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While China is a focus of attention for the healthcare industry as one of the world's largest markets, a chief concern for the medical device industry is the risk from IPR infringement. This guide takes a practical look at IPR protection and enforcement in China with a particular emphasis on issues for SMEs in the medical device industry. The guide looks at different types of activities, such as registration of IPR, managing IP through R&D and sourcing, and enforcement. Reference is also made to other publications of the SME Helpdesk which can provide more detail on related topics.

## Types of IP Rights

### 1.1 Patents

Given the growing importance of the Medical Devices market, the importance of China in global supply chains and the risk of infringement, companies should seriously consider filing Patents in China for new inventions. Examination of Invention Patents, granted by the State Intellectual Property Office (SIPO) currently takes around 3 years. Details of how to register Patents in China can be found in the IPR SME Helpdesk handbook "Patent & Trademark Protection in China."

For companies in the Medical Devices

industry, it is essential to ensure that the Patent filed in China is correctly translated by a qualified Patent attorney with the appropriate scientific background.

China has recently enacted the third amendment to the Patent Law, which will come into effect on 1st October 2009. This has a number of implications for the scope of protection and enforcement of Patents which companies should research in detail, including:

- The 'Bolar exemption', which states that producing, using or importing patented medicine or patented medicinal equipment for the purpose of obtaining approval does not constitute infringement. Bearing in mind that product approval is a lengthy process in the medical device industry, this rule may allow competitors to quickly launch competing products when the Patent of the originator company expires.
- The absolute novelty standard. In line with international practice, Patents must be examined against worldwide prior art, rather than only novelty in China. This will ensure that Patents filed in China are genuinely novel and prevent 'pirate' applications of other's

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technology patented elsewhere. It also means that foreign companies must be careful to ensure that disclosure outside China does not destroy novelty in China.

- New rules on compulsory licensing, which may allow licenses to be issued by the state where these are in the interest of public health. These rules have not been tested but have caused some concern amongst Patent owners in the healthcare sector.
- The new Law also increases damages and strengthens judicial weapons for dealing with Patent infringement.
- European companies are often concerned about how effectively Patents and other IPR can be enforced in China once they have invested in obtaining rights – this is outlined in Part 3 – ‘Enforcement of IPR’.

### 1.2 Utility Model & Design Patents

In addition to Invention Patents, China also recognises Utility Model Patents and Design Patents. Both types of Patent last for 10 years and as they are not examined, are granted within 1 year.

It is possible to apply for a Utility Model Patent and Invention Patent for the same subject matter, thereby protecting the invention more quickly. The applicant should abandon the Utility Model if an Invention Patent is granted.

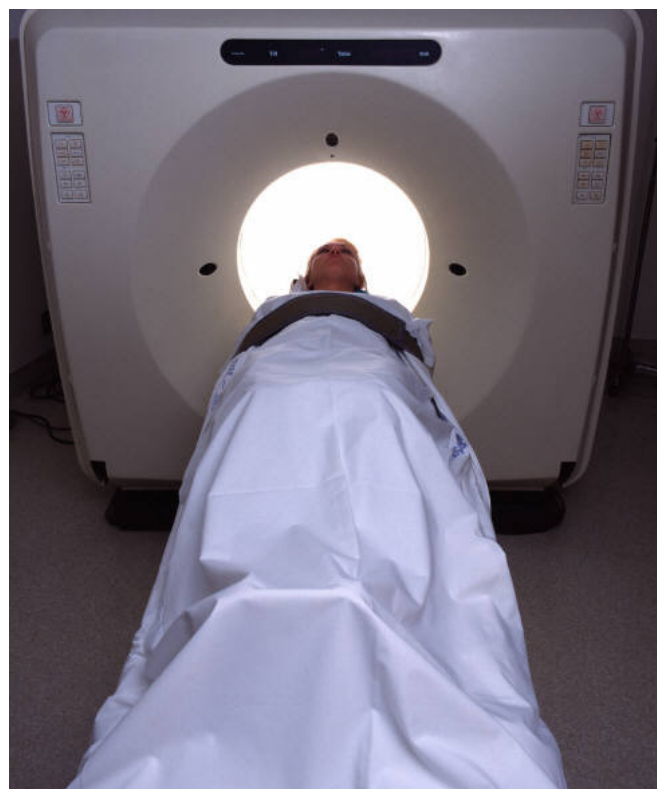
Design Patents cover only the outward appearance of a product. In practice, it is common for infringing companies to register the designs of others, and to use their registration to sell infringing products or even threaten action against the originator or its suppliers. While this kind of ‘pirate’ Patent can be invalidated, dealing with such an action by a pirate may consume considerable cost and time. Owning a Design Patent can be effective simply by deterring competitors from copying you.

