

中国遗传资源、传统知识法律保护的经验

China's Experience in IP Legal Protection of Genetic Resources and Traditional Knowledge



2026.03

1

遗传资源保护
Protection of Genetic resource

2

传统知识保护
Protection of Traditional Knowledge

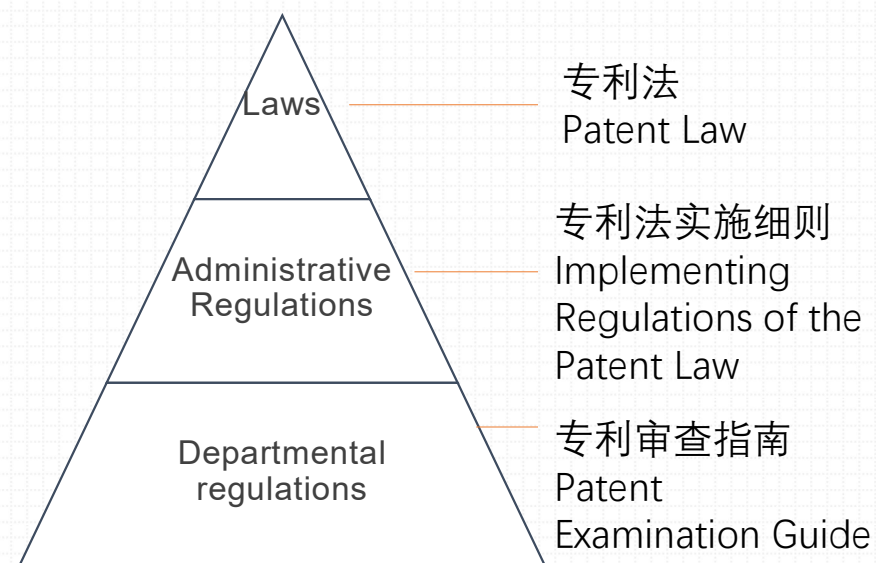
1

遗传资源保护

Protection of Genetic resource

近年来，在专利领域，中国持续完善遗传资源保护的机制，构建起了涵盖法律、行政法规、部门规章等在内的多层次、立体化遗传资源保护制度体系。

In recent years, China has continuously improved its mechanisms for the protection of genetic resources within the patent-related legal framework, establishing a multi-level system that encompasses laws, administrative regulations, and departmental regulations.



1.1 专利法 Patent Law

2008年,《中华人民共和国专利法》第三次修正,增加了关于遗传资源保护的规定:
In 2008, the Patent Law of the People's Republic of China was amended for the third time, introducing provisions on the protection of genetic resources.

➤ 一是增加禁止违法获取或者利用遗传资源的要求

First, it incorporated a requirement of prohibiting the granting of patents for inventions that involve illegal access to and utilization of genetic resources.

第五条第二款 “对违反法律、行政法规的规定获取或者利用遗传资源,并依赖该遗传资源完成的发明创造,不授予专利权。”

Article 5, Paragraph 2 "No patent right shall be granted for any invention-creation where the acquisition or utilization of the genetic resources, on which the development of the invention-creation relies, violates the provisions of laws or administrative regulations."

1.1 专利法 Patent Law

2008年,《中华人民共和国专利法》第三次修正,增加了关于遗传资源保护的规定:
In 2008, the Patent Law of the People's Republic of China was amended for the third time, introducing provisions on the protection of genetic resources.

➤ 二是增加来源信息披露要求

Second, it introduced a requirement for disclosing the source of genetic resources

第二十六条第五款 “依赖遗传资源完成的发明创造, 申请人应当在专利申请文件中说明该遗传资源的直接来源和原始来源; 申请人无法说明原始来源的, 应当陈述理由。”

Article 26, Paragraph 5 : "Where an invention-creation is accomplished by relying on genetic resources, the applicant shall indicate, in the patent application documents, the direct and original source of the genetic resources. Where the applicant fails to indicate the original source, he or it shall state the reasons thereof."

1.1 专利法 Patent Law

2020年, 《中华人民共和国专利法》第四次修正, 维持了上述规定。

In 2020, the Patent Law of the People's Republic of China was amended for the fourth time, and the above provisions were retained.

