# Monthly Newsletter May 2022





The Hague Agreement ("Agreement") came into force on May 5 2022 in China which makes it the 94th country to join the Hague System ("System"). Prior to joining the System, China has amended its Patent Law on June 1 2021 to accommodate the System, including increasing the protection period of design from 10 years to 15 years. One of the advantages of The System is that it enables applicants to register a design in multiple countries by filing one application in one language. As an international treaty which relates to international registration of industrial design, China's accession into the agreement will make it easier for foreign designers to enter the Chinese market.

### WHY DOES IT MATTER TO YOU

AN INCREASING NUMBER OF DESIGN PATENT APPLICATIONS THROUGH HAGUE SYSTEM Design patent applications through Hague System has increased 20.8%, a total of 22,480 design patent applications has been recorded since 2010. Given that applicants benefit from the System by filing one design application to seek IP protection for their designs in designated countries covered by the System, the accession of China to the System may lead to many more design registrations being in force in other countries around the world. Therefore, companies may need to pay more attention and do substantive prior design search to mitigate risks of infringements.

Not only the short examination period of design patents in comparison to invention and utility model, infringers of design patents are easier to identify. The comparison of the patented design and the accused infringed design can be straightforward. Therefore, design patents are especially advantageous to machanical and consumer products.

A USEFUL TOOL IN PROTECTING YOUR INVENTION IN LITIGATIONS

A COST EFFICIENT WAY TO PROTECT YOUR DESIGN PATENTS Traditionally, patentees applied for IP protection of design patents through Paris Convention where patentees need to prepare multiple documents for applications in various countries. However, through the Hague System, patentees pay less official fees and agent fees because applications are centralized. From our experience, clients may save 20%-50% of cost when applying for their designs through Hague System.



# TIPS OF APPLYING DESIGN PATENT THROUGH HAGUE SYSTEM IN CHINA

#### ISSUES OF NOVELTY AND DISTINCTIVENESS OF DESIGNS IN CHINA

WIPO examines formalities of international applications if the applications are filed with WIPO. While China does not provide substantive examination, the Patent Law in China has given examiners discretion to conduct limited prior design search, and novelty and distinctiveness examination to determine the substantive issues of designs. It is likely that the CNIPA will also check other formality issues relating to clarity of designs and drawings. Therefore, CNIPA is likely to reject the application on these grounds. To avoid disappointment, It is important for applicants to prepare drawings and illustrations according to the requirements and standards of different countries, especially for China and the U.S. as these countries have very different standards on drawings.

#### CHOICES BETWEEN HAGUE SYSTEM AND PARIS CONVENTION

Although Hague System is cost effecient and simple for design applications, it is recommended to apply for design patent protection through the Hague System when applicant intends to protect its designs in more than 5 countries including the U.S. and China. This would best utitlize the System and save cost. It is worthnoting that China has specified that the Hague System will not apply in the Hong Kong or Macao Special Administrative Regions

#### INTERIM MEASURES FOR HANDLING RELATED EXAMINATION MATTERS AS TO THE IMPLEMENTATION OF THE HAGUE AGREEMENT

CNIPA has released an interim measures as to the implementation of the Hague System which takes effect on May 5 2022. It is foreseen that the Regulation may be updated in near future. Applicants should keep their eyes or consult agencies on any updates in the implementation in China if they intend to apply design patent protection through Hague System via CNIPA.

## HOW CAN WE HELP



66 Purplevine is experienced in handling Hague System applications. Unlike our competitors in China, Purplevine has handled more than 100 Hague System applications for its clients. Purplevine has also built a strong network with WIPO so it is at the forefront of the regulatory updates of the Hague System.

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# Lessons learned from the representative cases of the Intellectual Property Court of the Supreme People's Court (IPC)

On February 28, 2022, the Intellectual Property Court of the Supreme People's Court (IPC) of the People's Republic of China released 48 selected representative cases from a pool of 3,460 cases concluded in 2021. We analyze three of the most interesting cases and provide key takeaways.

#### **Case 1 - Scope of Patent Protection and Doctrine of Equivalents**

#### **Lessons Learned**

For patentees to argue infringement based on the doctrine of equivalents, it is essential to disclose all potentially applicable fields for the technical solutions provided by the invention in the specification of the patent.

This requires patent owners to carefully strategize the drafting of patent applications with potential litigation in mind. The Court explained the reasons why the specification of the patent-insuit does not warrant the application of the doctrine of equivalents against defendants.

#### **Background**

Company C, the patentee, accused Company A and B of patent infringement, and the patent-in-suit involves the technology of automatic hedge trimmers. Company A claimed it purchased only the blades of the patent in question from Company B and the latter acknowledged the transaction. However, Company B argued no infringement on its side because it was Company A that assembled the blades with other parts and resold the finished products – a behavior that would constitute infringement. Company C obtained a judgment from the district court in its favor by applying the doctrine of equivalents.

