Legal Actions on the Marketing of Generic Drugs

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LEGAL ACTIONS ON THE MARKETING OF GENERIC DRUGS

SPEAKER PROFILE

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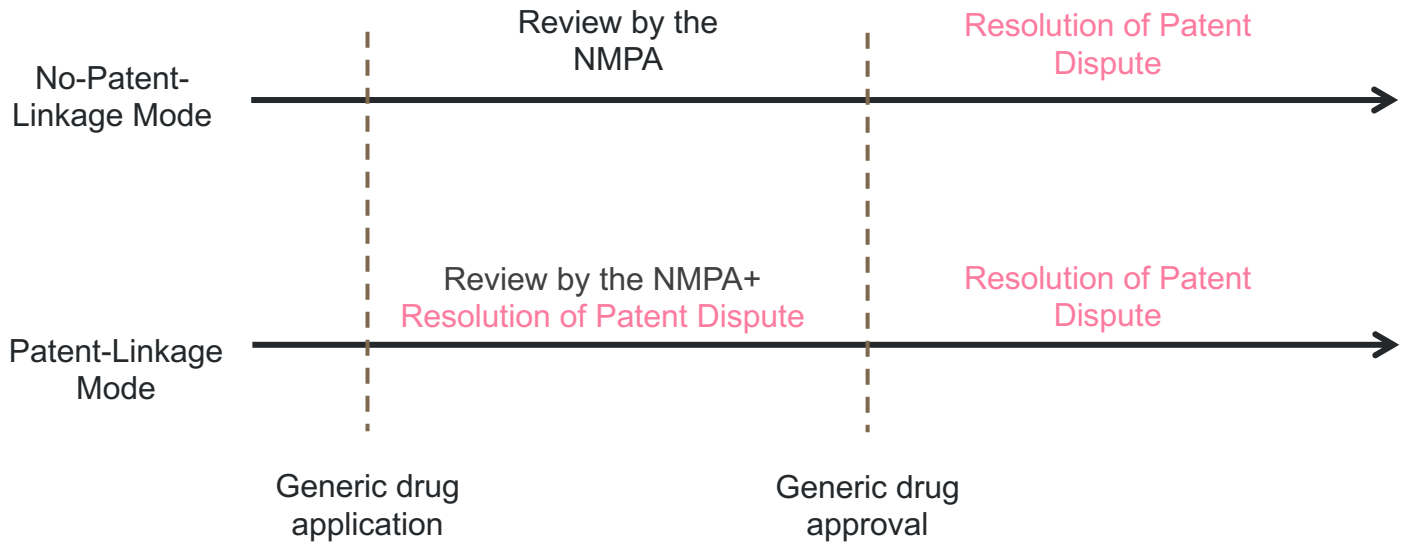
Peking University, University of London

- Ms. TAI has more than 30 years' experience as an IP practitioner, and worked with one of China's largest IP firms for ages as the executive member.
- Ms. TAI is one of the most influential figures in IP law in the pharmaceutical and healthcare sectors.
- Ms. Tai was recognized in the international intellectual property community as one of the World's Leading Patent Practitioners and Leading Lawyer by MIP and IAM for many consecutive years.
- Ms. Tai was selected as one of the first National IP Leading Experts
- Ms. Tai was awarded by the CNIPA as one of the "First Leading Patent Attorneys in China".
- Representative Cases
  - Represented Pfizer Inc. in the high-profile Viagra® (Sildenafil) case;
  - Represented AstraZeneca in the Ticagrelor Case;
  - Represented Novartis in the Glivec Case;
  - Represented Roche in the Actemra Patent Linkage Case;
  - Represented Roche in the Xofluza® Patent Linkage Case;
  - Represented Novo Nordisk in an important drug patent case; and
  - Represented Novartis in an important drug patent case.

SUCCESSFUL CASES

The drug patent linkage system refers to the linkage between the marketing approval of generic drugs and the expiration of the patents of innovative drugs.