It is important to note that, apart from Design Patents there are few effective means to protect the exterior shape or design of a product through other laws in China. Registration is relatively cheap compared with the cost and difficulty of enforcing your rights through other means.

Under the new Patent Law, a Design Patent is infringed through ‘offer for sale’. Therefore, a Design Patent owner can sue a competitor offering a product at a trade fair which infringes the Patent. This was not the case under the old law.

It is advisable to:

- Register Design Patents for design features of your products, even for a new version of an old product.
- As with other Patents, the design must be novel, so the application should be made before the product is launched.
- Have basic documentation ready to support your Patent application, as it is common for infringers of the Patent to file an invalidity procedure.



### 1.3 Copyrights

Electronic diagnostic devices are often operated with software and technical manuals. Both software and printed material such as technical manuals are protectable as works of copyright in China. Unlike Europe, China has a system for the registration of copyright. While this is not necessary to enforce one's rights, it is a convenient way to show evidence of ownership, and is a straightforward procedure.

For devices that require clinical trials, the database resulting from the trials is also registerable as a work of copyright.

Copyright may also be infringed where another party has used similar text or artwork in product manuals, website content or design.

Information on how to register your copyright can be found on the Helpdesk online portal [www.china-iprhelpdesk.eu](http://www.china-iprhelpdesk.eu).

## 1.4 Trademarks

The key issues for SMEs when dealing with trademarks are:

Due to a backlog of applications, it can take 2-3 years for a trademark to reach registration in China. As with the Patent system, large numbers of new staff have been recruited to make the process quicker.

In China's first-to-file system, unregistered trademarks are not protected unless they are deemed 'well known' in China. Few European SME brands meet this criterion.

- It is common for domestic applicants to register the English or Chinese trademarks of foreign companies in bad faith, and use them to produce infringing products or to sell them back to the rightful owner. Specialist advice must be sought in recovering trademarks infringed in this way.

Companies are recommended to:

- Register new marks as early as possible, given the long time it takes to reach registration.
- Register, and consistently use, Chinese versions of their trademark. This avoids the problem of an unofficial 'nickname' for your product being adopted, which others might register.
- To avoid 'pirated' registrations, companies should engage a trademark watching service (either internationally, or with their local agent in China) to watch for similar marks that are published for registration.

For detailed advice on trademark registration and enforcement, refer to the China IPR SME Helpdesk guide "Patent & Trademark Protection in China".

## 1.5 Unfair Competition

China also provides protection for distinctive product markings packaging and decoration (trade dress) under the Anti-Unfair Competition Law.

It is common for competitors to try to make a product appear similar to other well-known products through using similar decoration and presentation, but without infringing trademarks or Design Patents. Where the original product can be proved to be well known in China, and the competing product has copied distinctive features sufficient to cause confusion, it may constitute Unfair Competition.

Except in some special circumstances this Law does not explicitly cover the **shape of products themselves**, therefore Design Patents are the most direct method to protect product designs.

## 1.6 Trade Secrets

China recognises protection for trade secrets, provided that physical and contractual barriers are in place for maintaining confidential information. For example, the owner of the trade secret should mark the information 'confidential', identify the information as confidential in a written agreement, and take steps to limit access to the information such as requiring the signing of confidentiality agreements.

