Lesson 7

Loss of Patent Rights

Circumstances：

- Abandonment: Art. 44 (2)
- Not paying annual fees
- Invalidation

Loss of Patent Rights

- Annual fees:
  - Statutory basis: Arts. 43; 44
  - Policy reason: There are costs associated with maintaining a patent system. Annual fees partially cover this cost on the one hand, and on the other hand induce rights holders who do not see the economic value of their patents to abandon them.
  - Time of Payment: One month before the expiration of the previous year.
  - Grace period: 6 months

Invention		Utility model and design	
1-3 yrs.	900 ¥	1-3 yrs.	600 ¥
4-6 yrs.	1200 ¥	4-5 yrs.	900 ¥
7-9 yrs.	2000 ¥	6-8 yrs.	1200 ¥
10-12 yrs.	4000 ¥	9-10 yrs.	2000 ¥
13-15 yrs.	6000 ¥	11-15 yrs.	3000 ¥
16-20 yrs.	8000 ¥		

https://www.cnipa.gov.cn/module/download/down.jsp?i_ID=155983&colID=1518
https://www.ndrc.gov.cn/xxgk/zcfb/tz/202203/t20220330_1320929_ext.html

Loss of Patent Rights

- Invalidation
  - Not patentable subject matter
  - Not novel, inventive, or useful
  - The application does not meet requirements, such as enablement

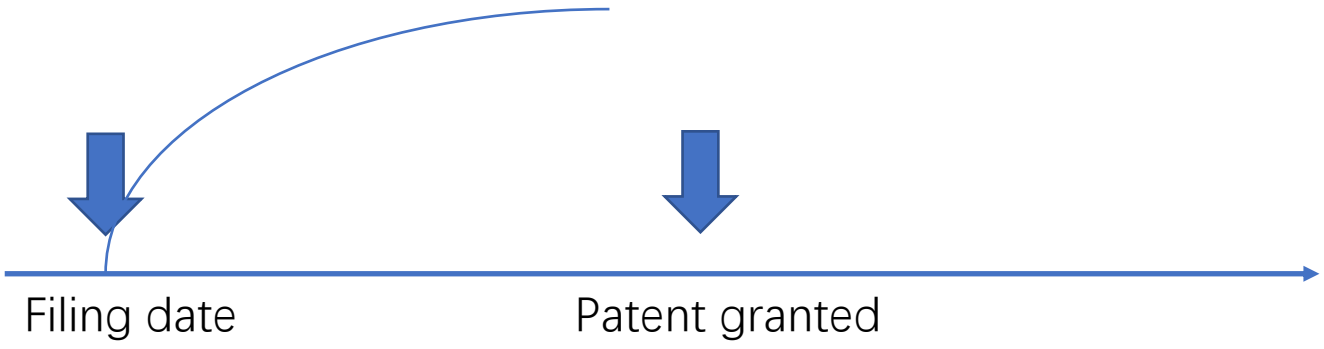
Loss of Patent Rights

- The invalidation has retroactive effect （Art. 47）
  - Default: Invalidated patents are considered to have no legal effect from the beginning
  - Exceptions:
    - Judgments and mediations on patent infringement that made by the People's Court before the invalidation of the patent right, and that have been enforced.
    - Patent infringement dispute decision that has been fulfilled or enforced
    - Patent licensing contracts and patent assignment contracts that have been executed
      - Exceptions to exceptions:
        - The patentee who has caused damage to others in bad faith should make compensations.
        - Not to return the patent infringement compensation, patent royalties, patent transfer fees clearly violate the principle of fairness, shall return all or part of the above-mentioned payments

Duration of protection

- **Article 42** The term of a patent for an invention shall be 20 years, the term of a patent for a utility model shall be 10 years, and the term of a patent for a design shall be 15 years, all commencing from the date of filing of application.
- …

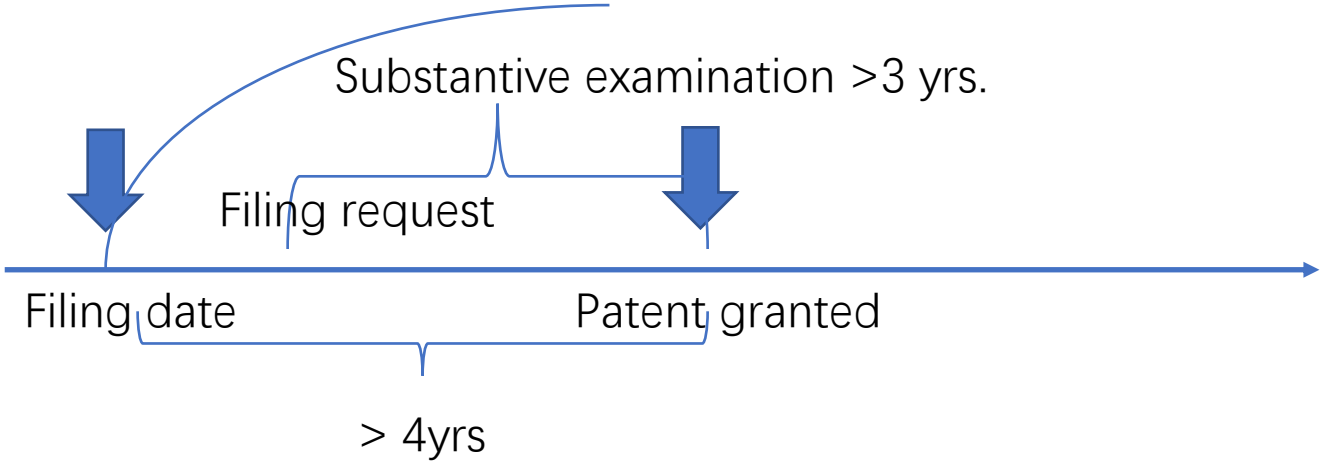
- Invention patent 20 yrs.
- Utility model 10 yrs.
- Design 15 yrs.



Extension of the duration of protection

- **Article 42** …
- Where a patent for an invention is granted four years from the date of filing of application and three years from the date of filing of request for substantial examination, the patent administrative department of the State Council shall, at the request of the patentee, provide patent term extension **for unreasonable delay in the patenting process** for the invention, except for unreasonable delay caused by the applicant.

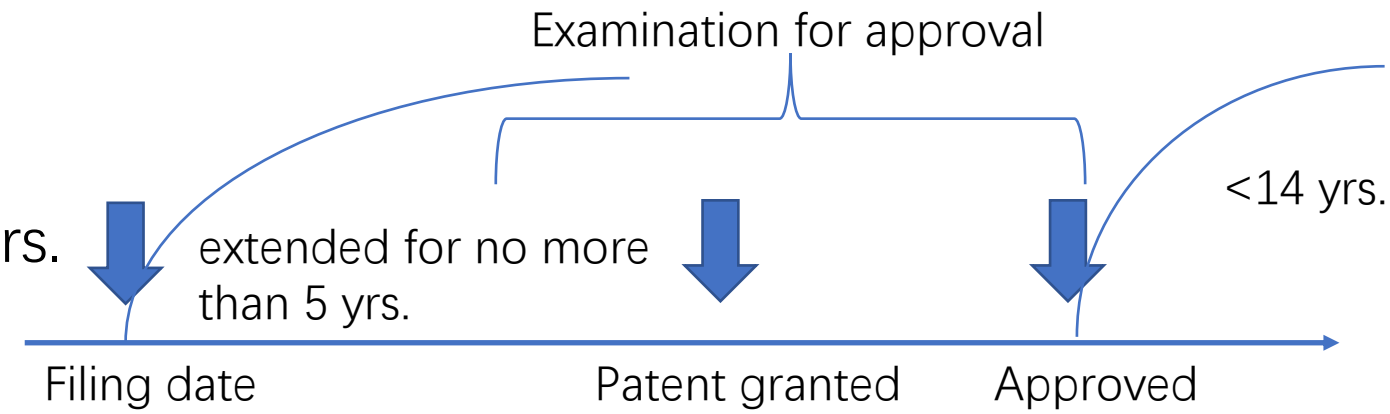
- Invention patent 20 yrs.
- Utility model 10 yrs.
- Design 15 yrs.



