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Global Vision

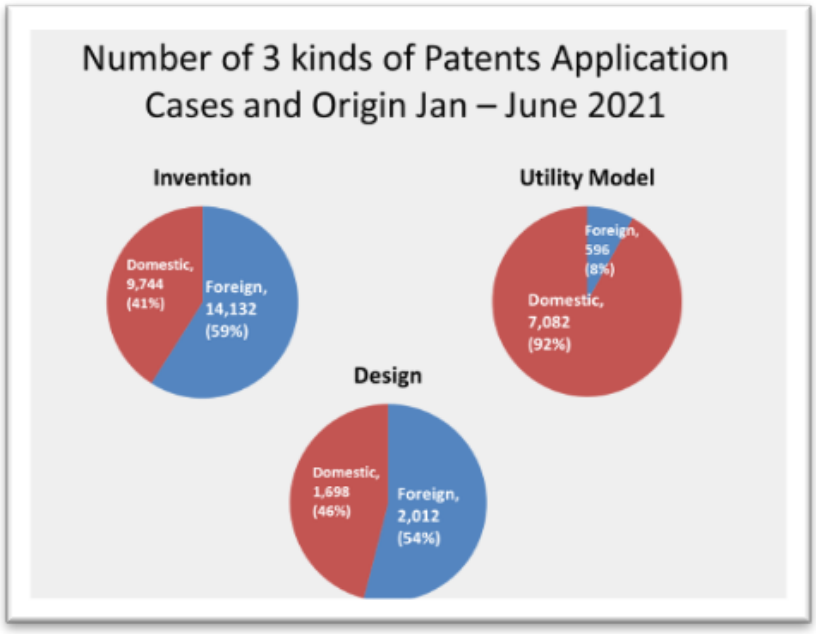
Taiwan and China IP Experts

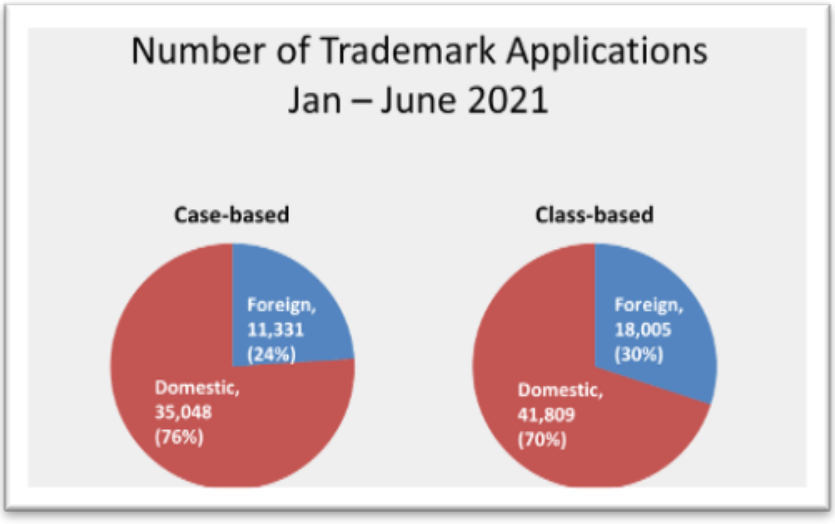
Taiwan's First Semi-Annual Statistical Report in 2021 for Patent and Trademark Filings

Taiwan Intellectual Property Office has released new statistics of patent and trademark filings for the first two quarters of 2021.

35,264 new patent applications and 46,379 new trademark applications were filed, representing increases on the previous year of 4% and 7% respectively for the same time period. The number of filings for domestic large enterprises went up significantly, with a 21% increase. Among these, TSMC filed for 1,263 applications, breaking through the 1K threshold for the first time and surpassing all other domestic and foreign applicants. The highest number of invention patent applications from foreign entities was made by Qualcomm, who filed 454 applications.

The number of trademark applications hit a record high, and the number of filings from both domestic and foreign applicants increased by 7%. Generally speaking, the trend for patent and trademark filings for the first half of 2021 was one of continued steady growth.





Patent Applications

1. The number of invention patent applications by domestic applicants has increased by 10%.

   There were 23,876 invention patent applications filed. The number of filings by both domestic and foreign applicants increased, by 13% and 6% respectively. The number of utility model and design patent filings from foreign applicants also increased, by 22% and 5% respectively.

2. The number of TSMC invention patent applications for the first half of 2021 is the highest in history.

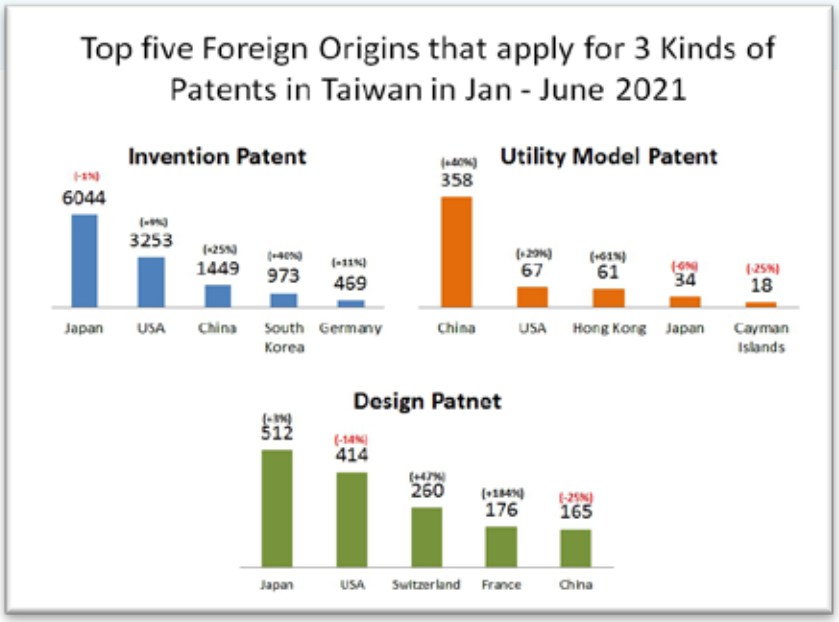
   There were 7,650 invention patent applications filed by corporate applicants, accounting for a full 79% of all domestic applications and contributing to a positive growth rate over five consecutive years. Among the applicants, TSMC filed 1,263 invention patent applications, representing a healthy growth rate of 237%. This is the first time an applicant has exceeded the 1,000-application figure over a six-month period, signifying the increasingly pivotal role played by TSMC in Taiwan's research and development in technological innovation. As for design patents, the car parts producer Coplus filed a total of 59 applications, the highest figure of all domestic applicants, enjoying a growth rate of 90%.

