Drug Patent Related Aspects in the Fourth Amendment of China's Patent Law
专利法第四次修正与药品专利相关的部分

Roy Yee-Loi Chan, Ph.D., LL.M.
Albert Wai-Kit Chan Intellectual Property Limited

Background Information

- October 17, 2020: Passed Fourth Amendment of Chinese Patent Law 中国专利法第四修正案 (Takes Effect: June 1, 2021)

Article 42, Paragraph 3：Patent Term Extension (专利保护期限延长)

With regard to the patent for invention related to new drugs that have been approved in China, in order to compensate the time spent on review and approval of new drugs, the patent administration department under the State Council shall, upon the request of the patentee, provide a remedy of patent term extension. The extension shall not exceed five years, and the total valid patent term after the new drug is approved shall not exceed 14 years.

Article 76: Drug Patent Linkage (药品专利链接制度)

In the process of review and approval of a drug, where there is a dispute over the patent right relating to the drug between the applicant, relevant patentee or interested party, the relevant parties may file a lawsuit with the people's court to request a judgment on whether the related technical solution of the drug applied for registration falls within the patent protection scope of others' drugs. The drug regulatory authority under the State Council may, within the prescribed time limit, make a decision on whether to suspend the approval of the related drugs based on the effective judgment of the people's court.

With regard to disputes over patent rights related to the drug, applicants for drug approval and relevant patentees or interested parties may also file a request for administrative rulings before the patent administration department under the State Council

The drug regulatory department under the State Council, in conjunction with the patent administrative department under the State Council, shall formulate specific measures to resolve patent dispute at the stage of drug review and approval and drug listing application. The measures shall be implemented after the approval of the State Council

Background Information

- National Medical Products Administration (NMPA) and China National Intellectual Property Administration (CNIPA)
  - Draft Measures on the Early Resolution Mechanism for Drug-Related Patent Disputes
    《药品相关的专利纠纷早期解决机制办法草案》
- Supreme People's Court
  - Draft Legal Provisions on Several Issues Concerning the Application of Laws in the Trial of Disputes over Drug Patent Linkage
    《药品相关的专利权纠纷民事案件适用法律若干问题的规定草案》
- China National Intellectual Property Administration (CNIPA)
  - Draft Measures on Administrative Adjudication in the Early Resolution Mechanism for Drug-Related Patent Disputes
    《药品专利纠纷早期解决机制行政裁决办法草案》

NDA Applicant

1. Chemical Drug* 化学药物*
2. Biologics# 生物制品#
3. TCM 中药

Within 30 days of Patent Grant/
When filing NDA

NMPA Approved Drug Patent Registration Platform

Publication on Platform

Generic Drug Application and Certification Status

Generic Drug Applicant

Type1: no relevant patent
Type2: relevant patent terminated or invalidated
Type3: generic will not market until patent expires
Type4: Relevant patent invalid or not infringed

45 days

Patent Owner/NDA Holder files Art. 76 action in Beijing IP Court or CNIPA
（北京知识产权法院） （国家知识产权局）

NMPA Administrative Review Regulatory Stay (Chemical Drugs Only)
9 Months

Infringement

Resume 20 days before Patent Expires

Non-Infringement/
No Ruling/
Patent Invalid/
Settlement

Resume
（12-month exclusivity for first successful challenger for Chemical Drugs）

* Hatch-Waxman: Chemical Drugs
# Biologics Price Competition and Innovation Act: Biologics

Type 4 Certification: 3 Main Differences

- No Notice Letter Requirement
  - Patent Owner/NDA holder must regularly monitor the publication of Generic Drug information to initiate patent litigation within 45 days to stay generic drug approval
- Nine-Month Stay of Generic Drug Approval（US: 30 months）
  - The period of the stay is designed to approximate a reasonable time period to resolve patent issues before a generic drug will be granted approval and enter the market. CNIPA shall close within 3 months from receipt of an infringement disputes according to Article 21 of Measures for Patent Administrative Law Enforcement（专利行政执法办法第21条）
- 12-Month Exclusivity (US: 180 days)
  - Likely greater incentive for generic drug companies to be the first to successfully challenge brand-name patents and bring generic pharmaceuticals to the market.