Extension of the duration of protection

- **Article 42** …
- For the purpose of making up the time required for the assessment and approval of the marketing of a new drug, the patent administrative department of the State Council may, at the request of the patentee, provide patent term extension for an invention patent relating to the new drug approved for marketing in China. The extension may not exceed 5 years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years..

- Invention patent 20 yrs.+ max. 5 yrs.



Infringement to invention and utility model patents

Step 1

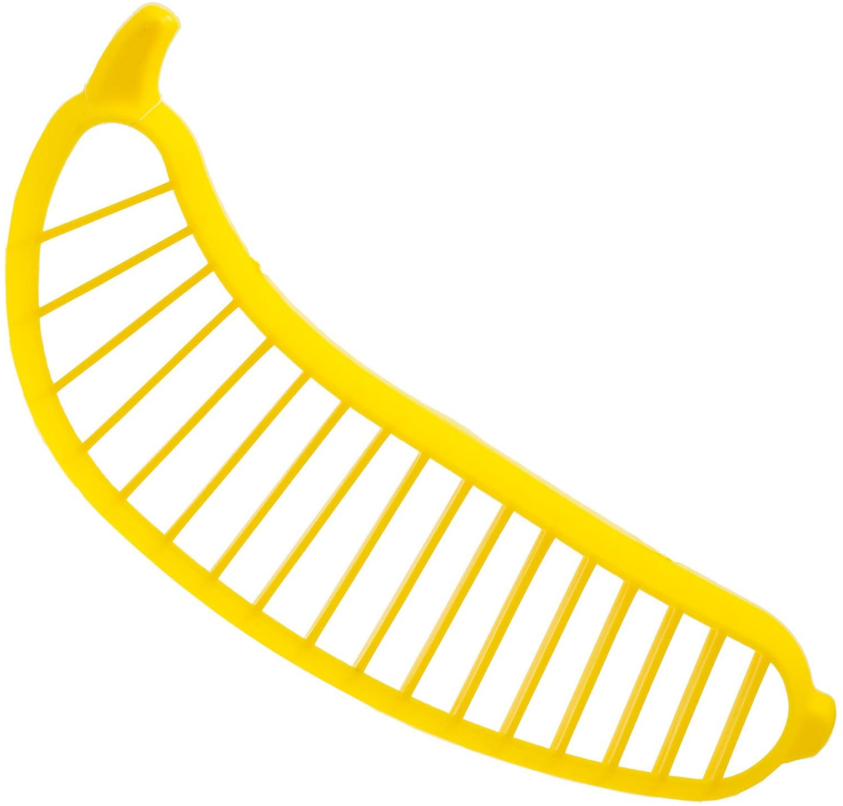
- Define the scope of protection of invention and utility model patents
  - Delineate the scope of protection by the technical features recorded in the claims
  - The specification and its accompanying drawings are used to construe the claims
    - From the perspective of a person skilled in the art
    - Deference to the definition of terms in the specification

1. A utensil for slicing bananas comprising:

an elongated plastic frame conforming to the shape and area of a typical banana, the frame having curvilinear opposite longitudinal sides, and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, each of the ribs being sufficiently thin to form means for cutting transversely through a banana, the spaces between the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein each rib is approximately 1 mm thick.

3. The banana slicing utensil of claim 1 wherein the ribs are disposed at an approximate distance of 4 mm from one another.



1. A utensil for slicing bananas comprising:

an elongated plastic frame conforming to the shape and area of a typical banana, the frame having curvilinear opposite longitudinal sides, and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, each of the ribs being sufficiently thin to form means for cutting transversely through a banana, the spaces between the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein each rib is approximately 1 mm thick.

3. The banana slicing utensil of claim 1 wherein the ribs are disposed at an approximate distance of 4 mm from one another.

A plurality of spaced, substantially parallel disposed blades or ribs interconnect two elongated sides of the frame. The positioning of the blades or ribs is such that when the banana slicer is laid to rest on a substantially horizontal flat support surface (not shown), the blades or ribs are disposed substantially vertically. In accordance with the invention, the blades or ribs must be sufficiently thin so as to be able to serve as cutting tools capable of cutting through a banana, without having a specially sharpened wedge shaped cutting edge. On the other hand, because the blades are preferably made from plastic, they cannot be so thin or narrow that their structural integrity would be compromised, or so thin that they could not be manufactured by suitable manufacturing processes, such as plastic molding. For these reasons, the blades or ribs of the preferred embodiment are approximately 1 mm wide, although it should be understood that their width can vary for as long as the foregoing requirements are met. For example, when the blades are made from high density polyethylene, their thickness can be as little 0.9 to 0.8 mm, without compromising their structural integrity.

Infringement to invention and utility model patents

Step 2

- **All-elements rule**
  - Each technical feature recorded in the patent claims has a corresponding technical feature in the allegedly infringing product or process.
    - **Literal infringement**
    - The technical features corresponding thereto literally fall within the scope of the corresponding technical features recorded in the claims.
    - **Equivalent infringement (doctrine of equivalents)**
    - The technical features corresponding thereto perform substantially the same function and produce substantially the same effect in practically the same manner; they can be achieved without creation.

Infringement to invention and utility model patents

Step 2

- **All-elements rule**
  - The infringing product or process should fall completely within the scope of all technical features recorded in the claims
    - **Literal infringement**

