chi Fu Kae is substantially similar to the graphical work at issue whose copyright is owned by Itoya. Thus, the act of using the image to reproduce the accused product constitutes infringement. However, both Presicarre and Test Rite argued that they had exercised the due care of good administrators as retailers by contracting with suppliers in order to avoid any possible infringement. It is unreasonable to request retailers to remove all potential infringements of intellectual property rights among the vast range of commodities displayed in their stores.

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[1] 107-CivilCopyTrial-No.6

With regard to the standard of care in intellectual property infringement cases, the IP Court indicated a way to approach this:

First of all, **the level of care depends on the role assumed by the party.** Is the party a professional manufacturer or seller? What type of intellectual property right is infringed? Unlike patent and trademark rights, for which the law requires the publication of the complete contents of the right as the manifestation of rights for public access, there is no such similar publication of copyrights available for the public to check the existence of copyrights.

On the other hand, a case of patent infringement analysis involves a comparison of technologies in a particular field, while a case of trademark infringement requires an examination against the standard of likelihood of confusion. Both of these should be conducted on a case-by-case basis by the IP Office or the IP Court. Therefore, before judging whether a person has failed to exercise the duty of care, specific circumstances should be taken into account in an individual case.

Secondly, **there should be different levels of care imposed on manufacturers and sellers.** A blind imposition of the same level of duty of care on all entities would mean nothing more than to require the strictest "liability without fault" . This not only exceeds the original regulatory purpose of the law but also interferes with the efficiency of economic activities.

Presicarre and Test Rite have both contracted with their suppliers in order to prevent possible IP infringement. Both retailers also declared that they could withdraw the infringing products if any infringement were found. However, neither of the retailers was requested by Itoya to withdraw the accused product before this lawsuit was initiated. As such, there was deemed to be no negligence on the retailers' side. The IP Court in the second instance stated that the retailers had not failed to exercise the degree of care which they should and could have exercised. The IP Court therefore reversed the first instance judgment, finding an absence of negligence on the part of Presicarre and Test Rite.

Although this appellate judgment concerns copyright, it also provides a guideline regarding the level of care in other intellectual property infringement cases. Since information regarding patents or trademark rights can be obtained through official publications or via search engines, the manufacturers or sellers have a minimum obligation to confirm the risk of infringement by conducting due diligence. The act will be considered to have been committed negligently if the party fails to carry out background checks, or intentionally if the party foresees possible infringement but still exploits the intellectual property rights of others.

Taiwan Requires Examination Before Transfers of Investments Concerning Key Tech Exported to China

The Ministry of Economic Affairs (MOEA) amended the provisions of the Regulations Governing the Approval of Investment or Technical Cooperation in Mainland China (hereinafter the "Regulations"); the amendments took effect on April 21, 2022.[1]

The Regulations, promulgated in 1993, have been revised several times in accordance with the increasingly frequent commercial activities between Taiwan and China. The last revision, effective on December 30, 2020, had broadened restrictions—from the direct transfer or authorization of professional skills or IP rights to the indirect transfer or authorization of the same.[2] In view of the current political relationship, the Taiwan government has considered it necessary to further restrict cross-strait investments or technical cooperation.

According to Article 7(1) of the Regulations prior to the amendment, for any investment or technical cooperation in China undertaken by Taiwanese citizens, juridical persons, associations and other organizations, permission should be requested from the Taiwanese Investment Commission of the MOEA beforehand. However, one may only need to declare such an investment or technical cooperation beforehand if the outbound capital accumulated is below a certain threshold. Furthermore, according to Article 10(1) of the Regulations prior to the amendment, for any subsequent transfer of Taiwanese investments and technical cooperation for which permission has already been requested or a declaration has been made, the Taiwanese transferor could make a post-transfer declaration to the Investment Commission within two months following the transfer. The definition of technical cooperation, as stipulated in Article 5 of the Regulations prior to the amendment, includes both direct and indirect transfers as well as the licensing of professional skills or IP rights.

In the April 2022 revision, the MOEA introduced a new Article 5(2) in the Regulations to broaden the definition of "technical cooperation." Under this broader definition, the transfer and licensing of

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1 https://www.moeaic.gov.tw/news.view?do=data&id=1610&lang=ch&type=new_ann

2 https://www.moeaic.gov.tw/news.view?do=data&id=1491&lang=ch&type=new_ann

computer program copyrights are subject to restriction. The transfer of investments to individuals or entities in China will also be considered an act of technical cooperation; such transfers were previously only required to be examined by a special key technology team organized by the controlling authorities and then approved by the Investment Commission. In other words, Taiwanese investors seeking to transfer their shares of investments to China must apply to the Investment Commission for permission in advance (rather than just making a post-transfer declaration, as was stipulated previously); this applies especially to the semiconductor and display industries. The purpose of this is to avoid the situation of the transfer of a shareholder' s right resulting in the use of the key technology by China; this is no different from the transfer or licensing of professional skills or IP rights.

