Key IP issues for life sciences companies doing business in China

Life sciences companies seeking to crack the challenging yet lucrative Chinese market must arm themselves with the necessary knowledge to minimise risk and maximise gain

By **Cedric Lam** and **Isabella Liu**,
Dorsey & Whitney LLP

Doing business in China can be tough, due to a plethora of legal and practical concerns. It is tougher still for a life sciences company, whose most valuable assets are its IP, given the high risk of infringement, counterfeiting and theft of trade secrets. Despite such challenges, China has witnessed explosive growth in technology output, R&D activities and the life sciences market over the past decade. Most major drug companies have now established R&D centres in China. The annual output of China's pharmaceutical and medical industries grew by an average of 16.1% per annum between 1978 and 2005, with realised sales income reaching RMB427.1 billion in 2005. The message is therefore not to stop venturing forth, for the promised rewards are staggering, but to go armed with the necessary knowledge to minimise risk and maximise gain. This article provides an overview of the key IP issues throughout the lifecycle of a life sciences company that its executives should be aware of in order to achieve that goal.

Pre-investment market research and evaluation

Permissibility of technology

First, you must assess whether you can do what you plan to do with the subject technology under China's regulatory environment. China has regulations governing the importation and use of various transgenic materials and genetic resources, and a framework of bio-safety laws that are generally in line with international protocols. Furthermore, essentially any transfer or licence of technology (eg, assignments or licences of patents and know-how) in or out of China by means of trade, investment or economic and technological cooperation (eg, technology service or consulting arrangements) with a Chinese entity is subject to China's technology transfer regime, under which the cross-border transfer of technology is either prohibited, restricted subject to licences (eg, technology for the direct processing of transgenic agricultural products) or unrestricted. This means that before you embark on any technology-related arrangements with a Chinese element, you must first check the permissibility of the subject technology.

Clearance searches

Chinese companies are now filing more patents and are not shy to enforce them, as some multinationals have discovered recently. Eli Lilly faced a counter-patent infringement suit when enforcing its insulin drug Humalog patent in China, while Schneider Electric is looking at a potential payout of US$45 million in damages for patent infringement. Before parting with any money, therefore, you should evaluate the subject or target technology/product/brand by conducting clearance searches and address any potential validity and infringement issues identified. Full due diligence analysis of the technology and related IP should be conducted to ensure that it is worth the money asked for. Particular attention should be paid to issues such as sufficiency of disclosure and defects

in the chain of title. You should also question diligently whether what you see is indeed what you will get. For instance, some Chinese patents are granted without any substantive examination and their validity and ultimate value may therefore be questionable.

Invest in innovation

R&D through collaboration

Joint ventures (JVs) are still the most common way of collaborating with Chinese parties. Before setting up any technology JV with R&D capabilities, you should find out what IP your potential JV partner owns and assess its value, especially if it is to make a significant technical contribution to the proposed collaboration. Since many Chinese enterprises were once state owned or affiliated with the government, it is very common to see defects in the chain of title of IP rights that can result in possible claims by, for example, inventors and/or organisations funding the underlying research.

In addition to defining the background technology that each JV partner is contributing, the ownership, development, use and further exploitation of any technology achievements and ensuing IP generated by the JV should be clearly stipulated in writing. While current Chinese law generally permits parties to agree on such issues and the rights of patent co-owners are now clarified under the newly revised Chinese Patent Law (which will become effective on 1st October 2009), the default legal position in China may be very different from that in the United States and other jurisdictions (eg, copyright in commissioned work vests in the commissioned party in the absence of any agreement).

Given that IP abuse and "runaway" business partners are common in China, JV agreements should provide for sufficient control over the JV and any resulting innovation (eg, right to inspect research site and access to records), and contain safeguards such as warranties on proper conduct of R&D and indemnities against IP infringement. Take note also of various mandatory – generally pro-transferee (ie, Chinese companies in most cases) – provisions governing technology-related contracts under Chinese law that must be observed regardless of the applicable law agreed by the parties. The inclusion of prohibited terms, such as unduly restricting a transferee from further use of or research on the transferred technology, may render an agreement invalid or unenforceable. Further considerations may apply if the JV partner is a hospital or a state-owned or government-affiliated enterprise, since these entities are often subject to additional regulations. In sum, agreements must be drafted with care to avoid falling foul of such legislation.