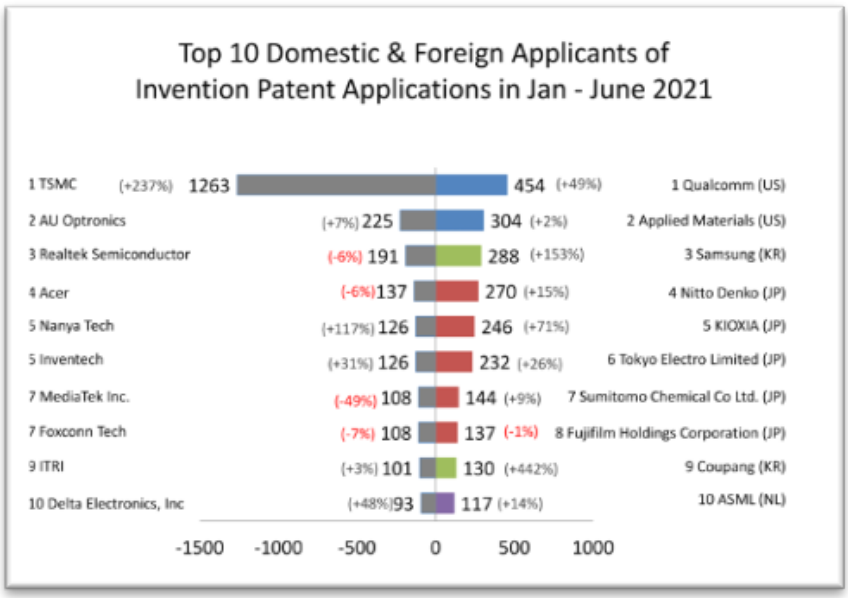
3. Filings from research institutions increased by 4%.

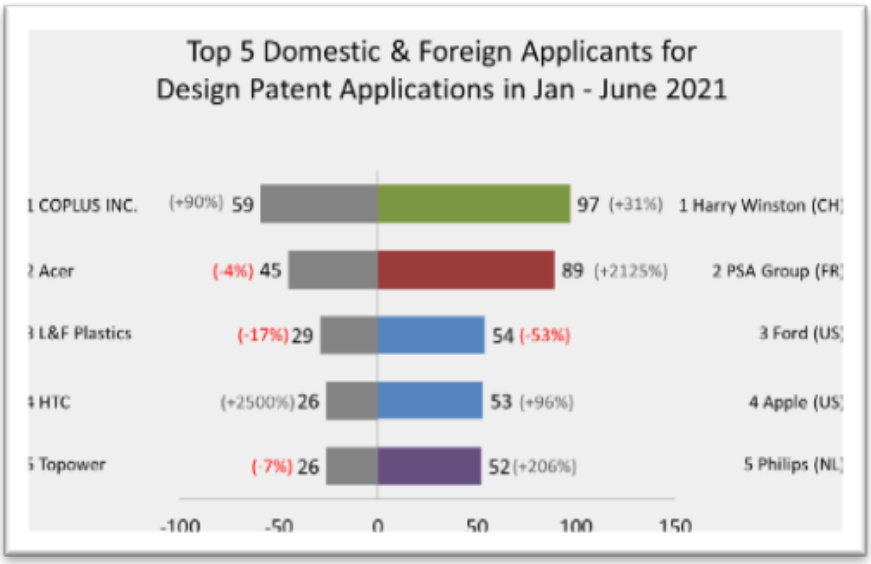
   The government-affiliated Industrial Technology Research Institute (ITRI) filed 101 applications, the highest number in this category.

4. Qualcomm and Harry Winston filed the most invention and design patent applications respectively.

   Among the countries with the largest number of patents in Taiwan, Japan topped the list for both invention and design patents, with 6,044 and 512 applications respectively. As for utility model applications, mainland China had the largest number, with 358 applications. The highest number of invention patent filings by a foreign applicant came from the world wireless technology leader Qualcomm, who filed 454 applications, whereas Coupang from Korea enjoyed the largest growth rate, with a figure of 442%. The American jeweler Harry Winston headed the list of foreign design patent applicants, with 97 design applications, as well as a 31% growth rate.


Top five Foreign Origins that apply for 3 Kinds of Patents in Taiwan in Jan - June 2021
Invention Patent
(-1%) 6044
(+9%) 3253
(+25%) 1449
(+40%) 973
(+11%) 469
Japan
USA
China
South Korea
Germany
Utility Model Patent
(+40%) 358
(+29%) 67
(+61%) 61
(-6%) 34
(-25%) 18
China
USA
Hong Kong
Japan
Cayman Islands
Design Patnet
(-3%) 512
(-14%) 414
(+47%) 260
(+184%) 176
(-25%) 165
Japan
USA
Switzerland
France
China


Top 10 Domestic & Foreign Applicants of Invention Patent Applications in Jan - June 2021
1 TSMC (+237%) 1263
454 (+49%) 1 Qualcomm (US)
2 AU Optronics (+7%) 225
304 (+2%) 2 Applied Materials (US)
3 Realtek Semiconductor (-6%) 191
288 (+153%) 3 Samsung (KR)
4 Acer (-6%) 137
270 (+15%) 4 Nitto Denko (JP)
5 Nanya Tech (+117%) 126
246 (+71%) 5 KIOXIA (JP)
5 Inventech (+31%) 126
232 (+26%) 6 Tokyo Electro Limited (JP)
7 MediaTek Inc. (-49%) 108
144 (+9%) 7 Sumitomo Chemical Co Ltd. (JP)
7 Foxconn Tech (-7%) 108
137 (-1%) 8 Fujifilm Holdings Corporation (JP)
9 ITRI (+3%) 101
130 (+442%) 9 Coupang (KR)
10 Delta Electronics, Inc (+48%) 93
117 (+14%) 10 ASML (NL)
-1500 -1000 -500 0 500 1000


Top 5 Domestic & Foreign Applicants for Design Patent Applications in Jan - June 2021
1 COPLUS INC. (+90%) 59
97 (+31%) 1 Harry Winston (CH)
2 Acer (-4%) 45
89 (+2125%) 2 PSA Group (FR)
3 L&F Plastics (-17%) 29
54 (-53%) 3 Ford (US)
4 HTC (+2500%) 26
53 (+96%) 4 Apple (US)
5 Topower (-7%) 26
52 (+206%) 5 Philips (NL)
-100 -50 0 50 100 150

