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

中國医药知识产权制度改革下欧洲企业的创新与挑战

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Mr. Matias Zubimendi is the IP Business Advisor at China IP SME Helpdesk, where he advises European SMEs on intellectual property rights matters. Mr. Zubimendi holds a Master's degree in Chinese Civil and Commercial Law from Peking University as well as a Master's degree in Intellectual Property Law from Austral University in cooperation with the World Intellectual Property Organisation. Mr. Zubimendi has a strong background in both business development and intellectual property rights protection, having previously worked as a China Business and Legal Consultant at Terragene, where he focused on business development, and as a Director of Legal Affairs at Conquer Europe. Previously, he has also worked as a Patent and Trademark Attorney at Phoebus Abogados and Mazzeo & Canet, where he represented SMEs as well as Fortune 500 companies.

Mr. Zubimendi has given lectures at various conferences including the Ibero-American Conference on Chinese Studies and published several articles including "The legal protection of intangibles in the video games industry." As a Professor Assistant, he has also given lectures on Commercial Law and Procedural law, while focusing on Copyright and AI in his research. Mr. Zubimendi is a native Spanish speaker fluent in English.
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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. Amendment of the patent law (2021)
   中国专利法修正案 (2021年)
   - Patent term extension (pharmaceutical)
   - Patent linkage system
   - Design patents
   - Infringement damages
   - Patent term adjustment (administrative delay)
   - 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)
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
3.1 Registration time 注册时间
- 3 up to 6 years 3-6年

3.2 Risk 风险
- Enforceability 执法力

3.3 Registration vs Market access 注册和市场准入
- Different channels 不同渠道

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
Registration  注册
- Opportunities  机会

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
Enforcement 专利执法
- Challenges 挑战

4.1 Market size 市场规模
- Potential multiple infringers 潜在的多个侵权者
- Costs 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
Enforcement 专利执法
- Opportunities 机会

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

4.6 Evidence collection 取证
- Reverse burden of proof 反向举证责任
Licensing 专利许可

- Challenges 挑战

**Difficulty in negotiations**
- Pandemic-related travel restrictions

**Enforceability of contracts**
- Should be tailor-made
- China as applicable law
- China as jurisdiction for disputes
5.4 Advantages
- Easy to license (no negotiations)
- Annual fees reduced or except
- Revocable (doesn’t affect on-going licenses)

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

Licensing 专利许可
- Opportunity 机会

Open license system 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）

Advantages 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）
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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