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铸信而立 智圆行方

Introduction of Drug Patent Linkage System in China

by Li WU, J.D.&Ph.D.

Oct. 3rd, 2024

Background of Introduction of Patent Linkage System to China

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From introduction of "Bolar exemption" to promise in the US-China trade agreement

- **China adopted the Bolar exemption in its patent system since 2008**
  - Article 69 of the Patent Law (2008 amendments) provides that: "*None of the following circumstances shall be deemed an infringement upon a patent right: … 5) producing, using or importing patented medicine or patented medicinal equipment for the purpose of providing the information as required for administrative review and approval, and producing and importing the patented medicine or patented medicinal equipment exclusively for said purpose*."
  - However, the Bolar exemption was **"unilaterally"** introduced into the patent system without being accompanied by the drug patent linkage system, and eventually it has been applied without any restrictions, **which seriously damages the "balance between the innovative drugs and the generic drugs"** in the pharmaceutical industry.

- **China promised to establish an effective mechanism for early resolution of drug patent disputes in the SINO-US trade agreement (phase I) executed on January 15, 2020.**

Interpretation of Article 76 of 2020 Patent Law

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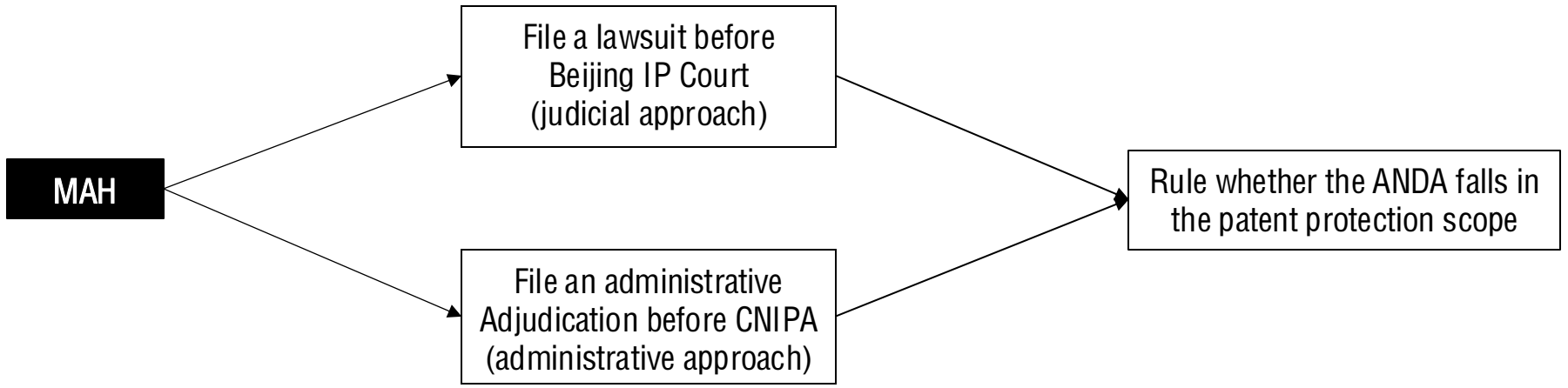
"Patent Law" (2020 amendments) specifies a patent linkage system with Chinese characteristics

Article 76 of Patent Law (2020 amendments)



