

October 2023

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Page/02

China Launches New Competition Regulations against IPR Abuse

Page/05

Supreme Court Affirmed that Excessive Borrowing of a Registered Mark in Advertising is Not a Fairly Descriptive Use

Page/10

Court Favored TIPO in Formality Requirements for Priority Documents

Page/15

CFMoto v. Segway: China Court Brought Forward Analytical Elements in Resolving Ownership Dispute of Patent

Page/19

Report Preparation Period in a Foreign Clinical Trial Confirmed Countable toward PTE

Page/22

Brief Introduction to Inspection as a New Technique for Evidence Gathering

www.tsalee.com



info@tsalee.com.tw

China Launches New Competition Regulations against IPR Abuse

On August 1, 2023, the revised Regulations on Prohibiting the Abuse of Intellectual Property Rights to Eliminate or Restrict Competition (“**Regulations**”) promulgated by the State Administration for Market Regulation (“**SAMR**”) came into effect. Of the new Regulations comprising 33 articles, 18 were revised and 14 were newly added. They systematically implement the guiding rules in the Anti-Monopoly Law (“**AML**”) with a balance between encouragement of innovation and fair competition, in the hope of creating a roadmap for fair, transparent and predictable behavior in the course of IPR operation. Some highlights are summarized below.

In alignment with part of the AML’s legislative goal of driving innovation, the enterprise having market dominance shall not abuse its market power to eliminate or restrict competition. The possession of IPR may be a factor in identifying the dominant market position. However, it is not the only factor. In view of a given circumstance, the possibility and switching cost for a counterparty in a relevant market to switch to a replaceable technology or product, the downstream market’s degree of dependency on the product incorporating an IPR, and the counterparty’ s ability to counterbalance the enterprise may all be evaluated. (Article 8) The new Regulations set forth the factors for determining if the IPR exercises are legitimate such as whether an activity

- (1) promotes innovation and competition;
- (2) is necessary for using or protecting IPR;
- (3) is necessary to ensure product safety, technical effects and quality performance;
- (4) meets both the actual needs of the counterparty in transaction and the proper customary norms in the industry; and
- (5) fulfils certain other factors of legitimacy. (Article 20)

More unlawful types of monopoly agreement are exemplified. Enterprises shall not by means of using IPR enter into monopoly agreements, meaning the agreed deals, decisions or other concerted activities that eliminate or restrict competition. In addition to contracting for oneself, an enterprise is further forbidden from using IPR to either abet others to reach a monopoly agreement or provide substantive assistance to others in reaching the same. (Article 6) However, a safe harbor clause is available. Should the enterprise be able to prove to the contrary that said agreement—even if contracted—does not eliminate or restrict competition, said agreement may be deemed lawful. (Article 7)

The Regulations feature the prohibition of the event of excessive pricing in the monetization of IPR. The enterprise that possesses market dominance shall not license IPR or sell IPR-inclusive products at an unfairly high price in order to weaken or limit competition. What constitutes an unfairly high price may take into account

- (1) the R&D expenses and the break-even time of said IPR;
- (2) the royalty calculation and licensing terms;
- (3) the comparable former royalty rate or standards;
- (4) the promises made to the IPR license; and
- (5) other factors. (Article 9)

Several types of abuse of market dominance have been defined in more detail; these include the refusal of licensing under fair conditions (Article 10), restrictive transactions (Article 11), tie-in regardless of the customary practice in the industry or a product's functionality (Article 12), attachment of unreasonable terms and conditions (Article 13), and discriminative treatment (Article 14).

