

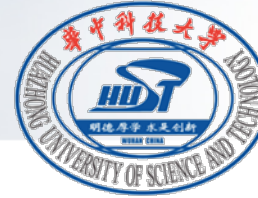
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The Regulations of Protecting Traditional Chinese Medicine (TCM) and Its Interface with Patent Law

Sydney, Oct. 2, 2014

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Contents

I. Introduction

II. Regulations for the Protection of TCM Varieties

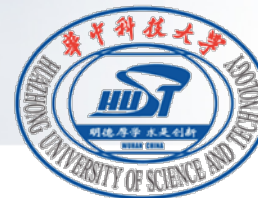
III. Patent Protection

IV. Comparison between the above Two Ways of Protection



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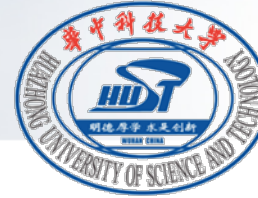
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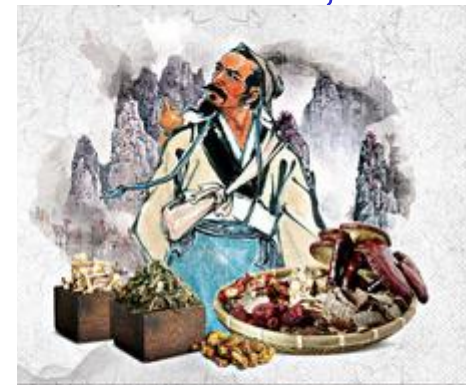
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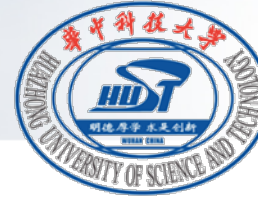
I. INTRODUCTION



1. Background of TCM

- TCM has a long history of **thousands of years**, and it is the precious wealth of the Chinese nation. Treatment concept of traditional medicine **is gradually accepted worldwide**, traditional medicine has attracted increasing attention from the international community. With the ever-increasing acquaintance and appetite for traditional medicine worldwide, the relevant protection regulations in China, the birth land of TCM, become more and more important and attracted much interest.



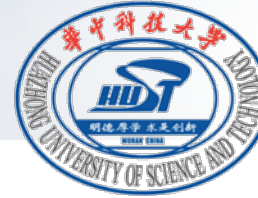


- Traditional knowledge about Chinese Medicine is a huge and complicated system, which includes rich content and various forms of expression and related resources. The core and important traditional knowledge involves Chinese medicine theories, Chinese medicine resources, processing and boiling of Chinese herbal medicine, prescription of TCM, diagnosis method of TCM, Chinese health care, unique markings and symbols of TCM.



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Chinese medicine resources



processing and boiling of
Chinese herbal medicine



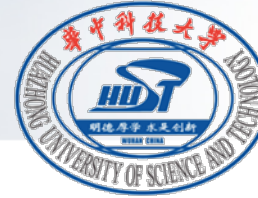
prescription of TCM





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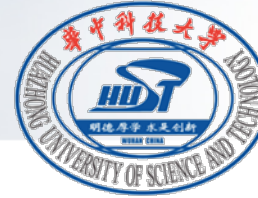
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diagnosis method of TCM



unique markings and
symbols of TCM





2. Necessity of the TCM Protection

- Like other traditional knowledge, TCM is also more and more misappropriated by third.

Patent US6256539 states: “A method for healing an injury of a patient using an electrical stimulator and acupuncture needles is provided. The method can include the step of **positioning a plurality of acupuncture needles** coupled to the **electrical stimulator** at **specific acupuncture points**”

