China's Pharmaceutical Patent Linkage System

Scott A. McMurry, PhD
Counsel
New York

Jing Zhang
Partner
Washington DC

Yang Luo
Zhilin Law

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In 2020 Article 76 was Added to China's Patent Law to Establish a Small Molecule Drug Patent Linkage System

- In the process of drug marketing review and approval, if a drug marketing license applicant and the relevant patentee or interested party have disputes over the patent rights related to the drug for which registration is being applied, the relevant parties may file a lawsuit with the People's Court, requesting a judgment on whether the generic drug applied for registration infringes the scope of protection of others' drug patent rights. Upon a judgment of the People's Court on this issue, the Drug Regulatory Department of the State Council may, within the prescribed time limit, decide whether to suspend the approval for marketing of the generic drug.
- The applicant for a generic drug marketing license and the relevant patentee or interested party may also request an administrative ruling from the China National Intellectual Property Administration regarding the patent dispute related to the drug for which registration is applied.
- The Drug Regulatory Department of the State Council in conjunction with the Patent Administration Department of the State Council shall issue specific rules on the connection between approval of a generic drug marketing authorization application and resolution of patent disputes, which shall be implemented after being reported to the State Council for approval.

Timeline of China's Patent Linkage System

On July 4, 2021, the State Food and Drug Administration and the Intellectual Property Office jointly issued the "Implementation Measures for the Early Resolution Mechanism of Drug Patent Disputes (for Trial Implementation)"

On July 5, 2021, the Intellectual Property Office issued the "Administrative Adjudication Measures for the Early Resolution Mechanism of Drug Patent Disputes"

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

On April 15, 2022, the first batch of civil cases involving the early settlement mechanism of patent disputes was pronounced in Beijing Intellectual Property Court

On April 25, 2022, the first batch of administrative adjudication cases of the early resolution mechanism for patent disputes were concluded at the China National Intellectual Property Administration

Registration of Pharmaceutical Patents

- The drug regulatory department of the State Council established a patent information registration platform for drugs authorized in China and for drug marketing license holders to register patent information related to drugs registered in China.
- The drug marketing authorization holder is required to, within 30 days after obtaining the drug registration certificate, self-register the drug name, dosage form, specification, marketing authorization holder, relevant patent number, patent title, patentee, patent licensee, patent authorization date, he expiration date of the patent protection period, the patent status, the type of the patent, the correspondence between the drug and the relevant patent claims, the mailing address, the contact person, the contact information, etc. If the relevant information changes, the drug marketing authorization holder shall update the registration within 30 days after the information change takes effect.

Types of Patents that can be Registered

- **Chemical drugs:** patents on small molecule active pharmaceutical ingredients; pharmaceutical compositions containing the active ingredient; medical uses of the active ingredient
- **Chinese medicine:** patents on Chinese medicine compositions; Chinese medicine extracts; and their medical uses
- **Biologic drugs:** patents on the sequence of the active ingredient; medical uses of the active ingredient
- **Types of Patents that can not be Registered:** patents on intermediates; metabolites; crystal forms; preparation methods; and detection methods

Generic Drug Applications

- When an applicant for a chemical (small molecule) generic drug submits an application for a drug marketing authorization, it shall make a statement on each listed drug patent relevant to the generic drug in accordance with the patent information that has been published on China's Listed Drug Patent Information Platform.

Required Patent Statements

- The statements that a generic applicant must make are divided into four categories

1. No patent information related to generic drugs is listed in China's Listed Drug Patent Information Registration Platform
2. The patent rights related to generic drugs included in China's Listed Drug Patent Information Registration Platform have been terminated or declared invalid, or the generic drug applicant has obtained a license to the patentee's relevant patents
3. China's Listed Drug Patent Information Registration Platform in China includes patents related to the generic drugs, and the generic drug applicant promises that the generic drugs it applies for will not be sold prior to the expiration of the relevant listed patent right
4. The patent rights related to generic drugs included in the Chinese Listed Drug Patent Information Registration Platform are **invalid (category 4.1)**, or the generic drugs **do not infringe the listed patent rights (category 4.2)**

Required Patent Statements (cont'd)

- Within 10 working days after a generic drug application is accepted, the national drug review agency shall disclose the application information and corresponding statement to the public on the information platform; the generic drug applicant shall notify the marketing authorization holder of the corresponding statement and the basis for the statement, and if the marketing authorization holder is not the patentee, the marketing authorization holder shall notify the patentee.
- Where the statement is that the generic drug does not fall within the scope of protection of the relevant patent right, the basis for the statement shall include the comparison table of the relevant claims of the generic drug technical scheme and the relevant patent and relevant technical data. In addition to the paper materials, the generic drug applicant should also send the statement and the basis for the statement to the e-mail address of the marketing authorization holder registered on the China Listed Drug Patent Information Registration Platform, and keep relevant records.