On appeal to the IPC, both Company A and B asserted the blades in question can only be used in gasoline-powered hedge trimmers (the patent-in-suit is about electrically-driven hedge trimmers); therefore, the technology was substantially different from the patent-in-suit.

#### Outcome

The IPC overruled the district court judgment and explained the adoption of the doctrine of equivalents in patent litigation.

There are certain limits to applying the doctrine of equivalents:

- A product is only equivalent if it performs the same function in the same way to achieve the same result as the patent-in-suit.
- If the patentee knows there is another technical solution which relates to the invention when drafting the patent application but does not include the technical solution in the specification of the patent application, the doctrine of equivalents cannot be used in infringement litigation as a way to expand the protection scope.
- The patentee's intention to include a certain technical solution for an invention when drafting the patent application is determined by how a person having ordinary skill in the art would interpret the patent application after studying all the documents submitted by the patentee.

In this case, the patent involved has a subject title: "electric hedge trimmer." The subject title has confined the technology solution it applied: "electric." In the introduction of the specification, there is a clear disclosure about its characteristic: an "electric machine." In the specification, the patentee argues that environmentally friendly is a rather new concept and the patent involved is entirely "electrically driven," not gasoline powered. A person with ordinary skill in the art would determine the patentee had no intention to include a gasoline-powered hedge trimmer within its protection scope.

To conclude, the doctrine of equivalents was wrongly applied by the district court, and the IPC has provided guidance on how the doctrine of equivalents should be applied.

Case No.:(2021) Supreme Court Intellectual Civil Final No. 192



#### Case 2 - Liabilities and Damages Caused by Offer for Sale

#### **Lessons Learned**

Prior to this case, Chinese courts generally did not take the position that "offer for sale" actually causes damage to patentees, and they would not order compensatory damages. However, the IPC adopted a different analysis in this case. The Court started to consider the negative impacts of "offer for sale," intending to strengthen IP policy in China. This is no doubt good news for patentees. Infringer will be stopped at the offer for sale stage, and patentee will be awarded compensatory damages.

For defendants, litigation strategy should align with the new developments. During litigation, defendants must put forward a legitimate defense to mitigate the risk of paying a large sum of compensatory damages.

#### **Background**

Company A, the accused infringer, produced vertical secondary construction column pumps. It displayed the products on its Alibaba online store and website, which amounted to an "offer for sale."

In the district court, Company A had no objection to the judgment that its products fell within the protected scope of the patent held by Company B, the patentee. The court ordered Company A to terminate its sales of the product and pay a compensatory damage of RMB30,000 (US \$4,709) to Company B.

Company A then appealed, arguing it had removed the products from its Alibaba online store and website before receiving the summons from the district court. Company A also claimed no financial gains for itself, nor economic losses to Company B. Therefore, it said, paying compensatory damages to Company B lacked a legal basis.

#### **Outcome**

The IPC upheld the district court's judgment and provided analysis of the negative impacts of the offer for sale.

Article 11 of China's Patent Law prohibits the offer for sale of infringing products. Also, Article 65 states that if the losses of the patentee, benefits of the infringer, or royalties of the patent are all hard to determine, the People's Court may, based on factors such as the type of patent right, nature of the infringement, and seriousness of the case, determine the amount of compensation ranging from RMB10,000 to RMB 1 million (US \$1,569 to US \$156,988).

Although Company B could not provide proof of its loss due to Company A's offer for sale, the Court explained that:

- 1. The civil liability of an offer for sale does not rely on whether actual damage occurs.
- 2. There are foreseeable impacts of the offer for sale, such as:
- a) The prices of the infringing products are usually lower than that of the patented products, and this adversely affects the reasonable pricing of the patented products; or
- b) Consumers will turn away from the patented products and purchase from the infringer instead, causing delays or even reduction in sales of the patented products.
- 3. The purpose of ordering an infringer to compensate the patentee in the case of an offer for sale is to promote innovation and protect patent rights.
- 4. The difficulty of accurately proving the specific damage caused by the offer for sale should not become an excuse; otherwise, it would ruin the legislative purpose of the patent laws. This is when Article 65 should be properly considered by the court in determining the loss of patentee.

In conclusion, the compensatory damages for offer for sale ordered by the district court is reasonable and legitimate.

Case No.: (2020) Supreme Court Intellectual Civil Final No. 1658



#### Case 3 - Burden of Proof and Jurisdiction on Internet-Related Patents

#### Lessons Learned

The IPC lowered the burden of proof for patentees with respect to Internet or programming-related patents. Also, Chinese courts recognise extra territorial jurisdiction regarding the global Internet. Companies are advised to conduct a global search of prior art to avoid potential disputes.