Contract research

Similar considerations apply when engaging a research establishment in China. It is important to run thorough due diligence (including on-site visits and third-party references whenever possible) to ensure that the service provider can deliver what it promises. Avoid using legal terms such as "work for hire" in the research contract (since their legal effect can differ between jurisdictions), and expressly state that everything generated by the research belongs to you, the commissioning party. Further considerations may apply depending on the nature, identity and location of the contracting party. Universities, for example, may have their own IP policies as regards IP ownership and publication rights.

Setting up R&D facilities

Central to the success of such an undertaking is the hiring and retention of talent, including management and research teams. Talent retention in China is a hot issue and many trade secret disputes are between employers and their ex-employees. To minimise the risks of loss of IP and theft of trade secrets and know-how, due diligence checks on all potential hires should be performed, security controls put in place (eg, limiting access to proprietary data), and employment contracts containing suitable confidentiality and non-compete provisions prepared and signed by all managers and researchers. Beware that former employers may have claims over works of your new hires under Chinese law. Likewise, you may have claims over works of your ex-employees under the right circumstances. Moreover, Chinese employees are generally entitled to receive "rewards" and "reasonable compensation" (which can amount to 30% of after-tax profits arising from the commercial exploitation of an employee invention, depending on the applicable local rules and the employer's legal standing) – this should be addressed properly in employment contracts to avoid surprises. Internal IP policies and procedures written in Chinese will also help to raise awareness of IP protection.

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Acquiring or licensing Chinese technology
Technology agreements with Chinese assignors and licensors should contain extensive warranties and indemnities, other relevant safeguards to minimise risks of potential IP infringement claims and ownership disputes, as well as mandatory terms prescribed by Chinese law. Administrative approval or recordation is generally required to perfect an assignment or licence of technology and IP rights under Chinese laws.

Protecting innovation
Register your IP (eg, trademarks, patents, plant varieties) early and record any registered rights with Chinese Customs for border protection. Generally, only IP registered in China is enforceable locally. Since it usually takes time to secure registered IP rights in China and it is a first-to-file jurisdiction for both patents and trademarks, early assessment and build-up of IP portfolio in China is highly recommended.

Pharmaceuticals are protected in various ways in China, including patent protection, administrative protection (a quasi-patent protection available to qualifying pharmaceutical products) and new drug protection available to new drugs manufactured in China. A pseudo-patent linkage (ie, a Hatch-Waxman-like) provision and a six-year data exclusivity period are available under Chinese law. The State Food and Drug Administration can revoke market approvals on the basis of patent infringement, but there is currently no mechanism to intervene against an application for market approval.

For other types of innovation, obtaining patents is generally the key to securing protection in China. If you have any R&D in China, be sure to limit the publication rights of the researchers: Chinese researchers are particularly motivated by publications and such disclosure can destroy the novelty of the subject innovation. In addition, you should take steps, such as splitting up stages of R&D among different sites, to protect any unregistrable rights such as trade secrets and know-how.

Be mindful of China’s extensive administrative laws and regulations that affect the import, export and use of technologies and products, some of which can impact on your IP filing and enforcement strategies. For example, only registered trademarks may be used on pharmaceuticals in China and the length of time required to obtain market approval may raise non-use issues for registered trademarks.

Apart from looking inward at your own IP portfolio, you should monitor Chinese prior art and keep an eye on what competitors are doing in China as your technology evolves in order to minimise risk of infringement. At the same time, you need to monitor third-party trademark and patent applications (whether local or international filings), so that timely objections can be raised where necessary.

Invest in product development and further commercialisation of technology
Clinical trials
Clinical trials are usually inevitable as part of the product market approval process in China. It is crucial to maintain sufficient control over the conduct of clinical trials, a relatively new business in China. Provisions allowing you, for example, to supervise the use of any personal data and the disclosure and presentation of any trial data should be explicit in all clinical trial agreements. Contractual IP protection through watertight confidentiality provisions and extensive warranties and indemnities should be sought wherever possible.
Market approval for regulated products

Obtaining market approval for pharmaceuticals, health foods and medical devices is generally very complicated in China and consultants are often engaged to assist in navigating the regulatory maze. In addition to the usual due diligence checks, you should have in place a comprehensive consultancy agreement with confidentiality provisions, and which provides sufficient control over the handling and use of any application materials and technology secrets they contain. Local consultants should do nothing without your prior approval: this not only protects your technology and IP rights, but also minimises potential bribery concerns.

