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2018, another glorious year for us

By Beibei Gu

s it always be, the year of 2018 has witnessed great achievements for CCPIT Patent and Trademark Law Office. Our competent attorneys and paralegals, depending on their excellent work, are highly appreciated by our clients from home and abroad.

In retrospect, CCPIT Patent and Trademark Law Office has successively won 19 awards, among which including the honorable titles of Firm of the Year 2018 for China Trademark Prosecution by MIP, Tier 1 in both "Patent Prosecution" and "Patent Contentious" by MIP, Band 1 in non-

Outstanding IP Law Firm by Asia Law Profiles, IP Law Firm of the Year (China) by ALB, Tier 1 in both Patent and Trademark/Copyright by ALB, The 2018 Asia IP Awards Winner by Asia IP, 2018 Top 10 Patent Agency in China by IPR daily and Capital Intellectual Property Service Association, AAAA-class Patent Agency by Beijing Patent Attorneys Association.

All the awards are fruits of a whole year's efforts and dedication of the great team. We thank you for your support in the past and will continue to spare no efforts in protecting your IP assets in China and abroad.





Initiative brings Hong Kong opportunities for IP development

he 2018 Intellectual Property Business
Asian Forum (BIP), co-organized by
the Hong Kong Special Administrative
Region Government together with the
Hong Kong Trade Development Council (TDC)
and the Hong Kong Design Centre (HKDC), was
held on the 6th and 7th of December at the Hong
Kong Convention and Exhibition Centre.

This is the 8th Forum held annually since 2011. The theme of the Forum is "IP and Innovation in the New Socio-technological Landscape". Launched in 2011, the BIP Asia Forum has become one of the premier IP events in not only Hong Kong but also the Asia Pacific region. This remarks the critical role played by Hong Kong as a regional IP trading hub. The Forum attracted



some 2500 participants from local and overseas.

As one of the sessions of the Forum activities. CCPIT Patent and Trademark Law Office held a corporate stage focused on how "Belt and Road" Initiative brings opportunities for the IP development in Hong Kong", well attended by Ms. Maria Ng, Deputy Director of the Intellectual Property Department of Hong Kong, Mr. Thomas Tsang, Assistant Director of IPD, Ms. Lee Sau Kong, Deputy Solicitor General (Policy Affairs) of Legal Policy Division of Department of Justice, Dr. Lewis Luk, President of the Hong Kong Institute of Patent Attorneys, Dr. Wang Wenying, Secretary General of the China International Economic and Trade Arbitration Commission Hong Kong Arbitration Centre, Ms. Amy Wang the president of Macao Trademark Association, and some 50 guests from Hong Kong, the Mainland and Macau as well as overseas.

Mr. Andrew Liao, GBS, JP, who is one of the founders of the BIP Forum, chairman of Advisory Committee on Review of the Patent System in Hong Kong and past member of the Executive Council of the SAR Government, delivered a warm speech to the forum. He reviewed the background and process of the founding of the forum and said that in the new stage of reform and opening up of the country, the development of the "Belt and Road" and the Greater Bay Area of Guangdong, Hong Kong and Macao depend on technological innovations, which involve many intellectual property industry issues. "Belt and Road" brings both new challenges and opportunities for parties of Greater Bay Area where "one country two systems" are applied. Different regions have different laws and systems and it is desirable to explore a set of mechanisms under different systems, for instance for IP dispute solutions. Therefore, to strengthening communication and cooperation in various regions is the way to ensure that legal services

such as arbitration and mediation are resolved at one time, avoiding multiple treatments one by one.

Mr. Ma Hao, President of CCPIT Patent and Trademark Law Office and former President of the International Association for the Protection of Intellectual Property (AIPPI), pointed out with his remarks that Hong Kong has a unique advantage in the "One Belt, One Road" intellectual property work. Hong Kong is the world's freest economy and China's most international city. The "Belt and Road" Initiative and the "Guangdong, Hong Kong and Macau Greater Bay Area" strategy have brought huge policy dividends and created huge demand space for the development of intellectual property in Hong Kong. Hong Kong's geographical advantages, talent advantages, capital advantages and institutional advantages are also in-depth. Participating in and doing a good job of cross-border intellectual property rights in the "Belt and Road" provides a solid guarantee to meet the challenges. Hong Kong's sound legal system and distinctive intellectual property protection system will play an important role in the construction of the Greater Bay.

According to Mr. Ma Hao, CLT Patent & Trademark (H. K.) Limited, as a subsidiary and representative office of CCPIT Patent and Trademark Law Office, has witnessed Hong Kong's rapid development and brilliant achievements in the field of intellectual property for 20 years. According to statistics, Hong Kong now attracts more than 35,000 trademark applications, more than 13,000 standard patent applications and more than 4,000 design applications from around the world annually recent years. CLT has proudly provided its quality services for domestic and overseas clients with IP registration in Hong Kong, being listed within top 20 e-filers according to the monthly statistics of Hong Kong Intellectual Property Department.



n October 26, 2018, Decisions on Several Issues Concerning the litigation Procedures of Patent and Similar Cases (hereinafter referred to as "Decision") proposed by the Supreme Court was passed during the sixth vote of the Standing Committee of the 13th National People's Congress and will take into effect since January 1, 2019.

This means that, the part of IP cases involving technical issues and requiring more expertise will be heard before a specialized IP tribunal of the Supreme Court for the second instance, in place of those high courts of each province. Noting that an IP tribunal for hearing IP retrial cases has already been established within the Supreme Court, the "specialized IP tribunal" shall be a different one and shall be at a lower level in structure.

So, when a party is not satisfied with a decision made by a specialized IP court or an intermediate court for the following cases, he shall appeal the decision to the IP tribunal of the Supreme Court, once the latter is established.

- (1) Civil cases in relation to invention and utility model patents, new plant varieties, layout designs of integrated circuits, technical secrets, software as well as monopoly etc.
- (2) Administrative cases in relation to patents, new plant varieties, layout designs of integrated circuits,

technical secrets, software as well as monopoly.

In China's judicial practice, most of the IP cases relate to patents, trademarks, copyrights, new plant varieties, layout designs of integrated circuits, technical secrets, monopoly, among which, patents mean inventions, utility models and designs. Appeal cases in relation to trademark, copyright and design are not within the jurisdiction of the specialized IP tribunal of the Supreme Court, and shall be heard by the local higher people's courts, though it is still possible for the Supreme Court to hear a trademark, copyright or design case such as during a retrial procedure or during a second-instance procedure when a provincial high court is the first-instance court.