1.2 专利法实施细则

Implementing Regulations of the Patent Law

《专利法实施细则》（2010修正）

Implementing Regulations of the Patent Law (2010 Amendment)

第二十六条 专利法所称遗传资源，是指取自人体、动物、植物或者微生物等含有遗传功能单位并具有实际或者潜在价值的材料；专利法所称依赖遗传资源完成的发明创造，是指利用了遗传资源的遗传功能完成的发明创造。就依赖遗传资源完成的发明创造申请专利的，申请人应当在请求书中予以说明，并填写国务院专利行政部门制定的表格。

Rule 26 The term "genetic resources" in the Patent Law refers to any material of human, animal, plant, or microbial origin containing functional units of heredity, which has actual or potential value. The term "invention-creation that is completed by relying on genetic resources" in the Patent Law refers to an invention-creation that is completed by utilizing the genetic function of the genetic resources. Where an application is filed for a patent for an invention-creation the development of which relies on the use of genetic resources, the applicant shall state that fact in the request, and fill in the forms provided by the patent administration department under the State Council.

1.2 专利法实施细则

Implementing Regulations of the Patent Law

《专利法实施细则》（2023修正）

Implementing Regulations of the Patent Law (2023 Amendment)

第二十九条 专利法所称遗传资源，是指取自人体、动物、植物或者微生物等含有遗传功能单位并具有实际或者潜在价值的材料**和利用此类材料产生的遗传信息**；专利法所称依赖遗传资源完成的发明创造，是指利用了遗传资源的遗传功能完成的发明创造。

就依赖遗传资源完成的发明创造申请专利的，申请人应当在请求书中予以说明，并填写国务院专利行政部门制定的表格。

Rule 29 The term "genetic resources" in the Patent Law refers to any material of human, animal, plant, or microbial origin containing functional units of heredity, which has actual or potential value, **and the genetic information generated from utilizing such material**. The term "invention-creation that is completed by relying on genetic resources" in the Patent Law refers to an invention-creation that is completed by utilizing the genetic function of the genetic resources. Where an application is filed for a patent for an invention-creation the development of which relies on the use of genetic resources, the applicant shall state that fact in the request, and fill in the forms provided by the patent administration department under the State Council.

遗传资源保护 Protection of Genetic resource

CNIPA

遗传资源来源披露登记表

Registration Form for Disclosure of the Source of Genetic Resource

请按照“注意事项”正确填写本表各栏

第②和第④栏未确定的由国家知识产权局填写

①发明名称		②申请号	
③申请人		④申请日	
⑤遗传资源名称			
⑥遗传资源的获取途径 I 遗传资源取自： <input type="checkbox"/> 动物 <input type="checkbox"/> 植物 <input type="checkbox"/> 微生物 <input type="checkbox"/> 人 II 获取方式： <input type="checkbox"/> 购买 <input type="checkbox"/> 赠送或交换 <input type="checkbox"/> 保藏机构 <input type="checkbox"/> 种子库（种质库） <input type="checkbox"/> 基因文库 <input type="checkbox"/> 自行采集 <input type="checkbox"/> 委托采集 <input type="checkbox"/> 其他			
⑦直接来源	⑧获取时间	____年____月	
	非采集方式	⑨提供者名称（姓名）	
		⑩提供者所处国家或地区	
		⑪提供者联系方式	
	采集方式	⑫采集地（国家、省、市）	
		⑬采集者名称（姓名）	
⑭采集者联系方式			
⑮原始来源	⑯采集者名称（姓名）		
	⑰采集者联系方式		
	⑱获取时间	____年____月	
⑲获取地点（国家、省、市）			
⑳无法说明遗传资源原始来源的理由			
㉑申请人或专利代理机构签字或者盖章		㉒国家知识产权局处理意见	
____年 月 日		____年 月 日	