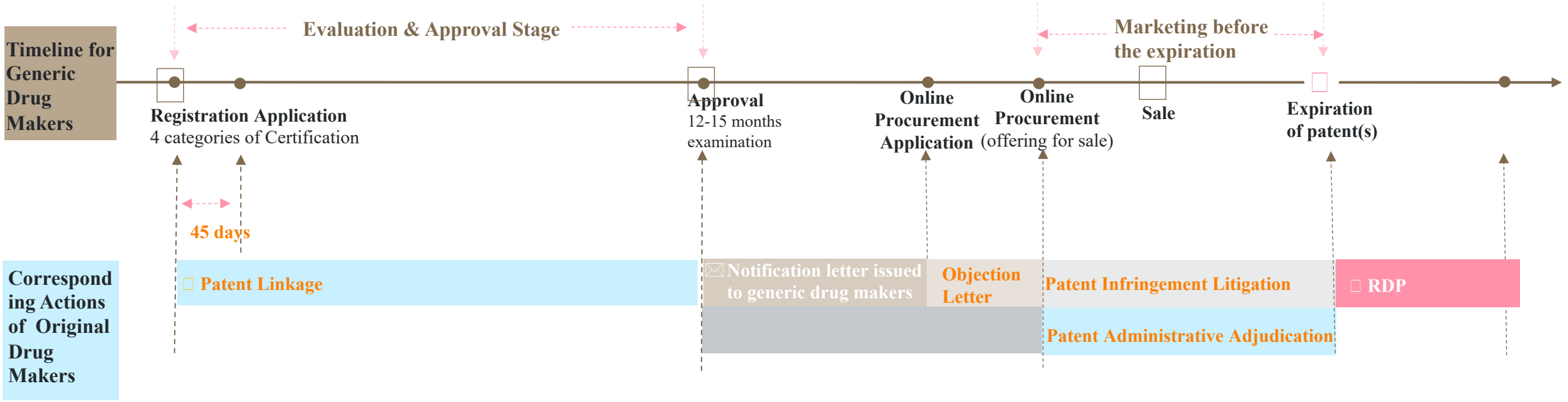


PATENT LINKAGE PROCEDURE

Development History

• June 1, 2021	***Patent Law of the People's Republic of China***	✓ Article 76 formally establishes the drug patent linkage and requires the formulation of convergence approach
• July 04, 2021	***Implementation Measures for a Mechanism for Early Resolution of Drug Patent Disputes (Trial)***	✓ Implementation Measures drug patent linkage
• July 05, 2021	***Guidelines on Several Issues Regarding the Application of Law in Adjudicating Civil Patent Cases Relating to Drug Registration***	✓ Civil litigation rules
• July 05, 2021	***Measures for Administrative Adjudication Concerning Early Resolution of Drug Patent Disputes***	✓ Administrative adjudication rules
• December 30, 2022	***Opinions on Strengthening the Protection of Intellectual Property Rights in the Field of Centralized Pharmaceutical Procurement***	✓ CNIPA + CNHSA Centralized Procurement + Patent

ACTIONABLE GUIDANCE



LEGAL ACTIONS

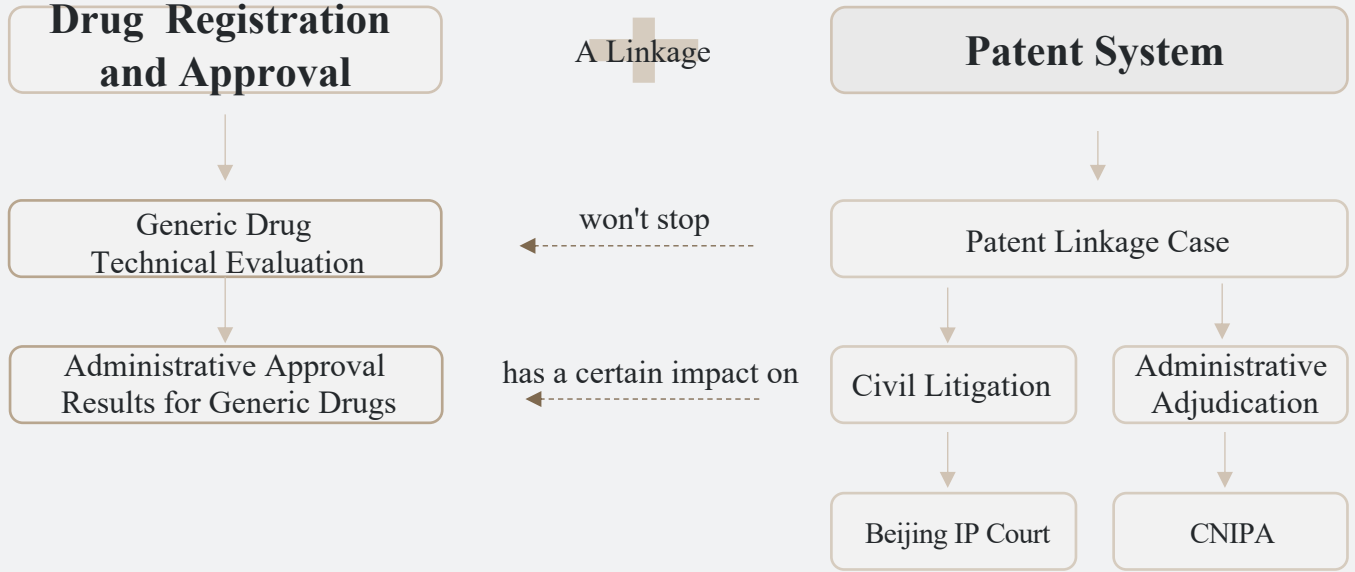
Patent Linkage

Linkage between Patent and Centralized Procurement

Offering for sale : centralized online procurement application

PATENT LINKAGE PROCEDURE

Graphical System



PATENT LINKAGE PROCEDURE

Record Procedure:

