



China IP SME Helpdesk

Jian XU

10 September 2021

Jian XU, PhD



Gowling WLG (Beijing)

Managing Director | Head of IP Prosecution

Email: jian.xu@gowlingwlg.com

LinkedIn: <https://www.linkedin.com/in/xujian/>

Dr. Jian Xu is a dually qualified Chinese lawyer and patent/trademark attorney. He currently heads up the intellectual property practice at the China office of Gowling WLG.

Dr. Jian Xu joined the firm in 2008 and has been the head of the intellectual property practice of its China office since that date. Prior to that, he was a senior patent attorney at China Sinda, one of the largest intellectual property law firms in Beijing.

He has handled all aspects of IPR in business including drafting, prosecution, acquisition, enforcement and licensing of patents, trade marks and brand, design rights, copyright and content. He has conducted litigation and administrative actions against infringers all over China.

He also has a strong background in the chemistry and life science sector, with a bachelor's degree from Beijing and a PhD degree in Biochemistry from the University of Manchester.

Agenda

- **Overview of the Chinese law on IP protection for pharmaceuticals**
- Patent and design registration for pharmaceuticals and for medical devices
- Preventative measures to minimise the risk of leaking technical secrets
- Company and product brand protection

Typical IP rights and tools

- *Patents: Invention | Utility model | Design*
- *Trademarks*
- *Copyright*
- *Trade Secret*
- *Anti-unfair competition*
- *Anti-monopoly*

Typical IP enforcement options

- *Civil litigation before the court*
- *Administrative action*
- *Criminal action*
- *Customs seizure*
- *Warning letters*
- *Trade fair complaints*
- *Online take-downs*

Licensing/assignment and technology transfer

- *IP rights can be licensed or assigned in China.*
- *Technology transfer to foreign parties under three categories:*
 - Prohibited
 - Restricted
 - Freely importable/exportable

New China Patent Law on pharmaceutical patents

- *Pharmaceutical patent term extension – maximum 5 years*
- *Patent linkage system*
 - Resolve patent infringement disputes (originator vs. generics) during FDA approval
 - Patent information recordal for originator's patents
 - Marketing exclusivity period for up to 12 months to the first generic applicant with a Type 4 certification

Agenda

- Overview of the Chinese law on IP protection for pharmaceuticals
- **Patent registration for pharmaceuticals and for medical devices**
- Preventative measures to minimise the risk of leaking technical secrets
- Company and product brand protection

Overview of patents

Types	Subject	Term	Substantive examination	Timeline for registration
Invention	Technical solution: product or process	20 years	Yes	2-4 years
Utility model	Technical solution: product with a definite shape/structure	10 years	No	<1 year
Design	Outward appearance of a product	15 years	No	<1 year

Common subject matters for biopharma

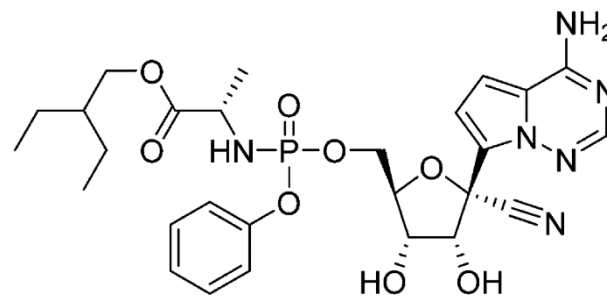
- *Compound*
- *Gene/amino acid sequence*
- *Pharmaceutical composition*
- *Polymorph*
- *Manufacturing/purification/detecting methods*
- *Medical use*
- *Medical device*

Particular aspects for biopharma patents

- **Unpatentable subject matter:** *methods of diagnosing or treating diseases*
- **Patent term compensation:** *up to 5 years more protection for pharmaceutical patents*
- **Bolar exemption:** *providing info for regulatory approval (FDA)*
- **Patent linkage system:** *originator (patentee) vs. generics*
- **Compulsory licensing:** *national or public health concerns*

Case study 1: Remdesivir

- Remdesivir is a broad-spectrum antiviral medication. Remdesivir is approved or authorized for emergency use to treat COVID 19 in around 50 countries. Remdesivir is the first treatment for COVID 19 to be approved by the US FDA.*



4a Sp and Rp isomers (~1:1)

4b Sp isomer (GS-5734)

4c Rp isomer

Case study: Remdesivir patent strategy

Year	Number of patents	Protection scope
2008-2009	2	Compound, modifying heterocycle
2009-2015	4	Compound, modifying ribose or phosphate
2015	1	Intermediate
2016-2018	4	Medical use
2018	1	New crystalline form
2019	1	New dosage form
2019	1	Compound, modifying ribose and extending medical use

