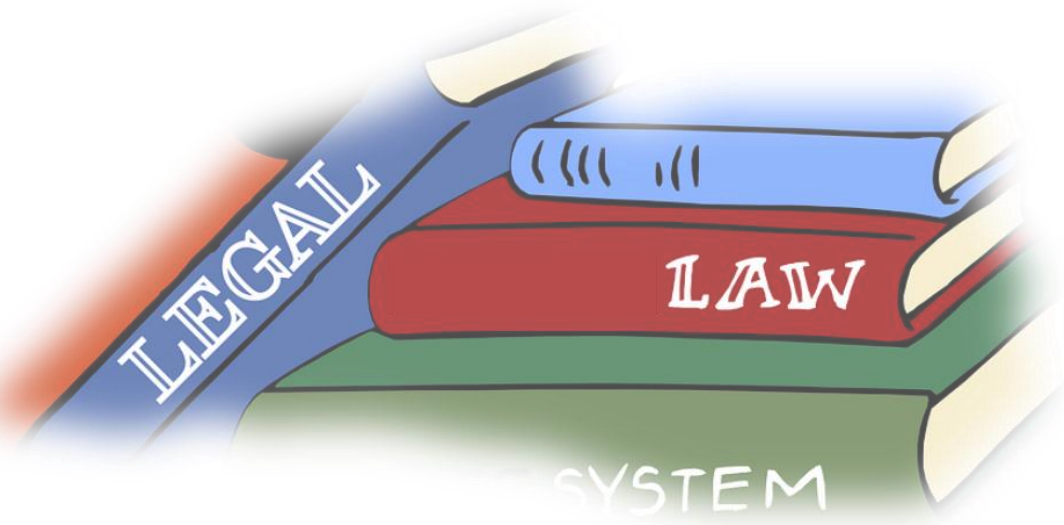


Challenges and Innovations of European Enterprises under the Reform of China Pharmaceutical IP System

中国医药知识产权制度改革下 欧洲企业的创新与挑战

Matias Zubimendi

26 May 2022





China IP SME Helpdesk

欧盟中小企业知识产权服务处

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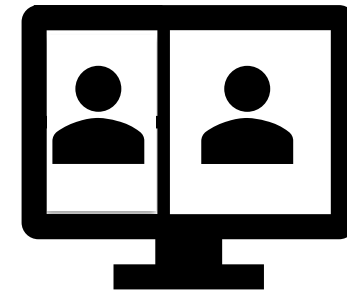
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IP Factsheet: Mainland China



1. THE FACTS: Business in Mainland China for EU Companies
(Source: DG Trade)



SIZE of Market:

- EU exports to Mainland China: EUR 173.5 billion
- EU imports from Mainland China: EUR 299.9 billion
- Total trade in goods: EUR 473.4 billion

> Mainland China is the EU's second largest trading partner, after the USA.
 > The EU is China's largest trading partner.

Key INDUSTRY SECTORS:

- > EU exports to Mainland China are dominated by machinery and equipment, motor vehicles, aircraft, and chemicals.
- > Mainland China's key export items to the EU include machinery and equipment, footwear and clothing, furniture and lamps, and toys.

1 THE FACTS: Business in Mainland China for EU Companies
Key INDUSTRY SECTORS

2 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?

3 IP Rights in Mainland China THE BASICS
A. Copyright
B. Patents
C. Trade Marks
D. Geographical Indications (GIs)
E. Trade Secrets

4 Using CUSTOMS to block counterfeits

5 Enforcing your IP
Administrative actions
Civil Litigation
Criminal Prosecution

6 RELATED LINKS and Additional Information

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Protecting Your Trade Secrets in China

Prevention is the key to protection.



WHAT EXACTLY CAN BE A TRADE SECRET

SOMETHING THAT

- 1 is not publicly known
- 2 has commercial value
- 3 you took measures to keep secret

expressions of ideas

know-hows, manufacturing or design techniques

status of products or services under development

valuable business information, lists, cost and price information

TRADE SECRETS

KEEP IT SECRET, KEEP IT SAFE

It is important to remember that once trade secrets become publicly known, they can no longer be protected as trade secrets.

CONFIDENTIAL

DON'T FORGET YOUR EMPLOYEES

- Limit access and copying rights to the personnel who actually need it.
- Require all employees to sign an employment agreement with strict confidentiality provisions.
- Be sure to hold exit-interviews and have them return documents, materials, computers, and files.
- Establish an internal management system for trade secrets. Training and clear written guidelines are essential.

DEALING WITH THIRD PARTIES

Business dealings or negotiations with third parties, potential partners, suppliers, contractors, licensees, or customers

monitor your partners, suppliers or licensees to make sure they are complying with your trade secrets protection policy

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Commission

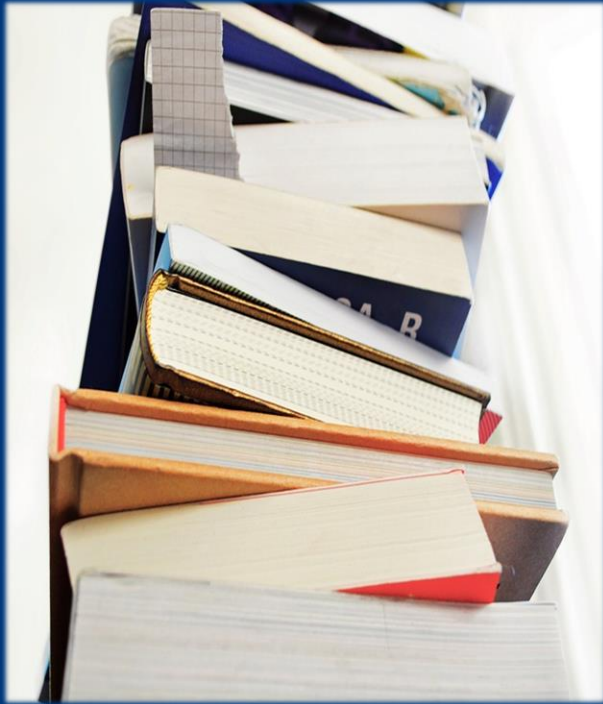


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4. Enforcement 知识产权执法
5. Licensing 专利许可
6. Take away messages 要点

