Intellectual Property Office

British Embassy Beijing

Department for International Trade

Intellectual Property and Life Sciences in China

China offers significant opportunities for British life sciences companies, including access to a large market, world-leading research facilities, institutional and private Chinese investors, and partners with manufacturing, distribution and other supply chain expertise. But China also presents a number of regulatory and market access challenges, including how to protect intellectual property (IP).

Domestic and international companies have benefited from improvements to China's IP system over the past 25 years. Since patent protection for pharmaceutical compounds was introduced in 1993, the China National Intellectual Property Administration (CNIPA) has developed a sophisticated examination system.

IP rights are territorial, so an IP right registered in the UK, Europe or Hong Kong will not provide adequate protection in China. See our factsheet on Intellectual Property in China for general information on IP registration and enforcement.

Several elements of the IP, legal and life sciences regulatory systems in China are different to those in the UK and other developed markets. Companies should take expert advice ahead of any China opportunity to ensure that IP risks have been identified and resources secured to manage these risks.

Regulatory issues

Regulation in China's life sciences sector is driven by a variety of policy factors. As a developing country with a large population, China has a need for affordable medicines. But a large geographical area, over-stretched supply networks and fragmented regulatory oversight have also led to public concerns over quality, and a demand for reliable, cutting-edge imported medicines.

Since the early 1990s, China has had ambitions to build its own strong life sciences companies, with recent efforts aiming to bring together the thriving biotechnology ecosystem of investors, academic research capacity, generic manufacturing expertise and (often state-owned) enterprises with extensive distribution networks in China and overseas.

Patent linkage and regulatory data protection

China operates a rudimentary patent linkage system, where marketing approvals for generic products is linked to the status of related patents. The high-level principles of patent linkage appear in Chinese policy documents, and the National Medical Products Administration (NMPA) is responsible for marketing approvals.

However, detailed statutes and regulatory procedures on patent linkage have not yet been developed in China, including for verification of non-infringement declarations by generic producers.

Given challenges to securing interim injunctions in China (see below), originator life sciences companies often need to devote significant resources to managing relationships with NMPA in order to prevent premature generic entry, including ensuring NMPA rules on patent linkage and regulatory data protection are upheld.

Patent registration

China takes an approach to **biological data requirements** in patent applications that can be different to other IP jurisdictions. In general, applicants in China should always include data to prove an unexpected technical effect in the original patent filing, even if the effect is consider plausible and so would be patentable in the UK and Europe. Opportunities to provide supplementary data can be limited during examination or future validity challenges.

There is currently no mechanism available in China for patentees suffering delays in regulatory approval to apply for a **patent term extension**

beyond the standard 20 year patent term, though this may be introduced in the coming years.

Validity

China operates a bifurcated patent system, with invalidation considered in separate legal proceedings to infringement claims. Invalidation is determined by the Patent Re-Examination Board (PRB, part of CNIPA), with judicial reviews to PRB decisions available via the Beijing courts.

International companies in a range of sectors report **invalidation risk** from frequent attacks on foreign-owned patents in China, often with limited differences in cited prior art to previous cases. Chinese parties can more easily make requests to fast-track invalidation hearings. Pending invalidation challenges can negatively affect pricing negotiations in government drug procurement, with some provincial governments paying less for drugs covered by "unstable" patents (i.e., patents with disputed validity).

Invalidation procedures have also been used by Chinese generic companies to successfully overturn patents covering **compounds, polymorph crystal forms**, **new dosage regimes** and other claims common to patents in the life sciences sector. Applicants should be aware of difficulties in patenting – and maintaining granted patents – for these inventions in China. **Second medical use** claims are also difficult to protect and enforce under current Chinese patent law.

Trade marks

It is especially important to register trade marks in China as early as possible. China has a large and systemic problem with **pre-emptive, unauthorised trade mark applications**. British companies should secure rights to Chinese trade marks covering their company house name, brands, product names, and other important trade marks.

Trade mark applications should cover English-language marks, Chinese-language marks and stylised logos. For more on pre-emptive trade mark applications in China please see our factsheet on Bad-faith Trade Marks in China.

Enforcement

China offers a range of enforcement options for rights holders to address IP infringement. The Chinese IP enforcement system operates at high volumes and is particularly sensitive to the risks of counterfeit and substandard medicines.

Civil enforcement claims can be filed with China's specialized IP courts in Beijing, Shanghai or Guangzhou, or specialist IP tribunals in cities across the country. China has also established a dedicated IP appeals court in Beijing.