Events of market concentration are subject to stricter controls specifically. According to the Regulations, when the level of concentration of undertakings involving IPR meets a particular threshold set by the State Council, the enterprise shall report and then receive an approval before carrying on any actions for concentration. (Article 15) In furtherance, as to whether a market formed of IPR-involved enterprises is considered concentrated, more restrictive factors in addition to the conventional ones required by the AML shall be considered, such as

- (1) the nature of the divested IPR or the business associated with the IPR;
- (2) the maintenance of independent operation of IPR-related business;
- (3) the licensing of IPR under reasonable terms; and
- (4) others. (Article 16)

Standard essential patent-related anti-competitive activity is another focus of the Regulations. Not only may the enterprises be forbidden from engaging in behaviors detrimental to competition using patent pools in the course of exercising IPR, they are also prohibited from reaching an anti-monopoly agreement through exchange of sensitive intelligence regarding pricing, production capacity and exclusive territory, etc. unless no elimination or restriction to the market is demonstrated. Furthermore, an enterprise having market dominance shall not exercise its market power to license




a pooled patent at an unfairly high price, to restrict the pool member or licensee' s scope of use of the patent without due cause, or to forcibly demand a licensee to exclusively or solely license back an improvement or developed know-how to the pool member. (Article 17)

Without due cause, an enterprise shall not take advantage of the formulation and the implementation of a standard to become party to a monopoly agreement and shall not unreasonably engage in behaviors that undermine competition such as licensing in violation of FRAND requirements. (Articles 18 and 19)

Article 24 and below of the Regulations set forth the penalties. One who illegally practices an anti-monopoly agreement will be punished with an injunction, a confiscation of unlawful income, and a fine amounting to 1-10% of the sales of the previous fiscal year. Instead, should there be no sales in the previous year or if the agreement has been entered but not yet practiced, a maximum fine of RMB 5 million or RMB 3 million will be imposed, respectively. (Article 25) One who illegally abuses market power will likewise be punished with an injunction, a confiscation of unlawful income, and a fine amounting to 1-10% of the sales of the previous fiscal year. (Article 26) For one who illegally engages in IPR concentration events that have or may have anti-competitive effects, the SAMR shall require the cessation of the concentration events, disposal of the shares or assets, transfer of the business, and adoption of necessary means to return to the status prior to the commencement of the events of concentration. A fine amounting to less than 10% of the sales of the previous fiscal year will be imposed. Notably, concentration is per se illegal. Even if a case of disallowed concentration does not cause anti-competitive effects, the SAMR will impose a fine of RMB 5 million. (Article 27) Lastly, as per the AML, a punitive fine from two times to five times may be imposed in the event of grave malice or negative consequence. (Article 29)

Supreme Court Affirmed that Excessive Borrowing of a Registered Mark in Advertising is Not a Fairly Descriptive Use

CMP, founded in 1972, owns a business cluster ranging from residential real estate to retail shopping centers. It is the owner of the following three registered trademarks.

TM Number 01872485		Class 036
Name Parklane by CMP (Phonetically QingMeiLvYuanDao)		Appl. Date 2016/11/04
TM Number 01872487		Class 036
Name CMP World (Phonetically QingMeiTianDi)		Appl. Date 2016/11/04
TM Number 01872723		Class 042
Name CMP World (Phonetically QingMeiTianDi)		Appl. Date 2016/11/04

Apex group, another realty developer, was found to have widely adopted expressions and slogans associated with “CMP” such as “Parklane by CMP,” “CMP on Gongyi Road” and “CMP x Gongyi” in Apex’s advertisements for a project called Omotesando on Facebook pages and other platforms. CMP sued Apex for infringement of trademarks, while Apex argued that they had used these phrases fairly.



The trial court stood with Apex and rejected CMP’s infringement claims.¹ As the court explained, even though “Parklane by CMP” was a trademark owned by CMP, it also referred to a famous landmark—The Park Lane by CMP, a shopping plaza complex.

¹ IPC-110-CivilTMTrial-No.49 (2022.05.04)

Apex did indicate its company name on its project advertisements. In the perception of interested consumers, these phrases incorporating the name of CMP would be considered as eye-catchers given that Apex' s project site was in the vicinity of the shopping mall and the nearby commercial area.

CMP appealed the trial decision with the outcome turning against Apex. In reverse, the appellate court found trademark infringement as a result of failed fair use defense.²

The core question in the case was whether Apex' s use of the phrase in dispute constituted infringement, and if yes, whether a fair use defense was established. As the court analyzed, these phrases printed on construction project advertisements constituted “application of a trademark to commercial documents relating to goods or services” in the course of trading activities. Hence, Apex engaged in the use of a trademark as legally defined in the Trademark Act. Secondly, Apex' s use of the same trademark fell under the category of realty rental and sale services, the exact same class to which CMP' s registered trademarks were designated. Therefore, Apex were found to have infringed CMP' s trademark rights. Only under a lawful defense would Apex have been free of liabilities.