The Supreme Court shall make a pilot report on the implementation of this Decision to the Standing Committee of the National People's Congress three years later.

By integrating the adjudication of civil and administrative cases at the second instance within the specialized IP tribunal of the Supreme Court, the validity procedures and the infringement procedures will be unified with respect to the same references, which helps to reconcile the adjudication disagreement constraining scientific and technological innovation from the perspective of mechanism, enhance case quality and efficiency, establish a sound business environment and improve judicial protection of IPRs, according to Qiang ZHOU, the president of the Supreme Court.

In view of the high volume of IP cases in China and also the fact that the Supreme Court itself is simultaneously the top retrial court and the court directing IP trials and IP policies in the country, the IP tribunal within the Supreme Court may finally grow into an independent IP appeal court.

In 2018, which Chinese companies filed more PCT patent applications?

By Kaifang Wang



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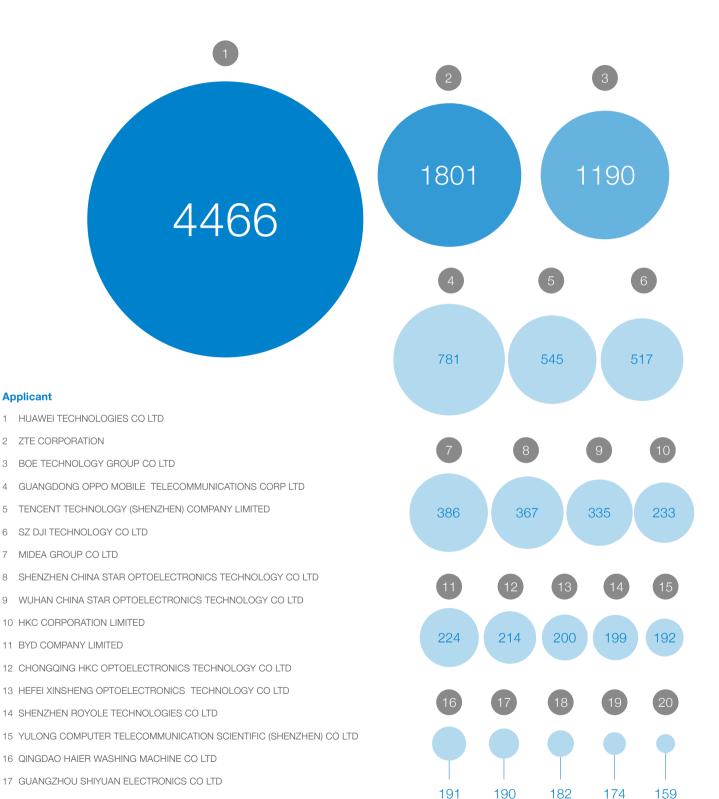


recent press release revealed the list of top 100 Chinese companies filling the most PCT patent applications in 2018, specifically based on the data published by the World Intellectual Property Organization (WIPO) from January 1, 2018 to October 31, 2018. Huawei Technologies Co Ltd ranked the first with 4466 PCT patent applications, followed by ZTE Corporation and BOE Technology Group Co Ltd, noting the dominance of information technology companies in the domain.

With the acceleration of economic globalization, more and more Chinese

companies are going abroad, laying out their patent portfolios internationally and participating in international competition and cooperation actively. According to WIPO, the number of PCT patent applications from China had increased from more than 18,000 in 2012 to more than 48,000 in 2017, with an average annual growth of 21.3%. In 2017, China's PCT patent applications ranked second in the world.

The table below is the list of the top 20 Chinese companies filing the most PCT patent applications from January 1, 2018 to October 31, 2018.



18 BEIJING XIAOMI MOBILE SOFTWARE CO LTD19 GREE ELECTRIC APPLIANCES INC OF ZHUHAI

20 SANECHIPS TECHNOLOGY CO LTD

First sound trademark case in China: registrable but only on the product actually using the mark

By Kaifang Wang

encent launched QQ chat software in 1999, since then the new message notification sound "Di Di Di Di Di Di" can be heard instantly once a new message arrives. Tencent began to apply for a trademark for the sound in 2014, which was rejected by the China Trademark Office (CTMO) and Trademark Review and Adjudication Board respectively for lacking distinctiveness. Tencent appealed. On Sep. 27, 2018, Beijing High People's Court made the final decision siding with Tencent and holding that QQ notification sound trademark is distinctive and registerable. This is the first sound trademark case adjudicated before a court.

According to the Chinese Trademark Law of 2014, sound becomes eligible for registration as a trademark. A sound trademark is a sound that is used to perform the trademark function of uniquely identifying the commercial

origin of a product or service. The opening tune of China Radio International has been reviewed and approved as the very first sound trademark. Other examples include the Nokia tune and the "I'm lovin' it" jingle of McDonald's.

In this case, at issue is the distinctiveness of QQ notification sound. CTMO deemed the sound "Di" could be commonly found from many electric devices and could not be used to specifically distinguish the service provider. While Tencent argued that the sound was not just a simple repetition of "Di" by providing the court with a spectral catalogue, frequency spectrum and oscillogram of the sound, as well as 152 documentary evidence from the National Library of China, to prove that QQ notification sound had been used widely for a long time and could serve to distinguish the service provider.



Beijing High Court held that:

A specific mark may lack the distinctive feature required for trademark registration by itself. However, when the mark has been used for a long time and can function as an identifier, it may be registered in accordance with the provisions of Article 11, paragraph 2 of the Trademark Law of China. Since the salient features of this kind of mark is based on actual use, the registration of the mark shall be limited to the scope of the actual product or service applying the mark.

In this case, QQ notification sound of "Di Di Di Di Di Di" itself is a common and simple repetition and lacks a distinctive feature for trademark by itself. However, this notification sound has been used on QQ software for such a long time that it has established a stable correspondence relationship with QQ instant messaging software. Tencent submitted sufficient evidence proving that this sound can identify the source of the specific service.

Beijing High Court therefore upheld in part the decision of Beijing Intellectual Property Court that QQ notification sound is registrable on the product already using it, while rejected its registration on other products not using it.



IP protection in China: new policies and changes

By Weiwei Han, Xiaojun Guo

he extraordinary progress in China's intellectual property protection in recent years has been witnessed worldwide.

"A comprehensive IP protection system has come into shape in China since the 40 years' of reform and opening up, making outstanding achievements to the great undertakings," said Director General of the World Intellectual

Property Organization (WIPO), Mr. Francis Gurry, who attended 2018 High-Level Conference on IP for Countries along the Belt and Road and the 9th China Patent Annual Conference recently. Mr. Francis concluded that, "China has made outstanding contributions to patent system" and "at present, Chinese government has formulated a host of policies to support IP work. Under



such circumstance, the outcomes in China's IP work can be shared by other countries in the world."