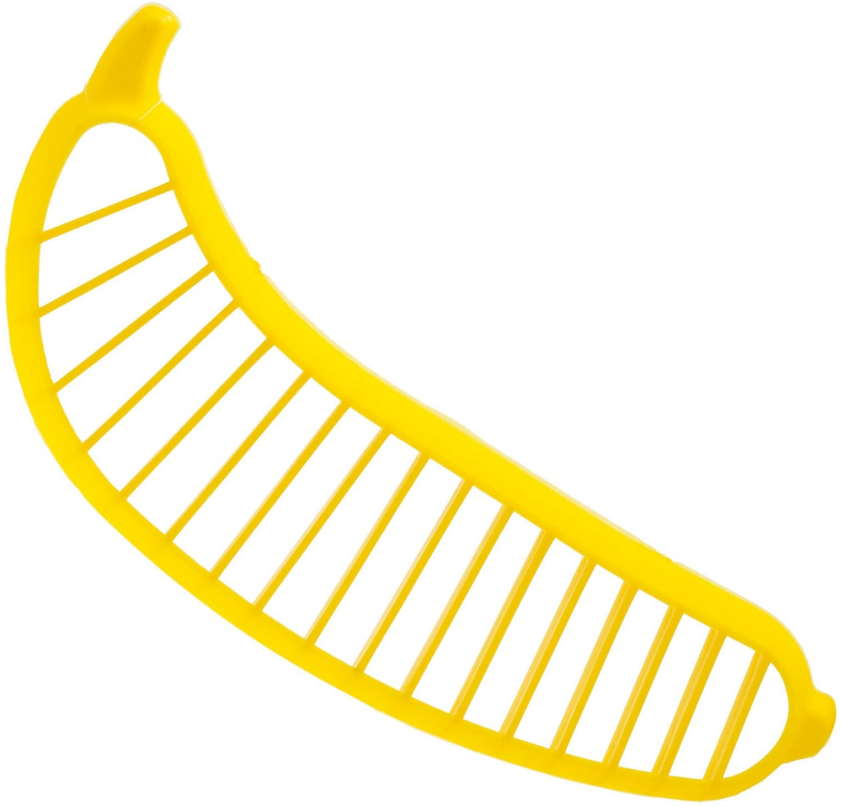
    - **Equivalent infringement (doctrine of equivalents)**

1. A utensil for slicing bananas comprising:

(A) an elongated plastic frame conforming to the shape and area of a typical banana, (B) the frame having curvilinear opposite longitudinal sides, (C) and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, (D) each of the ribs being sufficiently thin to form means for cutting transversely through a banana, (E) the spaces between the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein (F) each rib is approximately 1 mm thick.

3. The banana slicing utensil of claim 1 wherein (G) the ribs are disposed at an approximate distance of 4 mm from one another.



D’ s product

1. A utensil for slicing bananas comprising:

(A) an elongated plastic frame conforming to the shape and area of a typical banana, (B) the frame having curvilinear opposite longitudinal sides, (C) and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, (D) each of the ribs being sufficiently thin to form means for cutting transversely through a banana, (E) the spaces between the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein (F) each rib is approximately 1 mm thick.

3. The banana slicing utensil of claim 1 wherein (G) the ribs are disposed at an approximate distance of 4 mm from one another.

The technical features corresponding thereto literally fall within the scope of the corresponding technical features recorded in the claims.

1. A utensil for slicing bananas comprising:

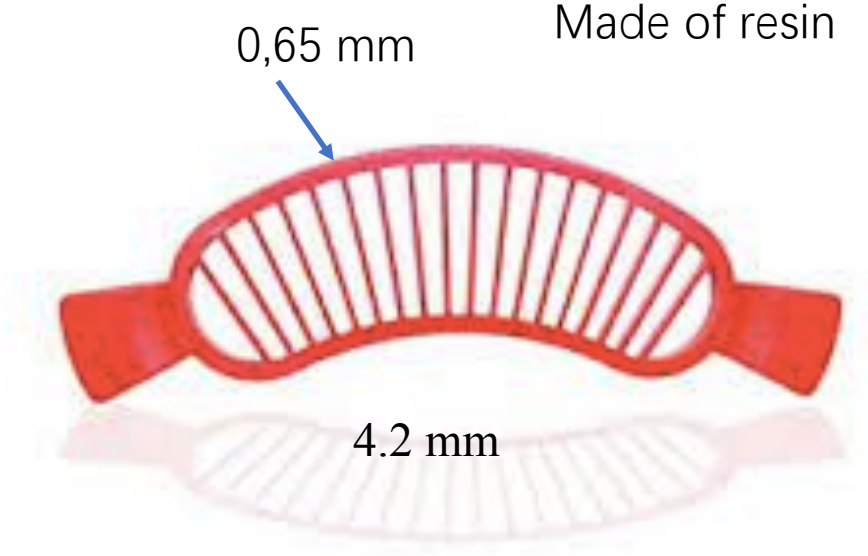
(A) an elongated plastic frame conforming to the shape and area of a typical banana, (B) the frame having curvilinear opposite longitudinal sides, (C) and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, (D) each of the ribs being sufficiently thin to form means for cutting transversely through a banana, (E) the spaces between the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein (F) each rib is approximately 1 mm thick.

3. The banana slicing utensil of claim 1 wherein (G) the ribs are disposed at an approximate distance of 4 mm from one another.

D’ s product

Made of resin （树脂）



The technical features corresponding thereto perform substantially the same function and produce substantially the same effect in practically the same manner; they can be achieved without creation.

Infringement to invention and utility model patents

Limitations on the doctrine of equivalents

- Defense based on doctrine of dedication
  - The doctrine of equivalents does not apply to technical features disclosed in the specification but not written in the claims.
- Defense based on doctrine of estoppel
  - The doctrine of equivalents does not apply to technical features that the patent owner waives in the claims during the prosecution process.

1. A utensil for slicing bananas comprising:

an elongated plastic frame conforming to the shape and area of a typical banana, the frame having curvilinear opposite longitudinal sides, and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, each of the ribs being sufficiently thin to form means for cutting transversely through a banana, the spaces betwee the ribs defining thickness of banana slices cut by the utensil.

2. The banana slicing utensil of claim 1 wherein each rib is approximately 1 mm thick

3. The banana slicing utensil of claim 1 wherein the ribs are disposed at an approximate distance of 4 mm from one another.

Specification:

…

The frame of this utensil is best composed of plastic; resin is also fine.

… D’ s product

Made of resin （树脂）

Claim scope does not extend to resin based on the doctrine of equivalents

Doctrine of dedication

1. A utensil for slicing bananas comprising:

an elongated plastic or resin frame conforming to the shape and area of a typical banana, the frame having curvilinear opposite longitudinal sides, and a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with the frame and interconnecting the curvilinear opposite longitudinal sides of the frame, each of the ribs being sufficiently thin to form means for cutting transversely through a banana, the spaces between the ribs defining thickness of banana slices cut by the utensil. **(before amendment)**

D’ s product

1. A utensil for slicing bananas comprising:

an elongated plastic frame conforming to the shape and area of a typical banana, the frame having curvilinear opposite longitudinal sides, anc a plurality of substantially evenly spaced, substantially parallel disposed ribs integral with th frame and interconnecting the curvilinear opposit longitudinal sides of the frame, each of the ribs being sufficiently thin to form means for cutting transversely through a banana, the spaces betwee the ribs defining thickness of banana slices cut by the utensil. **(after amendment)**

Made of resin （树脂）

Claim scope does not extend to resin based on the doctrine of equivalents

Doctrine of estoppel

Infringement to design patents

- Unauthorized adoption of a design identical or similar to a patented design on the same or a similar type of product.