In its analysis of the fair use defense, the court cited that “trademark right does not restrain a third party if a trademark is employed primarily as a descriptor of, for example, the name, exterior, quality or function of a product or service rather than as an indicator of the source of goods/services”³. In the present case, the CMP-related terms appeared repeatedly in Apex' s advertising materials and far more prominently than the Apex terms themselves. Although the phrases “CMP on Gongyi Road” and

² IPC-111-CivilTMTrial-No.14 (2022.11.24)

³ SC-97-TaiwanAppeal-No.364 (2008.02.29)

“CMP X Gongyi” might be deemed to be descriptive in explaining the relative location of the Omotesando project (since Gongyi was the name of a particular road on the map), “CMP” was conceptually irrelevant to Omotesando and “The Parklane by CMP” was not indicative of the quality of Omotesando. The use of terms bearing CMP was not an act necessity of neutral description. “The Parklane by CMP” and other terms containing it were clearly used to promote Apex’s own Omotesando project.

Apex insisted that “The Parklane by CMP” served only to denote the proximity of Omotesando and the shopping mall. However, this argument was similarly untenable. Omotesando was in fact closer to another street market. The distance between Omotesando and The Parklane by CMP was at least 1.1km. Additionally, a running creek separates the two places spatially; thus, general consumers would not consider them to be geographically located in the same commercial area.

After the finding of infringement and failure of fair-use defense, the court awarded damages in favor of CMP.

Apex further filed an appeal to the Supreme Court. However, without the support of new evidence and arguments, the appeal was rejected as a result of the finalized third-instance adjudication.

The Supreme Court’s decision denotes a further clarification of the concept of trademark use and fair use exception; this is echoed by another recent judgment as summarized below.⁴

⁴ SC-111-TaiwanAppeal-No.835 (2022.05.25)

A Company is the owner of pesticide trademarks “ZhengFeng (with a logo)” and “ZhengFengDong (with a logo).” B Company printed the words ZhengFeng in combination with another product name on its pesticide packaging, claiming that such practice was in line with the pesticide administration measures. Both the courts of first and second instances ruled in favor of B, stating that the use of the words ZhengFeng on its packaging was descriptive in nature, since it presented the brand name and displayed the quality of the product. Hence, the fair use exception was applicable. Following an appeal, the Supreme Court reversed and remanded the case, opining that B Company’s terms on its packaging constituted use of the trademark.

The Supreme Court emphasized that, even though the pesticide measures require that information be disclosed by labeling both the brand name and product’s own name on packaging, whether such practice of combining terms constitutes infringement of a trademark use depends not only on the pesticide measures but also on the Trademark Act, also taking into account the knowledge of the consumer. In this case, the accused packaging bore the term ZhengFengDong accompanied by the symbol ®. Other than ZhengFeng, many other brand names were registered as trademarks. ZhengFeng was an arbitrary term with a higher level of distinctiveness. These were critical factors pending further evaluated to determine whether they constituted use of a trademark. In short, compliance with an administrative measure does not necessarily amount to fair use by harboring an act from trademark infringement.



Court Favored TIPO in Formality Requirements for Priority Documents

Lensar is a manufacturer of innovative medical laser technologies and systems adaptive for ophthalmic procedures such as cataract removal. In Taiwan, Lensar (“the applicant”) filed a patent application on December 31, 2020 claiming priority to a US application filed on January 3, 2020. The priority document accompanying the Taiwanese application was a photocopy (“photocopy”) of a priority application, which was previously filed at the US Patent and Trademark Office (“USPTO”), with a cover page reading “This is to certify that annexed is a true copy from the records of this office of the filed wrapper and contents”.