- Self-registration by the MAH within 30 days of obtaining the drug registration certificate
- Submission to the NMPA
- Publicity of information related to approved drugs via the Chinese Marketed Drug Patent Information Record Platform (DPIRP)

PATENT LINKAGE PROCEDURE

- Category I Certification: The related patent information is not recoded on the DPIRP;
- Category II Certification: The original drug patent included in the DPIRP has expired or been invalidated, or the generic drug applicant has been licensed with related patent by the patentee;
- Category III Certification: The original drug patent is included in the DPIRP, and the generic drug applicant commits not to market the proposed generic drug until the corresponding patent expires;
- Category IV Certification: The original drug patent included in the DPIRP **should be invalid**, or the generic drug **does not fall within the protection scope of the relevant patent.**

PATENT LINKAGE PROCEDURE

Item	Administrative Adjudication	Civil Litigation
Jurisdiction Institution	CNIPA	Beijing IP Court
Term	Short	Long
Investigation and Evidence Collection	A specific staff is put in charge of getting the generic drug application materials	A generic drug applicant is responsible for submitting generic drug application materials
Technical Understanding	Deep	Not Deep
Previous Infringement Cases Experience	Less	More

OBJECTIONS BASED ON PATENT INFRINGEMENT

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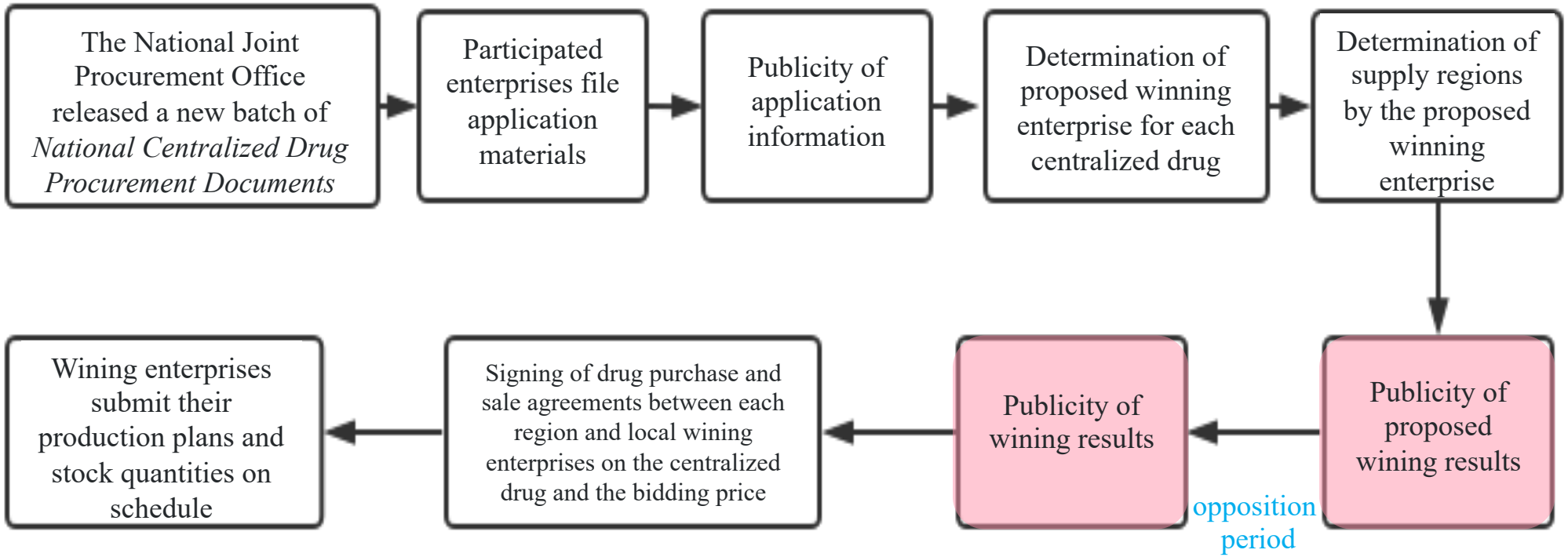
(4) Establish a system for self undertaking by enterprises.

Where an enterprise participates in centralized procurement or apply for listing of drugs and medical consumables on the centralized pharmaceutical procurement platform (hereinafter referred to as the online procurement), it must undertakes by itself that the relevant products do not violate the "Patent Law of the People's Republic of China" and other relevant laws and regulations.