Innovation and IP protection have been encouraged by the Chinese government. President Xi Jinping and Premier Li Keqiang have highlighted the importance of IP under many scenarios. In his message to the "One Belt, One Road" High-Level Meeting Conference of August 28, 2018, President Xi Jinping, pointed out that, China will unswervingly strengthen the protection of intellectual property right by establishing a sound environment for business and innovation to protect the IP right of all enterprises. China is ready to strengthen dialogue and expand cooperation with

all participants to achieve a win-win result in advancing the protection and application of intellectual property right for the benefit of all the people.

Resources have been put into innovation and IP protection, and investments have been attracted into Chinese market. Based on Global Innovation Index 2018 issued by WIPO, China ranked 17th, and China Hongkong ranked 14th, which are the highest ranking for China historically. As reported in the "Index", "China's rise in the GII rankings over the last few years has been spectacular. Since 2016 China has featured in the top 25 group and has consistently moved upward in the rankings to 17th this year." It was also highlighted that, "China's innovation prowess becomes evident in various areas. It shows some of its greatest improvements in global R&D companies, high-tech imports, the quality of its publications, and tertiary enrolment." The number of PCT filings in 2017 ranked the second in the world. and the rapid growth trend has been maintained.

In this article, we will share some recent update on IP protection in China, particularly patent protection, which backs the above messages.

Applicant-Friendly IP filing and examination system

The pilot reform in the comprehensive management of intellectual property and the restructuring of the State Intellectual Property Office have been going on. China has realized the integrated management of patent, design, trademark, geographical indication of origin and the layout designs of integrated circuit, which, in turn, has

greatly improved the management efficiency of intellectual property.

In accordance with the restructuring plan approved by the 13th National People's Congress, the State Intellectual Property Office of China (SIPO) was renamed China National Intellectual Property Administration (CNIPA) on August 29, 2018. CNIPA will not subordinate to the State Council, but under the supervision of the newly established State Administration of Market Supervision and Administration.

Regarding one of the most important IP rights, a series of measures or policies have been adopted to advance patent examination.

Fee reduction

As of August 1, 2018, the charging of some types of official fees has been suspended or adjusted for Chinese patent applications. Firstly, patent registration fee, publication printing fee, and fee for change of bibliographical data (change of patent agency or patent attorney) are ceased to charge. Secondly, for patent applicants or patent holders who meet the relevant conditions of the "Measures for the Reduction of Patent Fees" (Ministry of Finance [2016] No. 78, the period for the reduction of the annual patent fees shall be extended to ten years if the patent has been existing for six years from the date of grant. Thirdly, for invention patent applications already in substantive examination stage, if the response to the first office action were not filed and the applications were withdrawn before the expiration of the reply period of the first office action, 50% of substantive examination

fees for patent application may be refunded. Besides the favorable fee policies for Chinese patent applications, advantageous policy is also available for a PCT application. Namely, the transmission fee for a PCT application filed at CNIPA (i.e., 500 RMB) is also suspended. These policies will lower the cost for patent filing and maintenance in China.

Shortening examination period

Prioritized patent examination, often called a "green path", is an effective way in shortening examination cycle, benefits patent applicants, and may contribute to economic development. Since the issuing of "Administrative Regulations of Prioritized Patent Examination" (hereafter referred to as "Regulations") by CNIPA, which took effect as of August 1, 2017, more and more domestic and foreign patent applicants are taking advantage of this prioritized patent examination system.

It is worth noting that, Premier Li Keqiang suggested this year that, the duration for trademark registration and examination be shortened from 8 month to less than 4 month, the examination period for patent applications be reduced by one third, and particularly, for high-value patent applications, the examination period be reduced by half.

In addition, to realize rapid grant of patent rights and efficient enforcement measures, up to now, around 20 intellectual property protection centers have been established nationwide.

These new measures will collaboratively provide applicants with more opportunities to obtain a trademark or patent right within a much shorter period, which may in turn benefit patent enforcement and commercialization.

Enhanced protection of IP rights via judicial system

China is drawing a new roadmap for reform of IP judicial protection.

1. Issuing of Opinions on Several Issues in Enhancing Reform and Innovation in Hearing Intellectual Property Cases

The Opinions on Several Issues in Enhancing Reform and Innovation in Hearing Intellectual Property Cases issued by the "Two Offices" (the General Office of the CPC Central Committee and the General Office of the State Council) on Feb. 6, 2018 is the first programmatic document of milestone significance issued by the "Two Offices" exclusively designated for IP judicial protection, establishes the guiding ideology, basic principles, reform objectives and key measures in judicial protection of intellectual property rights (IPRs), according to Tao Kaiyuan, vice president of the Supreme People's Court of China.

In particular, Tao explained that, first, the Opinions serves an objective need of safeguarding the interests of innovation in science and technology; second, the Opinions is a major move to strengthen the protection of IPRs and aims at solving such challenges as "hard proof, low compensation"

and long cycle" in IP enforcement; third, the Opinions is a necessary requirement for bring in play a leading role of IP judicial protection; fourth, the Opinions is an important guarantee for the modernization of the judicial protection system and judicial capability in hearing IP cases.

Regarding how to ensure that the judgment scales of courts in various places are unified? Tao pointed out that the Supreme Court guarantees that through several approaches including, trying IP cases by the Supreme Court itself, formulating judicial interpretations, making real-time judicial policies, releasing IP guiding cases and continuously enhancing the training and education of IP judges. The latter two points are also raised in the Opinions.

The Opinions, which holds onto the modernization of the IP judicial system and the modernization of the judicial power, endeavors to make Chinese courts preferred venues for international IP disputes. This relies on the high-level trial quality and efficiency of Chinese courts as well as the expertise of the IP judges, Tao said.

The Opinions definitely responds to the demands of some IP right holders.

For example, the Opinions restates the intention of enhancing IP infringement compensation to reflect the value of IP, and increasing efforts to crack down on IP infringement by increasing penalties for infringement and reducing the costs for

safeguarding rights.

The Opinions also calls for exploring ways to rationally allocate the burden of proof in order to solve the problems of "hard proof" for the holders of intellectual property rights.

Further, the Opinions sets forth the establishment of a IP appeals court with centralized jurisdiction for better unifying the trials of IP cases.

The Opinions points out that the number of IP judges should be adjusted dynamically, which implies that the number of judges may be increased in the near future, since the year of 2017 marks for the first time the first instance IP cases in China exceeded 200,000, with a growth of 40.36% compared with the same period of the year 2016.