The name of Genetic Resource

Direct source

Original source

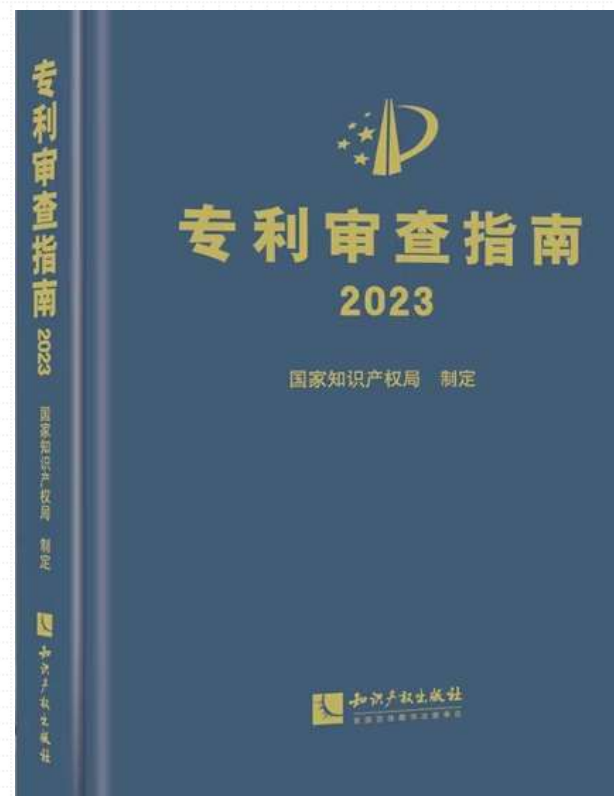
100023
2010.2

1.3 专利审查指南 Patent Examination Guide

定义
defination

专利申请中遗传资源来源披露的审查
Examination Practices on the Applications
Concerning Genetic Resources

违法获取或者利用遗传资源的审查
Examination of Illegal Acquisition or
Utilization of Genetic Resources



1.3 专利审查指南 Patent Examination Guide

定义

defination

- **遗传功能**是指生物体通过繁殖将性状或者特征代代相传或者使整个生物体得以复制的能力。

Genetic function refers to the ability of a living organism to transmit traits or characteristics from generation to generation through reproduction, or to enable the replication of the entire organism.

- **遗传功能单位**是指生物体的基因或者具有遗传功能的 DNA 或者RNA片段。

A genetic functional unit refers to a gene or a DNA or RNA segment with genetic functions in an organism.

- **发明创造利用了遗传资源的遗传功能**…

The utilization of the genetic function of genetic resources …

2

传统知识保护

Protection of Traditional Knowledge

2.1 专利审查中的传统知识保护

Protection of traditional knowledge in patent examination

2023年12月21日，中国国家知识产权局发布第78号局令，修订《专利审查指南》，结合产业发展需求，把握中医药发明创新的特点，在第二部分新增“第十一章 关于中药领域发明专利申请审查的若干规定”，对涉及中药领域发明专利申请审查的特殊情形作出具体规定。

On December 21, 2023, CNIPA issued Order No. 78, revising the Patent Examination Guide. In response to industrial development needs and to capture the characteristics of innovation in traditional Chinese medicine, a new "Chapter 11: Provisions on the Examination of Invention Patent Applications in the Field of Traditional Chinese Medicine" was added to Part Two, providing specific provisions for special circumstances in the examination of invention patent applications in the field of traditional Chinese medicine.

传统知识保护Protection of Traditional Knowledge

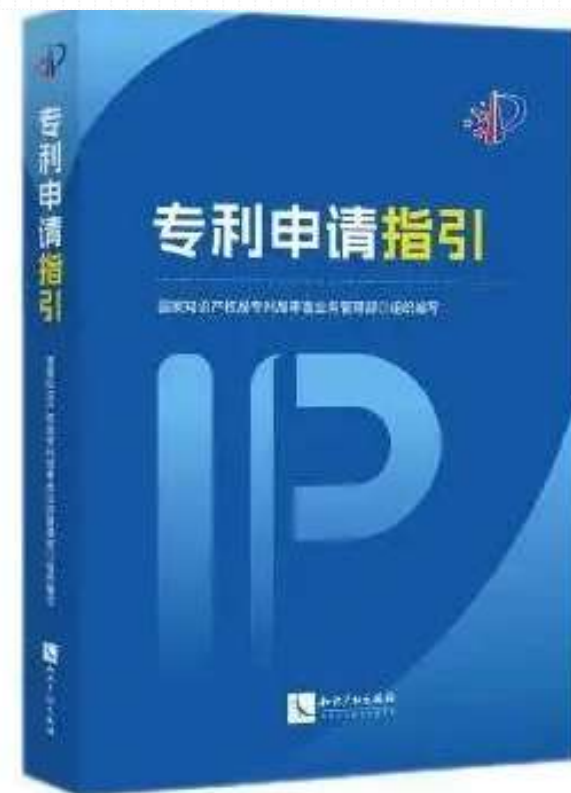
CNIPA

2.1 专利审查中的传统知识保护

Protection of traditional knowledge in patent examination

为使中医药发明创新得到有效和更高质量的专利保护，国家知识产权局2025年出版了《专利申请指引》，立足中医药领域特点和审查实践，给出了中医药专利申请文件的撰写原则和具体指引。

To ensure more effective and higher-quality patent protection for innovations in traditional Chinese medicine (TCM), the China National Intellectual Property Administration issued the Guidelines for Patent Application in 2025 to address prominent issues in current TCM patent application documents and provide principles and specific guidance for drafting.



