

# Strategies relating to Biopharma Innovation

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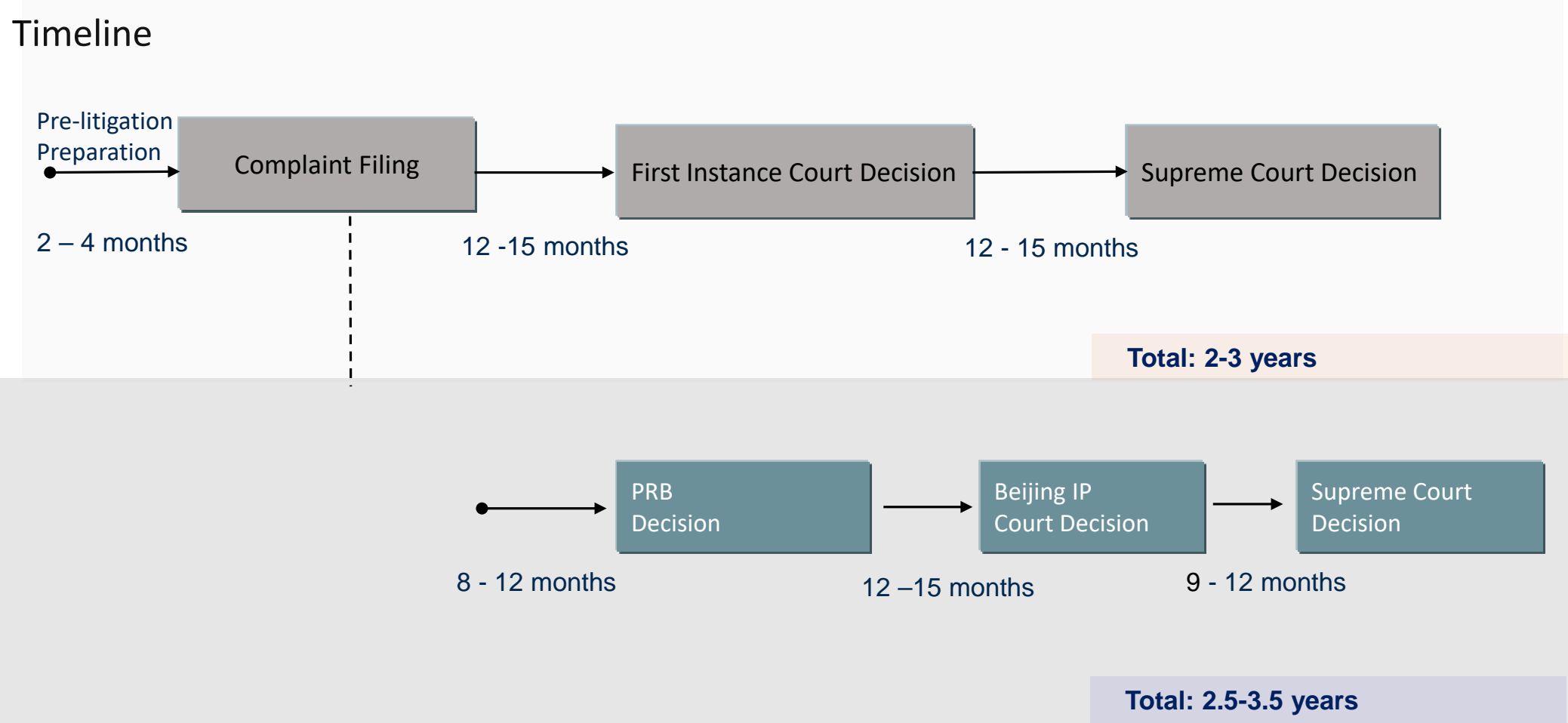
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# Anatomy of a Patent Dispute

## ■ Timeline



# Hurdles in Enforcement of Pharma Patents

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## ■ High Rate of Invalidation

- According to some reports, if invalidity petition is filed against a pharmaceutical patent, there is a 75% chance that at least part of the patent claims will be declared invalid.
- Even for compound claims, over 50% are declared invalid.

## ■ High Evidentiary Burden for Plaintiff

## ■ Other Hurdles

# Patent Linkage

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## Current status – no real patent linkage

- NMPA, *Provisions for Drug Registration (2007)*
  - **Article 18 - Duty of disclosure:** the applicant should disclose any existing patents on a should have known basis
  - **Article 19 - 2-year rule :** the drug application should not be filed earlier than 2 years before the expiration of the patent of another
  
- Patent Law
  - **Article 69(5) Exemption:** Exempt drug applicants from patent infringement for production, use and import of patented drug for obtaining regulatory approval
  
- *Hunan Fangsheng v. Huaihua*, Xiang Gao Fa Min San Zhong Zi No. 51 (Hunan High Ct. 2014): the applicant has the duty to declare the patent information on the applied drug
  
- No punishment if the applicants fail to meet Articles 18 and 19. The NMPA only conducts formality review based upon non-infringement declaration of the drug applicant.
  