Upon receipt of these documents, the TIPO rejected the priority claim on January 13, 2021, on the basis that the paperwork submitted by the applicant was not a lawful priority document in conformity with TIPO’s Patent Examination Guidelines (“PEG”). In particular, the TIPO insisted that an admissible priority document should have borne the verbatim wording “[T]his is to certify that annexed hereto is a true copy from the records of the United States Patent and Trademark Office of those papers of the below identified patent application that met the requirements to be granted a filing date under 35 USC 111 [exhibiting a secured filing date]. The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US” . The reason for this was, as the TIPO emphasized by citing its own promulgated PEG, that said photocopy was not reviewed and verified by the foreign IP authority to entitle it to a filing date to a extent which would substantiate the document itself as being one received and docketed at the foreign IP authority.

The applicant sued the TIPO. The main argument was that the TIPO’ s source of law which formed the basis of its rejection of the photocopy was merely the Patent Examination Guidelines—the TIPO’ s own authoritative regulations. The TIPO’ s interpretation of what constituted a priority document unduly narrowed the textual definition for priority documents from the Patent Act. As the applicant stressed, the Patent Act was silent on which paper of a particular formality issued from a foreign patent authority will be considered a lawful priority document serving as admissible evidence to enjoy the benefits of an earlier priority date. Instead, the Patent Act demanded minimally that a submission of “a docketed application certified by a priority-reciprocated country or a WTO member” would suffice. As a part of the administrative body, TIPO has the obligation to rule and be bound by statutory law.

The TIPO should not add excessively redundant elements on top of statutory requirements, which would lay on unnecessarily additional burdens on applicants and the general people at large.

On April 28, 2022, the IPC Court issued a first-instance judgment to dismiss Lensar' s complaint on the grounds that the TIPO' s decision of rejection was correct.¹ Lensar appealed the case to the Supreme Administrative Court (“SAC”) for the second instance review. On May 25, 2023, the SAC affirmed the lower court's decision.²

In the opinion of the SAC, the formality requirements of a priority document stipulated by the TIPO do not exceed the meaning of statutory law. The Patent Act enacted by the legislative body authorizes the government agency (here the TIPO) to plan and formulate corresponding Implementation Rules for carrying out specific measures including, among others, the form of a priority document. In the Implementation Rules, a priority document must be an original copy in paper or electronic form. They are essentially only procedural and supportive guidelines; they do not exceed policy mandates or the textual boundaries of statutory law.

A priority document is a legal instrument for authenticating the “institution of an earlier filing” in order to decide whether the benefit of priority is applicable. Such a document should contain sufficient information to allow the TIPO to determine whether the earlier application was filed in a WTO member or reciprocal state, whether the Taiwanese application was filed within 12 months of the earlier filing date, and whether the Taiwanese and the earlier applications claim the same invention. Therefore, a qualifying priority document should bear both the filing date of the earlier application and the application number, and should include a copy of content equivalent to the earlier filed application for review by the TIPO. Furthermore, the priority document provisions in the Patent Act were drafted with reference to the Paris Convention, which requires priority documents to be issued by the patent

¹ IPCC-110-PatentTrial-No.55 (2022/04/28)

² SAC-111-Judgment-No.492 (2023/05/25)

authorities of member states. Taiwan must abide by the Paris Convention, which states that a photocopy in substitute of the original copy is invalid.

The PEG provides that a lawfully admissible priority document is one issued by a WTO member's patent authority after said earlier filing has been docketed. It should include a cover page bearing details such as the name of the office in full, an embossed seal, the title of the invention and the filing date; it should also include a patent specification, drawings and other basic information, and all pages must be bound together like book. Conversely, electronic application receipts, notices of acceptance or allowance, patent certificates themselves, patent gazette clippings, and full-volume photocopies of applications are not acceptable. The PEG do not add excessive restrictive requirements and are in line with the legislative policies of the Patent Act, the SAC opined.

In the present case, the photocopy submitted by the applicant did not bear an official filing date to demonstrate acceptance by the USPTO or any text specifying priority. It was not a lawful priority document capable of establishing priority right. The lower court's finding was not erroneous; therefore, its judgment was affirmed.

This was not the first case in which the SAC found in leaned towards the TIPO on the issue of the formality requirements of a priority document.³ The TIPO is the specific authority responsible for IP administration, including patents. Supportive administrative measures such as documentation procedures are subject to only low-intensity judicial review. In the pursuit of correct and professional identification of whether the particular requirements are met, the court conceded to the TIPO's rules and decision.