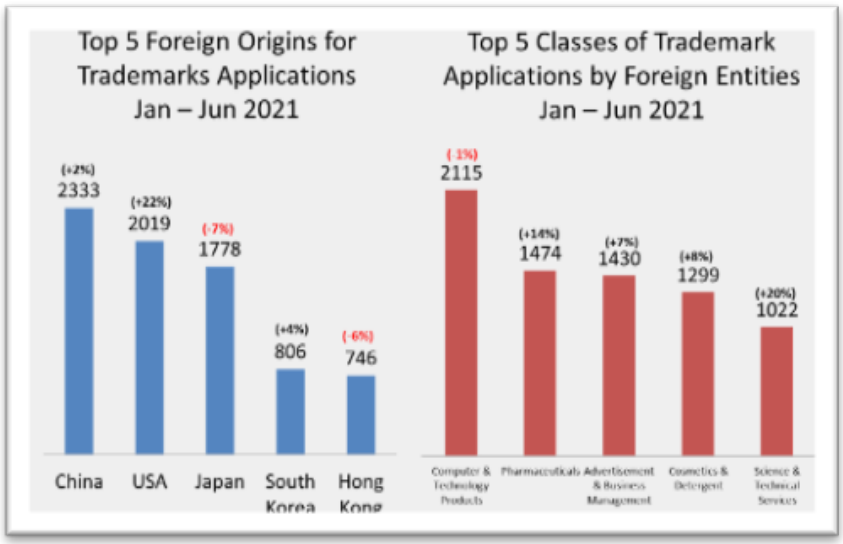
Trademark Applications

1. The number of trademark filings from domestic applicants hit a new record high.

   There were 46,379 trademark applications filed to include a total class count of 59,814 presenting an increase of 7% on last year over the same period. While filings from both domestic and foreign applicants both increased, the number of filings from domestic applicants reached a total of 35,048.

2. The class with the most domestic applications made was class 35; the class with the most foreign applications was class 9.

   Domestic applicants filed 6,919 applications (with a growth of 16%) in class 35 for "advertising, business management, retail and wholesale services." Foreign applicants filed 2,115 applications in class 9 for "computer and technology products." Among the foreign origins with the most trademark applicants for this period, China took first place.



A Market Pioneer in Battery Swapping Networks Won an Infringement Lawsuit[1]

Gogoro is a Taiwan-based spearheading enterprise for innovative vehicles. Since the rollout of the first model in 2015, Gogoro has established itself as not just a two-wheeled smart scooter manufacturer but also a core developer of a battery swapping platform that strategically partners with many interested electric vehicle companies. With its superior reliability and compatibility, the Gogoro Network has become the most widespread battery swapping infrastructure in Taiwan, used by partnering brands including Aeonmotor, eReady, eMoving, PGO, Yamaha and Hero (India).

Stone Energy Technology ("Stone Energy") is another company engaged in the development of novel electrical power storage systems. Stone Energy accused Gogoro of infringing two Taiwan invention patents: I423140 for "anti-counterfeiting battery pack and the authentication system thereof", and I308406 for "battery pack" (See Fig. 1), alleging that Gogoro had implemented the patented technology in—at the very least—their S Performance model series scooters.

Stone Energy claimed damages amounting to over TWD 350,000,000, or about USD 12,550,000. Gogoro entrusted Tsai, Lee & Chen to defend.

With the decision having been pending for less than 18 months, the IP Court ruled in May 2021 that all of the plaintiff Stone Energy's pleas would be rejected.

The court started with the conventional claim construction of the two asserted patents. Next, the court analyzed whether each and every element recited in the patent claims term-by-term corresponded to the disassembled parts of the allegedly infringing batteries of Gogoro.

Firstly, for the '406 patent, in the several disassembled elements, the court found that at least three such elements in Claim 1 were different from the corresponding ones in the accused product of Gogoro. An example of this was Element 1C, which had multiple cells connected to form "cell strings," each of which was defined by the court as "multiple cells connected to each other, with one cell's positive terminal connected to another's negative terminal in series."(See Fig. 2) In contrast, the cells in the accused product were not all connected in this precise fashion. More specifically, the positive terminal of one particular cell was connected to another cell's positive terminal "in parallel." To give another example, Element 1E required the claimed battery to have a minimal amount of cells arranged in a 4x4 matrix. However, the accused product's cells were arranged in seven columns, with the number of cells in each column being 5, 6, 6, 6, 6, 6 and 5. The court found this not to be a matrix formation as claimed. For the foregoing reasoning, the accused product was not read on by Claim 1 (or indeed by any of its dependent claims) of the '406 patent.

1 https://law.judicial.gov.tw/FJUD/data.aspx?ty=JD&id=IPCV,109%2C%E6%B0%91%E5%B0%88%E8%A8%B4%2C20%2C20210528%2C3

Secondly, for the '140 patent, there were likewise several elements in Claim 1 of that patent which were distinguishable from those in the accused product of Gogoro. For example, Element 1E in Claim 1 had "an inside identifier", securely mounted inside the cell body, in which was stored a first identifier code. (See Fig. 3) However, after disassembling the accused product, it was discovered that there were text and symbols of a darker tone on the protective external layer of the battery cells. It was made clear by the court that these were supposedly an "outside identifier" rather than the "inside identifier" which the plaintiff had erroneously asserted them to be. Furthermore, Element 1F had an outer identifier, "securely attached" to the outside of the protection layer, which stored a second identification code. In the accused product however, it was found that the external model code and the caution notes on the protection layer did not suffer damage when the protection layer was removed from the battery cells, meaning that the outer identifier was not as "securely attached" to the protection layer as was claimed in the '140 patent. Besides, the model code NCR18650BE0 was consistently printed on each of the battery cells. It was not possible to distinguish one cell from another, nor could the counterfeits be authenticated from the genuine ones. It cast some doubt over whether the model code NCR18650BE0 qualified as an "identifier" as was stated in Claim 1.

For similar reasons, other claims in the '140 patent were not read on.

To briefly conclude, the court did not find that Gogoro's batteries fell within the scope of Stone Energy's alleged two patents after the process of construction and element-by-element analysis. Therefore, it was ruled that Stone Energy's patents had not been infringed. This being the case, the court did not further investigate or review the validity of patents, the damage claims, injunction requests, etc.