The Opinions clearly shows that China does have placed the reform of IP judicial protection on its priority, since "Intellectual property protection is a basic means to stimulate innovation, a basic guarantee for the motive force of innovation, and a core element of international competitiveness" and is of great significance to the country.

2. Issuing of Provisions on Several Issues Concerning the Trial of Administrative Cases Involving the Granting and Affirmation of Patent Right (I) (Draft)

The Supreme People's Court (SPC) of China published "Provisions on Several Issues Concerning the Trial of Administrative Cases Involving the

Granting and Affirmation of Patent Right (I) (Draft)" on June 1, 2018 to ask for public opinions.

The "Provisions" gives further guidance on: the interpretation of the claims; substantial grounds for invalidation of inventions and utility models such as insufficient disclosure, clarity, support by description, amendment. inventiveness; design space of the product protected by the design patent, design features determined by technical function, identical invention-creation, design teaching given by prior designs, unique visual effects and legal rights; and procedural issues, including violation of legal procedure, exceeding authority, submitting evidence, legal effect of administrative judgement.

3. Establishment of internet courts

The first internet court was established in Hangzhou in August 2017. Recently, two new internet courts have been established in Beijing and Guangdong. Internet courts are convenient routes for a plaintiff to lodge a lawsuit. And the judicial examination is also conducted online. As of September 9, 2018, the internet court in Beijing began to accept cases. Among the cases which can be examined by internet courts, one kind in connection with IP is internet copyright ownership and infringement disputes.

The newly established internet courts may ease the protection of copyrights of music, movie, audiovisual performance, gaming and publication, among others, and better meet the challenges brought by expanding of global digital market.

Enhancing international cooperation

In recent years, CNIPA has been strengthening the cooperation with more and more countries in IP issues. Over the last five years. foreign applicants filed 650,000 patent applications s and 840,000 trademark applications in China. The number of PCT filings also grew 12.5 percent year-on-year to reach 51,000 in 2017, ranked second in the world. Further, CNIPA is enhancing the cooperation with countries along the Belt and Road. The amount of patent filing in these countries increased by around 16% annually in the past 3 years. And from January to June, 2018, the filing in these countries grew by 27% compared to last year.

Besides the cooperation at the level of country, the investment and resources put by foreign companies are also growing. More companies are established their R&D centers and IP department in China, and there are more inventions and IP filings generated in China.

In summary, China is creating a more and more favorable IP environment for IP owners, in the aspect of not only administrative examination but also judicial protection. And it can be expected that applicants may obtain an IP right in a shorter period and at a lower cost, and in the meantime the judicial protection for IP rights will be more powerful.



Patenting regenerative medicine in China

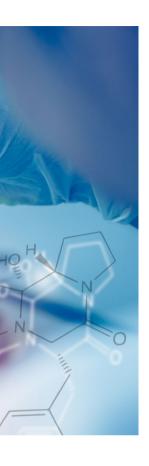
By Juhua Luo, Weiwei Han

egenerative medicine, which aims at the process of replacing, engineering or regenerating human cells, tissues or organs, so as to restore or establish the normal function of a living organism, is a prospective branch of medicine. Regenerative medicine is popular worldwide in the recent decade, and has broad applications. Many biological companies, research institutions and universities are conducting research in this field. In the same time, a large amount of patent applications in this field have been or are being

filed. In this article, we will discuss typical issues in connection with patenting regenerative medicine in China, by referring to reexamination and invalidation decisions.

Key words: regenerative medicine · stem cell · patent · reexamination · invalidation

I. Current status and challenges in connection with patenting regenerative medicine in China



The patent filing is active in the field of regenerative medicine. Upon a preliminary search, it is found that, the applications in this field are mainly filed by US, European, Japan and Korean applicants. Among the applications, most are associated with stem cells. Considering that stem cells are often obtained from an embryo, and closely associated with living organisms, there are some unique issues regarding the patent applications in this field. Of these issues, patent eligibility of subject matter, practical applicability, as well as social morality or ethnics are of particular interest.

As it is known, in Chinese patent examination practice, if a patent application is rejected, the applicant may request reexamination in front of the reexamination board. During the reexamination procedure, the application will be further examined by a reexamination panel consisting of three reexaminers. Further, any party may challenge the validity of a patent in front of the reexamination board by filing a request for invalidation.

Accordingly, the opinion of the reexamination board is authoritative, and may reflect the examination standard to some extent. In practice, some examiners may refer to reexamination or invalidation decisions during their examinations.

We will discuss the above-mentioned issues in detail in the following sections by referring to some representative reexamination and invalidation decisions.

II. Subject matter and patent eligibility

The first question to ask is about which kind of subject matter could be patented. It is well known that, claims include product, method and use claims. This is the same for patent applications based on regenerative medicine. Typically, the patent-eligible subject matter in this field can be divided into the following types.

Products

Product claims may relate to a cell, a tissue, or an organ per se, or a pharmaceutical composition comprising a cell or the extract thereof.

Methods

Methods for consideration are, for instance, methods for preparing a specific cell, tissue, or an organ, methods for oriented differentiation, and methods for treatment with a non-diagnosis or treatment purpose.

Uses

Although methods for treatment or diagnosis are not patentable in China, Swiss-type use claims are allowable in current Chinese practice. As an illustrative example, the use claim may be drafted in the format of "use of a substance, a cell, a tissue, an organ or a composition in the manufacture of a medicament for the treatment of certain diseases".

III. Ethics and social morality

Principle and Legal Basis

The issue of social morality is the most prominent issue in the prosecution of patent applications on regenerative medicine.

It is prescribed in Art. 5.1 of the Patent Law of China that no patent right shall be granted for any invention-creation that is contrary to the laws or social morality or that is detrimental to public interest.

Further, it is addressed in the Guidelines for Patent Examination of China that, "social morality" refers to ethical or moral norms and rules generally recognized as justifiable and accepted by the public. Its connotation is based on certain cultural background, continuously changes with time and social progress, and varies from region to

region. Social morality in the Chinese Patent Law refers to the morality within the territory of China.

Examples of this kind of applications include a process for modifying the germ line genetic identity of human beings or a human being thus modified, a process for cloning human beings or a cloned human being, use of human embryos for industrial or commercial purposes, and a process for modifying the genetic identity of animals which is likely to cause them suffering without any substantial medical benefit to human-beings or animals.