In the Patent Examination Guidelines, the TIPO provides a number of examples of cases where priority claims were rejected due to incorrectly filed documentation.

³ SAC-108-Judgment-No.516, 517, and 518 (2019/11/13)



Example 1

A photocopy of the entire file wrapper (USPTO).

Example 2

A filing receipt with a photocopy of the specification (USPTO).

Example 3

A filing receipt with a photocopy of the specification (Design under the Hague Agreement)

Example 4

A certificate of registration for design (EUIPO).

Recently, in September 2023, the TIPO launched an online mini-database in collection of examples of priority documents from the peer Offices acceptable by the TIPO. (In Chinese only; <https://topic.tipo.gov.tw/patents-tw/cp-997-926445-74a4f-101.html>)

On a separate note, Taiwan is currently engaged in bilateral electronic priority exchange (PDX) programs with Japan and Korea. Both the Taiwan-Japan and Taiwan-Korea PDX programs are available for all types of patents, be they inventions, utility models or designs. In order to take avail of the PDX in Taiwan, a first filing applicant in Japan needs to obtain an access code from the JPO and then provide the same in addition to the application number, filing date, and the type of patent filed in Japan. As for a first filing in Korea, the applicant only needs to specify the application number and filing date in order to claim priority in Taiwan.

On a final note, the Digital Access Service (DAS) code administered by the WIPO is not accepted in Taiwan.

CFMoto v. Segway: China Court Brought Forward Analytical Elements in Resolving Ownership Dispute of Patent

CFMoto is a Chinese manufacturer of ATVs, motorcycles and other kinds of automobiles. Chen and Rong were two individuals who had been employed by CFMoto since about 2010. In July and September 2018, they left CFMoto and joined Segway successively. In 2019, Segway filed for a patent application for a utility model titled “Air filter and all-terrain vehicle with same” (hereinafter referred to as “the patent”). The application proceeded to grant in 2020, with Chen and Rong named as the first and second inventors, respectively. CFMoto (hereinafter “the plaintiff”) sued Segway, Chen and Rong in seek of a declaration that CFMoto was the true owner of the patent. The plaintiff complained that Rong was the chief individual responsible for a vehicle development project to, among other things, formulate designs and research plans, coordinate the research teams and supervise their daily work progress. A series of evidence were submitted to demonstrate that Rong and Chen were the receivers or senders of emails enclosing engineering drawings for air filters and the parts. They also signed a number of the drawings as the document creator or the proofreader. The application for the patent in dispute was filed within one year of their leaving the plaintiff.

The Suzhou Intermediate People’ s Court heard the case, finding that the patent was irrelevant to the plaintiff’s model.¹ In China, a service invention refers to (1) an invention made in the course of an employee’ s performance of the assigned work; (2) an invention made in the performance of tasks in addition to the assigned work; or (3) an invention in connection to the work assigned under the previous employment and performed within a year of termination of employment or transfer from the previous post. In the present case, Rong and Chen involved only partially in the research project for ATV-used air filters. Rong was more of a project

¹ (2020) Su-05-MinChu-No.1073

manager and the plaintiff's model was missing several features as claimed in the patent. A study of the technical fields of the patent and the plaintiff's model confirms that they both indeed involved air filters. However, regarding technical problems and their solutions, the patent put forward an integrated inlet to resolve the issue of the air filter having a shorter lifecycle and being costly to maintain due to its comprising multiple parts which are difficult to accurately fit, assemble and seal. By contrast, the plaintiff did not solve the above technical problem. In fact, the plaintiff's model itself embodied prior art in the background of Segway's invention. Hence, the court concluded that the contested invention had not been created by the plaintiff or its research team. The plaintiff appealed.