- Similarity of product types:
  - Determination based on the international design classification table, the function of the product, product sales, and actual use of the product
- Similarity of design:
  - Determination based on the overall visual effect to consumers, taking their level of knowledge and cognitive ability into account

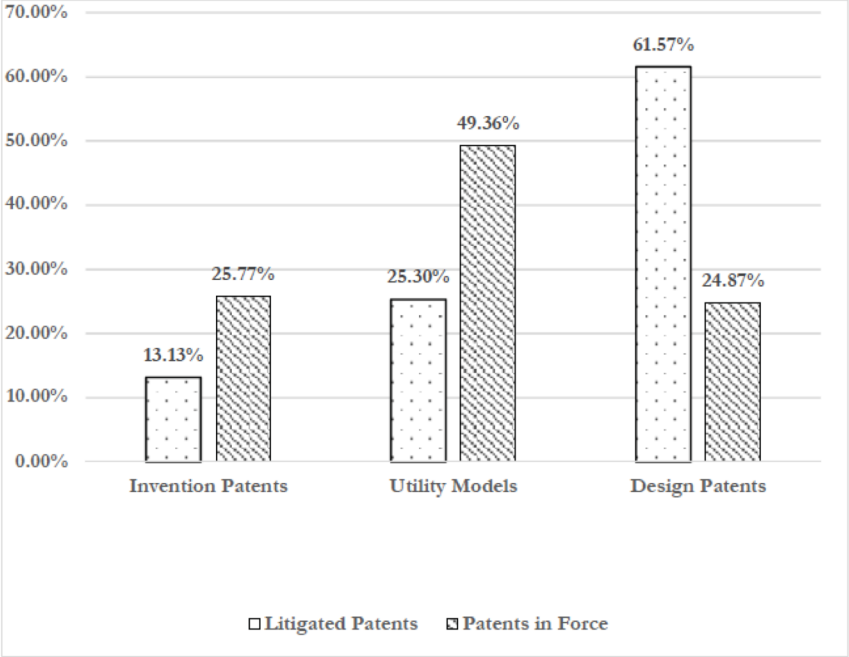
Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）.

Table 12: Patent Types

	Total	Invention Patents	Utility Models	Design Patents
Total	1,660[89]	218 (13.13%)	420 (25.30%)	1,022 (61.57%)
First Instance	1,053[90]	111 (10.54%)	213 (20.23%)	729 (69.23%)
Second Instance	607[91]	107 (17.63%)	207 (34.10%)	293 (48.27%)

Figure 2: Percent of Patents Litigated and In Force by Patent Type



Bian, R. (2018). Patent litigation in China: challenging conventional wisdom. *Berkeley Tech. LJ, 33*, 413.

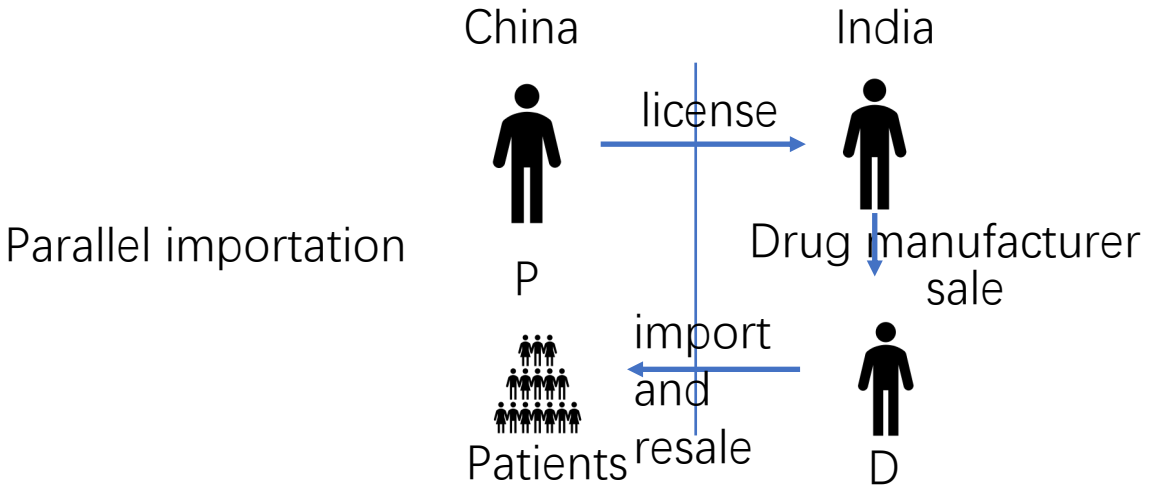
Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）.

Table 13. Cases Where Infringement Was Found, by Patent Type[93]

Patent Type	All Cases	Winning Cases	Percentage
Invention Patents	218	157	72.02%
Utility Models	420	325	77.38%
Design Patents	1,022	848	82.97%

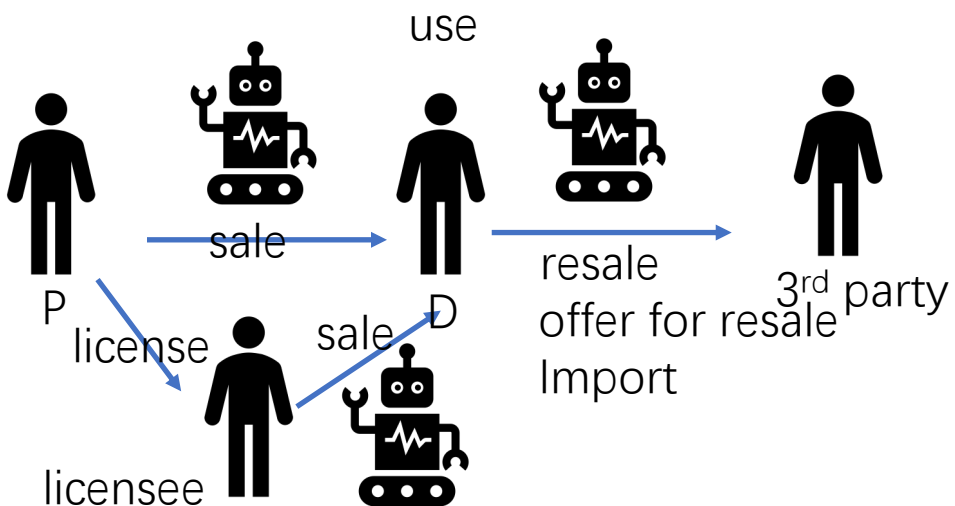
Defense



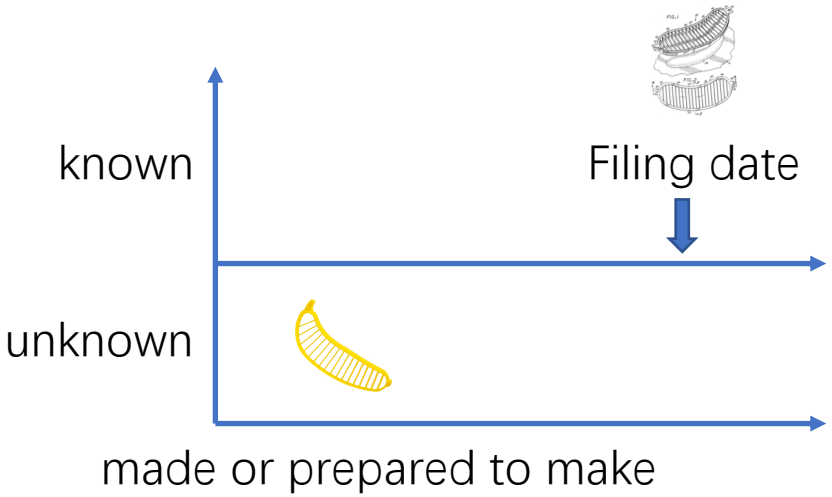
- Exhaustion

Article 75 None of the following circumstances shall be deemed an infringement upon a patent right:

(1) using, promising to sell, selling or importing any patented product or product directly obtained under the patented process after the said product is sold by the patentee or by its (his) licensed entity or individual;