Tsai, Lee & Chen successfully defended Gogoro in the trial.

The case is currently on appeal.

On a side note, Taiwan adopts a bifurcated IP system for IP right invalidation and infringement actions; however, the power to determine the validity of a patent claim is also vested in the IP court. In a patent infringement proceeding, a defendant may raise the invalidity of the patent claim in question as a defense. The IP court may exercise their discretion in determining whether the defendant has an effective defense without the need to stay the proceeding for an administrative judgment on the issue of validity. If the court admits the defendant's defense, the plaintiff loses its infringement claim against the defendant. However, the court's determination of invalidity is case-specific, meaning that the patent

right owner is not prevented from enforcing or asserting its right in other proceedings. In practice, the court does not have an adjudicative order on the infringement and validity of a patent claim; therefore, the question of which should be examined first is addressed on a case-by-case basis. In this case, the court firstly adjudicated infringement before the validity issue was addressed. When infringement was not found, there was no need to examine the defendant's defense.

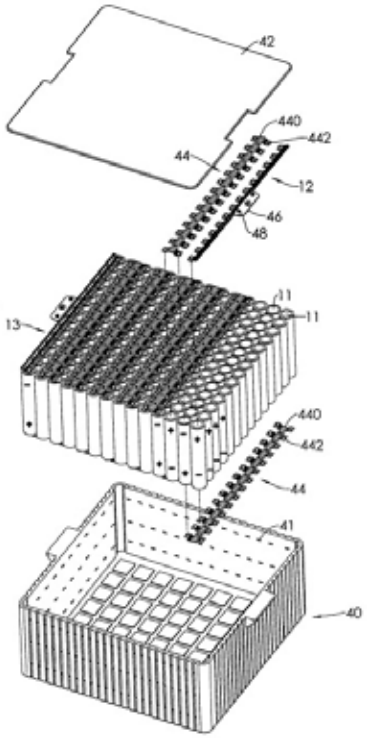


Fig. 1

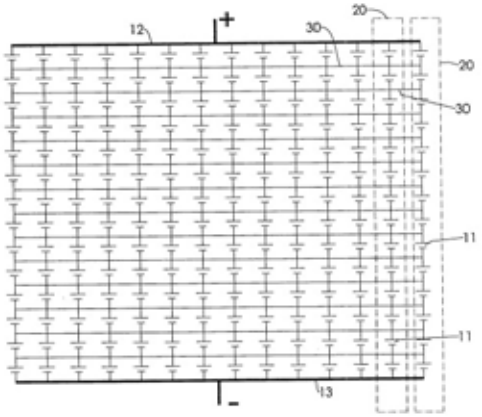


Fig. 2

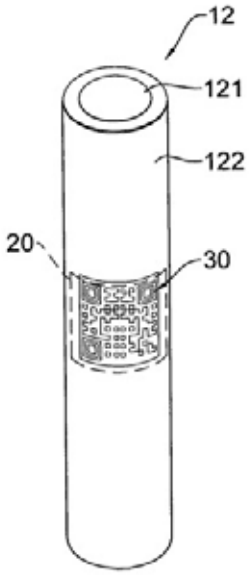


Fig. 3

Fig. 1 Exploded view of the anatomical structure of the battery pack for the '406 patent.

Fig. 2 Illustrative view of how the cells are connected in a circuit in the '406 patent. Each of the cell strings (20) consists of cells connectively arranged in series, where one cell's positive end connects to another's negative end.

Fig. 3 Perspective view demonstrating the cell (12), cell body (121) and the inside identifier (20) for the '140 patent.

The New Chapter for Computer Software-Related Inventions in the Patent Examination Guidelines

Taiwan IP Office has revised the chapter for Computer Software-Related Inventions in the Patent Examination Guidelines (PEG). It became effective on July 1, 2021. This was an overhaul from its previous structure which had been in place since 2014. The section layouts of the 2014 version began with subject matter, specification, claims, and then inventiveness requirement. In the revised chapter ("Version '21"), by contrast, the section for enablement in the specification and sections for the indefiniteness and support of claims were moved to the forefront. They were followed by subsequent sections outlining a new test to determine patentable subject matter, the negative factors undermining inventiveness, and a series of exemplary claims with explanations. The core concept for Version '21 had been largely driven by and had taken into account cutting-edge technologies such as artificial intelligence and blockchain.

Revising Requirements for Enablement, Indefiniteness and Support of a Claim

The substantive benchmark for enablement remains the same, namely that a skilled artisan would be able to understand or reproduce the invention to solve a technical problem without undue experimentation in view of the ordinary level of the art. In Version '21, more factors were provided to examine enablement requirements. In the case of a software-related invention, the description should sufficiently disclose the software or hardware toolkits that are specifically used to achieve the claimed function, such as the program languages, libraries, IDEs and neural network models.[1]

For drafting an apparatus claim, Version '21 reemphasized that not all of the elements were structural and it is not necessary to define every element in terms of structures; this suggests that some elements in an apparatus can be defined by "functions."[2] In addition, a "data structure product" or a "computer program" was affirmed to be an eligible preamble for a patent claim, alongside the traditional computer readable medium ("CRM") or computer program product. Examples of other patent-eligible preambles are included, such as programming models, libraries, support vector machines, neural networks, neural network models, etc.

A claim must find its proper support in the specification. Version '21 additionally stressed that a case does not meet the support requirements (1) when a person who is skilled in the art ("PHOSITA") would not know that there are alternative approaches to achieving the claimed invention not disclosed in the description or (2) when there are good reasons to believe that the specifically disclosed approach in the description cannot produce said claimed invention.[3]

1 Section 2.1.1
2 Section 2.2.1.2
3 Section 2.2.4

Introducing a New Test for Determining Patentable Subject Matter

To more efficiently and accurately establish whether a claim for a software-related invention is an eligible subject matter as per the Patent Act with respect to the definition of an invention, Version '21 has a a new two-step test. Please refer to the workflow in Figure 1 below for an illustration of the test.

The first question is whether the claimed invention is "obviously" patent-eligible. A claimed invention complies with the eligibility requirement if it either (1) specifically executes a control for a machine or a process associated with that control or (2) specifically executes information processing based on the scientific property of an object. A software-related invention immediately passes the test if it meets one of the above criteria.[4] The former case could be, for example, a control to operate a smart rice cooker's function to automatically finish cooking a pot of rice in a set time or, in another instance, a use of serial collaborative operations of the shipping devices and drones to complete the delivery of packages, whereby the integrative control of a distribution system composed of multiple associated machines (shipping devices and drones) is involved. An example of the latter case, meanwhile, could be a calculation or re-processing of the raw data from a cardiac electrophysiology (EP) study which converts said data to the QRS complex in order to obtain diagnostic information.