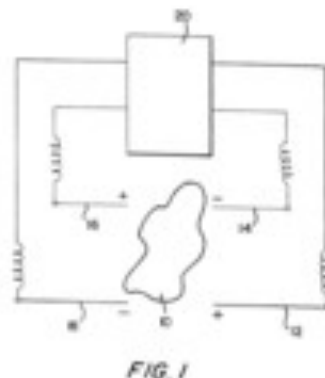
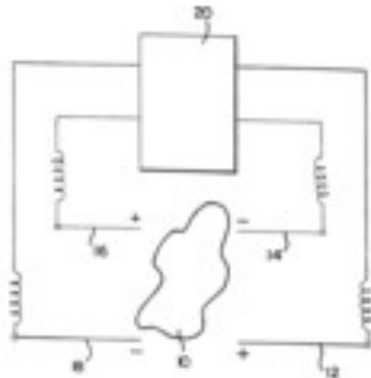
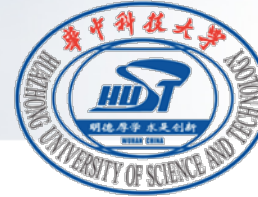


FIG. 1

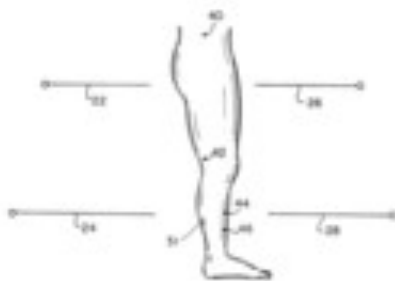


FIG. 2

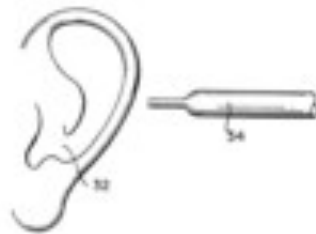


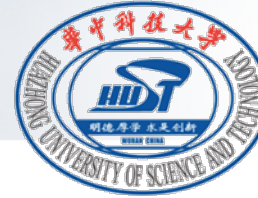
FIG. 3



The treatment methods and theory of this patent are derived from the basic theory of acupuncture and moxibustion (灸术) therapy, from a common TCM practitioner or acupuncturist's view, it seems that the patent can be said without any novelty and creativity.



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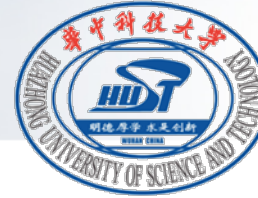


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**Enormous medical, commercial
and economic value of TCM**
made it become a kind of
knowledge resources, so the
protection on it becomes more
and more urgent.



3. Existed Protection Ways

State Secrecy protection

trademark protection

traditional medicine varieties protection

patent protection

trade secret protection

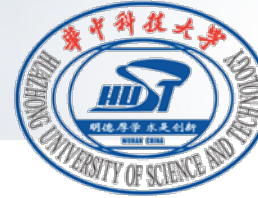
protection for products of
geographical indications

new drug protection

→ Regulations specially for TCM



This presentation introduces
these regulations and the
interface with patent protection.



II. REGULATIONS FOR THE PROTECTION OF TCM VARIETIES

(Hereafter referred to as the *Regulations*)

promulgated by the State Council on October 14,
1992, and came into effect since January 1, 1993.

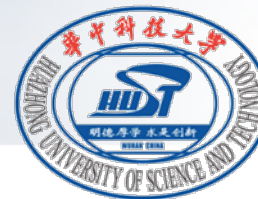
1. Subject & Object of TCM Protection

- Subjects: enterprises manufacture TCM in China.
- Objects: TCM varieties manufactured in China, including Chinese material medicine, extract of natural medicine and its preparation, artificial finished products of the Chinese medicine.

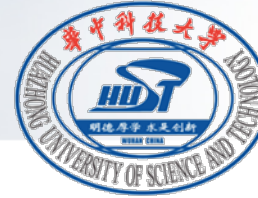


“TCM Variety
Protection Certificate”
issued by Chinese
Food and Drug
Administration (CFDA)





- Article 6 of *Regulations* provides that **first class protection** can be applied for while the variety meets one of the following conditions:
 - (a) have special curative effect to the specific disease, such as **Yunnan Baiyao** (云南白药), which has special curative effect to a variety of **hemorrhagic disease** (出血症);
 - (b) artificial manufactured goods with equivalent effect as a protected national first class wild medicinal species;
 - (c) used for the prevention and treatment of specific diseases.