If a centralized pharmaceutical procurement organ receives objections based on patent infringement of relevant products, intellectual property administration departments can be requested to issue a consultation or infringement determination opinion within the designated time limit for enterprises to participate in centralized procurement or apply for online procurement, as a reference for whether to allow related products to participate in centralized procurement or online procurement.

OBJECTIONS BASED ON PATENT INFRINGEMENT

National Centralized Drug Procurement (NCDP) Procedures



OBJECTIONS BASED ON PATENT INFRINGEMENT

Publicity of national proposed wining results of Centralized Drug Procurement

Issue Date: March, 29, 2023 【字体大 中 小】

To whom it may concern,

The national proposed wining results of Centralized Drug Procurement (procurement document number: GY-YD2023-1) are now published as below, please see the attachment for details.

During the publicity period, any objection should be brought to the National Joint Procurement Office with legal and valid evidence materials before the publicity deadline. Late objections will not be accepted. The National Joint Procurement Office will, in principle, not accept any failure to provide the appropriate evidential material.

Publicity time: March 30, 2023 to April 1, 2023

Acceptance time: March 30, 2023 to April 1, 2023

(Omitted)

- Prepare information in advance
- Timely initiation of objections
- Support with appropriate evidence

OBJECTIONS BASED ON PATENT INFRINGEMENT

(6) The healthcare security department should guide the centralized pharmaceutical procurement organ to reject the application for online procurement of the involved products, according to an administrative ruling or an effective judgment.

For the products that have been listed for online procurement or have been selected in centralized procurement, measures such as withdrawal from the online platform or cancellation of qualification of being selected should be promptly taken.

CENTRALIZED ONLINE PROCUREMENT APPLICATION CONSTITUTES OFFERING TO SALE

Typical Case: (2021) SPC Z. M. Z. No. 1158

Sandoz (China) Pharmaceutical Co., Ltd. *vs.* Jiangsu Hansoh Pharmaceutical Group Co., Ltd.
An appeal in a dispute over infringement of a patent for an invention

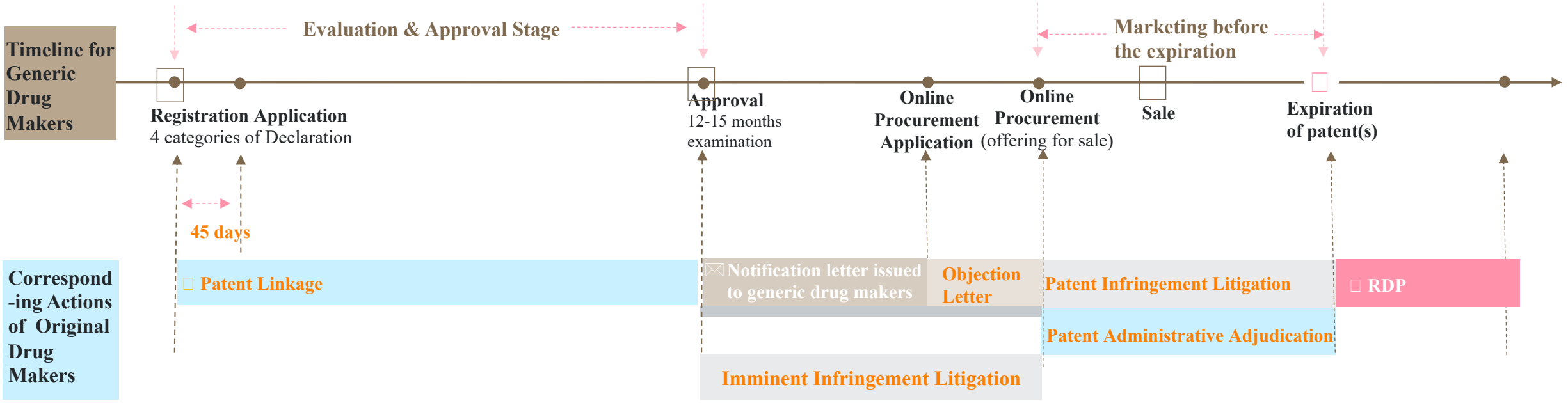
The Supreme People's Court：

The application act of a generic drug makers submitting the declaration of enterprise and drug qualification materials through the local drug centralized procurement platform during the patent protection period of the original drug should be deemed as offering to sale.

On the one hand, the application is an expression of intention to prepare for commercialization of related generic drugs. On the other hand, the relevant reporting behavior shows that it has clearly expressed its willingness to supply its own generic drugs to unspecified persons.

Whether the application was subject to administrative approval and whether the relevant drug was eventually successfully listed on the centralized drug procurement platform did not materially affect the aforementioned finding.

ACTIONABLE GUIDANCE



THANKS！

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