Development context of patent linkage system

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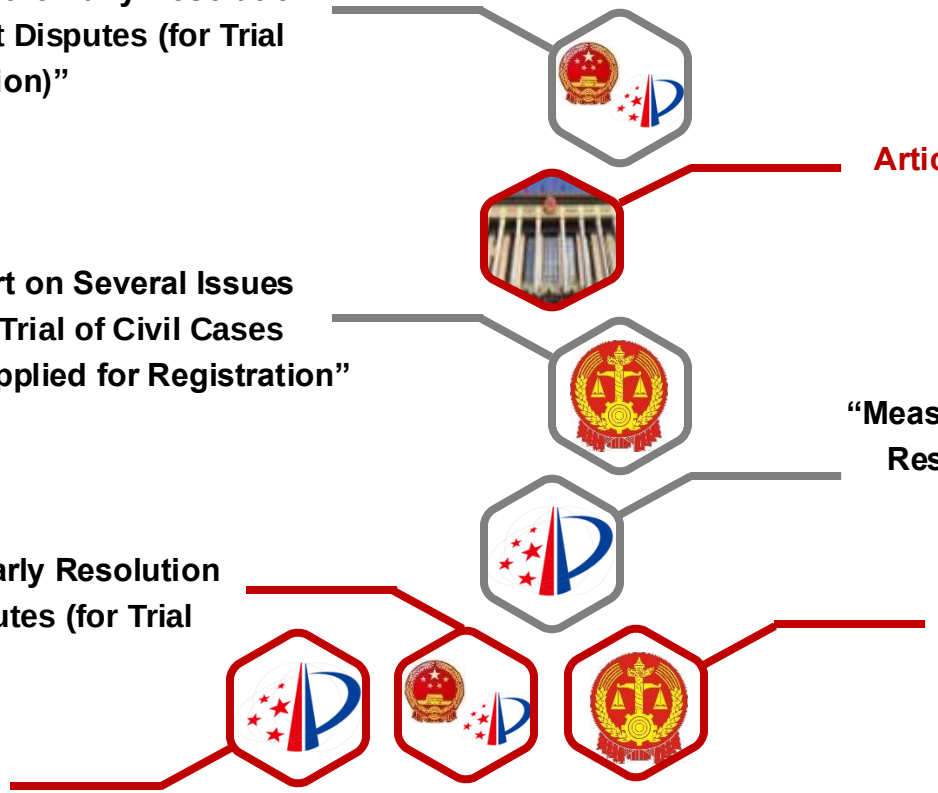
Sep 11, 2020
"Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation)" (draft)

Oct 29, 2020
"Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs Applied for Registration" (draft)

Jul 5, 2021
"Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation)"

Jul 5, 2021
"Measures for Administrative Adjudication under Early Resolution Mechanism for Drug Patent Disputes"



Oct 17, 2020
Article 76 of "2020 Patent Law"

Feb 9. 2021
"Measures for Administrative Adjudication under Early Resolution Mechanism for Drug Patent Disputes" (Draft)

Jul 5, 2021
"Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Civil Cases involving Patent Disputes Related to Drugs Applied for Registration"

Patent linkage system in China (Version 1.0)

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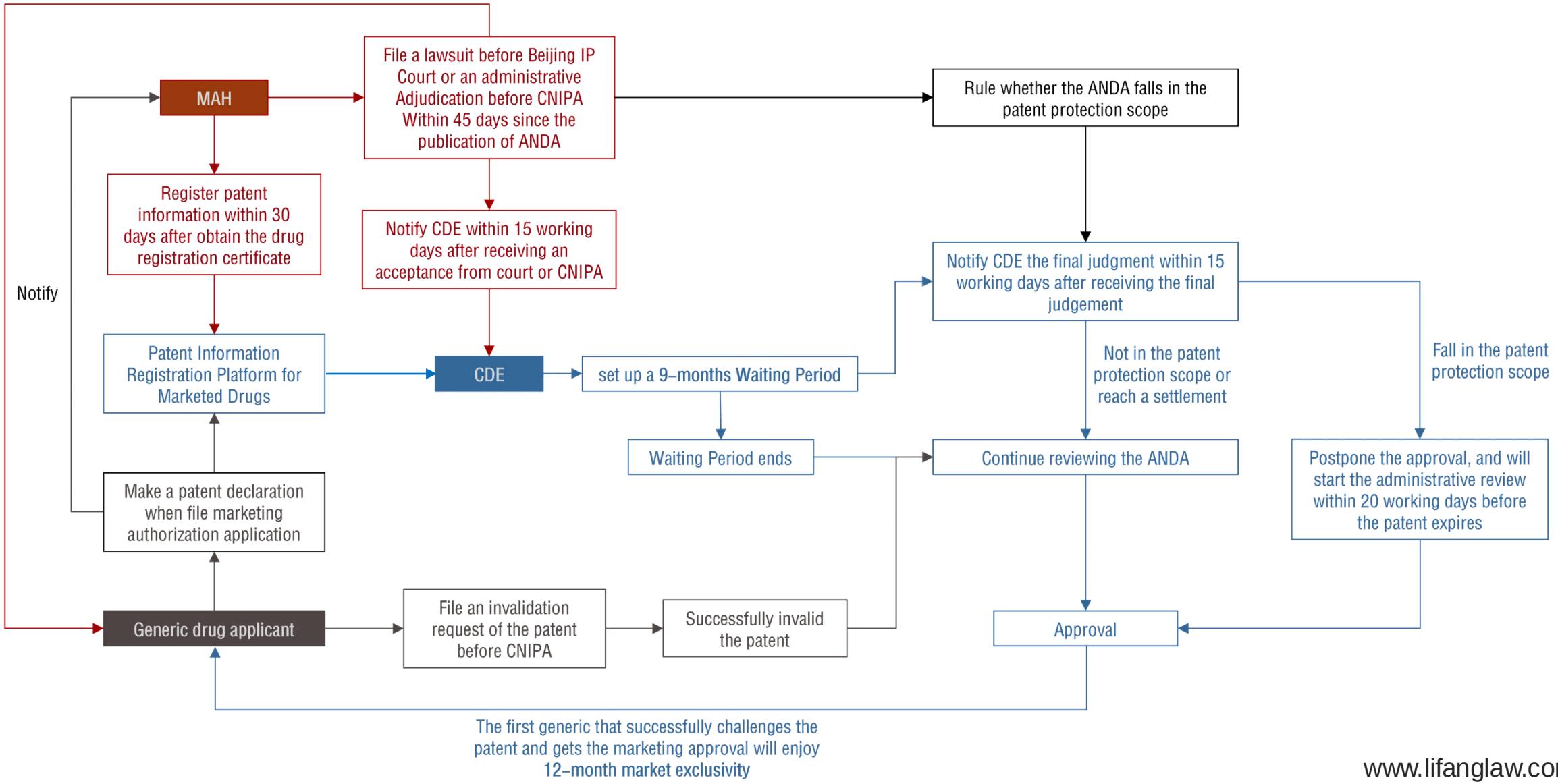

Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial Version)

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	Relevant provisions
Create Chinese "orange book"	Article 2. The drug regulatory department of the State Council shall establish a Patent Information Registration Platform for Drugs Marketed in China so as to allow drug marketing authorization holders to register the patent information relating to drugs registered and marketed in China.
Registering patents	Article 4. The MAH for a drug shall, within 30 days upon obtaining the drug registration certificate, independently register such information as……. In case of any change to relevant information, the MAH shall complete the update within 30 days after the change takes effect.
Making patent declarations	Article 6. When submitting marketing authorization application for a chemical generic drug, an applicant shall, by referring to the patent information that is made public on the Platform, make a declaration in regard to each drug patent pertaining to the innovator drug.
Patentee/ Interested party file lawsuits	Article 7. Where a patentee or interested party has any objection in regard to the aforesaid category IV patent declaration, it may, within 45 days upon the disclosure of the drug marketing authorization application by the national drug evaluation institution, file a lawsuit to the people's court or apply to the Patent Administrative Department under the State Council for an administrative adjudication regarding whether the technical solution pertaining to the drug under the application for marketing authorization falls within the protection scope of the relevant patent.

China Patent Information Registration Platform for Marketed Drugs (CPIRPMD)

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Patent declarations issued by generic drug applicants

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China	US
Category I declaration: No patent information related to the innovator drug is found on the Platform;	**Paragraph I certification:** when patent is not submitted for drug candidate (No Patent in Orange book).
Category II declaration: The patent pertaining to the innovator drug included in the Platform **has been terminated or invalidated**, or the generic drug applicant has obtained patent license from the patentee;	**Paragraph II certification:** the patent has already expired;
Category III declaration: The relevant patent of the innovator drug has been included in the Platform and the generic drug applicant undertakes that the generic drug under the application will not be marketed prior to the expiration of the valid term of the corresponding patent;	**Paragraph III certification:** the date on which the patent will expire, and that the generic drug will not go on the market until that date passes;
Category IV declaration: **4.1** The patent pertaining to the innovator drug included in the Platform **shall be invalidated** or **4.2** The corresponding generic drug does not fall within the scope of relevant patent protection.	**Paragraph IV certification:** the patent is not infringed or is invalid.