The Supreme People's Court as the appellate court stressed that the main query in this ownership dispute was whether the patent was relevant to Rong and Chen's assigned duties or tasks during their employment with the plaintiff to such an extent that the patent represented a service invention arising from work performance.² In the interpretation of the SPC, the law of service invention ownership should not be construed so broadly that it illegitimately restricts the horizontal mobility of a workforce or the carrying out of new technical research events. To figure out whether an invention relates to the previous employment, the SPC opined that several elements must be carefully investigated:

- ① The characterization of the invention: the invention's technical field, the technical problems to be solved, the purpose and the technical effects, the claimed scope of the invention, and the substantive features as compared to the prior art, among other things.

² (2022) SPC-ZhiMinZhong-No.1229

- ② The details of the previous employment: the job responsibilities, the level of employment, the actual ability to control or acknowledge the technical information related to the patent, and the relationship between the patented invention and the assigned works or the job responsibilities.
- ③ Whether the substantive features or ideas for improvement are presented in the former employer' s models/products, or whether the patented invention reveals derivation or advancement originating from the former employer' s models/products.

Having set forth the elements as the foregoing, the SPC conducted an analysis and found that the trial decision was correct. Firstly, the invention in dispute was an air filter which displayed the advantages of easy assembly, easy sealing, long intervals between maintenance and a long lifecycle. Secondly, the scope and responsibilities of Rong and Chen' s employment did not include the specific work of air filter research. There was insufficient evidence to ascertain that Rong and Chen had been assigned specific tasks involving the improvement of air filters. Thirdly, in the investigation of the plaintiff' s engineering drawings, it became clear to the court that the plaintiff' s model was unable to perform turning, the prevention of the intake of dust or debris at a particular section, or the defining of another component in a certain place, all of which the patented invention could perform. That is, the patented invention could not possibly have been derived from or created based on the plaintiff' s model.

The SPC further added that, since there was no derivative relationship between the plaintiff' s model and Segway' s invention, it remained far-off to conclude that Rong and Chen had secretly transferred the documents to Segway on the mere basis of Rong and Chen' s signatures being on the drawings and the activities of sending and receiving emails which enclosed said engineering drawings. Before concluding, the SPC once again emphasized that the interpretation of the technical "relevance" between the patented invention and the contesting model was pivotal in an ownership dispute. In accordance with the policy purpose of the law of service invention ownership, the arbitrary crediting of the former employer with all automotive part inventions was not fair or reasonable. Doing so would have materially deprived a skilled worker of the constitutional right to work, restrained creativity by curbing the mobility of innovative talents, and brought about an imbalanced share of interests in the triangle of the former employer, the current employer and the employee.

The lower court' s decision was affirmed. Thus, the case was concluded and final that the utility model patent remained at Segway.

Report Preparation Period in a Foreign Clinical Trial Confirmed Countable toward PTE

Patent term extension (PTE) in Taiwan includes both the period for conducting clinical trials domestically and/or abroad and the period for reviewing the application for regulatory approval by the health authority.¹ As required by the TIPO's Patent Examination Guidelines,² when the clinical trial is conducted abroad, the trial period shall be defined by a study initiation date and a study completion date provided by the standardized reporting format under the ICH guidelines.³ The study completion date means an earlier date of the last patient completed rather than a later date on which a report concluding said study is finished and presented. TIPO's interpretation has raised some questions because adopting an earlier end date inevitably excludes the period of producing the report from being counted towards the PTE.

Roche and MSD (collectively referred to as “the patentees”) filed PTE applications to the TIPO sometime before 2018. In 2019, the TIPO made two decisions to grant PTEs, but both were shorter than the lengths requested by the patentees. This was primarily because TIPO identified the end date of the foreign clinical trial period as being the study completion date, as mentioned previously. Opposing this, the patentees argued that it would only be fair if the end date was a later time point, that is the date on which a written report presenting the outcomes of a study is complete. Not satisfied with the TIPO's decisions, the patentees filed administrative appeals and subsequently lawsuits.