Deadlines

- If the patentee or interested party has any objection to the generic applicant's patent statement, they may, within 45 days from the date when the national drug review agency publishes the application for drug marketing authorization, determine whether the generic drug applied for falls within the scope of protection of the relevant patent rights and file a lawsuit in the People's Court or request an administrative ruling from the China National Intellectual Property Administration.

- If a patentee or an interested party files a lawsuit or requests an administrative ruling within the prescribed time limit, it shall submit a copy of the notice of filing or acceptance of the case to the National Drug Evaluation Department within 15 working days from the date when the People's Court files the case or the China National Intellectual Property Administration accepts the case, and notify the generic drug applicant of the same. After receiving a copy of the People's Court's notification of filing of the case or the notification of acceptance by the China National Intellectual Property Administration, the Drug Regulatory Department of the State Council shall set a waiting period of nine months for the application for registration of the chemical generic drug. The waiting period is set only once—either from the date the case is filed by the People's Court or the date the case is accepted by the China National Intellectual Property Administration. The National Drug Evaluation Agency will not stop its evaluation of the generic drug application but will not approve the generic drug during the waiting period.

Outcomes

- If it is confirmed that the generic drug falls within the scope of protection of the relevant patent right, the registration application for the relevant chemical generic drug will be transferred for administrative examination, but approval of the generic drug will be prohibited prior to the expiration of the relevant patent right.
- If it is confirmed that the generic drug does not fall within the scope of protection of the relevant patent rights or if the parties have settled, the relevant chemical generic drug registration application shall be transferred for approval in accordance with established procedures.
- If the relevant patent right is determined to be invalid, the relevant chemical generic drug registration application shall be transferred for administrative examination and approval according to established procedures.
- If the 9-month waiting period passes and the Drug Regulatory Department of the State Council has not received a final judgment or settlement letter from the People's Court, or a final administrative ruling from the China National Intellectual Property Administration, the relevant chemical generic drug registration application will be transferred for administrative examination and approved in accordance with established procedures.

Outcomes (cont'd)