If the answer to the first question is "obviously" no, a claimed invention is not patent eligible. Typical non-eligible examples are man-made rules, mathematical methods, mental activities, and mere presentation of information, among others.

However, when the answer to the first question is ambiguous, the examiner should proceed to address the second question—whether the information processing of software is implemented with the use of hardware resources.[5] An affirmative answer will eventually lead to the conclusion that the subject matter is patent-eligible. The aim of the second question is to find out if there is a synergistically collaborative operation of software and hardware to build a particular information processing apparatus or method in accordance with the purpose of said information processing. An example of this is when a pending claimed invention recites hardware resources such as an input unit, a processing unit and a display unit, and uses the information processing of computer software to realize the function of generating a literature art piece, but does not recite a specific technical means or a step involving a synergistic interplay among the units (hardware elements). In the absence of such interplay, the claimed invention which is considered failed to build a particular collaborative system to process information is thus not eligible for a patent.

4 Section 3.3.1
5 Section 3.4

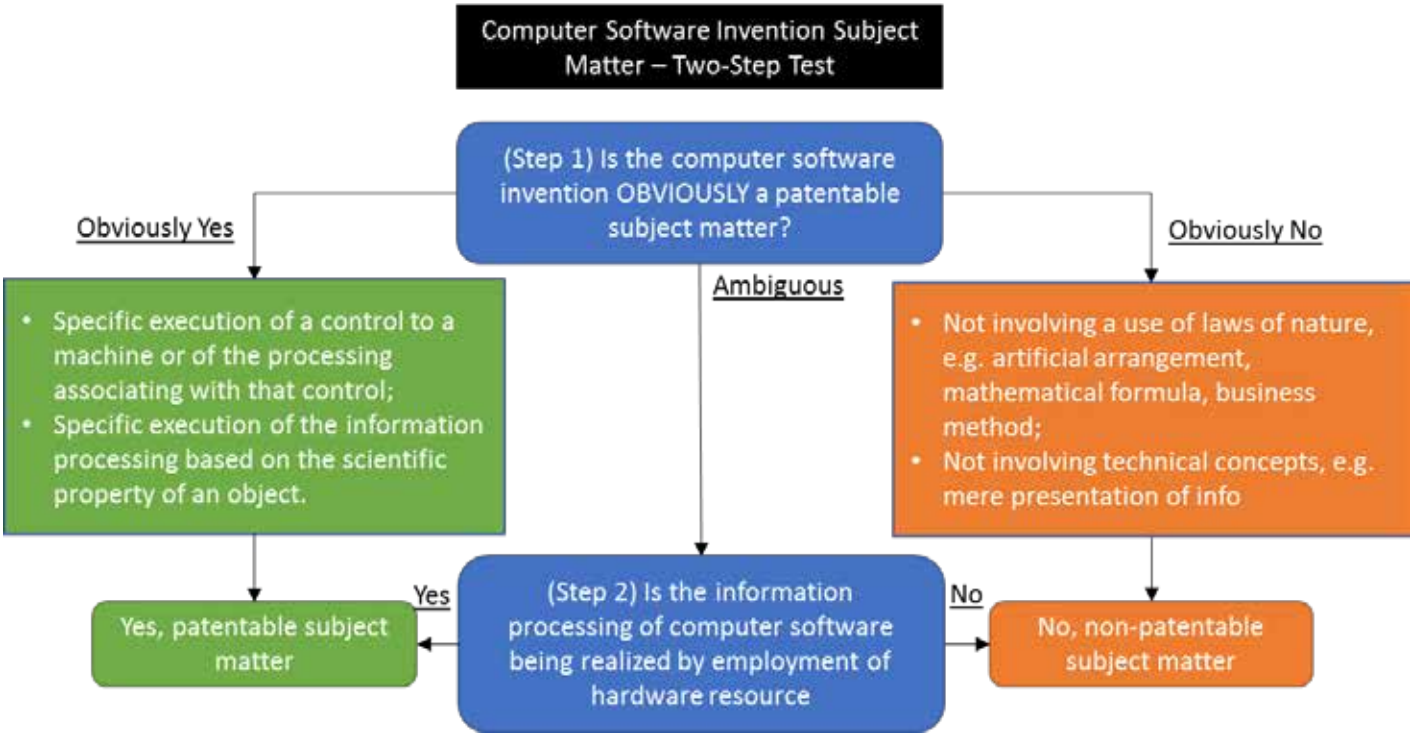


Figure 1:
Subject matter test for computer software inventions 2021

Modifying the Factors Evaluating Inventiveness

Simple variation from prior art is one of the typical grounds for inventiveness rejection. Version '21 highlighted the various circumstances in which a claimed invention may be regarded as a simple variation.

Transformative use of a technical means from one area to another to achieve substantially the same functions and results (where only data being processed are different) would not meet inventiveness requirement.[6] To give a specific example, a claimed invention directs to a medical information search system comprising a device capable of searching for medical information according to a provided list. However, a prior art reference of a file search engine cites a device with the ability to search for documents according to a provided list. The claimed invention for a medical information search system would not be inventive over the prior art reference of a file search engine.

6 Section 4.2.2.1.2.2

The recreation of known general knowledge in a computerized virtual space or in the combination of a virtual and a real environment is another example of simple variation.[7] This is not to exclude any VR, AR, MR or the like from patentability. However, it implies that a virtual application has to be more than the prior art. A racing game device comprising a particular processor which changes the possibility of a virtual vehicle to make a turn according to road conditions would not be inventive in view of a prior art reference for a racing game device that comprises a particular processor. In this case, the only additional feature in the claimed invention is the mechanism for cornering adjustment. But it is a generally understood knowledge in the field of automobile engineering that the insufficiency of grips due to a slippery road will cause a skid out of control. Hence, recreating such a known feature in a virtual racing device would not afford itself inventiveness.

Furthermore, if a different/added technical feature of the claimed invention makes no contribution to the prior art, it is regarded as a simple variation of the general knowledge.[8] This is more often seen in cases involving business methods. For example, a traditional e-commerce system is able to perform online payments based on the credit card authorization information entered by the customer; an invention is created for executing online payments based on the credit card information "pre-authorized" by the customer.