In June 2020, the IPC Court issued two separate but consistent trial judgments,⁴ ruling in favor of the patentee by finding that the study's end date was the reporting date rather than the study completion date. The IPC pinpointed that fact that before the study report is

¹ Article 4(1) of the Regulations Governing the Determination of Patent Term Extension

² Section 3.1.3.1.1, Chapter 11, Part II

³ International conference on harmonization of technical requirements for registration of pharmaceuticals for human use

⁴ IPC-109-AdminPatentTrial-No.5 (Roche; 2020.06.30) and IPC-109-AdminPatentTrial-No.88 (MSD; 2020.06.30)

complete, no regulatory approval will be issued. In other words, the patent right cannot either be exercised during the period in which a report is being prepared. Hence, from the perspective of the policy of the PTE institution, both the period of conducting a study and the period of preparing its report should be counted towards PTE. The TIPO appealed, insisting that the end date should be merely the date the study was completed.

In 2022, the Supreme Administrative Court (SAC) as the appellate forum vacated the trial judgments of both cases.⁵ The SAC did not specify which end date was correct but dictated to seek advice from the optimal agency in the particular field. In the opinion of the SAC, the competent authority for issuing regulatory approval for domestic or foreign clinical trials was the Ministry of Health and Welfare (MOHW). Hence, MOHW was the governmental body with the most capable expertise in medical affairs to ascertain the length of a study's duration. The TIPO should thus consult the MOHW in order to correctly determine the length instead of doing so by merely taking the study completion date. Similarly, under the rationale above, the IPC Court in the trial judgment also erred in failing to consult the MOHW when determining the correct clinical trial period. The lower court's straight adoption of the reporting date seemed similarly arbitrary.

Following up in September 2023, in adherence to the reasoning of the SAC, the IPC Court in remand rendered two other judgements. Opining in favor of the patentees, the IPC Court determined that the period for producing a report concluding a foreign clinical trial should be included in the PTE. The IPC Court reasoned firstly that the exclusion in the TIPO's Patent Examination Guidelines of the time spent for producing study reports unduly

⁵ SAC-109-Appeal-No.990 (Roche; 2022.04.13)

narrowed the policy purpose of the PTE, that is to adequately compensate for the time during which a patent stays unenforceable. Secondly, while the TIPO recognized the date of receipt of a clinical trial report as the end date of the study being conducted in Taiwan, the fact that it denied the reporting date as the end date in the present cases where the study was made overseas was deemed to be unfair. Thirdly, and most crucially, a clinical trial report that organizes, analyzes and demonstrates statistical data is an essential document to accompany an application for regulatory approval to the MOHW to better enable them to determine whether the drug product fulfills the requirements of biosafety, efficacy and other factors. Only when a conclusive study report is presented will the MOHW be able to decide whether or not to grant approval. Therefore, the clinical trial period to be countable toward PTE should end at the reporting date instead of the study completion date. In other words, in addition to the duration of conducting a study, the duration required to produce a study report was justifiably considered to be a part of the foreign clinical trial period to be countable toward PTE.

In accordance with the IPC Court' s holding, the PTE became five years in the Roche case, a total of 307 days more than the period previously granted by the TIPO; in the MSD case, the PTE was 624 days in total, amounting to an additional 113 days.

To encapsulate, the SAC emphasized that the foreign clinical trial period for PTE depends on whether the study is sufficient to enable the MOHW to issue regulatory approval. Production of an analytical report to edit raw data seems to be a necessary endeavor. In the latest judgments, the IPC Court interpreted the reporting date as the time when the necessary data can finally be presented for the MOHW to be able to decide the issuance of an approval. Despite it is unclear whether the TIPO had further appealed the IPC Court' s interpretation by the time this article went to press, it should more likely than not assure that a significant portion of the time spent on producing study reports can be counted towards PTE in the future.

Brief Introduction to Inspection as a New Technique for Evidence Gathering

On August 1, 2023, Taiwan' s new IP Case Adjudication Act came into effect. Among a number of other added or revised clauses, Articles 19 to 27 comprise a new institution known as inspection. Its introduction was intended to serve as a new means of evidence investigation, in seek of upholding the equal-arms principle in an IP lawsuit.

Inspection purports to solve the issue of evidentiary bias arising from the fact that the majority of evidence or more favorable evidence resides at one side of the litigating party, an imbalanced situation which is otherwise difficult to resolve. Inspection is available in cases of infringement of patents, computer program copyrights, and trade secrets. More specifically, it was designed in the hope that it could be efficiently used in cases involving methods. For example, in a litigation involving computer software or manufacturing processes, an inspector can manually operate a suspect computer program or observe a machinery function on-site in a factory in order to understand whether the claimed steps are performed one after another in accordance with the All Elements Rule in patent law. Notably, not only the defendant but also a third party may have to be inspected at an order of the court, since the evidence may often lie with the third party.