Defense



- Prior use or preparation

Article 75 None of the following circumstances shall be deemed an infringement upon a patent right: …

(2) having made identical product or having used the identical process or having made necessary preparations for making such a product or using such a process prior to the date of application, and continuing making such product or using such a process only within <u>the original scope</u>; D is not allowed to expand its production capacity

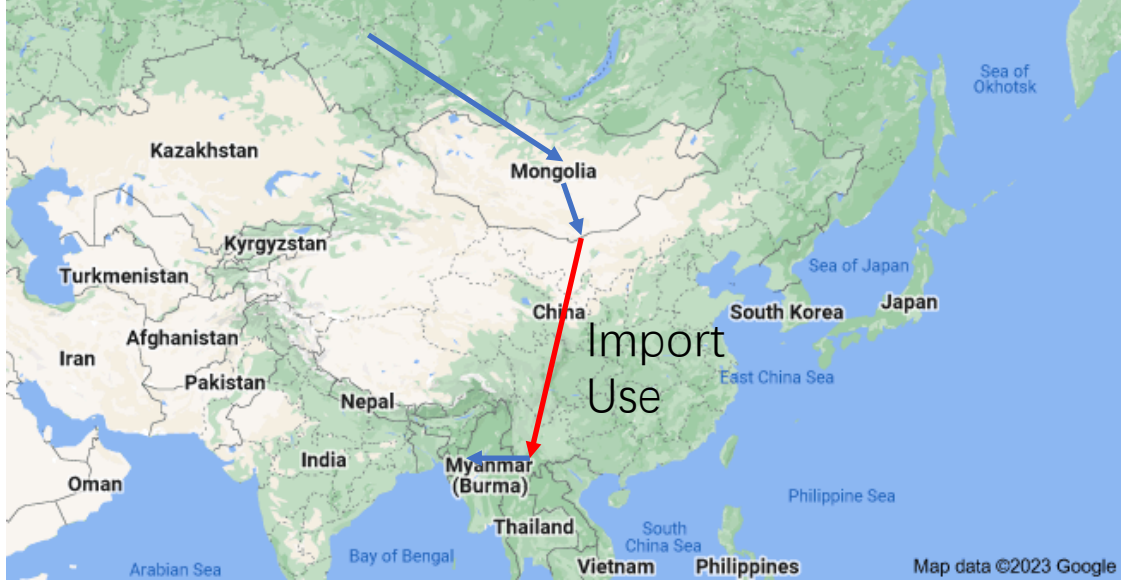
Policy reason: Protection of *prior* investments of D

Defense

- Temporary passing

Article 75 None of the following circumstances shall be deemed an infringement upon a patent right: …

(3) for any foreign means of transport which temporarily passes through the territory, territorial waters or territorial airspace of China, its using the relevant patents in accordance with any agreement concluded between China and that country to which the foreign means of transport belongs, or in accordance with any international treaty to which both countries have acceded, or on the basis of the principle of reciprocity, for its own needs, in its devices and installations;



patented machinery

P only has a Chinese patent

Defense

- Scientific research and experiments

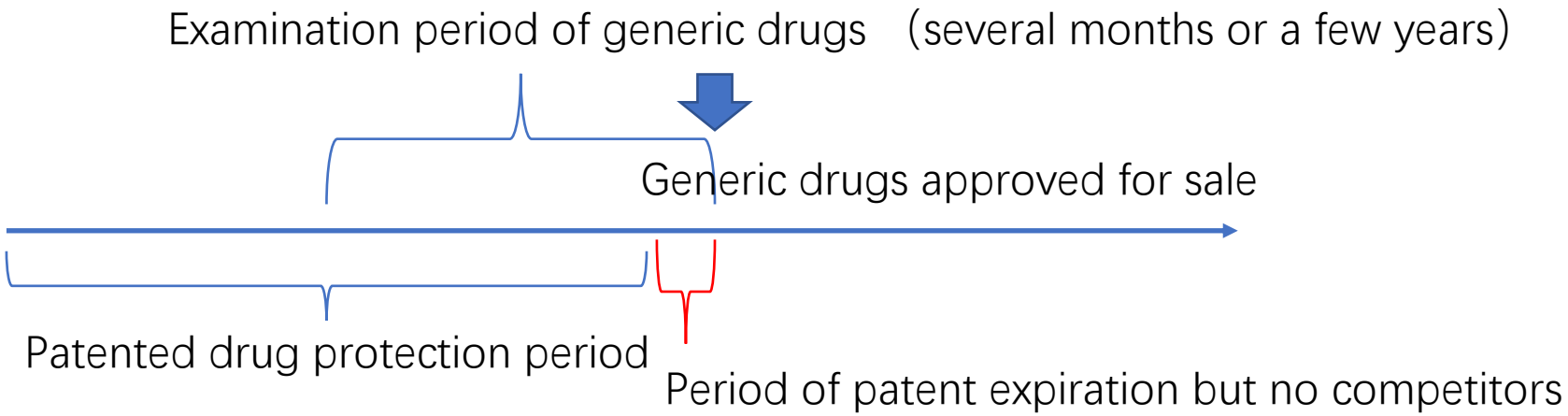
Article 75 None of the following circumstances shall be deemed an infringement upon a patent right: …

(4) using relevant patents solely for the purposes of scientific research and experiment; and

✓ Manufacture of patented microscopes to test the performance of microscopes

✗ Manufacture of patented microscopes to observe cells

Defense



- Use or provide patented drugs or medical devices for the purpose of providing administrative approval information

Article 75 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 examination and approval, and producing and importing the patented medicine or patented medicinal equipment exclusively for the said purpose.

Defense

- The technical solution or design used by D belongs to prior art

Article 67 In a dispute over patent infringement, if the accused infringer has evidence to prove that the technology or design it or he exploits is an existing technology or design, no patent infringement is constituted.

- P sues D for patent infringement
- D initiates proceedings to declare P patent invalid; If successful, no infringement （costly, time-consuming, affecting follow-up cases); or
- D defenses on the ground that what it uses belongs to prior art; ; If successful, no infringement （cheap, time-saving, binding only for one case ）

Remedies

- Civil Remedies
  - Damages
  - Injunctions

- Administrative remedies
  - Injunction

Remedies

P' s actual loss; or
D' s profits; or
reasonable multiple of royalty
} enhanced damages: X max. 5

or

statutory damages 30,000-5,000,000 ¥

+

reasonable disbursement

- Civil Remedies
  - Damages
  - **Article 71** The damages for a patent infringement shall be determined according to the actual loss suffered by the right holder due to the infringement or the benefits obtained by the infringer from the infringement; or if it is difficult to determine the loss suffered by the right holder or the benefits obtained by the infringer, the damages shall be reasonably determined by reference to the multiple of the royalty for this patent. In the case of an intentional patent infringement with serious circumstances, the damages may be determined as not less than one nor more than five times the amount determined in the aforesaid method.
  - Where it is difficult to determine the loss suffered by the right holder, the benefits obtained by the infringer, and the patent royalty, the people's court may, by taking into account factors such as the type of the patent and the nature and circumstances of the infringement, determine the damages as not less than 30,000 yuan nor more than five million yuan.
  - The damages shall also include the reasonable disbursements of the right holder for preventing the infringement.