Judicial approach – first court case under the patent linkage system

Administrative approach – first CNIPA case under the patent linkage system

Timelines of Judicial v. Administrative approach

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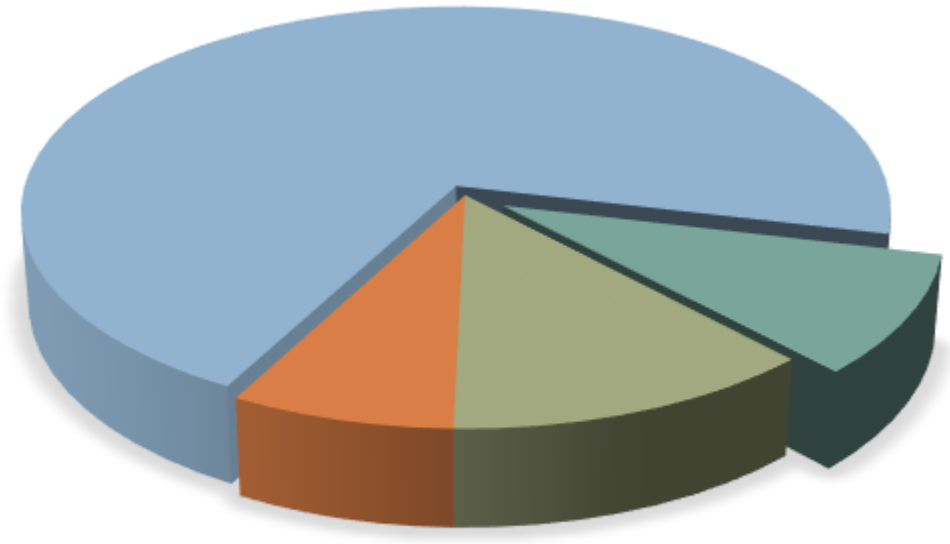
Court		
	Time	Events
First-instance	2021.09.21	File the complaint
	2021.11.08	Accepted by Beijing IP Court
	2021.12.01	First online pre-hearing interview
	2021.12.02	First evidence exchange session
	2022.01.05	Second online pre-hearing interview
	2022.01.24	Third online pre-hearing interview
	2022.02.28	Second on-spot evidence exchange session
	2022.03.10	Online hearing
	2022.04.15	Judgement issued (online)
Second-instance	2022.05.23	Accepted by IP Tribunal of Supreme Court
	2022.07.05	Hearing in private
	2002.08.05	Final judgment issued

CNIPA	
Time	Events
2021.10.26	File the request
2021.10.29	Accepted by CNIPA
2021.12.24	First evidence exchange session
2022.01.04	First pre-hearing interview
2022.01.25	Second evidence exchange session
2022.02.08	Third evidence exchange session
2022.03.03	Second pre-hearing interview
2022.04.11	Oral hearing
2022.04.22	Decision issued

Patent declarations issued by generic drug applicants – by 30 Sep. 2023



Category I	Category II	Category III	Category IV
5238	688	912	547

- **NMPA received 100 applications for setting up Waiting Periods for generic drugs, including 63 cases accepted by the CNIPA and 47 cases filed before the Beijing IP court (10 cases overlapped);**
- **80 generic drugs have been set up with Waiting Periods (49 cases filed by the CNIPA and 31 cases filed by the court, respectively), of which 17 cases were found falling within the scope of patent protection (13 administrative rulings by the CNIPA and 4 judgments by the courts).**

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Eligibility of Class 3 Chemical Drug under Chinese Durg Patent Linkage System

Implementing Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial Version)

	Relevant provisions
Create Chinese "orange book"	Article 2. The drug regulatory department of the State Council shall establish a Patent Information Registration Platform for Drugs Marketed in China so as to allow drug marketing authorization holders to register the patent information relating to drugs registered and marketed in China.
Registering patents	Article 4. The MAH for a drug shall, within 30 days upon obtaining the drug registration certificate, independently register such information as……. In case of any change to relevant information, the MAH shall complete the update within 30 days after the change takes effect.
Making patent declarations	Article 6. When submitting marketing authorization application for a chemical generic drug, an applicant shall, by referring to the patent information that is made public on the Platform, make a declaration in regard to each drug patent pertaining to the innovator drug.
Patentee/ Interested party file lawsuits	Article 7. Where a patentee or interested party has any objection in regard to the aforesaid category IV patent declaration, it may, within 45 days upon the disclosure of the drug marketing authorization application by the national drug evaluation institution, file a lawsuit to the people's court or apply to the Patent Administrative Department under the State Council for an administrative adjudication regarding whether the technical solution pertaining to the drug under the application for marketing authorization falls within the protection scope of the relevant patent.