In order to petition for inspection, the petitioner must submit a preliminary explanatory statement to the court setting forth inter alia the probable cause of the facts or risks of infringement (probability element), the inability of the petitioner to efficiently gather evidence on its own (complementariness element), the necessity of the means and objects to be inspected (necessity element), the physical location of the object, and the relevance between the object and the provable facts. Nevertheless, the court will not make its decision based solely on the statement of the petitioner. Before deciding whether or not to order an inspection, the court shall offer the defendant or the third party restrained by such an order the opportunity to argue as to why an inspection would illegitimately injure their procedural interests if granted.

Notably, inspection is not a supplementary means of evidence collection. It does not require the petitioner to firstly petition the defendant to proactively present the desired evidence and for the defendant to fail to do so before said petitioner becomes eligible to make use of inspection.

An inspector is a neutral expert in the field appointed by the court. Upon being ordered to do so, the inspector will enter the property where the suspect objects are located in order to conduct an investigation of documents or mechanical devices by means permitted by the court. The inspector is authorized to question the inspectees and may order them to present documents or materials deemed necessary.

As a coercive measure, obstruction of inspections will invite negative consequences. In the case of the defendant refusing the inspector' s entry or obstructing the inspection procedure without justifiable cause, the court may assume the facts of infringement in the plaintiff' s complaint to be true. However, even when the inspection is obstructed, the defendant is offered a chance to argue before a negative assumption is formed. Furthermore, if a third party is the inspectee involved in the act of refusal or obstruction, the court may order the payment of a maximum fine of TWD 100,000. Nevertheless, inspection does not require the involvement of police force, which means that a third party' s refusal of entry can ultimately end up with just a monetary fine. Some have suggested that petition for adding the uncooperative third party as another defendant could be a possible solution, despite the chances are that such addition may prolong the time and increase the costs of the legal proceeding.

At the conclusion of an inspection, the inspector must prepare and submit a report to the court. The inspectee, either the defendant or the third party, will receive a copy of the report from the court. In the case of the report revealing trade secrets to the extent that the

revelation of the confidential information brings greater injury than the procedural necessity would have required, the inspectee must petition to the court within fourteen days to conceal said confidential information before a copy of the report can be sent to the plaintiff.

The cost of inspection forms part of the total expenses of the proceeding, which will be borne by the losing party.

Inspection as a new system has raised a number of questions nevertheless. Firstly, a decision to grant inspection can only be made before the defendant or the third party is offered a chance to challenge or debate. In other words, the inspectees will be fully aware of a prospective inspection event and hence likely to conceal or destroy any related evidence before it takes place. In the new law, a counteracting mechanism is absent to cope with such potential tampering. Secondly, in contrast to a witness, an inspector is not an irreplaceable figure in a civil proceeding. Since a lawsuit may involve top-tier companies in the same field where elite expert are scarce, a chosen inspector may wish to stay away from a dispute in avoidance of displeasing either party even if the inspection is only a temporary service. What if an inspector chooses to voluntarily quit for any personal reason rather than being recused after his or her appointment? The new law does not appear to address this matter. Thirdly, it is unknown whether the plaintiff and the defendant and their attorneys are allowed to be present at the scene where an inspection is conducted.

Despite the challenges which lie ahead, it is nevertheless hoped that, by way of empirical practices in the courts, inspection can be leveraged effectively in order to achieve its policy aim for facilitating the equality of arms.



TSAI, LEE & CHEN
Patent Attorneys & Attorneys at Law



EDITORIAL PANEL

Publisher	ttsai@tsailee.com.tw	Thomas Q. T. Tsai
Editor in Chief	cjchen@tsailee.com.tw	Crystal J. Chen
Editor		Kevin C. W. Feng
Researcher & Writer		Tommy P. P. Chiu
Cover Photo Credit		(The autumn leaves of the Wuling Farm) PIXTA

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