01

Reform of China's pharmaceutical IP system 中国药品知识产权体系的改革

Latest changes 最新变化

1.1

Amendment of the patent law (2021)

- Patent term extension (pharmaceutical)
- Patent linkage system
- Design patents
- Infringement damages
- Patent term adjustment (administrative delay)

中国专利法修正案 (2021年)

- 专利有效期延长 (药品)
- 药品专利链接制度
- 外观设计专利
- 侵权损害赔偿
- 专利期限调整 (行政延误)



02

Review of basic IPRs 基础知识产权回顾

Chinese IPR rules 中国知识产权规则

2.1

Jurisdictions 管辖权

- Mainland China 中国大陆
- Hong Kong 香港地区
- Macao 澳门地区
- Taiwan 台湾地区

2.2

International agreements 国际协议

- PCT 专利合作条约
- Madrid protocol 马德里国际商标体系
- Hague agreement 海牙国际外观设计体系

2.3

Main principles 主要原则

- Registration 注册
- First to file 申请在先原则

Be careful – Only Mainland China is member of the international agreements
注意 – 只有中国大陆是国际协议的成员国

03

Registration 注册

- Challenge 挑战



3.1

Registration time 注册时间

- 3 up to 6 years 3-6年

3.3

Registration vs Market access 注册和市场准入

- Different channels 不同渠道

3.2

Risk 风险

- Enforceability 执法力

Parallel registration for medical devices – method of gaining fast enforceability
医疗器械的平行注册——获得快速执法的方法

03

Registration 注册

- Opportunities 机会



REGISTRATION

3.4

Patent term adjustment 专利期调整

- Administrative delay 行政延误
- Requirements 要求
 - 4 years from filing 申请后4年
 - 3 years from request for examination 自申请审查日起 3 年
 - Not caused by applicant 不是由申请人造成的

3.5

Patent term extension 专利期延长

- Pharmaceutical sector 医药板块
- Market access phase 市场准入阶段
- Requirements 要求
 - Market access of innovative pharmaceuticals 创新药的市场准入
 - No more than 5 years 不超过5年
 - Total life patent no longer than 14 years 专利期不超过14年

04

Enforcement 专利执法

- Challenges 挑战



4.1

Market size 市场规模

- Potential multiple infringers
- Costs
- 潜在的多个侵权者
- 费用

4.2

Long cases 漫长的司法程序

- Judicial process takes time
- 司法程序漫长

4.3

Evidence 证据

- Difficulties in collecting evidence
- 收集证据方面的困难

Tip – For complex cases the IP specialised courts are recommended
提示 – 对于复杂案件, 建议使用知识产权专门法院

04

Enforcement 专利执法

- Opportunities 机会



4.5

Damages 赔偿

- Increment of statutory damages
- Punitive damages
- 增加法定损害赔偿
- 惩罚性赔偿

4.6

Evidence collection 取证

- Reverse burden of proof
- 反向举证责任

05

Licensing 专利许可

- Challenges 挑战



5.1

Difficulty in negotiations

- Pandemic-related travel restrictions

谈判困难

- 疫情影响的旅行受限

5.2

Enforceability of contracts

- Should be tailor-made
- China as applicable law
- China as jurisdiction for disputes

合同的执行力

- 应该量身定做
- 中国适用法律
- 中国争议司法管辖区

05

Licensing 专利许可

- Opportunity 机会



5.3

Open license system

- New method of providing licenses
- Fees and conditions set by the patent owner (except exclusivity)

开放许可制度

- 提供许可证的新方法
- 专利所有人设定的费用和条件（排他性除外）

5.4

Advantages

- Easy to license (no negotiations)
- Annual fees reduced or except
- Revocable (doesn't affect on-going licenses)

优势

- 易于许可（无需谈判）
- 年费减免或除外
- 可撤销（不影响正在进行的许可证）

06 | Takeaway messages 要点



- ✓ Register your IP in advance 提前注册您的知识产权
- ✓ Pay attention to the jurisdictions when registering your IPRs, especially if using the international agreements 在注册您的知识产权时要注意管辖权，尤其是在使用国际协议时
- ✓ Get enforceable contracts – tailor-made by a local legal experts 获得具有执法效力的合同——由当地法律专家量身定制



- ✓ Extend or adjust the life of your patents if possible 尽可能延长或调整您的专利有效期
- ✓ Choose the right jurisdiction in case of litigation 诉讼时选择正确的司法管辖区
- ✓ Collect evidence before taking legal actions 在采取法律行动之前收集证据



- ✓ Contact the China IP SME Helpdesk 联系我们 **question@china-iprhelpdesk.eu**

Questions?

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days

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Your feedback is very valuable info for us.

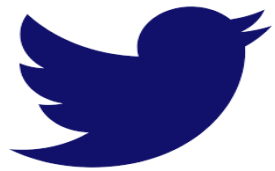
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