China's Labour Contract Law allows for restrictive covenants to be imposed on key employees post-employment for a period of up to one year, although reasonable remuneration should be provided.

Companies should:

- Conduct an internal review of what information or know-how should be properly protected as a trade secret and whether such information is used in China.
- Ensure that such information is properly identified and that security measures are taken to isolate it from being freely circulated. Those employees or third parties that have access to such information should be strictly bound by confidentiality terms not to disclose the secret to others.

## Management of IP in Your Business

This section deals briefly with the management of IPR in R&D, licensing and sourcing situations.

### 2.1 R&D and joint product development

While there are relatively few SMEs who have set up dedicated R&D initiatives in China, it is quite common for companies who are working with suppliers in China to be conducting some forms of joint development of new products.

When carrying out R&D in China:

- Ensure that you have audited the R&D process to ensure that key employees are covered by confidentiality agreements, that trade secrets are protected as recommended above, and that your Patent management policies comply with Chinese law.
- If conducting joint development with another party, the contract should state clearly how newly created IPR will be owned. Contracts which do not allow an other party to derive any economic benefit from improvements or new IP will generally not be legally valid.
- Under the new Patent Law (which will come into force on 1st Oct 09), inventions completed in China should file for a Patent in China first or seek a license from the State Intellectual Property Office to file overseas first.
- The new Patent Law also specifies remuneration for inventors under employment. Companies should ensure that their remuneration policy for inventors complies.

### 2.2 Product sourcing, distribution and licensing

If you are considering sourcing products from China, distributing products in China, or licensing into China any products that may contain IP in the form of brands, Patents or know-how, you should draft contracts that specifically identify and protect your IP from mis-use by business partners.

As explained further in Part 3 - Enforcement of IPR, there is increasing confidence in China's enforcement system. Some foreign companies have the impression that contracts in China are not really enforceable – this is a misconception and foreign companies should always treat contracts as fully enforceable as they would in their home country.

Where a breach of IP terms in a contract is discovered, companies should be sure they have

adequate evidence before deciding their options, even if they do not intend to sue their partner but only wish to negotiate with them. Not dealing decisively with a breach of IPR by another party often leads to a re-occurrence or even worsening of the problem.

Points to consider for SMEs sourcing, distributing or licensing in China:

- Companies should conduct comprehensive due diligence on potential partners. This should include background checks on whether they have been involved in IPR disputes and obtain references from other business partners.
- Contracts should be in Chinese, drafted in accordance with Chinese law, and both parties should ensure that they fully understand the terms.
- When approaching potential new suppliers for OEM production, companies should require them to sign a non-disclosure agreement (NDA). NDAs are recognised in the Chinese courts.
- In the contract, companies should carefully review clauses that relate to any product or components that contain IP, including how they are produced, supplied and to guard against disclosure of information and physical product that may contain proprietary IP.
- For more information on technology transfer, download the Helpdesks 'Technology Transfer handbook', available online at [www.china-iprhelpdesk.eu](http://www.china-iprhelpdesk.eu)





## Enforcement of IPR

Where IPR infringement has been discovered, there are a number of options that a company may take.

China has a dual track system of enforcement: the administrative process and the civil and criminal judicial process. The administrative route involves making a complaint to the administrative authorities who regulate various IP laws, and have their own powers to investigate and penalise acts of infringement. The administrative route does not involve court proceedings and is often favoured for quick, low-cost and straight-forward infringement cases. However, the administrative system is also considered a relatively weak enforcement route and may not be available at all for certain types of cases.

Companies that discover infringement can consider the following options, some of which can be combined. For more details see the Helpdesk publication “Protection of Patents & Trademarks in China” and the helpdesk website section on “Dealing with Counterfeiting”.