Outsource manufacturing

Unless you import or set up your own manufacturing facilities, chances are you will be looking for low-cost local contract manufacturers. IP abuses such as unauthorised production overruns and registration of trademarks by local business partners are very common in China. Apart from conducting thorough due diligence against the potential manufacturer, you should maximise contractual protection of your technology and IP rights and build into the manufacturing agreements provisions allowing close control over the manufacturing process (eg, through unscheduled audits), as well as specific IP provisions setting out how any licensed IP should be used.

Competing in the Chinese market

Build the brand

Having Chinese-character marks is central to brand building and marketing in China, due to the generally poor English proficiency of the Chinese public. In fact, if you do not have Chinese equivalents of your English marks, the local public might just make one (or more) up, whether you like it or not. You may in any event need to devise Chinese-character equivalents of your house marks and/or product names, due to applicable labelling laws. Devising Chinese-character marks is more an art than a science, having to take into account legal/trademark, regulatory, linguistic and marketing considerations. You should register all relevant marks as early as possible: trademark piracy is rampant in China and it is time consuming and costly to try to recover pirated marks.

Enforce IP rights diligently and be ready to defend your rights

Given China's size and possible channels of enforcement, especially in relation to life sciences products, formulating an IP protection plan early can help to focus resources and improve effectiveness.

An IP owner can enforce its rights in China by filing administrative/criminal complaints or initiating civil proceedings. For administrative enforcement concerning counterfeit pharmaceuticals, medical devices and food, there are multiple government authorities with jurisdiction and, as such, the most appropriate route of enforcement should be decided on a case-by-case basis. For disputes involving invention patents, it is generally advisable to opt for civil litigation for the range of remedies available.

Cedric Lam is a partner in Dorsey & Whitney's Hong Kong office and heads the firm's IP team in Greater China. He has over 12 years' experience in counselling IP transactions and implementing IP protection strategies, as well as advising on related regulatory and compliance issues, for many multinational and domestic pharmaceutical, biotechnology, medical devices and other healthcare companies. He has been recognised as an Asialaw Leading Lawyer in IP. Mr Lam is also experienced in anti-counterfeiting and other IP enforcement matters, and has served as Asia-Pacific regional legal counsel of an international IP collective.

Cedric Lam
Partner
Email: lam.cedric@dorsey.com
Tel: +852 2105 0289

Dorsey & Whitney LLP
China
www.dorsey.com

Isabella Liu is a senior IP associate at Dorsey & Whitney's Hong Kong office. She holds a PhD in molecular pharmacology and toxicology from Imperial College, London. Her area of practice covers a broad range of IP issues in China, including patent prosecution and enforcement and commercial IP matters such as brand acquisition, licensing and technology transfer. She also advises on various regulatory issues such as market approvals, product safety, labelling and advertising. Overall, she has considerable experience in helping pharmaceutical, biotechnology, medical device and other healthcare companies to register, defend, enforce, protect and exploit their IP rights in China.

Isabella Liu
Senior associate
Email: liu.isabella@dorsey.com
Tel: +852 2105 0272

Dorsey & Whitney LLP
China
www.dorsey.com

Beware, though: there is no meaningful discovery, deposition or extensive evidence exchange process available in China, and a plaintiff generally must collect sufficient evidence prior to commencing court proceedings to discharge its burden of proof.

Parallel imports, as well as the use, production and import of patented pharmaceuticals or medical devices solely for the purpose of obtaining market approval (ie, a Bolar-type exemption), will be exempted from patent infringement from 1st October 2009 under the revised Patent Law. These new codified exemptions should be kept in mind when formulating or revising patent enforcement strategy in China.

The risk of invalidation must be assessed when contemplating patent enforcement in China. Chinese companies are now unafraid to challenge patent validity when faced with infringement claims. All patent invalidation proceedings in China are dealt with by the Patent Re-examination Board (PRB), and the court generally has discretion to suspend a patent infringement proceeding pending the PRB's decision. This is detrimental to the patentee because invalidation proceedings can drag on for years (as is the case for Pfizer's Viagra patent). Formulating proper enforcement strategy is therefore important prior to taking actual action in China.

Consider soft approaches

Playing tough may not always be the right solution. In China, where "persons" comes before logic or law, employing soft approaches (eg, a good PR campaign or an informal chat with local authorities) may sometimes yield surprising results to otherwise difficult issues.

Conclusion

As can be seen from the above, building and managing IP for a life sciences company in China is a different ball game in many respects. By familiarising yourself with the applicable rules, however, you should be able to come out a winner having thoroughly enjoyed the game. *iam*