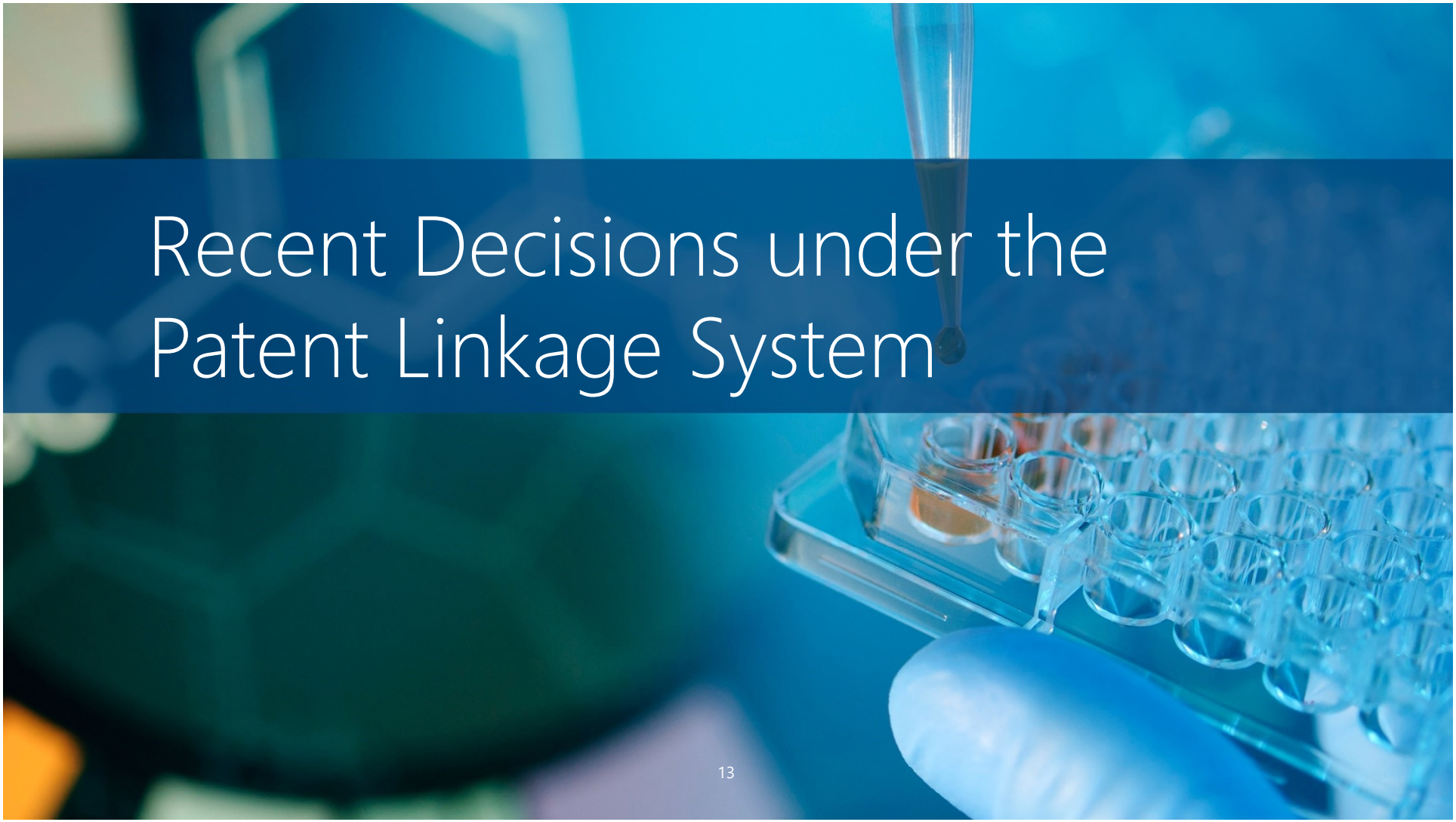
- If the Drug Regulatory Department of the State Council receives a final judgment from the People's Court or a final administrative ruling from the China National Intellectual Property Administration stating that the generic drug falls within the scope of protection of the relevant patent rights, the Drug Regulatory Department shall transfer the chemical generic drug registration application to the National Drug Evaluation Department. The National Drug Evaluation Department is authorized to evaluate the generic drug registration application even while the relevant patent rights are still in force but may not approve it.

- After the Drug Regulatory Department of the State Council has made a decision to suspend approval, if 1) the People's Court overturns the administrative ruling 2) the two parties settle, 3) the relevant patent right is declared invalid, or 4) if the patentee or other party withdraws the lawsuit or the request for administrative ruling, the generic drug applicant may apply to the Drug Regulatory Department of the State Council for approval of the generic drug, and the department may make a decision on whether or not to approve the generic drug.

Generic Exclusivity

- A market exclusivity period will be given to the first chemical generic drug applicant who successfully challenges the patent and is approved for marketing. The Drug Regulatory Department of the State Council will not approve the marketing of another of the same variety of generic drug within 12 months from the date of approval of the first generic drug. When two or more generic drug applicants jointly challenge the patent and are successful, all joint challengers will receive the 12 months of market exclusivity. However, the term of generic drug market exclusivity shall not exceed the term of the original patent(s) that were successfully challenged.

- A successful patent challenge means that the chemical generic drug applicant submits a category 4.1-compliant declaration, and the relevant patent right is declared invalid according to the request for invalidation of the patent right, so that the generic drug can be approved for marketing.