Since the late 1980s, Taiwanese companies have invested in and have opened many factories in China. In response to growing tension between Taiwan and China, the Investment Commission of the MOEA decided to further limit the potential risk of leaking of key technology in order to maintain Taiwan' s competitive advantage in the high-tech industry. In addition to the Regulations, the Taiwan Legislative Yuan also passed an amendment to the National Security Act on May 20, 2022, in which penalties were introduced for "Offenses of Economic Espionage" and "Offenses of Extraterritorial Use of Trade Secrets of National Core Technologies" . Cross-strait investors should pay close attention to the new rules and the potential risks regarding regulated transfers.

A Substantial Amendment to IP Case Adjudication Act is put on the Agenda

The IP Case Adjudication Act will undergo the largest-scale revision seen since its enactment more than a decade ago.[1] The IP Case Adjudication Act covers the procedural rules in the trials of intellectual property cases—encompassing patents, trademarks, copyright, plant varieties, trade secrets, and others. It serves to provide exceptions to the laws applicable to civil, criminal and administrative actions. For matters not provided for under the IP Case Adjudication Act, the Code of Civil Procedure, the Code of Criminal Procedure and the Administrative Litigation Act shall apply. It is a fundamental source of law to offer Technical Examination Officers in aid of the judges and the instrument of secrecy protective orders to protect information confidentiality in the stage of litigations.

The prospective amendment places particular emphasis on the increased protection of trade secrets, including criminal cases involving trade secret misappropriation amounting to a breach of national security. For civil cases, the amendment introduces institutions for centralized adjudication and increased participation of experts to facilitate the courts in handling cases involving newly emerging technologies. The essential aspects of the prospective amendment—albeit subject to change—are as follows.

1. The Intellectual Property and Commercial Court (IPCC) shall be vested with jurisdiction over trials of crimes of theft of trade secrets, committed in Taiwan and in foreign jurisdictions.
   It is noteworthy that under the current law, first instance criminal cases—including those involving trade secret crimes—are adjudicated by district courts where prosecutors are equipped.

2. Parallel to the February 2022 draft amendment to the National Security Act, the IPCC shall have jurisdiction over criminal offenses involving the infringement of significant trade secrets relating to national core technologies.

3. It was proposed to introduce the right to access to dossier information and to remove the use of code names and code signs as de-identification measures for documents in cases involving trade secrets.

4. Activities in breach of a secrecy protective order shall be subject to heavier penalties, and the crime of breaching a secrecy order beyond the border shall be codified in order to improve the protective mechanism for the trials of criminal cases involving trade secrets.

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[1] https://reurl.cc/OA8O77

5. For civil matters of IP, new measures—such as mandatory representation by a lawyer, formulation of a trial schedule, and expert witnesses—are proposed.

6. An “inspection” system shall be added as a means of evidence investigation. The court, by request, may select a neutral technical specialist who would be permitted to enter a defendant’ s premises to collect evidential material during a pending litigation, in reference to the Japanese Patent Law

7. An "amicus curiae" system shall be introduced, whereby the written opinions of individuals, societies or organizations other than the litigating parties may be recorded on the court’s website.

8. The "Patent or Trademark Review and Dispute Procedures" shall be instituted to conform to the current draft amendments to the Patent Act and the Trademark Act. An “adversary” system shall bring about the transitioning of remedial appeals for patent and trademark cases from administrative litigation procedures to civil litigation procedures.

9. In order to promote the development of e-justice, the scope of utilization of technological equipment in litigation shall be extended, and the original copy of a judgment can be served electronically.

10. The amendment shall introduce the following measures: the establishment of an information exchange mechanism between the proceedings of administrative reviews and judicial trials, the requirement of a duty of notification by an exclusive licensee to the patentee, the imposing of restrictions on the filing for a retrial due to inconsistency in judgments of patentability, as well as a revision of the rules regarding the defensive post-grant amendment of claims during an infringement trial. These measures are intended to avoid discrepancies in adjudication, resolve disputes arising in the course of trial procedures, and ultimately improve adjudication efficiency.

As of this date, the Judicial Yuan (The Department of Justice) has not yet released the proposed draft amendment to the public on its website. More information and comments shall be provided at a later stage.

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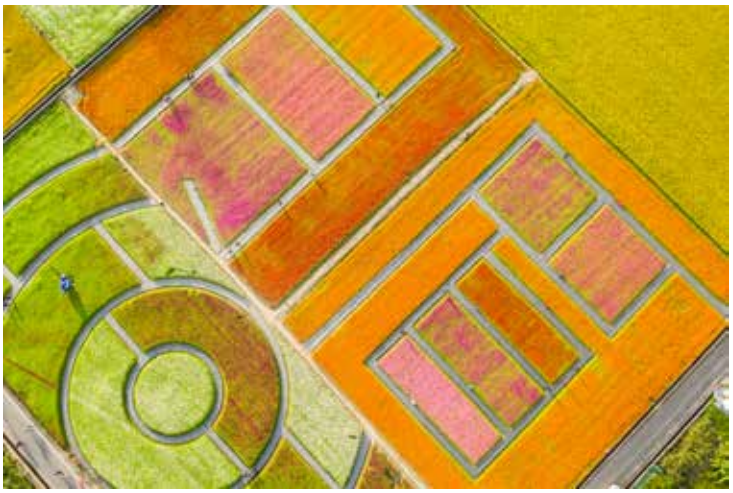

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