Remedies

- Civil Remedies
  - Damages
  - **Article 71** …Where the right holder has made best efforts to adduce evidence but the account books and materials relating to the infringement are mainly in the possession of the infringer, in order to determine the damages, the people's court may order the infringer to provide such account books and materials; and if the infringer fails to provide them or provides any false ones, the people's court may award damages by reference to the claims of and the evidence provided by the right holder.

Remedies

- Civil Remedies
  - Injunctions

  Permanent injunction
  - **Civil Code Art. 179**

  Preliminary injunction
  - **Article 72** Where a patentee or interested party has evidence to prove that another person is committing or will commit an infringement upon the patent or an act of interfering with the patentee's or interested party's realization of rights, and irreparable harm will be caused to the lawful rights and interests of the patentee or interested party if the infringement is not stopped in a timely manner, the patentee or interested party may, before instituting an action, apply to the people's court for attachment of property, ordering certain conduct, or prohibiting certain conduct, in accordance with the law.

Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）.

- Plaintiff's win rate: first trial, 81.14%; second trial, 78.45%
- Probability that a plaintiff will obtain injunctive relief in a winning case: overall, 90.25%; first trial, 89.49%; second trial, 91.61%

Table 7: Reasons for Not Granting Injunctions

Rank	Reason	No. Cases	Percentage
1	Not Requested by Plaintiff	50	38.46%
2	Patent Expired	38	29.23%
3	Equity & Public Interest	20	15.38%
4	Not Mentioned	9	6.92%
5	Infringing Activities Stopped	5	3.85%
5	Already Issued by Previous Procedure	5	3.85%
7	Wrongly Drafted	2[73]	1.54%
8	Patentee Changed	1	0.77%

Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）.

Table 8. Damages Awarded[74]

	Total	Damages Awarded	Damages not Awarded
Total	1,333	1,282 (96.17%)	51 (3.83%)
First Instance	856	820 (95.79%)	36 (4.21%)
Second Instance	477	462 (96.86%)	15 (3.14%)

Table 9. Reasons for Not Awarding Damages[75]

Rank	Reason	No. Cases	Rate
1	Infringing products were obtained from a legitimate source.	42	82.35%
2	Damages were already awarded in a previous procedure.	5	9.80%
3	The plaintiff did not request damages.	4	7.84%
4	The infringers did not acquire profits from their infringing activity.	2	3.92%
5	The plaintiff could not prove infringing activities.	1	1.96%

Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）.

Table 10: Damages Awarded[79]

	No. Cases	Mean	Median
All	1,281[80]	￥75,853.83 ($12,354.04)	￥30,000.00 ($4,885.99)
First Instance	819[81]	￥52,596.07 ($8,566.14)	￥22,000.00 ($3,583.06)
Second Instance	462	￥117,329.04 ($19,108.96)	￥50,000.00 ($8,143.32)

Table 15. Damages, by Patent Type[95]

Patent Types	Mean	Median	Minimum	Maximum
Invention Patents	￥259,154.64 ($42,207.60)	￥120,000.00 ($19,543.97)	￥6,000.00 ($977.20)	￥4,840,000.00 ($788,273.62)
Utility Models	￥83,620.94 ($13,619.05)	￥50,000.00 ($8,143.32)	￥1,000.00 ($162.87)	￥670,000.00 ($109,120.52)
Design Patents	￥39,167.20 ($6,379.02)	￥30,000.00 ($4,885.99)	￥1,000.00 ($162.87)	￥900,000.00 ($146,579.80)

Patent Litigation in China

Bian has the following findings based on 2014 Chinese court patent infringement decision data from China Judgements Online（1663 cases）

Table 23: Case Results, by Residency of Plaintiff

	Decisions	Infringed	Injunction	Avg. Damages
Total	1,663 (100%)	1,333 (80.16%)	1,203 (90.25%)	￥75,942.39 ($12,368.47)[119]
Foreign P.	115 (6.92%)	97 (84.35%)	90 (92.78%)	￥201,620.45 ($32,837.21)
Domestic P.	1,548 (93.08%)	1,236 (79.84%)	1,113 (90.05%)	￥66,217.93 ($10,784.68)[120]

Remedies

- Administrative remedies
  - Injunction
- **Article 65** In the event that a dispute arises out of any exploitation of a patent without permission of the patentee, that is, the infringement upon a patent right, the parties shall settle the dispute through negotiations. If they are not willing to negotiate or fail to reach an agreement through negotiations, the patentee or any interested party … request the patent administrative department, for settlement. If the patent administrative department ascertains at the time of settlement that infringement exists, it may order the infringer to immediately stop the infringement act. …

Case Study

- Forced technology transfer
- Using the market to capture technology
- Local protectionism

Metagenom Bio®
Life Science

Case Study

- China is rich in mineral resources and the mining industry is an important industry in China.
  - China has over 10,000 mines, mainly coal mines. China is the world's largest producer of coal, gold and most rare earth elements (or minerals).

24 types of mines

coal

rare earth

Case Study

- Mining may cause pollution to the environment and therefore requires environmental remediation after mining.
  - During the production phase of the mining process, these activities typically involve the separation and processing of geological material from its original form, requiring the use of various chemicals that end up in the mining tailings as wastewater. There are waste rocks and acid mine drainage (AMD)

Inner Mongolia Erdos coal mine wastewater polluted thousands of acres of pasture

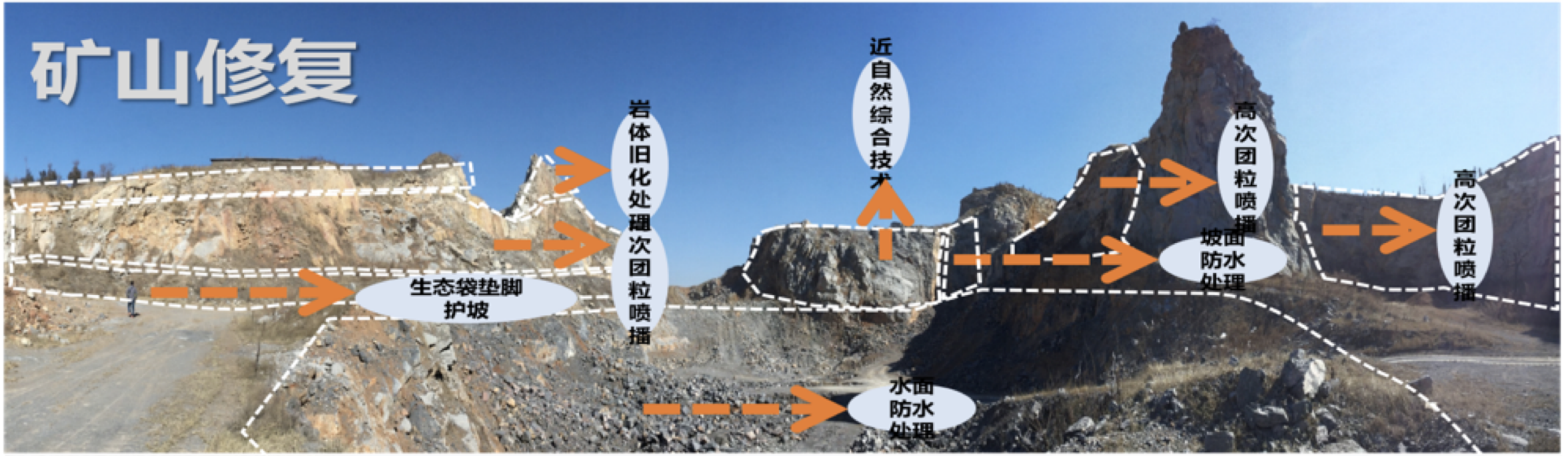
Guangxi rare earth mining causes pollution