It is worth noting that, in examination, when evaluating whether an application falls within the scope of the conditions under Article 5.1, the examiner will examine all the application documents, including the claims, description, drawings, and abstract. If a patent application is considered partially contravening Article 5.1 since a part of the application contains certain content that is contrary to the laws or social morality and the rest part of the application is not, an applicant may amend the application and delete the part contravening Article 5.1. If the applicant refuses to delete the part that is contrary to the laws, it cannot be granted a patent right.

Representative cases and rulings of reexamination board

Regarding the use of human embryos for industrial or commercial purposes

As discussed in the previous section, the use of human embryos for industrial or commercial purposes is deemed as contrary to the social morality.

What is an "embryo" under Chinese Patent Law?

Some reexamination decisions provide interpretations on the term "embryo."

It is stated in the reexamination decision No.18784 that, the human embryos refer to the embryonic embodiments at any stage from a zygote to a newborn, including cleavage stage, morula stage, implantation stage, and differentiation stage.



Regarding the source of an embryo, it is stated that, the source shall include any source, including blastula discarded after in vitro fertilization, blastula obtained via the transplanting of a body cell nucleus, embryos naturally or manually aborted.

Further, parthenogenetic embryos and parthenogenetic blastocysts also belong to the concept of an "embryo" by referring to reexamination decision Nos. 89657 and 73216.

What is "use of human embryos" under the scenario of "use of human embryos for industrial or commercial purposes"?

In one reexamination decision No. 50837, "use of human embryos" was expounded as "operation" and "contact". The patent in suit is directed to a method of assessing the viability of thawed cells, comprising incubating a grade I embryo in a culture medium and determining the change in concentration of at least one amino acid in the medium. It is contended in the reexamination decision No. 50837 that, such a method definitely involves the steps of culturing an embryo or an embryonic cell, and there is operation and contact with human embryo or embryo cell, and such operation and contact are for developing relevant assessing technology with a commercial purpose.

Further, the "use of human embryos" is irrelevant with whether the embryo is disrupted or not. In particular, even if embryonic cells are obtained from a human embryo without disrupting the human embryo, it also involves the use of human embryos for industrial or commercial purposes.

Inventions involving an embryonic stem cell

The prerequisite for the allowance of inventions involving an embryonic stem cell is that, the invention is merely the further usage of human embryonic stem cell lines which



are established, conventional and stable, and the patent application does not contain contents which relate to the direct description and use of human embryo (by referring to reexamination decision No. 103528).

In practice, it is necessary to amend the description of the patent application to cancel contents which relate to the use of human embryos for industrial or commercial purposes. Further, the patent application shall disclose the ways by which the stem cell lines used in the working examples can be obtained without disruption of a human embryo. Also, it may necessary to prove that the cell lines used in the working examples are matured and commercialized before the priority date. As for the claims, it shall be limited to cell lines which are established, conventional and stable.

There are several cases to illustrate this issue.

In one case, the invention is about the differentiation of human embryonic stem cells. It is described in the claims that the pluripotent stem cells are established human embryonic stem cell lines, and there is also similar recitation in the description. Also, it is described in the working examples that "non-limiting examples are established lines of human embryonic stem cells or human embryonic germ cells, such as, for example the human embryonic stem cell lines H1, H7, and H9 (WiCell)." During the prosecution, relevant contents concerning the direct use and disruption of a human embryo were cancelled. Accordingly, the reexamination board determined that the invention does not involve the use of human embryos for industrial or commercial purposes, and thus is not contrary to social morality.

Similarly, from a series of other reexamination decisions, we can learn the conditions under which human embryonic stem cells related inventions are patentable. In these reexamination

decisions, allowable human embryonic stem cells are specified as "established cell lines which are commercially available", "human embryonic stem cell lines H1, H7, H9 and BG01v", "established embryonic stem cell lines", "established pluripotent stem cell lines", "pluripotent stem cells other than embryonic stem cells, and embryonic germline stem cells from human embryos", and "the source of embryonic stem cells does not include human embryo sources, and the source of the embryo does not include human embryo source", respectively.

The above are cases with positive outcome after reexamination. However, in another case, the reexamination decision No. 97723 was different. Although it was defined in the claims and the description that the sources of the human embryonic stem cells are established cell lines, it was found that the patent application does not state that the human embryonic stem cells used in the working examples are established cell lines, and there is no evidence to prove that these cell lines are mature and commercially available human embryonic stem cell lines before the priority date. The conclusion was made that the invention falls within the scope of Article 5.1 of the Patent Law.

Regarding the "use of human embryos for industrial or commercial purposes," it is an important and debating area. There are multiple reexamination decisions and invalidation decisions to address this issue. Some are directed to totipotent stem cells, and some are directed to pluripotent stem cells.

Inventions regarding totipotent stem cells

In a case related to totipotent stem cells, the reexamination board held that, the totipotent stem cells have the capability to self-renew and differentiate into any type of cells, and also have the potential to develop into an entire human being, and thus belong to a certain stage of a human being, which is not patentable (reexamination decision 87655).

Inventions regarding induced pluripotent stem cells

Induced pluripotent stem cells (iPSCs) are pluripotent stem

cells that can be generated directly from adult cells. For the amazing discovery that mature cells can be reprogrammed to become pluripotent, a Japanese scientist, Mr. Shinya Yamanaka from Kyoto University, was awarded a Nobel Prize in 2012. iPSCs are typically derived by introducing an induction factor (for instance, a reprogramming factor) into a given cell type.

One of the cases on iPSCs, which is also the recent and the most influencing one, is regarding a patent entitled "nuclear preprogramming factor." This case is an invalidation case which was selected as top 1 reexamination and invalidation decisions by the Patent Reexamination Board in 2015. The most important reason for this case to be selected is that it is a typical case on the social morality of embryonic stem cells.

The patent was owned by Kyoto University and the inventor is Mr. Shinya Yamanaka. The patent was granted on February 12, 2014, and an opponent filed a request for invalidation on October 29, 2014. One ground for requesting invalidation is that the invention involves the operation on human embryo, and is contrary to social morality.

The independent claim 1 of the patent does not directly relate to iPSCs. Instead, it is directed to a nuclear preprogramming factor of a somatic cell. However, according to the description, in the example of "Establishment of iPS Cells from Embryonic HDFs in Mouse ES Cell Medium", embryonic human dermal fibroblasts (HDFs) were used. The opponent is of the opinion that, "embryonic" may imply that the cells are from human embryo; and under the condition that the patent in suit does not describe that the HDFs are derived from mature and commercially available cell lines, it should be considered that the obtainment of the dermal fibroblasts require the disruption of a human embryo.