Case study:

Echosens vs. Hisky

- *Medical device for liver fibrosis and liver steatosis assessment*
- *Plaintiff: Echosens – French company specialising in liver diagnosis*
- *Defendant: Hisky – Chinese company specialising in non-invasive liver diagnosis*
- *Patent in dispute: Chinese patent number CN1174246C entitled "IMAGING METHOD AND DEVICE USING SHEARING WAVES"*



Case study: Echosens vs. Hisky

Timeline	Actions/Decisions
Feb 2016	Echosens sued Hisky for patent infringement before the Beijing IP Court.
Feb 2019	Beijing IP Court found infringement and ordered injunction, with damage awards of RMB 30 million (c.a. EUR 3.95 million).
May 2019	Hisky appealed to the China Supreme Court.
Dec 2019	China Supreme Court overturned the Beijing IP Court decision and ruled non-infringement . The Supreme court deemed that the Echosens' patent employed a technical solution of " simultaneous observation and full receipt", while Hisky's is " deferred observation and partial receipt".

Agenda

- Overview of the Chinese law on IP protection for pharmaceuticals
- Patent registration for pharmaceuticals and for medical devices
- **Preventative measures to minimise the risk of leaking technical secrets**
- Company and product brand protection

Three criteria for trade secret

Trade secret can be any technical or business information which is

- ***unknown to the public,***
- ***has commercial value, and***
- ***for which the owner has adopted confidentiality measures.***

Examples: Processes; Formulas; Methods; Technical know-how; Customer lists; Pricing and profit margin information

Characteristics for trade secret

- *No registration required*
- *Lasting forever as long as secrecy is ensured*
- *Security measures needed to ensure confidentiality*
 - NDAs
 - Non-competing clauses
 - Confidentiality terms
- *Losing control after breach*

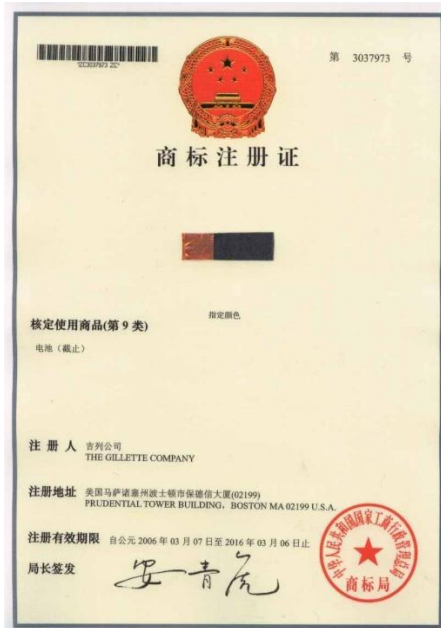
Case study: Eli Lilly vs. Huang

- *China's first preliminary injunction case for trade secrets*
- *Plaintiff: Eli Lilly; Defendant: Huang (a former employee of Eli Lilly)*
- *In November 2015, Eli Lilly sued Huang before the Shanghai IP Court, claiming that its former employee Huang has saved 28 pieces of trade secret on his personal IT device.*
- *Eli Lilly requested preliminary injunction (PI) and damages of RMB 30 million, and provided a bond of RMB 500,000 for the preliminary injunction.*
- *Shanghai IP Court granted the PI considering four factors:*
 - *Chance of success by the plaintiff*
 - *Irreparable harm to the plaintiff*
 - *The harm to the defendant by granting the PI vs. the harm to the plaintiff by not granting the PI*
 - *The harm to the public by granting the PI*

Agenda

- Overview of the Chinese law on IP protection for pharmaceuticals
- Patent and design registration for pharmaceuticals and for medical devices
- Preventative measures to minimise the risk of leaking technical secrets
- **Company and product brand protection**

Strict “first-to-file” system



- *Basically, you can only enjoy exclusive trademark protection, by “first-to-file” your trademark and formally register it with the China Trademark Office.*
- *DO NOT rely on any illusion of common law protection or unregistered trademark rights.*
- *10 year protection term, renewable.*
- *Takes about 9 months for registration.*

What can be registered as a trademark?