- Strategy: one can file opposition against a drug application claiming patent infringement. The NMPA may slow down or suspend review of the application

# Patent Linkage

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## Legislation development – hopeful change, but no timeline

### ■ NMPA

- *Policy on Encouraging Innovation on Drug and Medical Device and Protecting Rights of Inventors*

- May 12, 2017, for public comments
- Notifying the patentee within 20 days after filing drug application
- Filing infringement lawsuit within 20 days and notifying NMPA after receiving the applicant's notification
- No suspension of technical review of the application
- Issuance of drug decision on applications depends on the court's decision or expiration of waiting period

### ■ NMPA

- *Draft Provisions for Drug Registration (2017)*

- October 25, 2017, for public comments
- The applicant not only needs to provide the patent information on drug to NMPA, but also needs to inform the relevant patentee during a designated time

# Patent Linkage

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## Legislation development – hopeful change, but no timeline

- Supreme Court, NMPA and 10 other government agencies
  - *Accelerating the Implementation of the Work Plan for Supply Guarantee and Use Policies of Generic Drugs*
    - December 18, 2018
    - The drug patent linkage system shall be explored and gradually developed
  
- Nothing in the proposed *Amendment to Patent Law*
  
- NMPA
  - *Draft Provisions for Drug Registration (2019)*
    - September 30, 2019, for public comments
    - Nothing about patent linkage
  
- It may take years ....

# Patent Term Extension

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- Currently, No Patent Term Extension
  
- Standing Committee of National People's Congress
  - *Patent Law Amendment*
    - January 4, 2019, for public comments
    - Article 42: For the purposes of making up the time for the review and approval of the **marketing** of an **innovative drug**, the State Council may decide to extend the duration of the innovative drug invention patent of which the **marketing** in China and abroad **at the same time** is applied for, the duration may be extended for not more than 5 years, and the total effective duration of the patent after the **marketing** of the innovative drug shall not exceed 14 years.
  
- State Council
  - Executive meeting on April 12, 2018
    - If the marketing of the innovative drug is applied for in China and abroad at the same time, the patent protection duration of the patent behind the drug may be extended for not more than 5 years



# Patent Term Extension

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## ■ Terms not clearly defined

### ● New Drug

- “Drug that has not been marketed in China and abroad,” Article 6, *Opinions of the State Council on Reform of the System of Evaluation, and Review and Approval of Drugs and Medical Devices*, State Council, August 9, 2015
- “Drug that has not been marketed in China” Article 42, *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China*, State Council, March 2, 2019

### ● Innovative Drug

- “One type of new drug,” Article 6, *Opinions of the State Council on Reform of the System of Evaluation, and Review and Approval of Drugs and Medical Devices*, State Council, August 9, 2015
- “Drug having compound with new clear structure, pharmaceutical effects and clinical value,” Article 1, *Work Program for Reform of Chemicals Application and Classification*, NMPA

# Data Protection

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- 6 years for NME
  - *Provisions on Drug Application, July 10, 2007*
  - *Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, March 2, 2019*
  
- Possible changes
  - *Proposed Measures for Implementing Data Protection in Drug Tests, April 26, 2018*, for public comments
    - 6 years for innovative drugs
    - 6 years for innovative treatment of rare diseases
    - 6 years for innovative treatment of pediatric uses
    - 12 years for innovative therapeutic biologics

# Drug Marketing Authorization Holder

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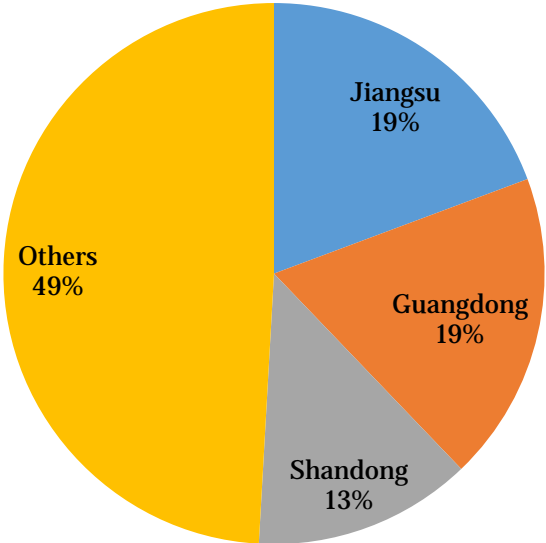
## Legislation Development