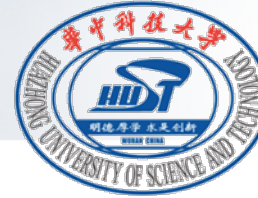


- Article 7 of the Regulations states:

Varieties that meet one of following preconditions can apply for **second class protection**: (a) comply with Article 6 of the Regulations or varieties have been lifted from first class protection; (b) have significant effect on the specific disease; (c) the effective substances and special preparation extracted from natural drugs.

The statistical data of CFDA shows that **totally 1,032 TCM varieties were awarded the second class protection**.





2. Duration & Content of Protection

- Duration of protection:
- first class — 30 years, 20 years or 10 years
- second class — 7 years

Note: 6 months prior to the expiration of each class of variety protection, enterprises can apply for **once** extension of the protection, and the extended duration is no longer than the former protection duration.

So far, only five Chinese Medicine varieties got first class protection under the Regulations:

Yunnan Baiyao (duration of 20 years)



Pien Tze Huang (20 years)

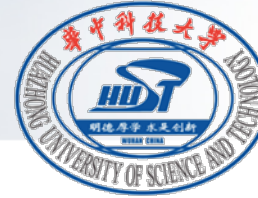


Liushen Pill (20 years, now on second class with duration of 7 years)

Longmu Zhuanggu Keli (10 years, expired)

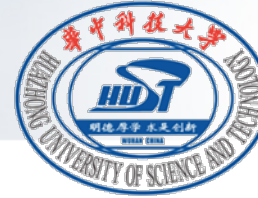
expired





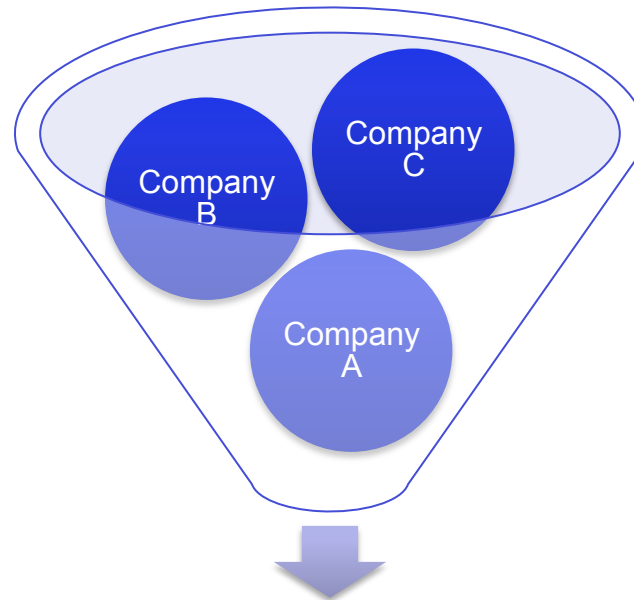
Content of Protection:

- The enterprise which obtained a certificate for TCM variety protection obtain an **administrative concession for manufacture**.
- More than one enterprises can own the same variety protection, that means, the right granted by CFDA is **non-exclusive right**.
- The certificate or the right of manufacture **cannot be free transferred**.

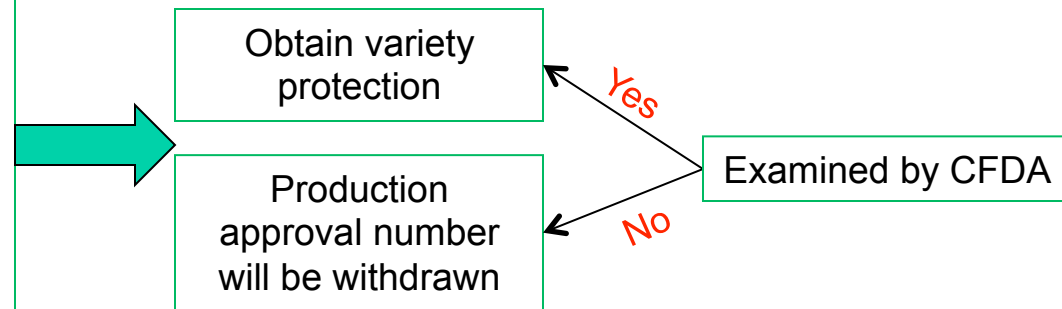


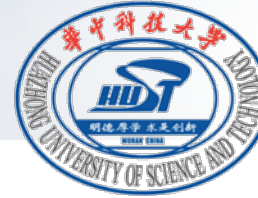
Priority Right:

There are three companies produce the same TCM variety on the market. Company A obtains “TCM Variety Protection Certificate” firstly. Company B and C can also apply for variety protection within 6 months of the announcement of Company A’s variety protection.



Company A obtains certificate





Limited Transfer:

1

For the scarce clinical TCM

**State
Administration
of TCM**

- Offers a imitation proposal

CFDA

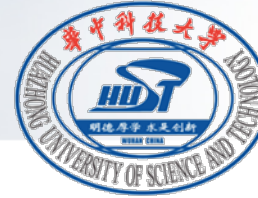
- Approves the proposal

**The Health
Administrative
Department in
Province Level**

- Issue the approval document number of the same TCM variety

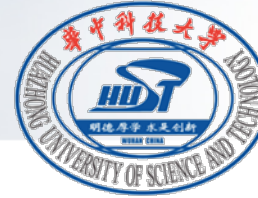
**Imitation
Manufactures**

- Pays reasonable use fees to the protected enterprise. The amount agreed by both parties; both parties fail to reach an agreement, decided by the health administrative department of the State Council



3. “Infringement” ?

- For imitation behavior without authorization during the protection period, punishment is carried out by the administrative department of health,
- But the holder of a “TCM Variety Protection Certificate” does not have the right to claim for compensation for their damage therefore.



Hainan Hengxin V. Jiangsu Pengyao

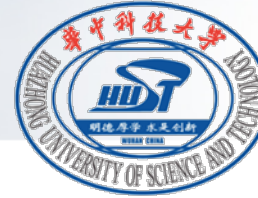
(plaintiff) (defendant)



V.



“Kang-ai Ping Wan” produced by
Hainan Hengxin Pharmaceutical
Co. Ltd had been obtained “TCM
Variety Protection Certificate”.
Duration of the protection was
2002.09.12-2009.09.12.



Details of the case:

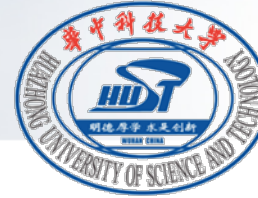


V.



The plaintiff alleged that according to the *Regulations* and other relevant laws and regulations, the protected TCM varieties must be produced by the certificate holder during the protection duration, other enterprises without certificate are not allowed to imitate and produce this medicine. The defendant's act infringed the plaintiff's "exclusive right" of TCM variety protection, and it is a tort of unfair competition.

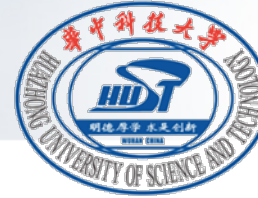
The defendant Jiangsu Pengyao Pharmaceutical Co. continued for mass production and sale of the same variety of “**Kang-ai Ping Wan (Anticancer Pill)**” after the plaintiff obtained the certificate of protection.



V.

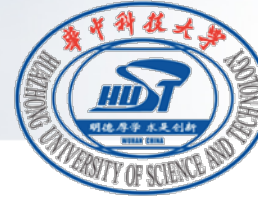


Accordingly, the plaintiff requested the court to order the defendant to stop infringement, apologize in Chinese Medicine News and compensate for damage of 4.8 million.

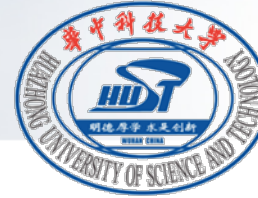


Judge's comments:

1. The defendant is an early enterprise to develop and manufacture “Kang-ai Ping Wan”, furthermore, all approval documents are available, the production act is legal.
2. The defendant has applied for TCM variety protection of “Kang-ai Ping Wan” in July 2002, defendant’s act of producing this medicine did not violate the *Regulations*.