### 3.1 Administrative Enforcement

The administrative authority for Patents is the local offices of the Intellectual Property Office (IPO). For copyrights, it is the Copyright Administration (CA), and for Trademark and Unfair Competition Cases it is the Administration of Industry and Commerce (AIC). Complaints are usually brought to the local level office of where the case occurs.

For Patent infringement the administrative system is used only for Design Patent infringement cases: the local IPO offices are not able to determine Invention Patent infringement. The local IPO offices do not have powers to seize all suspecting infringing items, but only take samples, and try to mediate a settlement. Thus the deterrent effect is considered quite weak.

For copyright, the administrative route is usually only applicable for pirated media products, and it may be difficult to request an administrative raid for other types of infringement, such as for software or technical manuals.

Only for trademark and unfair competition infringement is the administrative system commonly used, as the AIC have relatively powerful enforcement procedure, such as seizure of all infringing items and related materials on the spot, and may issue large fines.

It is recommended that IP owners not only use the administrative system as a form of sanction by itself, but as a simple and quick form of evidence gathering to bring other types of case, such as civil or criminal.

Where infringement is large scale or complicated (such as an Invention Patent case, which requires careful examination), civil action is usually recommended (see below).

### 3.2 Civil Courts

Information for litigants in the People's Courts are covered in the Helpdesk publication “Patent and Trademark Protection in China”. Detailed legal advice should be sought before pursuing action in the courts.

In the civil courts, awards are generally low compared to those in Europe – based on a sample of 1,253 IP judgments from Beijing, Shanghai and Guangzhou courts, average damages awards were RMB 84,119. Damages may be awarded based on loss of revenue or statutory damages. Under the new Patent Law, the maximum statutory damages have been raised to RMB 1,000,000.

A plaintiff generally has to identify evidence of infringement themselves and the success of the case depends very much on what evidence the plaintiff is able to gather. It is important to investigate and prepare evidence thoroughly, taking advice from experienced investigators and lawyers. In civil cases, it is normal and advisable to obtain an order for freezing accounts and assets of the defendant by placing a bond with the court. This can ensure that money is collected in the event of the court granting an award.

It is possible to obtain orders to search the infringer's premises for evidence, such as records of sale. However, these orders can be difficult and expensive to obtain and may not produce good results if the infringer does not have clear and complete documentation.

When prosecuting a civil case, it is important to note:

- Qualified PRC law firms with a track record in IPR litigation should be engaged. Patent and trademark agents and general commercial law firms may not necessarily have IPR litigation experience.
- Experienced investigators should be engaged that are familiar with how to prepare evidence for civil

litigation.

- The IP courts in Beijing, Shanghai and Guangzhou tend to be preferred for complex cases as they have more experience and training in IPR disputes.
- While interim injunctions (pre-trial orders to stop infringement) are available, they are rarely granted. Thus an infringer may be able to continue infringing until the case is concluded.

### 3.3 Warning letter

Warning letters alleging infringement and demanding the other party to stop should be sent by a qualified PRC law firm, and followed up with demands on the infringer provide written undertakings to stop infringement. When done properly, warning letters may be a low cost way to show that you are serious about enforcing your rights and stop an infringer's activities.

Note that for Patent infringement cases, however, a warning letter may trigger an invalidation action or pre-emptive civil suit for non-infringement in their home court, which may be less advantageous.

### 3.4 Counterfeit & Substandard Products

The high price of Medical Devices and lack of an official refurbished market in China creates a risk of counterfeit products being circulated.

Products which do not comply with a set standard, or which are falsely labeled and marked (ie, counterfeit products) may be dealt with in a number of ways.

1. Through an administrative raid by the AIC, the same as for any other trademark infringement case.
2. Through the Administration of Quality Supervision Inspection and Quarantine (AQSIQ). AQSIQ supervises product quality and safety, and is responsible for inspection of Medical Devices. Similar to the AIC, AQSIQ have independent powers to carry out raids and seizures and issue fines.
3. Through the Public Security Bureau (PSB, or police). Producers or sellers of counterfeit Medical Devices may be criminally prosecuted if the case meets the criteria.