Protest of villagers in Guangxi

Case Study

- Environmental remediation is a promising market in China.
  - Coal has been gradually replaced by cleaner and more efficient alternative energy sources, and the Chinese government has plans to close more than 1,000 coal mines in the next few years, which will require extensive cleanup efforts.
  - While China produces 85% of the global supply of rare earth elements, the mining process has created a plethora of social and environmental problems for the country.
  - China has a serious soil contamination problem. Along with increased penalties for environmental damage, Chinese government agencies are becoming more supportive of new cleanup technologies to remediate and contain future damage. Reuters estimates that the total cost of remediating all of China's soil contamination will be RMB 5 trillion ($760 billion).

扎赉诺尔百年露天矿
生态修复


矿山修复
生态袋垫脚
护坡
岩体旧化处理
次团粒喷播
近自然综合技术
水面
防水
处理
高次团粒喷播
坡面
防水
处理
高次团粒喷播

四宝山矿坑花园

Case Study

Potential solutions:

Physical and chemical remediation methods are common practice in China

神华集团 SHENHUA GROUP

紫金矿业 ZIJIN MINING

ChinaCoal 中国中煤能源集团公司 CHINA NATIONAL COAL GROUP CORP.

晋煤集团

Problems:

These methods often do not restore 100 percent of the land to a harmless state. Residual metals in the soil can lead to significant economic losses and potential future contamination. They often Leave chemical residuals in soil. Mining areas are no longer suitable for agricultural activities because of pollution.

MBI’ s bio tech as a solution: Use microbiome technologies (biodegradable)

Outcomes: Completely remove toxic chemicals, Restored land can be used for many purposes (agriculture, residential, etc.). The process only takes 1.5-3 yrs.

Case Study

- proprietary process for soil remediation techniques
- proprietary data collection of bacteria cultures
- other relevant intellectual property

Market or IP

Wholly foreign-owned enterprise

- Encounter some future government investment and regulatory decisions that favor domestic companies
- Public-private partnerships (PPPs) are often the source of funding for critical environmental remediation projects. Competing with domestic environmental companies to establish PPP projects with Chinese government agencies will face a significant disadvantage.
- The lack of a domestic partner makes it difficult to eliminate the market ‘s skepticism and resistance to MBI’ s new solution.

Metagenom Bio®
Life Science

Sino-foreign joint venture

- Require knowledge transfer for some of MBI’ s crucial intellectual property
- Would expose MBI to a greater risk of proprietary information leakage
- Knowledge leakage by its partner company could provide the building blocks for a copycat competitor

Chapter I GENERAL PROVISIONS

This contract for the establishment of an equity joint venture in Shijiazhuang, Hebei Province, People's Republic of China (the "PRC"), is entered into on June 15, 2000, through friendly negotiation based on principles of equality and mutual benefits, by and between Shijiazhuang Pharmaceutical Group Company, Ltd.("Party A") and Unigene Laboratories, Inc.("Party B") pursuant to the Law of the PRC on Joint Ventures Using Chinese and Foreign Investment (the "Law") and other relevant laws and regulations.

Sino-foreign joint venture

Chapter II CONTRACTING PARTIES

ARTICLE 1. Parties to the Contract

1.1. Party A is Shijiazhuang Pharmaceutical Group Company, Ltd., a legal person established under the laws of the PRC, registered with the Administrative Bureau for Industry and Commerce of Shijiazhuang, Hebei Province, PRC.
Legal Address: 276 Zhongshan West Road Shijiazhuang, Hebei Province, PRC
Legal Representative: Mr. Cai Dong Chen
Position: Chairman and President
Nationality: Chinese

1.2. Party B is Unigene Laboratories, Inc., established and registered under the laws of the State of Delaware, United States of America (USA).
Legal Address: 110 Little Falls Road, Fairfield, New Jersey, 07004, USA,
Legal Representative: Dr. Warren P. Levy
Position: President
Nationality: American

1.3. Party A and Party B are each referred to as a "JV Party" and collectively referred to as the "JV Parties".

Chapter III ESTABLISHMENT OF THE JOINT VENTURE

ARTICLE 2. Establishment of JV

Party A and Party B hereby establish "Shijiazhuang—Unigene Pharmaceutical Corporation Limited" (hereafter referred to as the "JV") in the PRC pursuant to this Contract, the Law and other relevant PRC laws and regulations.

ARTICLE 3. Name and Address of the JV

3.1 The name of the JV in Chinese is "_____"; and the name of the JV in English is "Shijiazhuang—Unigene Pharmaceutical Corporation Limited."

https://www.sec.gov/Archives/edgar/data/352747/000119312508073350/dex101.htm

3.2 The JV's legal address is High and New Technology Industrial Development Zone, Shijiazhuang, Hebei Province.

ARTICLE 4. The JV is established under the Law of the PRC and all activities of the JV shall conform to the pertinent laws, decrees, rules and regulations of the PRC.

ARTICLE 5. The JV takes the form of a limited liability company. Party A and Party B are liable up to amount of their respective capital contribution subscribed. Each party is entitled to the profits and liable to the risks and losses equivalent to such party's Distribution Ratio (as defined below), as set forth in Article 56.

ARTICLE 6. The JV shall be deemed to have been established as of the date its business license is issued pursuant to the Law (the "Establishment Date"). This Contract shall be effective as of the date it is approved by the National Administration of High and New Technology Industrial Development Zone, Shijiazhuang, Hebei Province (the "Effective Date").

ARTICLE 7. Promptly following the Establishment Date, the parties hereto shall cause the JV to ratify this Contract, whereby the JV shall agree to be bound by the provisions of this Contract as if it were a party hereto in its own right. An instrument evidencing such ratification shall be furnished to each of the parties.

ARTICLE 8. The JV Parties hereby adopt and shall execute the Articles of Association for the JV.

ARTICLE 9. Promptly after the first capital contributions required by Article 15.1(a) and 15.2(a) have been made by each party, the JV and Party B shall execute a Technology Transfer Agreement (the "Technology Transfer Agreement") pursuant to which Party B will (a) license the Technology to the JV (as defined in the Technology Transfer Agreement); (b) agree to sell to the JV its requirements of AE (as defined below); and (c) agree to sell to the JV its requirements of JV Products and bulk Calcitonin until such time as the JV can manufacture such JV Products and Calcitonin at the JV Facility, all in accordance with the terms and conditions of the Technology Transfer Agreement.