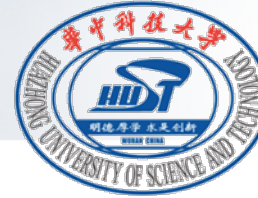


3. *Regulations* only provides the administrative liability, criminal liability, there is no legal basis for the plaintiff to claim for damage compensation and other civil rights.
4. Several right holders can co-exist under the *Regulations*, as CFDA may approve multiple drug enterprises produce the same variety of TCM, then the plaintiff shall not have the right to prohibit the production activities of other enterprises.



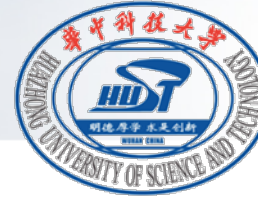
Enlightenments:

If the enterprises want to obtain an exclusive right, TCM variety protection is not the best choice, which just provides a right of special permission, and therefore have a kind of reputation for the produced TCM.



III. PATENT PROTECTION

Chinese Patent Law was promulgated by the Standing Committee of National People's Congress and enacted in 1984 firstly. Amendments of the Patent Law were made successively in 1992, 2000 and 2008.

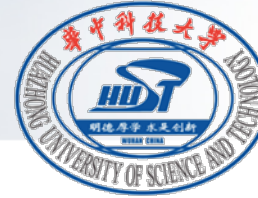


1. Precondition of Protection

There are three kinds of patent in China, which are invention patent, utility patent and design patent.

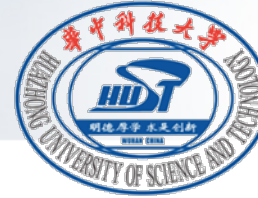
- Invention or utility model: for which patent right may be granted must possess novelty, inventiveness and practical applicability.
- Design: for which patent right may be granted shall not be a prior design, nor has any entity or individual filed before.





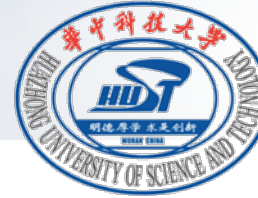
2. Duration & Content of Protection

- Duration of protection:
 - invention patent — 20 years
 - utility model and design patents — 10 years
 - from the filing date.
- The patent right is exclusive right, and can be transferred or licensed.