#### Background

Company A, the patentee, created an international logistics tracking system (a website) and alleged Company B had infringed its patent by creating a similar system with a similar set of programming and steps. The district court ruled in favour of Company A and ordered Company B to stop the infringement and pay damages of RMB 2 million (US \$313,981) due to the economic loss suffered by Company A.

Company B appealed and argued its tracking system has several distinctive features compared to what was described in the claims of the asserted patent. In addition, Company B has its server outside of mainland China, and for this reason, it said, it did not practice the patent-in-suit in China.

#### Outcome

1. Standard of proof should be lowered for patentee

In practice, the patentee has limited access to the source code of the website in the backend to fully and accurately restore the dynamic implementation process of the alleged infringing website. Therefore, it is unfair to place an excessive burden of proof on the patentee beyond the technical reality. On the contrary, the alleged infringer has full knowledge of the specific steps and technical details of its own website as well as a thorough understanding of its system. Such unbalanced information warrants a shift of the burden of proof in the litigation proceedings.

Therefore, as long as the company with the Internet-related / online programs patent has obtained preliminary evidence in its best reasonable efforts which can prove the technical features of the alleged infringing website are consistent with or likely equivalent to the claims of the asserted patent, then the patentee has passed the complaint threshold.

- 2. The fact that the server location is outside the jurisdiction where the court is located does not overturn the judgment that the accused infringer has infringed the asserted patent, because:
- a) The location of the server of the accused infringing website is not the only factor in judging where the infringing act was carried out.
- b) The Internet coverage features data transmission and interaction which are beyond the boundaries of countries. If the court decided the location of an infringing act based only on the location of the website server, it would significantly limit the scope of protection of such a patent.
- c) There is also evidence to infer that the infringing act took place in mainland China:
- I. The registered address of the accused infringer is in Shenzhen, China.
- II. The majority users of the accused infringing website are from mainland China.
- III. A considerable part of the logistics information comes from enterprises located in mainland China. Thus, one can infer the relevant data transmission and interaction occurred in mainland China.

To conclude, the standard of proof for the patentee should be lowered when it comes to patents related to the Internet. Also, the Court has a far-reaching jurisdiction on Internet-related patents.

Case No.: (2020) Supreme Court Intellectual Civil Final No. 746

The article was first published in the INTA Daily News on 1st May 2022. You may refer to the link here



#### China amends its law on the supervision and administration of medical devices

The medical device industry in China is now embracing its 'golden age'. As of December 31 2021, it has recorded 28,954 medical device manufacturers nationwide, an increase of 13.8% compared with 25,440 in 2020.

The pharmaceutical market is developing rapidly in China where the benefits from policies have made industrial competitors focus more on their patent strategies. Mainland China has become the world's largest region for technical innovation after the US, Japan and Europe.

In order to further protect human health and safety by supervising and administrating medical devices and ensure the safety and effectiveness of those medical devices, in 2000, the State Council of the People's Republic of China issued and implemented the 'Regulation on the Supervision and Administration of Medical Devices' (the regulation). The regulation was amended in 2014, 2017 and 2021.

The latest amendment to the regulation was officially implemented on June 1 2021. The highlights of the revision are discussed below.

First, the regulation continues to strengthen the administration of the life cycle of medical devices from registration/recording to production, operation and use. Through implementing the system for medical device registrants and recordation entities, the regulation strengthens the responsibilities of enterprises.

The regulation specifies that registrants and recordation entities shall establish the quality management systems commensurate with products and maintain the effective operation thereof, strengthen the administration after the marketing of medical devices, establish and implement the product traceability and recall rules, and assume responsibilities according to the law for the safety and effectiveness of medical devices in the process of research and development, production, operation and use thereof.

Medical device registrants and recordation entities may produce medical devices by themselves, or commission other parties that comply with certain rules. The regulation also specifies the responsibilities and obligations of entities engaged in the online distribution and the responsibilities of operators of e-commerce platforms.

The relevant provisions involved are:

- Responsibility of registrants and recordation entities (paragraph 2. Article 13);
- Registration and recordation process of overseas entities as registrants and recordation entities (Articles 15 and 16);
- Establishing the quality management systems commensurate with products and maintaining the effective operation thereof (paragraph 1, Article 20);
- Developing the plans for research after the marketing of medical devices and risk management and control and ensuring the effective implementation thereof (paragraph 1. Article 20);
- Conducting adverse event monitoring and re-evaluation according to the law (paragraph 1, Articles 62 and 66);
- Establishing and implementing the product traceability and recall rules (Article 67);
- Commission agreements for commissioned production and responsibilities and obligations of both parties (paragraph 2. Article 34):
- Prohibition of production of the implantable medical devices with high risks on a commission basis (paragraph 3. Article 34);
- Relevant provisions regarding online distribution of medical devices (Article 46).