Since a policy change in 2007/08, Chinese courts have been reluctant to award **interim injunctions** in civil IP cases. Interim injunctions are pre-trial or pre-judgment judicial orders to prevent large-scale, irreversible damage resulting from IP infringement before the conclusion of a full trial.

From 2019, Chinese courts are applying a new test for interim injunction awards. This has already led to successful interim orders for both domestic and international companies, though courts are reluctant to approve requests based on a biotechnology patent claim.

Public Security Bureaus (PSBs) are responsible for **criminal investigations** of breaches of China's criminal code, which includes IP and pharmaceutical-related criminal offences. China customs are responsible for **border enforcement**, with the vast majority of border detentions in China made against shipments being exported to markets overseas.

China also operates an **administrative enforcement** system, where investigations are undertaken by local government enforcement units. Cases can result in small administrative fines (but not damages paid to rights holders) and local government orders to cease infringing activity.

Checklist – Intellectual Property and Life Sciences in China

- **Secure patent protection in China**, including complying with Chinese requirements on biological data that are different to international approaches. Consider invalidation risk.
- **Don't forget trade marks**. China has a large and systemic problem with bad-faith trade mark applications. Get applications in early for a wide a range of products and brands.
- **Ensure in-house and external resources are allocated for research and regulatory compliance in China**. Especially consider remuneration schemes for employee inventions, data handling, human genetic resources, patent linkage and regulatory data protection.

A unified local government department is now responsible for undertaking administrative enforcement cases, namely the local State Administration of Market Regulation (SAMR). SAMR was set up in 2018 and it subsumed a number of local enforcement authorities, including the former local Food and Drug Administration (FDA, primarily cases involving regulated producers), Intellectual Property Office (IPO, patent and design cases), the former Administration of Industry and Commerce (AIC, trade mark, competition and trade secret cases) and Quality and Technology Supervision Bureau (QTSB, product quality and compliance cases).

Research and development

British life sciences companies undergo a range of research and development activities in China, ranging from drug discovery to clinical trials in Chinese hospitals. British businesses should ensure sufficient in-house and external resources are allocated to manage the IP and legal aspects of undertaking life sciences R&D in China.

Under Chinese law, companies are required to pay reasonable compensation for **employee inventions** (or "service inventions", patentable advances in technology made by salaried employees on behalf of their employer). Companies undertaking research in China should seek legal advice to ensure suitable compensation schemes are implemented.

Patent protection for inventions completed in China are usually filed first at the CNIPA as opposed to at an overseas Patent Office. If companies prefer to file first outside China then a **security review** should be filed at CNIPA. Security reviews are generally approved within 2-5 days and should not cause significant disruption to business. Failure to complete a security review could lead to rejection or invalidation of patents subsequently filed in China.

The prevailing Regulations on Technology Import and Export Administration (also known as the Technology Import-Export Regulations, TIER) is an administrative regulation managed the Ministry of Commerce (MoFCOM). It regulates most types of IP licensing to China, and requires original licensing contract be filed to MoFOM branches

Human genetic resources (HGRs) and related data on Chinese citizens are considered to be important strategic resources for national biosafety. The Human Genetic Resource Management Regulation published in July 2019 stipulates that foreign companies undertaking research which involves HGRs (including clinical trials) need to apply for approval from the Ministry of Science and Technology (MoST), and must undertake the research in collaboration with a Chinese partner. It further stipulates that patent generated from the collaboration must be shared between both parties. The patent sharing requirement triggers concerns among international stakeholders, but failure to fully comply can lead to significant fine, up to 10 times of the gaining generated from the project. .

The Chinese **Cybersecurity Law** (enacted from June 2017) provides a framework for Chinese government agencies to approve cross-border flows of data (or access to data hosted in China by overseas entities, including to run data analysis software). This especially applies to large volumes of personal data on Chinese citizens and data considered important for national security. Separate regulations cover the handling of data in research activities.

Details of the criteria for government agencies to approve cross-border data transfer/access remain unclear, and measures to address regulator concerns (e.g., anonymisation of data) will be considered on a case-by-case basis. British life sciences companies and researchers should seek legal advice on data handling ahead of any research or commercial project in China.

To arrange a discussion of particular IP cases with the British Embassy Beijing IP Attaché team – based on our experience working with other companies in China – please contact Commercialmail.beijing@fcdo.gov.uk. More information on IP in China can be found on our China IP Webpage. Every effort has been made to ensure that the information provided is accurate, however we accept no responsibility for any errors, omissions or misleading statements in this factsheet. This information is written in general terms and should be used as a guide only. It should not be used as a substitute for professional advice.