NOKIA 诺基亚

Morgan Stanley



- *Word*
- *Design*
- *3D shape*
- *Combination of colours*
- *Sound*

Goods/services: 45 classes

- *Nice Classification: Goods in 34 classes; and Services in 11 classes*

- **Class 5**

- Pharmaceuticals, medical and veterinary preparations; sanitary preparations for medical purposes; dietetic food and substances adapted for medical or veterinary use, food for babies; dietary supplements for human beings and animals; plasters, materials for dressings; material for stopping teeth, dental wax; disinfectants; preparations for destroying vermin; fungicides, herbicides.

- **Class 10**

- Surgical, medical, dental and veterinary apparatus and instruments; artificial limbs, eyes and teeth; orthopaedic articles; suture materials; therapeutic and assistive devices adapted for persons with disabilities; massage apparatus; apparatus, devices and articles for nursing infants; sexual activity apparatus, devices and articles.

- **Class 44**

- Medical services; veterinary services; hygienic and beauty care for human beings or animals; agriculture, aquaculture, horticulture and forestry services.

Why Chinese version?



亲近生活，美化生活。宝洁公司 P&G

- *You will need a Chinese version of your brand when you operate in the China market for some time.*
- *Otherwise the consumer or the media will devise their Chinese version for your brand, and gradually identify with that Chinese version brand.*

Case study: Viagra case



- *Pfizer failed to register the Chinese nick name for Viagra, 伟哥 (big brother).*
- *After a seven-year legal battle, Pfizer cannot get the Chinese trademark back.*
- *Pfizer has to change its Chinese branding of Viagra.*

Agenda

- Overview of the Chinese law on IP protection for pharmaceuticals
- Patent and design registration for pharmaceuticals and for medical devices
- Preventative measures to minimise the risk of leaking technical secrets
- Company and product brand protection
- **Conclusion**

Take-away messages

- *"Registration is the king". Register your IP rights early in China.*
- *Patent portfolio strategy is important for innovative drugs.*
- *Medical devices can be protected by all three types of patents.*
- *Don't neglect trademarks, and be aware of Chinese translations of foreign brands.*
- *Take measures to keep your trade secrets.*
- *Be prepared to enforce your IP rights in China.*

The Helpdesk in a nutshell

- Free initial advice to SMEs
- Geographic coverage:

- China
- Hong Kong
- Macao
- Taiwan



 100,000+ SMEs assisted to date

Helpdesk free services

Enquiry Helpline



Training Workshops



Webinars



Website & Blog



Guides & Factsheets





FACTSHEET

- THE FACTS: Business in Mainland China for EU Companies**
 - Size of Market
 - Key INDUSTRY SECTORS
- IPR in Mainland China for SMEs: BACKGROUND**
 - Intellectual Property Rights for SMEs: Why is this RELEVANT to you?
 - How does Mainland China's IP legal framework compare to INTERNATIONAL STANDARDS?
- IP Rights in Mainland China: THE BASICS**
 - Copyright
 - Patents
 - Trade Marks
 - Geographical indications (GI)
 - Trade Secrets
- Using CUSTOMS to block counterfeits**
- Enforcing of rights**
 - Administrative actions
 - Civil Litigation
 - Criminal Prosecution
- RELATED LINKS and Additional Information**




IP Factsheet: Mainland China

CHINA IPR SME HELPDESK




For free, confidential, business-focused IP advice within three working days E-mail: question@china-iphelpdesk.eu




Guide

- Technology Transfer to China
- Thinking of Transferring Technology?
- What Can Companies Do to Protect Themselves?
- SME Case Studies
- Technology Transfer Checklist
- Take-Away Messages
- Related Links



Technology Transfer to China: Guidance for Businesses

CHINA IPR SME HELPDESK



For free, confidential, business-focused IPR advice within three working days E-mail: question@china-iphelpdesk.eu

Five IP SME Helpdesk



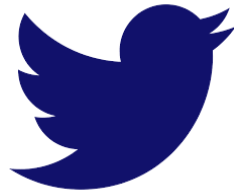
Internal Market, Industry, Entrepreneurship and SMEs

<https://ec.europa.eu/ip-helpdesk>

**CHINA
IP SME HELPDESK**

© European Union, 2021. Reuse is authorised provided the source is acknowledged. The reuse policy of European Commission documents is regulated by Decision 2011/833/EU OJ L 330, 14.12.2011, p.39.

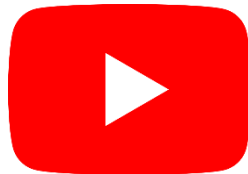
Stay connected!



@iprchina



@ChinaIPR-hd



China IP SME Helpdesk

Questions?

HELPLINE

free, fast & confidential

3 ^{working} *days*

question@china-iprhelpdesk.eu