Although the invention offers convenience by avoiding the need to re-enter credit card information before completing a second purchase, it is merely borne of a business idea without contributing to any technical effects. The pre-authorization limitation is thus a simple variation of general knowledge.

Lastly, while an unexpected result is a beneficial secondary consideration for evaluating inventiveness, Version '21 further emphasizes that this must constitute either a significant increase in efficacy or a new effect produced. Such a quantitative or qualitative improvement would be advantageous for bringing a claimed invention across the inventiveness threshold. However, the generally perceivable properties of convenience, speed, high accuracy, etc. should be achieved with the use of a computer. They are not unexpected results.

7 Section 4.2.2.1.2.4
8 Section 4.2.2.1.2.6

DABUS was Denied Inventorship by Taiwan IPC Court

DABUS, an acronym standing for "device for the autonomous bootstrapping of unified sentience," is a complex artificial intelligence ("AI") system developed by Imagination Engines Inc.'s founder Dr. Stephen Thaler. Dr. Thaler and his team filed patent applications in many countries, claiming DABUS to have conceived the inventions in question.[1] Indeed, Dr. Thaler named DABUS as an inventor in patent applications.

Most of the patent authorities which received Dr. Thaler's cases refused to grant inventorship to an AI system. Some rejected cases were brought to the courts. Recently, South Africa and Australia recognized the inventorship of the AI system, while the UK and US courts rejected it. The question of whether a non-human being can claim inventorship has sparked a huge controversy and has become one of the key topics of debate among the various legal communities of the world.

On November 5, 2019, Dr. Thaler filed a patent application with the Taiwan IP Office (TIPO) titled "Devices and Methods for Attracting Enhanced Attention". Six days later, TIPO rejected the case in an Office action on the grounds of the application form being incomplete. Thaler responded, but the inventor as stated on the form remained as DABUS, the AI system. TIPO concluded the case by dismissing the application. Dr. Thaler raised an administrative appeal but failed. He then filed a lawsuit against TIPO, taking the case to the Intellectual Property and Commercial Court (IPCC).

The IPCC handed down a judgement on August 19, 2021, which was published online on September 1. To briefly summarize, the IPCC upheld TIPO's decision by ruling that an AI system was not entitled to inventorship. There were three main inquiries and answers which together constituted the basis of the court's judgement to uphold TIPO's dismissal of Dr. Thaler's application.

❶ Does an inventor have to be a human?

Although there is no specific provision in the Patent Act that the entity filing for a patent must be a natural person, the interpretation of the Patent Act (the "Interpretation") clearly stipulates that the definition of an inventor should be limited to a natural person. The Interpretation goes on to say that an inventor is a person who actually carries out research and creation; since the right of paternity is a moral right for an individual, an inventor has to be a natural person. Furthermore, the inventor is the one who made a substantive contribution to technical features as claimed. "The one who made a substantive contribution" refers to the person engaging in intellectually creative activities for the

[1] Cases filed in the US, EP, UK, DE, TW, ZA, AU, CN, JP, KR, IL, IN, CA, etc.

purpose of producing an invention. Such a person establishes an inventive concept of the technical effect, and the technical solution for resolving a particular technical problem, as well as proposing the specific technical means to achieve said inventive concept. Furthermore, the Patent Examination Guidelines also define an inventor as a natural person, and require that all inventors' names be included on the application form for filing when more than one person has collaborated in an invention.

As can be seen from both the Interpretation of the Patent Act and the Patent Examination Guidelines[2], an inventor is not only a person who engages in creative activities to devise the claimed technical features but is also one who makes a substantive contribution to bringing about an inventive concept. The IPCC therefore concluded that an inventor should be a natural person.

❷ Is AI a person defined by the law?

The Civil Code is the fundamental source of the law to define the legal status of a person. "The legal capacity of a person commences from the moment of live birth and terminates at death." Such legal capacity of a person is not waivable and includes, among other things, the entitlement to enjoy moral rights. To be named in association with a patent as an inventor is one of the inalienable moral rights. When a moral right is infringed, one is entitled to relevant legal remedies.

However, in order to exercise moral rights and/or to request remedies, necessary actions should be taken to fully express the intention to realize a particular legal effect (the declaration of intent, or Willenserklärung, under the German law). The question is whether DABUS in the present case has the capability to perform an act and express an intention. The judgment cited the following interesting dialog between the Chief Judge and the plaintiff's attorney, which may shed some light on the question:

> **Chief Judge:** How do you define a "person"?
>
> **Plaintiff's Attorney:** Under the Civil Code, **a person is either a natural person or a legal entity.**
>
> **Chief Judge:** If DABUS reaches out to you to retain you in this lawsuit, would you agree to be retained as its representative? To whom would you charge the retainer fees? The reason I ask is that in a similar

2 Both the Interpretation of the Patent Act and the Patent Examination Guidelines were compiled and issued by the administrative authority, the TIPO. They are not the statutory law but belong to secondary authority.

situation where a company hires a lawyer, the lawyer would know whom specifically he or she should report to with any developments.

Plaintiff's Attorney: The main question should be separated into different sub-questions, and the first sub-question should be "whether DABUS can file for a patent."

Chief Judge: No. You should firstly answer the question "whether DABUS is a person" before moving on to the question about applying for a patent. How come you were not being hired by DABUS in the first place?

Plaintiff's Attorney: As I previously explained, under the definitions of the law, **DABUS is neither a natural person nor a legal entity. I cannot be retained by it.** However, the question of whether DABUS should possess legal capacity as well as the right to apply for a patent remains worthy of more deliberation.

In the light of the above responses, the court concluded that the plaintiff must accept that DABUS is not a person under the law.

❸ Is the dismissal of the present application attributable to the applicant?

As per Article 17 (1) of the Patent Act, where a person filing a patent application or taking other proceedings in connection with patent-related matters has failed to comply within a statutory or specified time period, the application filed or the proceeding initiated shall be dismissed.

On the application forms for the present case, the column for "Inventor's English Name" was filled as "NONE, DABUS." The columns for "Inventor's Nationality" and "Chinese Name" were left blank. In response to TIPO's Office action, the applicant insisted that the present invention was made solely by the inventor DABUS, who is an AI system; in other words, the present invention was not made by a human inventor. There then came a second Office action to urge the applicant to correct the name of the inventor (who must be a "person") within a designated period of time. The applicant failed to take the necessary steps to make corrections within the designated time period. TIPO therefore dismissed the case. As per the above findings,

the court reasoned that the lapse of time to correct the application was attributable to the applicant. The court ruled that TIPO's decision to dismiss the case was lawful.