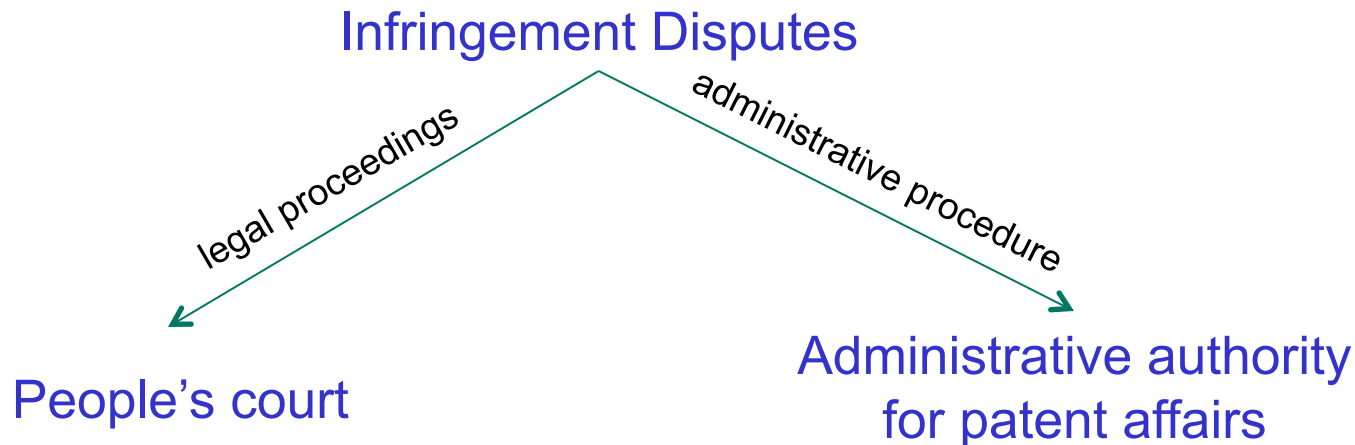


- Taking Taiji Group as example, when Taiji Group was formerly a small factory 20 years ago, it earned “the first bucket of gold” benefited from “acute bronchitis syrup (急支糖浆)” patent. After purchased acute bronchitis syrup test recipe from Shanghai Medical University, then improved the recipe and applied for a patent on it, turnout of Taiji reached about 10 million in 3 years. 65% of total sales of Taiji Group are handled by 20 patented products and the profit contribution rates over 80%.





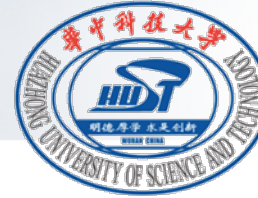
3. Consequences of Infringement



- When the people's court or administrative authority for patent affairs handling the matter considers that the infringement is established, it may order the infringer to stop the infringing act immediately. In addition, the parties may request for damage compensation.

- The patent protection is much stronger than TCM varieties protection. However, as the precondition for patent protections is strict, many kinds of Traditional Knowledge of TCM cannot meet these conditions. For instance, TCM has been disclosed cannot get patent protection because the lack of novelty; specific TCM diagnosis and treatment method of diseases are not in the protection scope of patent law.





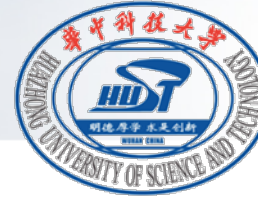
The Defect of TCM Patent Protection:

- (1). Patent Examination

Inventiveness: For the majority of TCM, most of them are mixture and it is **difficult to clearly illustrate the specific composition**. Because of the complexity of TCM ingredient, quantitative evaluation standard can not be adopted in the **evaluation of inventiveness** of TCM patent. ([Example](#))

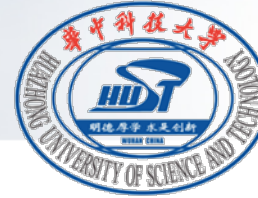
Practical applicability: Reproducibility of product and the medical effect.

Personalized medicine is an important characteristic of TCM, so the prove of practical applicability of TCM is difficult.



Regarding diagnosis and treatment of a patient for a disease, the prescription may be distinct in the different stages according to patients condition. A prescription is actually a creation activity, but the effect of the prescription treatment may be small to the whole effect of the disease and does not meet the requirement of prominent effect of the accident, then it is difficult to meet “creative” conditions.



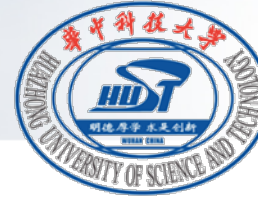


- (2) Patent Infringement

Structure and derivatives must be contained in a chemical drug patent application. TCM consists of the formula and dosage form and there isn't specific **structural formula**. In the process of actual infringement, if one or two kinds of herbs increase or decrease to a patented TCM compound, the act may be sentenced to tort. But if the infringer adds more flavor herbs with a **synergistic effect** or **non-substantial effect** to the patent TCM, the **infringement is difficult to be judged**.