Further, the opponent pointed out that, in the description, it was described that when the iPS cells derived from adult dermal fibroblasts were transplanted to the blastocysts, and then transplanted into the uteri of pseudopregnant mice,

embryos were obtained. The opponent deduced that, when the method is applied onto human cells, the established iPS cells will have the potential to develop into a human being once transplanted into human uteri.

Upon an oral hearing, the reexamination board made a decision on June 25, 2015.

The main points of the invalidation decision are as follows:

-for an invention related to cells that can either be obtained from an embryo or be commercially available, it shall be determined that the description excludes the contents on directly obtaining the cells from a human embryo, if:

(1) one of the objects of the invention is to avoid the ethical problems due to obtaining some cells from the embryo,

(2) the description does not include any operation on the embryo; and

(3)it can be determined be a person skilled in the art that there are routes to commercially obtain the cells

-for human cells that do not have the totipotency, if the obtainment and preparation thereof do not involve any process on the destruction or usage of human embryo, the cell per se and the preparation thereof do not involve industrial or business application of human embryos, and it cannot be considered that it is contrary to social morality.

Accordingly, the patent was maintained as valid by the reexamination board. After the invalidation decision was issued, the opponent has appealed to the court. A court hearing was held on January 18, 2018, and a further decision has not been issued. The only issue for the appeal is that social morality issue under Article 5.1.

In another case, the invention is directed to a method of preparing the pluripotent stem cells, kit and use. One claim relates to a method for preparing induced pluripotent stem cells, comprising providing induction factors to differentiated cells. During the prosecution, the applicant cancelled the description on embryonic cells, related experiments and data, and merely experiments and data on adult body cells are maintained in the working examples. Based on these facts, the reexamination board concluded in decision No. 77660 that, even though the iPSCs are pluripotent, they are just similar to embryonic stem cells in property, but are not embryonic stem cells. Accordingly, the method as claimed does not involve the preparation of human embryonic stem cells.

IV. Practical applicability

Principle and Legal Basis

Practical applicability is another notable issue that is often raised during prosecution of patent applications related to regenerative medicine.

It is prescribed in Art. 22.4 of the Patent Law that practical applicability means that, the invention or utility model can be made or used and can produce effective results.

It is further explained in the Guidelines for Patent Examination that, the expression "can be made or used" referred to in Article 22. 4 means that it is possible for the technical solution of an invention or utility model to be made or used industrially. A technical solution that satisfies the requirement of practical applicability shall be reproducible. Reproducibility means that, according to the technical contents disclosed, the technical solution adopted in the patent application to solve a technical problem can be implemented repeatedly by a person skilled in the art. Such repeated implementation shall not rely on any random factors and shall have the same result.

In the field of regenerative medicine, methods for surgery on human or animal body for non-treatment purposes do not have practical applicability.

Representative cases and rulings of reexamination board

In line with the principle and legal basis for practical applicability, the core for determining whether an invention has industrial application may be whether the invention is reproducible, and can be made or used in industry. We may see this in some reexamination decisions.

Regarding autologous products

One invention is directed to an autologous serum complex for the nourishment of skin mesoderm, comprising certain weight parts of fresh infertile autologous serum. In the reexamination decision No. 77419, the board is of the opinion that, for the product claim, the preparation of the products lies in a specific individual, and is performed on a specific individual, which cannot be manufactured industrially. The decision was made in view of the disclosure of the description. It was found that, the fresh serum contained in the product as claimed must be autologous, and thus is personalized, has no practical applicability.

In contrast, in another case which relate to the use of autologous transplants, the decision of the reexamination board (reexamination decision No. 88910) is different from the above one. The invention is directed to the use of autologous transplants in the manufacture of a medicament for treating a subject who is in need of liver or pancreas transplantation, wherein the autologous transplants are obtained by a method comprising inoculating a porous matrix comprising a biologically tolerated polymer with cells to form an autologous implant, wherein the cells are obtained from a subject's living liver cells and pancreas cells.

In reexamination decision No. 88910, the Board held that, if an invention complies with the following requirement, it has practical applicability:

- -the subject matter is not directed to a surgery method with a non-treatment purpose,
- -the technical solution can be reproducibly carried out, not relying individual or other any random factors and achieving

the same result.

Turning back to the patent-in-suit, the Board held that:

-the subject matter as claimed is "use of autologous transplants in the manufacture of a medicament", which does not belong to a surgery method;

-even though it is defined that "the cells are obtained from a subject's living liver cells and pancreas cells," this is just to define the source of the cells, and does not comprise surgery steps of obtaining liver cells and pancreas cells, so the assertion of the previous examiner that such a definition implied unavoidably surgery method is an extension of the technical solution as claimed:

-the "autologous transplants" can be generated from different individuals, and thus the technical solution can be reproducibly carried out, not relying individual or other random factors and achieving the same result, i.e., manufacture of a corresponding medicament.

Based on the above, it is believed by the Board that, the technical solution has the possibility of being produced or used in industry. Further, according to the disclosure of the description, the invention achieved advantages effects. So, the technical solutions of the above claim and its dependent claims are considered as having practical applicability.

In a series of other reexamination decisions including reexamination decisions No. 59995, No. 59167 and No. 99488, the Reexamination Board also held that, the expression "can be made or used" under Article 22. 4 means that it is possible for the technical solution of an invention or utility model to be made or used industrially. If the source of a technical solutions as claimed cannot be industrialized, the invention does not practical applicability. For instance, if the donor applied in the invention can only be dominated by a volunteer, such an invention would not be applied in industry.

decisions No. 59995, in the prior art, the neural stem cells which must be used in the application has quite limited source. Besides an embryo, the neural stem cells can only be prepared from the tissues donated by volunteers, and the donation of cells or organs normally are limited for medicine and research purposes, which cannot be applied for business, and cannot serve as the source for industrialization. In the meantime, the applicant also failed to provide any evidence that, besides the domination for the volunteers, other sources (for instance, commercially available sources) are available and can be industrialized.

Inventions which depend on individuals and relate to surgery methods

In addition, for the inventions which depend on individuals and relate to surgery methods, the practical applicability for these inventions are difficult to be established.

As an illustrative case, claim 1 of a patent application is directed to the use of bone marrow mesenchymal stem cells in the manufacture of a medicament for treating Crohn's disease, and the steps for preparing the bone marrow mesenchymal stem cells are defined in the claim, including dilution of posterior superior iliac spine bone marrow sprinkled with heparin diluting solution, and taking the cell surface markers of each generations of the bone marrow mesenchymal stem cells and obtaining the bone marrow mesenchymal stem cells with certain property.