The case was judged accordingly, but was appealable.

During the trial, the court delivered its specific observations on comparative laws and different perspectives. At one point in proceedings, the plaintiff argued that since an AI-made invention is subject to protection in other countries, so should it be in Taiwan. However, the court stressed that in view of the opinions and decisions of some foreign counterpart patent authorities, most countries - with the exception of South Africa - have unanimously rejected or dismissed cases involving the inventorship of AI (at least at the time when this judgement was written). The court found that in the case of the invention in question, DABUS was recognized under Taiwanese law as an "object" that can be dominated or possessed by another. DABUS cannot be the "subject" of rights so it does not enjoy any legal capacity.

Comment

The size of this first-instance judgment was rather small, consisting of only 10 pages. It did not involve particularly complex disputes, groundbreaking analysis, or out-of-the-box reasoning. The conclusion was seemly quite predictable by many. However, this Taiwanese judgement came quickly, at the beginning of September 2021; it is believed to be one of the first several countries in the world to have made such a judgment, after the United Kingdom, South Africa, and Australia. Regardless of how this case will develop in the context of a possible appeal and what position the Taiwanese courts will ultimately take, this trial judgment nonetheless significantly marks the Taiwan judicial branch's first determinative ruling on this controversial, hotly contested issue, which is at the forefront of discussion among patent communities globally.

Merck Sharp & Dohme v. TSH Biopharm: an alternative new drug for treating a hypercholesterolemia disease found not infringing

Merck Sharp & Dohme ("MSD") is the owner of Taiwanese patent I337076 entitled "The use of substituted Azetidinone compounds for the treatment of sitosterolemia." Sitosterolemia is a lipid metabolism disorder where the patient absorbs excessive amounts of plant sterols from vegetables or nuts. As plant sterols accumulate in the serum and are deposited in tissues, some patients may suffer blockages in blood vessels, elevating the risks of coronary heart disease or, in critical situations, stroke or cardiac arrest. Shering Corporation ("Shering") developed ezetimibe under the trade name Ezetrol (and others) as a cholesterol absorption inhibitor for curing certain hypercholesterolemia diseases including sitosterolemia. Shering applied for a patent for ezetimibe compound in Taiwan in 2002; the patent was granted in 2011 and is estimated to end in January 2022. Merck acquired Shering in November 2009 to become Merck Sharp & Dohme. MSD is, therefore, currently the patentee in title for I337076. After the pharmaceutical patent linkage system was instituted into the laws, MSD listed the '076 patent to declare it associated with Ezetrol 10mg tablets.

TSH Biopharm ("TSH"), established in 2010, is a Taiwanese local pharmaceutical company with an R&D program focusing on products related to cardiovascular, gastrointestinal and autoimmune disorders. TSH developed Cretrol tablets, a medication that contains ezetimibe and rosuvastatin calcium as active ingredients for curing primary hypercholesterolemia. In October 2020, TSH completed its duty in applying for regulatory approval and declared that Cretrol does not infringe the '076 patent pursuant to the Pharmaceutical Act and relevant regulations.

In response to TSH's declaration, MSD filed an infringement suit aiming to prevent the manufacture, use, sale, offer for sale, or import activities relating to Cretrol. MSD asserted that Cretrol also treats sitosterolemia as a result of treating primary hypercholesterolemia. TSH Biopharm retains Tsai, Lee & Chen to defend itself.

The court addressed several main issues arising from both parties' complaints and defensive responses.

The first question is whether Article 96(1) of the Patent Act constitutes sufficient grounds for raising an infringement suit in this case. TSH tried to argue that it had only filed for an application for regulatory approval for its alternative to ezetimibe and said that its activity was exempted by the patent right according to the Patent Act. TSH's application for drug approval did not mature to be of any threat to the patented invention since there was no exploitation of the patent at issue.

The court ruled that Article 96(1) is not only to stop an ongoing infringing activity but also to prevent the likelihood of patent infringement. In order to protect public health and interests, the patent linkage system was designed to resolve any patent disputes at any stage, even as early as the application for regulatory approval. The purpose of an infringement suit in the linkage system is not to

determine whether the generic applicant practices the patented invention but—more importantly—to ascertain whether the generic drug application embodies a product that would potentially infringe the patent at issue, and thus preemptively resolve a potential dispute before a generic drug is launched into the marketplace. Article 96(1) was the rightful grounds for the linkage system.

On a separate note, there is a drafted bill pending codification to the Patent Act (to become Article 60-1) which will serve as the specific grounds for action dedicated to linkage-related lawsuits. It reads that where the applicant for the generic's market approval submits a P4 challenge, within 45 days from receiving the P4 challenge, the patentee may sue to stop or prevent potential infringement. In fact, the institution of Article 60-1 was designed to benefit both parties. In addition to providing a means for the patentee to challenge, it also affords the generic applicant an opportunity to clear hindrances by seeking declaratory judgement of non-infringement as long as the patentee does not sue within said 45 days.

For the second question, of whether the '076 patent's Claims 1-6, 8-9, 11, 14 and 31 read on TSH's Cretrol tablet, the court's answer is no.

All the claims in dispute were "product-by-use" claims. Based on the patent examination guidelines prior to 2013, the features of use were limitations to the scope as claimed. Claim 1 directs to a pharmaceutical composition for the treatment of sitosterolemia comprising an effective amount of a sterol absorption inhibitor (this being the compound of ezetimibe), or a pharmaceutically acceptable salt or solvate of the sterol absorption inhibitor, or a mixture thereof, in a pharmaceutically acceptable carrier. The "treatment of sitosterolemia" was a limiting feature, while "treatment" suggested the therapeutic effect arising from "an effective amount of a sterol absorption inhibitor…" as claimed.

"Primary hypercholesterolemia" (excluding the heterozygous familial type) and "homozygous sitosterolemia" are two distinguishable disorders. Ezetimibe was confirmed to have beneficial effects for treatment of both "primary hypercholesterolemia" and "sitosterolemia." However, as the court found particularly noteworthy, the packaged inserts for Cretrol did not contain clinical data supporting the treatment of sitosterolemia, neither did it name sitosterolemia as one of the indications for treatment. While the pharmaceutical composition recited in Claim 1 of the '076 patent was limited to treatment only for "sitosterolemia," the Cretrol—composed of ezetimibe and rosuvastatin calcium for treating "primary hypercholesterolemia"—did not fall within the literal scope of said Claim 1.