Uniqueness in Registration Classification of Chemical Drugs

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US

The source of reference listed drug recognized under 505(j) of the FDCA is the U.S. Orange Book (FDA reference listed drugs are limited to drugs marketed in the U.S.)

China

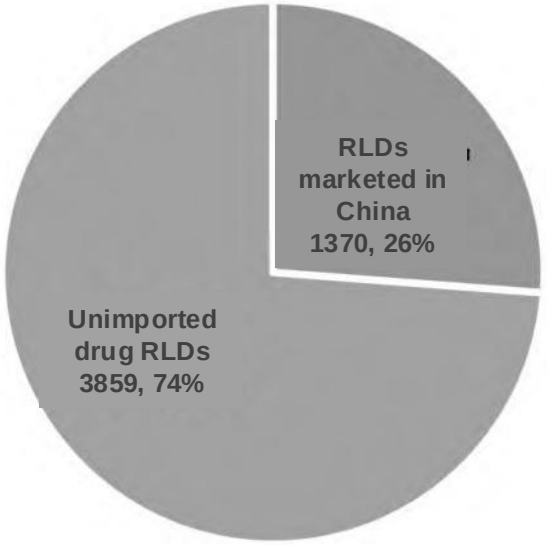

图1　1～57 批已发布参比制剂情况

Statistics of “reference listed chemical drug” issued by NMPA

Eligibility of Class 3 Chemical Drugs

	Categories	Description of Chemical Drug Product (2020)
Originator drugs	Class 1	Innovative new drugs that do not have marketing authorizations in or outside China.
Originator drugs	Class 2	Improved new drugs that do not have authorization in or outside China: drugs are optimized in terms of structure, dosage form, manufacturing process, route of administration, indications, etc. on the basis of a known active ingredient and that have distinct clinical advantages (which can be further subdivided into classes 2.1, 2.2, 2.3 and 2.4).
Generic drugs	Class 3	Domestic generic drugs of the original drugs which have been granted marketing authorization only outside China
Generic drugs	Class 4	Domestic generic drugs of the original drugs which have been granted marketing authorization in China
Imported drugs (Originator + Generic)	Class 5	**Imported drug products which have been granted marketing authorization outside China and are applying for marketing authorization in China** (which can be further subdivided into classes 5.1 and 5.2).

Eligibility of Class 3 Chemical Drugs

- Taking into account the registration and classification system of chemical drugs in China, it appears that the current version of Chinese Drug Patent Linkage System (V1.0) would only apply to **"Class 4 chemical drugs"**, but not to ""**Class 3 chemical drugs"**. **Accordingly, a big portion of generic chemical drugs would be excluded from the system.**

- The possible legislative intents underlying such settings:
  - To promote the early launch of originator drugs in China (to improve drug accessibility in China).

- Is there any loophole associated with such settings?

Eligibility of Class 3 Chemical Drugs

- Per NMPA's Requirements for Registration Classification of Chemical Drugs:
  - **Class 3 chemical drug**: Drugs that are manufactured by domestic applicants by imitating the originator drugs that **have been marketed overseas but not yet in China**, shall have **identical** **active ingredients, formulations, strengths, indications, routes of administration, usages and dosages** with those of the reference listed drugs, and have **proven consistency of quality and efficacy** with those of the reference listed drugs;
  - **Class 4 chemical drug**: Drugs that are manufactured by domestic applicants by imitating the originator drugs that **have been marketed in China**, shall have **identical** **active ingredients, formulations, strengths, indications, routes of administration, usages and dosages** with those of the reference listed drugs, and **have proven consistency of quality and efficacy** with those of the reference listed drugs."
- In practices, so long as **any one of the factors** is different in the generic drug, such as **active ingredient, formulation, strength, indication, route of administration, usage and dosage**, the generic drug might be treated as a **new drug** and be assigned a different NMPA's review and approval process.