In practice, assessment of counterfeit goods value in order to satisfy the economic threshold for criminal liability is a difficult area, and the PSB will often only accept very large cases where the threshold has very clearly been reached.

While the PSB can accept complaints directly from a rights holder, in practice it is more common for criminal cases to arise from an initial raid by administrative authorities, which is then transferred to the PSB. However, this approach can have its drawbacks, due to the different standards of evidence used by administrative authorities and the PSB.

Investigation to support a criminal complaint is often substantial – the PSB will expect a rights holder to have prepared the key evidence themselves, which may include identifying key suspects and connecting them to the counterfeit operations.

Those criminally convicted will usually face large fines and suspended sentences. Prison sentences are rare.

Following a criminal prosecution, the rights holder may file a civil suit to recover damages.

For **refurbished products**, while the law is not clear cut, in general rights holders have been able to treat refurbished products as counterfeit if examination finds that non-original components have been used.

### 3.5 Dealing with Infringements

Bearing in mind the critical importance of safety in the industry, medical device manufacturers selling in or sourcing product from China should have a procedure established in advance to deal with reports of suspect products, for example:

- Establish a quick reporting protocol with local business units and partners so that reports of potentially substandard or counterfeit products can be analysed quickly. Any substandard product reported should be considered potentially counterfeit.
- Monitor industry trade fairs / internet trade portals to find potentially competing products
- Work closely with the AQSIQ and SFDA who have direct regulatory supervision over Medical Devices, in order to gain their assistance in dealing with suspected counterfeit products and reduce the likelihood of a product recall.

- Use security marking on products and keep tight control over the system. This does not prevent counterfeiting but can greatly help with efficient authentication.
- Engage professional investigation firm with experience in the Medical Devices or healthcare industry that can work with you to identify potential problems and gather evidence in a way that gives you the widest options for enforcement.



### Take-Away Messages

- The European company would have had an even better result if they had Design Patent for their product in China which would have given them clear rights over the product design. Make sure that you register your rights as early as possible, to ensure maximum protection.
- Do not assume that litigation is the only way forward. Make use of the full IPR framework that exists in China to achieve your goals. You should also not assume that any legal action will be very costly.

### SME Case Study

A European company in the dental instruments sector was selling their product in China through a distributor. They discovered a competitor in China was offering a similar, but lower-specification product, using an identical exterior design, colours control interface. The technical manual, diagrams and parts of their brochure appeared in part to be directly copied from the original. Overall, the competitor's product gave the appearance of being similar in function to the European company's, although its performance and price were much lower.

The European company's representatives had previously approached the company at a trade fair to complain about the infringement but had not received a positive response.

The company sought legal advice. They did not have a Design Patent to protect the overall shape of their product, nor were there any Patents covering the product. Trying to claim infringement of the product shape and decoration by relying on other legal grounds was possible, but the chances of success were poor. The only clear legal grounds were copyright infringement of the contents of the technical manual.

To deal with copyright infringement on its own may not have given the company a strong case, however. Instead, the company decided to send a warning letter through their local lawyers that alleged infringement of the product shape (even though the legal grounds were not strong) AND copyright in the manual. The letter implied that the company would take the matter to court. The law firm and representatives of the European company followed up the letter and met with the infringer to press them to stop their infringement. The European company argued that a lawsuit would be wasteful for both parties, even if they were not successful, and that the Chinese competitor's imitation of a European product would harm their own image in the long run. As a result, the infringing company decided to change a number of exterior features of the product and produced new manuals and brochures which greatly reduced the similarities to the European product. Although the European company did not have very strong rights, in this case, use of a warning letter followed up with determined negotiation was able to give a satisfactory result.



*The China IPR SME Helpdesk provides free, confidential, business-focused advice relating to China IPR to European Small and Medium Enterprises (SMEs).*

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