Second, the regulation specifies that the state shall strengthen the information technology construction for the supervision and administration of medical devices, enhance the level of online government services, and facilitate the handling of administrative licensing and recordation of medical devices.

The relevant provisions involved are:

- Announcement of relevant recordation information by the State Council through the online government service platform (paragraph 3. Article 15);
- Announcement of relevant registration information by the State Council through the online government service platform (Paragraph 2, Article 18).

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Third, the regulation requires an implementation of certain reform of the medical device review and approval system of medical devices, and includes medical device innovation in the scope of development priorities to promote high-quality development of medical device industry.

The regulation specifies that the state shall give priority to the evaluation and approval of innovative medical devices to support the clinical promotion and use of innovative medical devices, support the basic research and application research of medical devices to facilitate the promotion and application of new medical device technologies.

In the meantime, enterprises shall be supported in establishing or jointly forming research and development institutions, and be encouraged to cooperate with institutions of higher education, scientific research institutes, and medical institutions, among others, in conducting research and facilitating innovations on medical devices, strengthen the IP protection for medical devices, and improve independent innovation capabilities in terms of medical devices.

The relevant provisions involved are:

- Giving priority to medical innovation review and approval to promote medical device innovation (Article 8);
- Supporting the basic research and application research of medical devices (Article 9);
- Commendation and reward of research and innovation of medical devices. (Article 12);
- Loosing requirements on registration and recordation of overseas innovative medical devices (paragraph 2. Article 15, and paragraph 2. Article 16);
- Encouraging medical institutions to conduct clinical trials of innovative medical devices (paragraph 3. Article 26).

Fourth, the regulation strengthens supervisions and punishments for illegal acts.

The regulation stipulates that the state shall establish professional and specialised inspector teams and unique identification systems for medical devices, conduct extended inspection and impose punishments for dishonesty.

In the meantime, the state shall impose harsher punishments for violation of laws, severely increase the cost for violation as a means to intimidate the enterprises and individuals and punish the violators for their illegal acts. In addition, those who are suspected in criminal cases should be held criminally liable.

#### The relevant provisions involved are:

- Establishing a professional and specialised inspector system (Article 68);
- Implementing the unique identification system for medical devices (Article 38);
- Prohibition of the import of used medical devices that have been expired, invalid or eliminated (paragraph 3. Article 57):
- Reporting on the surveillance of adverse events of medical devices (paragraph 3. Article 64);
- Extended inspection of other relevant entities and individuals by medical products administrations (paragraph 2. Article 69);
- Regulatory measures against potential quality and safety hazards that are not eliminated in a timely manner in the process of production and operation (paragraph 1. Articles 72 and 74);
- Increase of cost for violation and clarification of responsibilities of each individual (Articles 81, 82, 83, 85, 86, 88, 89 and 90);
- Addition of four punishable situations regarding recordation (Article 84):
- Guidance of punishment for purchase of medical devices and failure to implement the responsibilities related to the whole life cycle administration of medical devices according to regulations (Article 89);
- Punishment for violating the relevant regulations of online distribution of medical devices and failure to comply with the quality management norms for clinical trials of medical devices (Articles 92 and 94);
- Punishment for failure of domestic enterprise legal person designated by a medical device registrant or recordation entity to fulfill relevant obligations in accordance with regulations (Article 98)



Generally, the 2021 edition of the regulation optimises the review and approval procedures and further strengthens the supervision of the whole life cycle of medical devices, accelerating the development of China's medical device industry while alleviating the problem of clinical application.

It is expected that the issuance of relevant supporting measures will boost industrial development and drive the innovation of medical device enterprises, so as to force enterprises into completing or reviewing their compliance management (including IP) and better control relevant risks in the life cycle of new products.

Currently, the US remains a primary medical device manufacturing country with the biggest export of patented technologies in the world. As one of the world's important medical device manufacturing bases, China represents nearly 20% of the global medical device market and is grabbing greater market share. Therefore, impressed by the sheer size of the Chinese market, foreign enterprises are casting eyes on China and making a foray into patented technology development.

In a broad sense, the enterprises are advised to prioritise patent mapping, track and monitor the trends for keeping abreast of the latest market developments. Besides, the enterprises can target some key areas or technical fields for patent classification and management, in a bid to grip trends of technical development. Technically speaking, medical devices are a fast-evolving sector, where greater efforts may be spared on patent portfolio planning.

Like all the other national markets, China's medical device market has its own unique regulation and competition environment. In fact, Chinese authorities have unveiled a stream of preferential policies for domestic products in various ways in recent years.

Nonetheless, it's unrealistic to completely localise medical devices in China, especially with importation playing a crucial part in innovation and technology transfer in the industry.

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