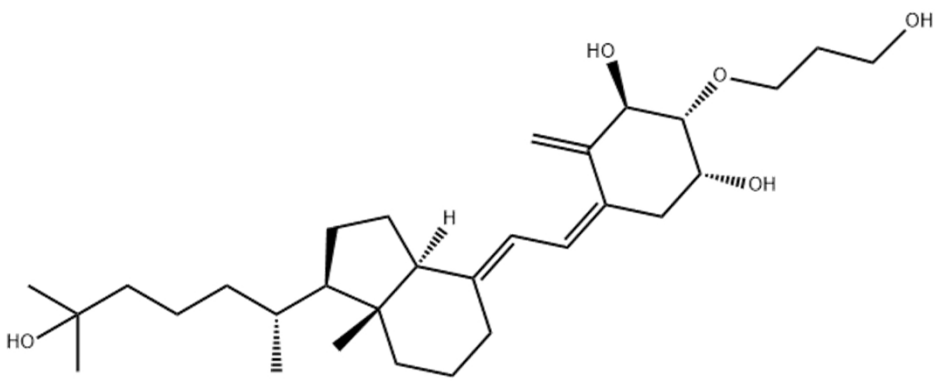


Recent Decisions under the Patent Linkage System

Decisions to date

- To date, a total of 11 marketed drugs have received 4.1-compliant (invalidity) declarations
- The China National Intellectual Property Administration received 59 requests for administrative adjudication, and accepted 39 cases as meeting the acceptance criteria
- On April 15, 2022, the first decisions in lawsuits under the early settlement mechanism of patent disputes were pronounced by the Beijing Intellectual Property Court
- On April 25, 2022, the first decisions in administrative adjudications under the early resolution mechanism for patent disputes were issued by the China National Intellectual Property Administration

Eldecalcitol case



- **Patent No.:** ZL200580009877.6
- **Patent name:** ED-71x preparation
- **Drug:** Eldecalcitol Soft Capsules
- **Patentee/Plaintiff:** Chugai Pharmaceutical Co., Ltd
- **Defendant:** Wenzhou Haihe Pharmaceutical Co., Ltd
- **Cause of Action:** Whether the generic drug infringes the patent

Eldecalcitol case

当前位置：首页 > 专利声明列表

药品类型：请选择　批准文号/注册证号：请输入批准文号/注册证号　受理日期：请选择受理日期

受理号：请输入受理号　药品名称：艾地骨化醇　企业名称：请输入企业名称

查找

化学仿制药/中药同名同方药/生物类似药信息				被仿制药相关信息		专利声明
受理号	药品类型	注册分类	申请人名称	批准文号/注册证号	持有人名称	
CYHS2200324国	化学药品	4类	南京海融医药科技股份有限...	国药准字HJ20200057	Chugai Pharmaceutical Co.,...	查看
CYHS2200325国	化学药品	4类	南京海融医药科技股份有限...	国药准字HJ20200058	Chugai Pharmaceutical Co.,...	查看
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CYHS2101447国	化学药品	4类	四川国为制药有限公司	国药准字HJ20200058	Chugai Pharmaceutical Co.,...	查看

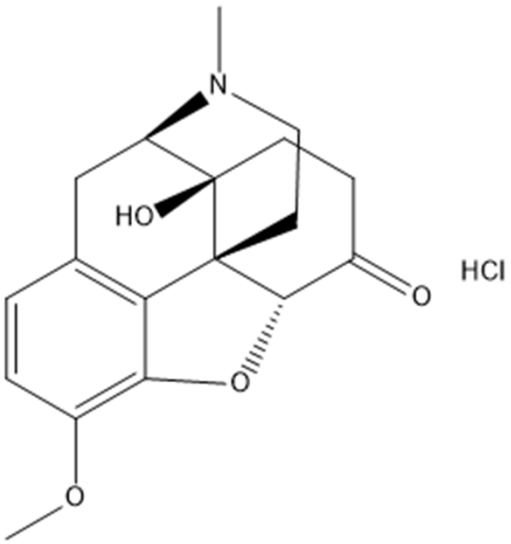
Eldecalcitol case

- On April 15, 2021, Sichuan Guowei Pharmaceutical Co., Ltd. filed a request for invalidation of this patent with the China National Intellectual Property Administration
- On June 10, 2021, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. filed a request for invalidation of this patent with the China National Intellectual Property Administration
- On August 16, 2021, Wenzhou Haihe Pharmaceutical Co., Ltd. made a Category 4.2 statement on Eldicalcidol Soft Capsules
- On November 10, 2021, Beijing Intellectual Property Court accepted the lawsuit of Zhongwai Pharmaceutical Co., Ltd.
- On December 30, 2021, the China National Intellectual Property Administration rendered invalidation decision no. 53498, declaring that this patent is invalid
- On April 15, 2022, the Beijing Intellectual Property Court ruled that the plaintiff's did not establish that the generic drug falls within the scope of protection of claims 1-6 of the patent involved

Eldecalcitol case

- **1. A formulation , comprising**：
  - (1) (5Z,7E)-(1R,2R,3R)-2-(3-Hydroxypropoxy)-9,10-Cholesterol-5,7,10(19)-triene-1,3,25-triol;
  - (2) Lipids; and
  - (3) an antioxidant; the antioxidant is d-1-α-tocopherol
  - Wherein, the antioxidant inhibits degradation of the compound after 12 months of storage at room temperature in the dark to produce [certain named compounds] at 1% or less.