Eligibility of Class 3 Chemical Drugs

- E.g., **different formulation** of the **same API** could end up in different categories:

	Capsule Form	Tablet Form
Originator drug marketed in China	Yes	No
Chemical drug category the Generic drug may claim when filing ANDA	Class 4 chemical drug	Class 3 chemical drug

Eligibility of Class 3 Chemical Drugs

- E.g., even for the **same formulation** of the **same API**, different strength could end up in different categories:

	Powder for Injection (10mg)	Powder for Injection (30mg)	Powder for Injection (60mg)
Originator drug marketed in China	No	No	Yes
Chemical drug category the Generic drug may claim when filing ANDA	Class 3 chemical drug	Class 3 chemical drug	Class 4 chemical drug

Eligibility of Class 3 Chemical Drugs

- E.g., **different formulation** of the **same API** could end up in different categories:

	Capsule Form	Tablet Form
Originator drug marketed in China	Yes	No
Chemical drug category the Generic drug may claim when filing ANDA	Class 4 chemical drug	Class 3 chemical drug

What good it may achieve if these generic drugs are excluded from drug patent linkage system?

Eligibility of Class 3 Chemical Drugs

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- E.g., even for the **same formulation** of the **same API**, different strength could end up in different categories:

	Powder for Injection (10mg)	Powder for Injection (30mg)	Powder for Injection (60mg)
Originator drug marketed in China	No	No	Yes
Chemical drug category the Generic drug may claim when filing ANDA	Class 3 chemical drug	Class 3 chemical drug	Class 4 chemical drug

1) What good it may achieve if these generic drugs are excluded from drug patent linkage system?
2) Can generic drug easily change its drug strengths to purposely avoid being categorized as class 4 chemical drug?

Eligibility of Class 3 Chemical Drugs

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Case I: Palbociclib

- **Same active ingredient but with different formulations**
- The originator drug being **capsule** was approved in China; whereas the generic drug being **tablet** are under application for marketing authorization.
- The originator drug registered patents for its already marketed **capsules**, **which were active ingredient compound patent covering the relevant capsules and tablets**.
- The generic drug filed ANDA application for **tablets**, which was filed as **Class 3 chemical drug,** and a **category I patent declaration** was made.
- The patentee accordingly initiated drug patent linkage proceedings, arguing that the generic drug applicant had in fact conducted bioequivalence studies using the **tablets** of the originator drug as a reference listed drug and took advantage of the fact the **capsules** of the originator drug is marketed in China, yet it had intentionally disregarded the originator's patents registered for the **capsules** and made a **false Category I declaration**.

Case II: Carfilzomib

- **Same active ingredient and formulation but with different strengths**
- The originator drug as powder for injection was approved **outside China** in **three strengths of 10/30/60mg**, but only a **single strength of 60mg** was applied and approved **in China**.
- The originator drug registered patent covering the active ingredient compound of the drug.
- The generic drug filed ANDA applications for all **three strengths of 10/30/60mg**; **the strengths of 10/30mg were applied as Class 3 chemical drugs**, but Category 4 patent declaration was made.
- The patentee accordingly initiated drug patent linkage proceedings.

Focus of Disputes concerning Eligibility of Class 3 Chemical Drugs

- **Viewpoint from Generic Drugs:** Chinese drug patent linkage system purposely exclude Class 3 chemical drugs.

- **Viewpoint from Originator Drugs:** According to the current regulations, the drug linkage system should be interpreted in the following way:
  - Articles of the Implementation Measures only ensure or encourage that the originator drug to be introduced into China as soon as possible;
  - Once the originator drug is introduced in China, the "**relevant patents**" registered should also be available for other relevant drugs (even though these relevant drugs have not been "granted a registration certificate" in China, e.g., drugs with the **same active ingredients** but with **different formulations and/or different strengths),** provided that the relevant drugs are also protected by the **relevant patents**.
  - To deprive the application of Chinse drug linkage system on Class 3 chemical drugs do not help to strike a sensible balance between the originator drugs and generic drugs.
  - To flatly reject all Class 3 chemical drug could eventually destroy the very purpose of the drug patent linkage system.

Eligibility of Class 3 Chemical Drugs

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- **CNIPA/Beijing IP court** conclude that cases with **different formulations** should not be eligible for drug patent linkage system:
  - Despite the identical active ingredient, different formulation mean that the generic drug and the originator drug shall be regarded as two different drugs during the NMPA's review and approval processes; **under such circumstance, the Class 3 chemical drug should not be treated as the originator drug's genuine copy in the true sense,** accordingly the drug patent linkage system should not be used.