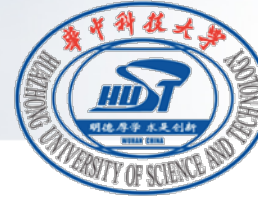


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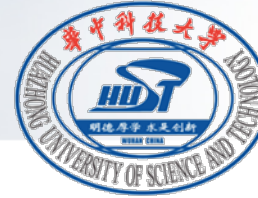
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IV. COMPARISON BETWEEN THE ABOVE Two WAYS OF PROTECTION

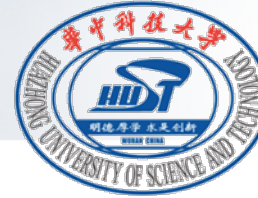


1. Influence and Significance of These Two Complementary Protection

	Patent Protection	TCM Varieties Protection
Effective Time	April 1, 1985	Jan. 1, 1993
Promulgation Department of Law or Regulations	Standing Committee of National People's Congress	State Council
Applicant	Natural or legal person inside or outside China	Chinese domestic pharmaceutical enterprises
Duration of Protection	20 years; 10 years	30 years, 20 years or 10 years; 7 years
Characteristics of Right	Exclusive	Non-exclusive
Contents of Right	Property right	Administrative concession
Liability for Infringement	Stop infringement act and fines, compensate for damage, penalties.	Stop infringement act, penalties and fines

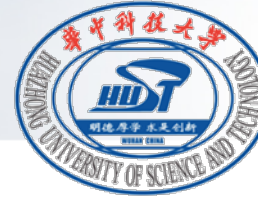


- The patent right is exclusive right, so the strength of patent protection of TCM is higher than that of TCM varieties protection, but the grant of TCM varieties protection certification is easier than the grant of patent.
- In addition, most TCMs are not fulfill the requirement of patent protection (**Novelty, Repetitiveness**)
- Therefore, these two ways of TCM protection are different and complementary.



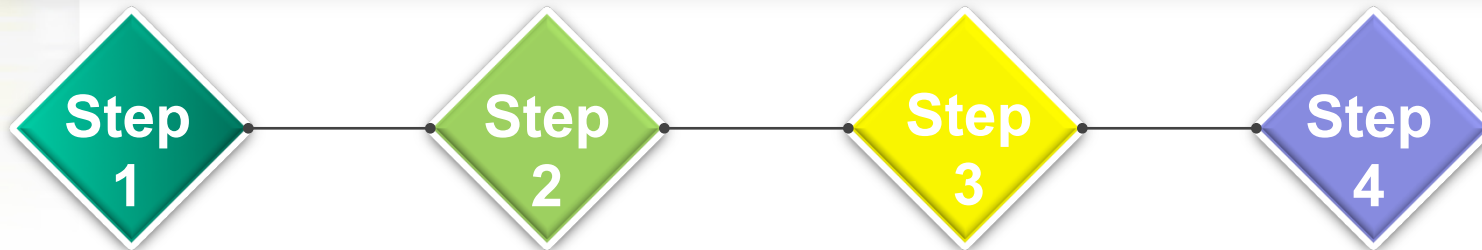
2. Inspiration from International Experience

- Many developing countries are rich in medicinal and biological resources, and they face the common problem of protection of Traditional Medicine Knowledge at the same time. Some countries improved the protection for Traditional Medicine Knowledge effectively. **India and Laos** for example, their governments play an important role in protection Traditional Medicine Knowledge.
- The protection systems in some countries such as **Brazil, Cuba, Kenya, the EU, Pakistan and Switzerland**, are also worth to be studied as references.



In India:

Under the guidance of the government

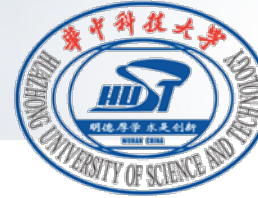


- collect and file the traditional medicine knowledge
- with the guidance of the government

- establish digital library of the traditional knowledge

- establish the system of invention and patent registration

- establish specialized investment funds to promote the industrialization of traditional medical knowledge



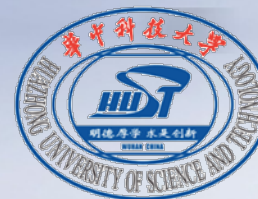
In Laos:

founded in 1976
by the support of
Laos Health
Department



The initial objective
is completing the
investigation of
medicinal plants in
all provinces of Laos
and promoting the
domestic mass
industrialization of
traditional medical.

collaborate with
traditional
physician trough
the establishment
of Traditional
Medicine Stations



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Thanks for your attention !

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