Oxycodone Hydrochloride Sustained Release Tablets Case



- **Patent No.:** ZL201210135209.x ZL201510599477.0 ZL201010151552.4
- **Drug:** Oxycodone Hydrochloride Sustained Release Tablets
- **Applicant/Patentee:** Purdue Pharmaceuticals
- **Requestee:** Yichang Humanwell Pharmaceutical Co., Ltd
- **Cause of Action:** Whether the generic drug infringes the patent

China's Drug Patent Information Platform Listing for "Oxycodone Hydrochloride Sustained-Release Tablets"

专利声明详情

化学仿制药/中药同名同方药/生物类似药信息

药品名称：盐酸羟考酮缓释片　　药品类型：

剂型：片剂　　规格：10mg

申请人：宜昌人福药业有限责任公司　　通讯地址：湖北省宜昌开发区大连路19号

联系人：屈钦　　联系电话：0717-6345860

电子邮箱：quqin@renfu.com.cn

被仿制药等相关信息

药品名称：盐酸羟考酮缓释片　　批准文号/注册证号：国药准字HJ20210052

持有人名称：Purdue Pharma L.P.

序号	登记的专利号	登记的权利要求项编号	专利声明类型	备注
1	CN 201210135209.X	1-3, 12, 13, 15, 16, 30-33	4.1类	
2	CN 201510599477.0	1, 2, 17, 18, 20-26, 36, 55, 61, 63	4.1类	
3	CN 201010151552.4	1-3, 10-12, 19-23, 26, 27, 37	4.1类	

ZL201210135209.x

1. A solid oral extended-release pharmaceutical dosage form comprising an extended-release matrix formulation comprising a composition comprising at least the following components:

- (1) At least one polyethylene oxide having an approximate molecular weight of at least 1,000,000 based on rheological measurements; and
- (2) at least one active agent selected from opioid analgesics, wherein the opioid analgesic is oxycodone hydrochloride, and the dosage form comprises 5 mg to 20 mg of oxycodone hydrochloride, and
- wherein the composition comprises at least 80% by weight of polyethylene oxide having an approximate molecular weight based on rheological measurements of at least 1,000,000.

ZL201510599477.0

1. A solid oral extended-release pharmaceutical dosage form comprising an extended-release matrix formulation comprising a composition comprising at least the following components:

- (1) At least one polyethylene oxide having a molecular weight of at least 800,000 based on rheological measurements; and
- (2) at least one active agent selected from opioid analgesics, and
- wherein the composition comprises at least 80% by weight of polyethylene oxide having a molecular weight of at least 800,000 based on rheological measurements.

ZL201010151552.4

- 1. An oxycodone hydrochloride composition containing a level of 14-hydroxycodeinone in an amount of less than 25 ppm.

Oxycodone Hydrochloride Sustained Release Tablets Case Filings

- On September 9, 2021, Yichang Humanwell Pharmaceutical Co., Ltd. made a Class 4.1 statement on oxycodone hydrochloride sustained-release tablets
- On April 25, 2022, the China National Intellectual Property Administration concluded the above three administrative adjudication cases under the early resolution mechanism for drug patent disputes, and confirmed that the technical solutions of the generic drugs did not fall within the scope of the above patent rights.
- At the same time, in the administrative adjudication involving the patent right of invention no. 201010151552.4, the panel also considered the invalidity defence raised by Yichang Humanwell Pharmaceutical Co., Ltd. that the patent was registered in error, and determined that the patent was not invalid.

Summary
Chinese Drug Patent Linkage System

Chinese Medicine Patent Linkage System

- Patent challenges currently are only allowed for chemical drugs, not biological drugs.
- 9-month period for the court or patent office to issue a decision from the date the Drug Regulatory Department receives notification of acceptance of the case
- 12-month market exclusivity period for successful patent challenge
- Two ways to determine whether generic drugs fall under the scope of valid patent protection:
  - File a lawsuit with the Beijing Intellectual Property Court or
  - File for an administrative ruling with the State Intellectual Property Office


Thank you.