- **Supreme Court** supported the above view, by providing the following interpretation of the specific meaning of "each relevant pharmaceutical patent" in Article 6 of the Implementation Measures:
  - **From the perspective of systematic interpretation**....., the "**originator drug**" here should refer to the **originator drug** that has been marketed in China, and the "**relevant patents**" must refer to the **originator drug** that has been marketed in China.

Eligibility of Class 3 Chemical Drugs

- **CNIPA** further acknowledges that that cases with **different strengths** should be eligible for drug patent linkage system:
  - **Firstly, the relevant laws and regulations do not expressly exclude Class 3 generic drugs from the applicable scope of the Implementation Measures.**
  - **Secondly,** such Class 3 chemical drug might be managed according to Class 4 chemical drug standard during the drug review and approval process in practice, to apply drug patent linkage system to this type of Class 3 generic drug could better fulfill the goal of Article 76 of the Chinese Patent Law.

- **The Supreme Court** supports the CNIPA's position in a dictum.

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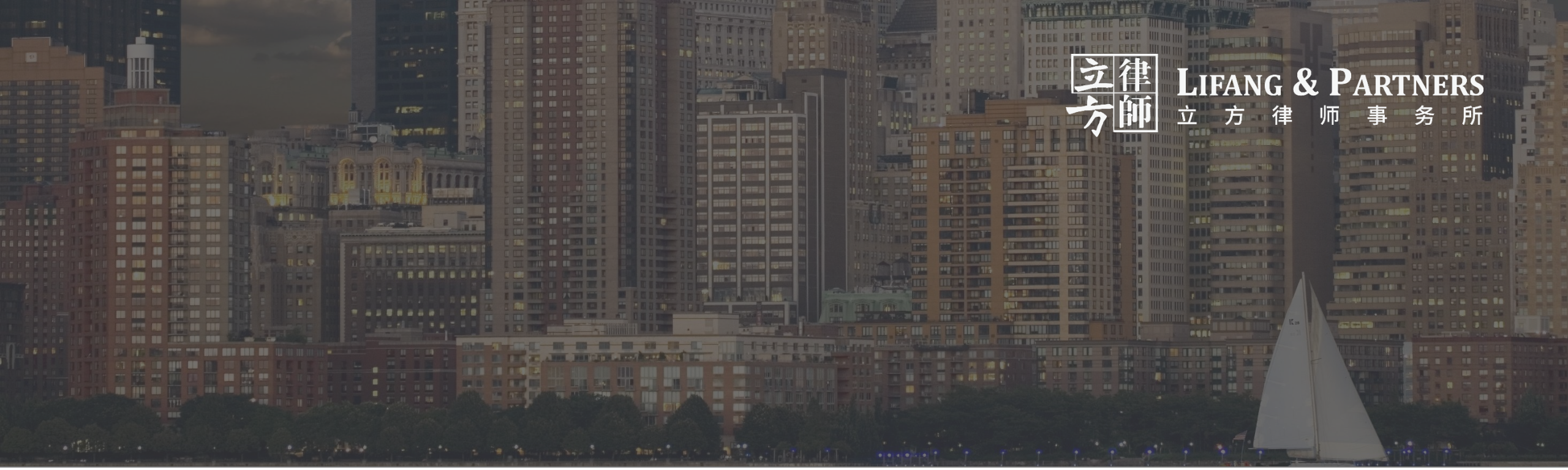

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CONTACT US

欢迎致电
8610-64096099

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info@lifanglaw.com

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Types of patents can be registered (Orange Book in China)

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China	US
Article 5. The MAH for a chemical drug may register on the platform its API compound patent, patent for pharmaceutical composition containing API, and medical use patent.	The Orange Book contains patents on: active pharmaceutical ingredients, polymorph, compositions, formulation, and methods of use.
The MAH for a chemical drug cannot register patents on: intermediates, metabolites, **polymorph**, preparation methods, detection methods, etc.	The Orange Book does not contain patents on: manufacturing processes, packaging, metabolites, intermediates, unapproved uses.