2.2 商标审查审理中的传统知识保护

protection of traditional knowledge in trademark examination and adjudication

《类似商品和服务区分表》增加了“中药成药”“中药材”“针灸”“拔罐疗法”“医疗按摩”等中医药特有商品和服务。

The Classification of Goods and Services has been updated to include TCM-specific goods and services such as "Chinese Patent Medicines," "Chinese Herbal Medicines," "Acupuncture," "Cupping therapy," and "Medical Massage."

截至2025年底，中医药特有商品/服务上已注册商标70余万件。
By the end of 2025, over 700,000 trademarks had been registered for TCM-specific goods and services.



2.2 商标审查审理中的传统知识保护

protection of traditional knowledge in trademark examination and adjudication

商标审查指引词库（避免不当授权）：

Trademark Examination Guidance Lexicon (to prevent improper registration):

将“中医针灸”“中医正骨疗法”等58项中医药相关国家级非物质文化遗产项目和联合国教科文组织非物质文化遗产项目纳入商标审查指引词库，供审查员在审查时参考。

Incorporated 58 TCM-related items on the national list of intangible cultural heritage, such as "TCM acupuncture and moxibustion" and "TCM bone-setting therapy," as well as items inscribed on UNESCO's intangible cultural heritage lists, into the trademark examination guidance lexicon for reference by examiners during review.

传统知识保护Protection of Traditional Knowledge

CNIPA

2.3 地理标志保护中的传统知识保护

protection of traditional knowledge in geographical indications



南阳艾

Nanyang *Artemisia argyi*

证明商标

certification

核定使用商品/服务项目

good/service:

第5类; 医用艾草

Class 5; medicinal *Artemisia argyi*

截至2025年底，累计在中医药相关商品上核准地理标志注册为集体商标、证明商标449件；认定中医药相关地理标志产品450余个，建设国家地理标志保护示范区8个。

By the end of 2025, a cumulative total of 449 geographical indications had been approved for registration as collective marks or certification marks for TCM-related goods. Over 450 geographical indication products related to traditional Chinese medicine have been recognised, with eight national geographical indication protection demonstration zones established.

2.3 地理标志保护中的传统知识保护

protection of traditional knowledge in geographical indications

专家审查机制
Expert
examination
mechanism

➤ 中医药道地药材相关地理标志

Geographical indications related to Dao-di herbs (geo-authentic herbs) in traditional Chinese medicine (TCM)

➤ 相关领域专家

experts in relevant fields

➤ 对品质、工艺等提出专家意见

Provide expert opinions regarding their quality and processing techniques.

2.4 中医药传统知识保护立法

Legislation on the Protection of Traditional Knowledge of TCM

《中华人民共和国中医药法》（2016年12月25日通过，自2017年7月1日起施行）
Law of the People's Republic of China on Traditional Chinese Medicine (Adopted on December 25, 2016, effective as of July 1, 2017)

第四十三条第一款 国家建立中医药传统知识保护数据库、保护名录和**保护制度**。
Article 43 , Paragraph 1 : The State shall establish a database, a protection list, and a **protection system** for the preservation of traditional knowledge of traditional Chinese medicine (TCM).

中国正在制定《中医药传统知识保护条例》，以进一步加强中医药传统知识的保护，规范获取和利用。《中医药传统知识保护条例》已列入国务院年度立法工作计划，将加快推进出台。

China is formulating the Regulations on the Protection of Traditional Knowledge of Traditional Chinese Medicine to further strengthen the protection, regulate the acquisition, and regulate the utilization of TCM traditional knowledge. The Regulations on the Protection of Traditional Knowledge of Traditional Chinese Medicine has been included in the annual legislative plan of the State Council, and its promulgation will be accelerated.



国家知识产权局
China National Intellectual Property Administration

Thank you!

CNIPA