Claims 2-6 and 8-9 directly or indirectly depended from Claim 1. While Claim 1 did not read on Cretrol, neither did the subsequent claims read on Cretrol.

Claim 11 is a pharmaceutical composition—as Claim 1—which further comprises an effective amount of a bile acid sequestrant or other lipid-lowering agent, and Claim 14 is a pharmaceutical composition—as Claim 1—which further comprises an effective amount of sterol biosynthesis inhibitor. However, the indication treatable by Cretrol is primary hypercholesterolemia rather than sitosterolemia, meaning that Cretrol does not have all elements found in either Claim 11 or Claim 14.

Lastly, regarding Claim 31, it has "treatment of sitosterolemia" as an essential element. The court's investigation particularly focused on the prosecution history of the case and its attention was drawn to one of MSD's responses to an Office action; the agent for MSD stressed that this invention for which a patent was requested was a new use for a known compound. Hence, such a new use—that of specifically treating sitosterolemia—surely amounted to a higher weight of significance in constructing the scope of the claim. Yet for the same reasoning that sitosterolemia was different from primary hypercholesterolemia wherein Cretrol does not include the former as an indication, the court found that Cretrol did not have all elements in Claim 31.

To conclude, although MSD was entitled to raise an infringement action under Article 96 (1) of the Patent Act in view of the policy of the patent linkage institution, none of the Claims 1-6, 8-9, 11, 14 or 31 were found to read on TSH Biopharm's Cretrol tablet. Finally, the court made the judgement (IPC-110-CivPatTrial-No.4) that Cretrol did not infringe and dismissed all of MSD's requests in the suit. According to TSH Biopharma, Cretrol was originally projected to be launched in mid-2022.

The judgement remains appealable until the end of November.

On a different but similar note, earlier this year there was another P4 patent linkage-related lawsuit concerning a generic version of the same Ezetrol tablet of MSD. The outcome of the case was a defeat for the P4 challenger. (MSD v. CCPC; IPC-109-CivPatTrial-No.46; January 2021)

A Quick Glance over the Newly Introduced Patent Term Adjustment in China

Pursuant to the fourth Amendment to the Patent Law in Article 42(2) effective on June 1st, 2021, for any unreasonable delay during prosecution of an invention patent, the patentee is entitled to request for patent term adjustment (PTA), provided that the patent is granted after four (4) years from filing date and after three (3) years from the date of substantive examination. The PTA is eligible only for patents granted on June 1st and onwards, suggesting no retroactive effects, according to the "Interim Measures for Implementation of the Amended Patent Law during the Transitional Period" issued on May 25th .

Related administrative rules were subject to revisions in correspondence to the new Patent Law. CNIPA drafted an Amendment to Patent Examination Guidelines to solicit public comment in the beginning of August, where the procedural rules and structural provisions for PTA are detailed. Some highlights in the draft Amendment are digested as follows.

Timeframe to Request

A request for PTA must be made within three (3) months from the grant of a patent.

Determining PTA

The PTA is commensurate with the delay attributable to the CNIPA but precluding delay caused by the patentee/applicant. In the event of a parallel filing (to file for an invention patent and a utility model application at the same time by the same applicant for the same invention-creation) where the utility model is successfully granted, the PTA is not eligible for the invention patent.

Relevant Time Points

There are four (4) points in time - filing date, date of requesting for substantive examination, allowance date, and grant date - used for assessing whether the patent meets the PTA criteria. As of now the revised Patent Examination Guidelines remaining as a draft, each point in time has different interpretations.

Filing date refers to the "actual filing date" for a Chinese application, the "date of entering China national stage" for a PCT application, or the "divisional request date" for a divisional application.

Date of substantive examination refers to the "issue date of notification of entering the substantive examination," rather than the date to make a request for substantive examination.

Allowance date refers to the "issue date of notification to grant patent right for invention application."

Grant date refers to the "grant publication date."

Calculation of PTA

The basic temporal unit of PTA is a calendar day. CNIPA would grant the number of day(s) that will be immediately followed by the expiry of a projected patent term. The number of days in PTA is equal to the unreasonable delay caused by the CNIPA minus that caused by the

patentee/applicant. The number of days that exceeds four (4) years from filing date to grant, or days that exceed three (3) years from the date of substantive examination should be compensated. Therefore, by default in the draft Patent Examination Guidelines, the grantable PTA term can be mathematically expressed as:

> (grant date – the date after four(4) years from filing date or the date after three(3) years from substantive examination, whichever is later) – (days of patentee/applicant's own delay)

Time in any of prosecution suspension, preservation, administrative litigation, re-examination is not included in PTA.

Patentee/Applicant's own Delay

The drafted Amendment to Patent Examination Guidelines set forth five cases where the PTA calculation shall preclude the time -

- Beyond the designated period for responding an Office Action;
- During deferment for examination;
- For incorporation by reference of missing parts;
- For reinstatement of rights; and
- From national phase entry date to the deadline of 30 months period since priority.

Review and Grant

Upon rejecting a request, the patentee shall be offered at least one Office Action to make a respond and/or amendment in seek of preventing an unfavorable decision. A decision of grant of PTA made by the CNIPA shall be published on the Patent Gazette as well as recorded in the Patent Register.

TLC's Comments

PTA is a brand new system effective since June 1st whereas all the above auxiliary rules are not yet finalized or operable as of today. These rules are subject to changes, including an overhaul or a fine tune. Taking a few steps back however, what is definite is that the PTA is officially a part of China's patent system (A standardized form available[1]) and CNIPA has started to receive PTA requests accordingly.

As for the official fee for the PTA, no fee is required at the time of requesting for the PTA; however, if the request is accepted by the CNIPA, a payment notice regarding the compensated patent term agreed by the CNIPA will be issued. How the fees will be calculated is still unknown at the present stage.

In a nutshell, the PTA is now eligible for patents granted on and after June 1st and the applicants wish to make up the delayed time, provided that the patent(s) were granted more than four years from filing and also more than three years from examination. To avoid losing any opportunities in obtaining the compensated patent term, we recommend submitting your PTA request(s) at the earliest as possible.

[1] https://www.cnipa.gov.cn/module/download/down.jsp?i_ID=159757&colID=192

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Photo Credit Spring Morning Twilight Scenery of Olympus Bridge and Chimei museum architecture reflected in pond & Sunrise & Pink poui petals fall is traditional French Romanticism style. Tainan, Taiwan. Asia. (shutterstock)

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