In reexamination decision No. 98995, the Board is of the opinion that, for an invention which is directed to the use of a product using bone marrow as a source via specific methods, if there is no evidence to prove that the raw material, i.e., the bone marrow, is commercially available, it is impossible to exclude the step of obtaining the bone marrow via surgery from a specific human body, and thus the technical solution cannot be made or used industrially, and does not have practical applicability.

Turing back to this case, it is believed that, the use as claimed

In the scenario of the invention addressed in reexamination

does not have practical applicability, based on the following grounds:

- -it is an indispensable step to obtain the bone marrow raw material, so as to carry out the technical solution as claimed;
- -the reexamination petitioner failed to provide evidence to prove that the commercial availability of the bone marrow raw material:
- -the petitioner failed to demonstrate in the description that the bone marrow obtained from one donor can be applied into multiple patients, and there is no evidence to support the petitioner's opinion that the marrow bone does not rely on an individual; instead, according to the common knowledge in the art, when mesenchymal stem cells are extracted from bone marrow in clinical trials, the bone marrow is extracted from the body before using, which implies that, in each process of the manufacture of a medicament, bone marrow needs to be extracted from a living human body;
- -since the source is not commercially available, rendering that the step of extracting bone marrow from a living human body is a necessary step in the manufacture of a medicament, that is, such a process of manufacture relies on a living human being, by carrying out surgery on the human being, so that the technical solution cannot be produced or used in industry.

Inventions on heterologous products

The patent-in-suit is directed to an isolated hair follicle stem cell, which in certain stage of its growth circle, was obtained from mammalian animals.

The main holding of the Reexamination Board is the same as that in the decision No. 88910. Specifically, the Board held that, the invention as claimed, if an invention complies with the following requirement, it has practical applicability:

-The subject matter is not directed to a surgery method with

a non-treatment purpose,

-the technical solution can be reproducibly carried out, not relying individual or other any random factors and achieving the same result.

Turning back to the patent patent-in-suit, the Board held that:

- -the subject matter as claimed is "isolated hair follicle stem cell", which does not belong to a surgery method;
- -the raw material can be obtained as long as a skin can be obtained; and the obtainment of the hair follicle stem cells from a skin can be performed without relying on a living human or animal body, and thus does not relate to a surgery with non-treatment purpose
- -the hair follicle stem cell does not require a particular source of skin, and thus the technical solution can be reproducibly carried out, achieving the same result, i.e., manufacture of a corresponding medicament, without relying on a particular individual or other any random factors.

In another similar case, the Board made a similar decision in decision No. 89329. In that case, the source does not rely on a specific source, and is commercially available. And the practical applicability was acknowledged.

V. Other issues

Besides the above issues, some other issues are also worth of noting, for example, the disclosure of genetic resources.

As prescribed in Article 26.5 of the Patent Law, where an invention-creation is developed relying on the genetic resources, the applicant shall indicate the direct and original source of such genetic resources; where the applicant cannot indicate the original source, he or it shall state the reasons thereof.

According to the Guidelines for Patent Examination, "genetic

resources" referred to in the Patent Law mean the material obtained from such as human body, animal, plant, or microorganism which contains functional units of heredity and is of actual or potential value. The invention-creation is developed relying on the genetic resources means that the invention-creation is developed relying on the use of the heredity function of the genetic resources. Functional unit of heredity refers to a gene, or a DNA or RNA fragment having heredity function of an organism. With regard to an invention-creation, using the heredity function of the genetic resources refers to, for example, isolating, analyzing and/ or processing the functional units of heredity to develop the invention-creation and to realize the value of the genetic resources. "Acquisition or use of the genetic resources is not consistent with the provisions of the laws and administrative regulations" means that the acquisition or use of the genetic resources is not beforehand approved by relevant administrative departments or licensed by relevant right holder in accordance with the provisions of relevant laws and administrative regulations of China.

VI. Future Perspectives

In the above sections, we discussed the typical issues in the patenting of regenerative medicine in China, with a brief review on a series of reexamination and invalidation decisions. These decisions may reflect the examination standard to some extent. In view of our experiences, current examination practice has been pursued in line with the legal principles as well as the gist of the opinions of the reexamination board.

Among the typical issues, patent eligibility, social morality and practical applicability are most important.

Regarding patent eligibility, we suggested several kinds of possible subject matter which could be covered in the claims. An applicant may consider covering diverse types of claims in an application, for instance, a product claim covering a cell, a tissue, or an organ per se, or a pharmaceutical composition comprising a cell or the extract thereof; a method claim covering the process for preparing a specific cell, tissue, or an organ, methods for oriented differentiation, and methods for treatment with a non-diagnosis or treatment purpose; and

Swiss-type use claims.

Regarding social morality, the examination will be conducted in view of the specification as an entirety, including the claims, description and drawings. The bottom line seems that, any human embryo could not be involved in the specification.

And, it is not allowable to generate an embryo or a cell with totipotency. But it appears that the iPSCs are allowable under many conditions. This would be clearer if the court make a decision in the case regarding "nuclear preprogramming factor" in the future.

Regarding practical applicability, surgery methods are generally considered as having no practical applicability. Further, under some conditions, the obtainment of raw material may also trigger this issue. For instance, for autologous products, the raw material may be deemed as individualized, and cannot be reproduced in industry. And for heterologous products, it seems to be more likely to establish practical applicability. In brief, for every product, the principle is that, whether the invention is reproducible, and whether it can be produced or used industrially.

Particular attention shall be paid to the source of the materials. The source of the material is related to issues of social morality, practical applicability as well sufficient disclosure. It is advisable to set forth different sources of cells in the description and in the working examples. In case some sources are considered as not complying with relevant provisions, the applicant may cancel them from the description, and alternative options are kept. It would also be favorable for an applicant to list the conventional and stable embryonic stem cell lines which are available before the priority date. With the disclosure of multiple sources of materials, particularly the recitation of the conventional and stable embryonic stem cell lines, an application may go more smoothly towards the grant of a patent right.

In summary, when filing an application or during the prosecution of an application, the applicant is suggested to take the above issues into account. The entirety of the application documents is recommended to be considered in details, so as to advance the prosecution.



New progress in judicial protection of Chinese patents

By Guoxu Yang, Chuanliang Lu

rom last year, with the improvement of China's industrial technological level as well as the tremendous changes in the international competitive environment, China's patent protection system and patent protection practices have also been changed and adapted to the same. With the imminent drug patent link system, the patent application ability is continuously improved, the patent judicial protection system is further perfected, the amount of infringement compensation is obviously raised, and the punitive damage standard of deliberate infringement is strongly

supported.