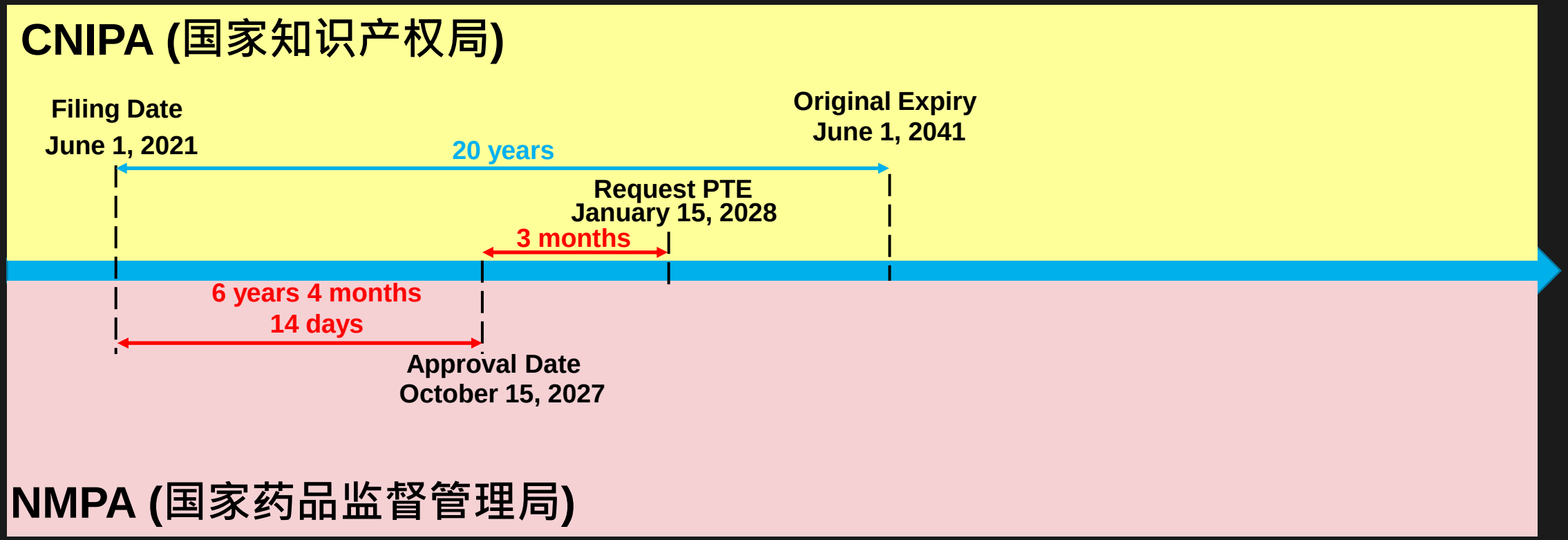
Patent Term Extension

- Rules for Implementing the Patent Law Article 85 (Draft):
  - Chemical Drug, Biologics, TCM patents on product, preparation method or medical uses (产品、制备方法或医药用途)
  - Only 1 patent shall be given PTE when there are multiple patents covering a drug
  - Multiple drugs in one patent: only 1 drug can request PTE
  - Patent has not received PTE previously
  - Patent term >6 months

Patent Term Extension

药品专利期限补偿时间的计算方式为申请注册的新药在中国获得上市许可之日减去专利申请日，再减去5年。

PTE = Approval Date – Filing Date – 5 years (Max: 14 years from Approval Date)