- **SCNPC**, *Decision on Authorizing the State Council to Conduct the Pilot Program of the System of the Holders of Drug Market Authorization in Certain Areas and the Relevant Issues (2015.11.4)*
- **General Office of State Council**, *Notice on Issuing the Plan for the Pilot Program of the System of the Holders of Drug Marketing Licenses (2016.5.26)*
- **NMPA**, *Notice on Effectively Conducting the Pilot Program of the Drug Market Authorization Holder System (2016.7.6)*
- **NMPA**, *Notice on Facilitating the Work on the Pilot Program of the System of the Drug Market Authorization Holders (2017.8.15)*
- **SCNPC**, *Decision on Extending the Period of Authorizing the State Council to Carry out the Pilot Program of Drug Market Authorization Holder System in Certain Areas (2018.10.26)*

# Drug Marketing Authorization Holder

- **State Council, Report on the Pilot Program of the Drug Market Authorization Holder System (2018.10.13)**
  - As of September, 2018
  - Summary of the pilot program

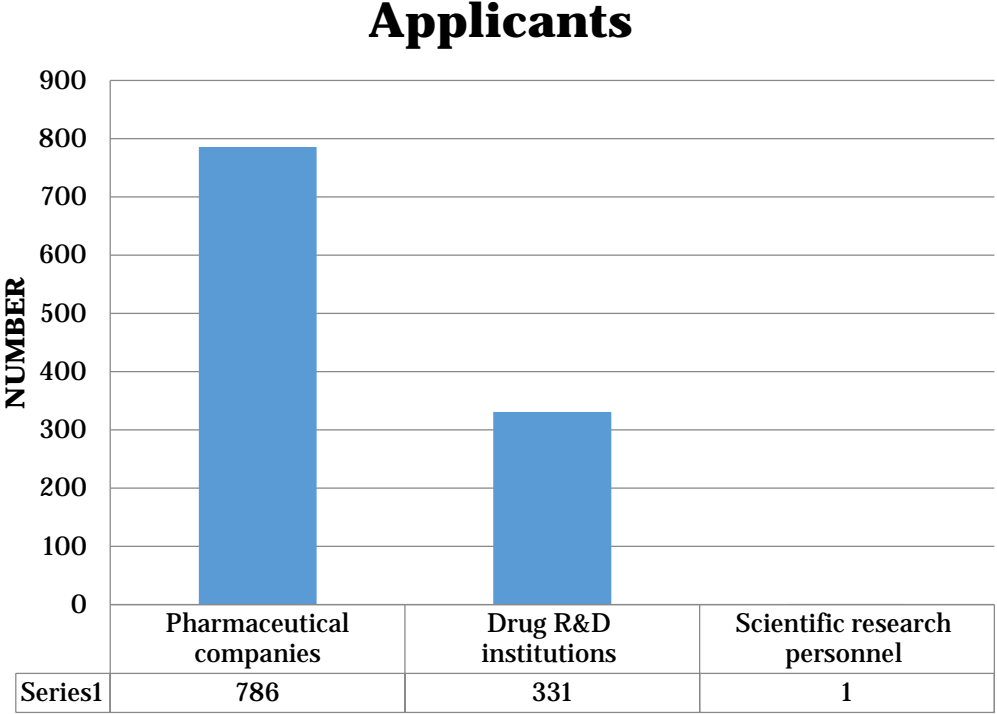
## Application numbers



Jiangsu	216
Guangdong	207
Shandong	146
Others	549

# Drug Marketing Authorization Holder

- **State Council, Report on the Pilot Program of the Drug Market Authorization Holder System (2018.10.13)**
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  - Summary of the pilot program



Scientific research personnel tends to take a lead to establish a R&D institute to apply for drug application

- Risk and cost sharing
- Capacity to be responsible for the safety and efficacy of the drug for its life cycle
- Capacity to be responsible for possible damages incurred

# Drug Marketing Authorization Holder

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## ■ *Pharmaceutical Administration Law of the People's Republic of China* (2019.08.26)

- Effective date: December 1, 2019
- MAH:
  - Responsible for the safety, efficacy and quality control in the process of drug researching and developing, manufacturing, operating and using, e.g., recall, post-market monitor
  - Holders: enterprise or R&D institute
  - Sale and manufacture: the applicants or entrusted companies that have the required licenses
  - Drug traceability management system
  - Foreign holder -> designated Chinese company assuming the duties of MAH and bearing joint liability with the foreign holder
  - Transfer: approved by NMPA
  - Compensation in advance

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**Thank You!**