The number of patent litigation cases has increased significantly. In 2017, the Chinese courts newly received 213,480 first-instance intellectual property cases and closed 202,970 cases in total, with a rise of 46.04% and 43.13% respectively from 2016, in which 16, 044 cases are related to patent right. In the same period, the intellectual property courts in Beijing, Shanghai and Guangzhou accepted a total of 26,698 IPR cases in the first and second instances, and concluded a total of 22,631

cases. Beijing Intellectual Property Court accepted 1,161 patent administrative litigation cases, with an increase of 5.2% compared with the same period in the previous year, and closed 753 cases, with an increase of 27.2% compared with the same period in the previous year. With a magnificent scale in creation and application of various types of intellectual property rights and enhanced values of some intellectual property rights, there are intellectual property disputes that are prone to occur frequently, while the supply side of non-litigation dispute resolution mechanisms is insufficient, so that the rigid demand for judicial protection is continuously on the rise.

The intellectual property tribunals have been successively founded, to make the patent judicial trials more specialized. After the Supreme People's Court summarized and promoted the practical experience of the intellectual property courts in Beijing, Shanghai and Guangzhou. Last year, it was approved to establish the intellectual property specialized trial tribunals for crossregional jurisdiction in 11 cities including Nanjing, Suzhou, Wuhan, Chengdu, Hangzhou, Ningbo, Hefei, Fuzhou, Jinan, Qingdao and Shenzhen, so as to enhance the unification of standards, scales and quality of verdict, and provide better verdict guidelines for the creation and application of intellectual property.

The technical investigator system

has been introduced in patent litigation, to make the patent infringement litigation trials more specialized. In the trial of patent cases, the court often needs to identify a number of technical facts, and to conduct in-depth research and comparison of technical solutions. With substantial involvement and great difficulty in specialized technology, how to overcome the technical obstacles in the identification of facts is a key point that has long harassed the enhancement of the quality and efficiency of trials. In response to this practical problem, the Chinese courts explored to establish the system that the technical investigator neutrally performs duties to assist in the trial, and appointed a number of technical investigators with professional technical titles of medium and above, who were respectively from multiple channels such as enterprises and institutions, universities, scientific research institutions, national patent agencies, and patent agent associations. Thus, the "four-inone" mechanism jointly participated by professional people's jurors, technical investigators, expert assistants, and judicial appraisal agencies for identifying technical facts is constructed to assist the judges in cracking technical doubts, and clearing the technical obstacles for impartial trial of the cases.

The patent link system that the patent infringement litigation taking place during the listing approval of drugs will have certain impact

on the approval of generic drugs has been established. In view that the drugs in the process of listing approval may not be examined for patent infringement, the original drug research enterprise has to resort to legal means to restrain the infringement after the listing of the drugs of the opponent. However, restricted by the drawbacks of small infringement damage amount and difficult enforcement under the current patent system in China, such right protection actives are usually almost in vain. As stipulated in the "Opinions on Deepening the Reform of the Review and Approval System to Encourage the Innovation of Drugs and Medical Instruments" issued by the Chinese government, in order to protect the legitimate rights and interests of patentees, reduce the patent infringement risks of generic drugs and encourage the development of generic drugs, we explore to establish the drug review & approval and drug patent link system. When an applicant for drug registration submits an application for registration, he or it shall state the relevant patent involved as well as its ownership status, and notify the relevant drug patentee within the specified time limit. Where there is a dispute over the patent right, the parties concerned may file a lawsuit with the court without aborting the technical review of the drugs during the period. For drugs that have passed technical review, the food and drug supervision department shall make a decision on whether to approve the listing according to the court's effective judgment, ruling or

mediation; if the effective judgment, ruling or mediation is not obtained within certain time limit, the food and drug supervision department may approve the listing. According to the aforementioned provisions, after the receipt of the notification from the drug listing applicant, the relevant drug patentee who believes that its patent right has been infringed may bring a patent infringement lawsuit to the judicial authority, which to a large extent discourages the generic drug manufacturer to employ the "Bolar exception" to apply for drug listing before the drug administration department. The establishment and improvement of the drug patent link system may also significantly reduce the time for the drug patent expiration and the drug listing in the near future.

The patent infringement compensation system has been further perfected, which greatly enhances the amount of compensation. There are always such problems as difficult investigation and evidence collection and low amount of compensation in patent infringement. According to the current patent law, the compensation first follows the "bridge principle", which is to bridge all the losses of the patentee and is not punitive to the infringer. The revised patent law is expected to stipulate that, where the patent right is intentionally infringed, the court may raise the amount of compensation to a

maximum of three times according to the circumstances, scale and damage consequences. As long as the patentee can prove that the opponent is present with intentional infringement, for example he or it has infringed once and has lost the case, a punitive damage judgment may be made against the infringer. The people's court may determine the amount of compensation to be more than double and less than three times based on the aforementioned method. according to factors such as the circumstances, scale, and damage consequences of the infringement act. The amount of compensation for the damage shall also include the reasonable expenses of the right holder incurred for stopping the infringing act. The amount of compensation should also include reasonable expenses paid by the right holder to restrain the infringement act. The Patent Infringement Guidelines (2017) issued by Beijing Higher People's Court combines the practical needs and also exploratoryly proposes the idea of punitive damages for "malicious infringement" behavior. It is set forth that, where it pertains to malicious infringement, it is possible to support the plaintiff's appeal within the statutory compensation limit or determine the amount of compensation at a higher level.

In the judicial practice of patent infringement litigation, the magnitude of the compensation for damages to the patentee

has increased substantially. For example, in the case of Beijing Watchdata System Company v. Hengbao Co., Ltd. for the infringement of patent rights, Beijing Intellectual Property Court judged that the defendant compensated for economic losses of 49 million RMB and legal fees of 1 million RMB, which is the highest amount of damage ever judged since the establishment of the court, and also for the first time explicitly supports the timing charge of an attorney in the judgment. Also, in the case of LG v. NEC Corporation for the patent for invention titled "SPINDLE MOTOR", Beijing Intellectual Property Court supported the right holder's compensation request and reasonable expenditure of nearly 4 million RMB; in Qingdao CO-NELE's case for the patent for utility model titled "HIGH-**EFFICIENCY TRANSMISSION DEVICE FOR PLANETARY** STIRRER", supported the right holder's compensation request and reasonable expenditure of 3.6 million RMB. In the application of statutory compensation cases, a discretionary compensation mechanism that conforms to the law of the market and meets the requirements for protection of patent rights has been gradually established, so that the amount of compensation for damages matches the market value of the patent right, so as to adapt to the contribution rate of the patent right to the profit of the infringement behavior.

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