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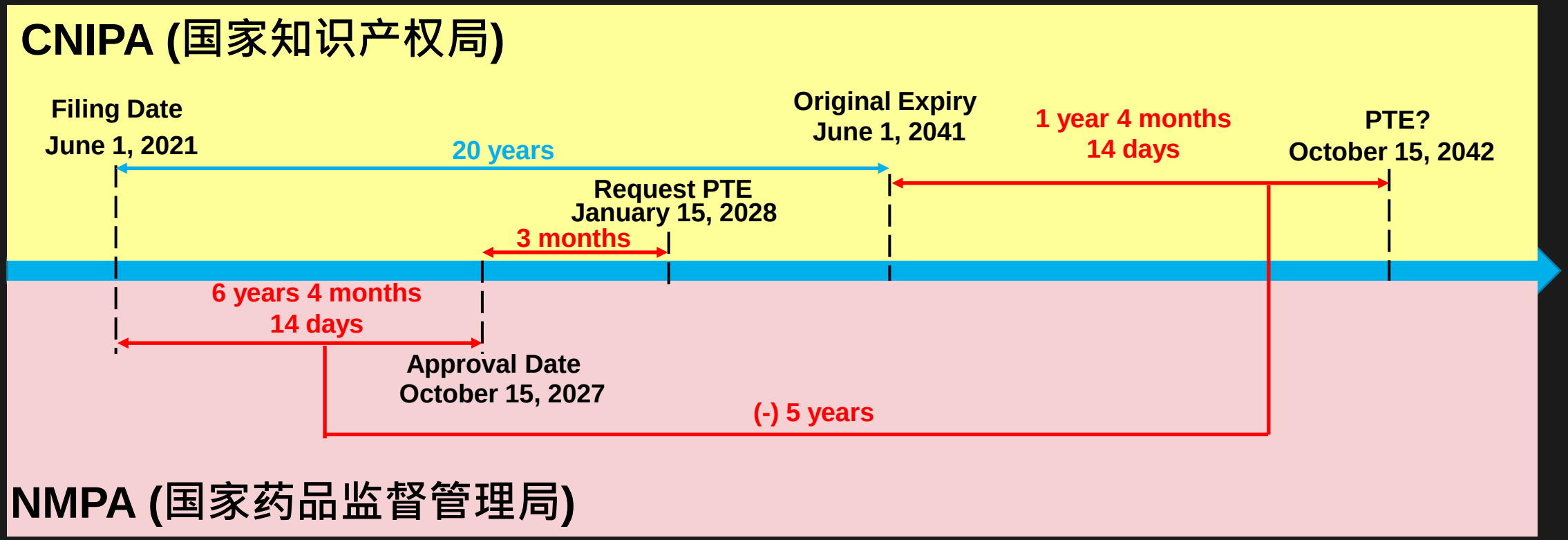

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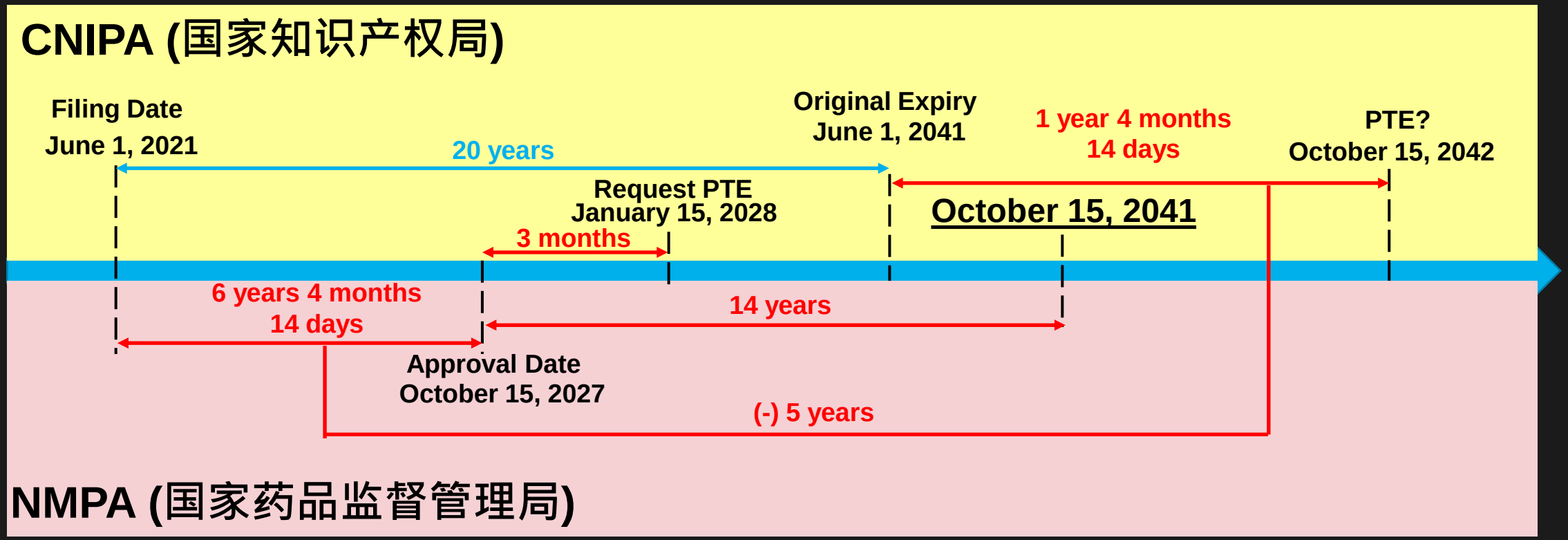

Thank You!