18.2 Party B shall, at its sole cost and expense, except as otherwise expressly provided:

(a) Offer support to the JV not inferior to other substantially similar joint ventures in which Party B is currently engaged or will be engaged in the future;

(b) Provide the JV with bulk Calcitonin and AE necessary for the production of Calcitonin at the cost defined in the Technology Transfer Agreement;

(c) Provide technical guidance and assistance with respect to the Technology and with respect to equipment installation, testing and validation for Phase II production, as set forth in the Technology Transfer Agreement;

(d) Facilitate entry visas to the United States for employees of Party A and the JV;

(e) Provide training to the technicians and workers of the JV with respect to the Technology, as set forth in the Technology Transfer Agreement;

(f) Transfer the Technology, which shall meet the designed capacity and quality requirements defined by the Technology Transfer Agreement;

(g) Assist the JV in developing an international network for the distribution of JV Products in areas in the Territory but outside the PRC, including, without limitation, developing effective marketing plans and strategies for each of the JV Products, securing suitable advertising for the JV Products, and generally promoting the market for the JV Products; and

(h) Perform such other matters entrusted to Party B by the JV and accepted by Party B.

Chapter VII TECHNOLOGY CONTRIBUTION

ARTICLE 19. For the purposes of the JV Business, Party A and Party B agree that Party B will provide advanced technology including product designs, manufacturing processes, testing methods, material recipe, quality standard and training as set forth in the Technology Transfer Agreement.

ARTICLE 20. Party B agrees to provide certain guarantees regarding the Technology.

1. Provided that the JV constructs and operates the JV Facility, and manufactures the Calcitonin and the JV Products, all in strict conformance with the requirements, specifications, Technology and training provided by Party B from time to time and as set forth in the Technology Transfer Agreement, Party B will guarantee, as set forth in the Technology Transfer Agreement: (A) that the Technology is identical to that in use by Party B in manufacturing the JV Products on a commercial basis at the time when the Technology Transfer Agreement enters into force; (B) that the Technology is suitable for the achievement of the JV's business purpose; (C) that the Technology is suitable for the achievement of the product quality and production capacity required by this Contract.

2. Party B will provide the JV with the Technology.

3. Party B will provide the JV with a list of the Technology and technical assistance calculated as capital contribution.

4. Party B will promptly deliver the designs, technical know-how and other detailed materials as part of the Technology, as required by the Technology Transfer Agreement.

5. Party B will contribute its proprietary Technology for the production of Calcitonin.

6. Party B will guarantee that it is not aware of any current legal disputes in any format affecting its use of the Technology in the PRC, or of any infringement by its proposed use of the Technology in the PRC on any third party patent or intellectual property rights. If Party B fraudulently concealed such legal disputes or infringement, Party B shall be liable for damages thus caused to Party A or the JV.

ARTICLE 21. In the event that the JV constructs and operates the JV Facility, and manufactures the Calcitonin and the JV Products, all in strict conformance with the requirements, specifications, Technology and training provided by Party B from time to time and as set forth in the Technology Transfer Agreement, but, as a result of fraudulent concealment on the part of Party B in not providing the Technology in accordance with the Technology Transfer Agreement, the Technology fails to reach the originally designed capacity set forth in the Technology Transfer Agreement, Party B shall be liable for the damages to the JV as set forth in the Technology Transfer Agreement.

ARTICLE 22. Party B is free from responsibility for damages to the JV that result, in whole or in part, from non-compliance with the requirements, specifications, Technology, training, guidelines and standards provided to the JV by Party B with regard to the construction and operation of the JV Facility and the manufacture of Calcitonin and the JV Products.

ARTICLE 23. The Technology is regarded as conforming to the contract specifications if it can meet the technical indexes listed by Party B for three (3) consecutive batches after the Technology is officially put into trial operation, which will be jointly confirmed by representatives from Party A, Party B and the JV.

ARTICLE 24. Both Party A and Party B are under the obligation to keep the Technology confidential in accordance with the Confidentiality Agreement between the parties dated October 29, 1998.

ARTICLE 25. Party A and the JV shall not provide in any format to any third party the Technology after Party B has provided the Technology to the JV unless unanimously agreed by the JV Board. Party B shall not transfer the Technology to any third party in the Territory after the Establishment Date.

ARTICLE 26. The JV will have access to improvements to the Technology developed by Party B after Party B has provided the Technology to the JV to the extent permitted by, and on the terms and conditions provided in, the Technology Transfer Agreement.

ARTICLE 27. The JV shall be entitled to any new improvements developed through its own efforts on basis of the Technology. No party shall use or transfer or release any such new technology to any third party without the permission of the JV. Party B shall have a right to use such improvements outside the Territory in accordance with the Technology Transfer Agreement.

ARTICLE 28. The JV has right of first refusal to other products independently developed by Party B for use in the PRC. New products developed by the JV shall belong to the JV, shall be considered JV Products, and Party B shall have a right of first refusal to such products outside the Territory. If the new products developed by the JV entail the use of AE, Party B or its successor shall provide the JV's AE requirements for such new products under the terms of the Technology Transfer Agreement provided there is no conflict with any obligation of Party B.

ARTICLE 29. Without the written permission from the other party after the establishment of the JV, neither Party A nor Party B as well as their subsidiaries and assignees shall independently or jointly with any third party manufacture, distribute JV Products in the Territory.

ARTICLE 30. Party B shall be the exclusive source of AE for the JV and the JV shall purchase all of its requirements of AE from the JV. The JV shall not sell AE.

Chapter II Definitions

2.1 "Technologies" are as set forth in Chapter 1 and the applicable appendices.

2.2 "Product(s)" refers to bulk recombinant salmon calcitonin, bulk recombinant PTH and such final products as may be determined by JV (which may include, for calcitonin products, injectable, nasal and oral formulations; and for PTH products, injectable and nasal formulations).

2.3 "Technical Data" refers to all technical data necessary for the manufacturing of the Product(s).

2.4 "Specifications" refers to the specifications set forth in the appendices, and shall include any specifications adopted and formulated by JV or Party B in connection with the manufacturing, research or development activities under this agreement.

2.5 "Term" is specified in 11.3.

Chapter III License; Delivery of Technology

3.1 Part B hereby grants to JV, during the Term, a license to use the Technologies, Specifications and Technical Data in the manufacture of Products in the People's

Republic of China ("PRC"). The license shall be exclusive for the PRC, non-sublicensable and non-transferable. In the event that the JV desires to acquire rights for territories other than the PRC, unanimous agreement is required from the Board of Directors of the JV. During the Term, Party B agrees not to grant to any third party the right to use the Technologies, Specifications or Technical Data in connection with the manufacture of Products in the PRC, or in connection with such other manufacturing, research and development activities of JV in the PRC, but Party B expressly reserves the right, for itself and through its licensees, to practice and use the Technologies, Specifications and Technical Data, elsewhere worldwide outside PRC, in the manufacture of products other than Products, or in manufacturing, research and development activities unrelated to the activities of JV. For the avoidance of doubt, JV obtains no right, title or interest in or to the Technologies, Specifications or Technical Data other than the license granted hereunder.

3.2 Party B should provide JV the Technical Data provided for in Chapter I.

3.3 Party B should make available to JV the Technical Data stipulated in appendix 1,2,3,4,5,6,7,11 and JV shall confirm receipt.

3.4 Party B should complete the obligations cited in appendix 8 and 9 before JV initiates production.

3.5 Party B shall assist JV in constructing facilities that meet ICH guidelines and FDA requirements.

3.6 The time of training shall commence *** before JV begins production of Products. Technical service from Party B shall continue under the terms of appendix 9 until JV is able to *** produce *** of Products.

Chapter IV Improvement and Modification of the Technologies

4.1 In the event JV desires to modify or change the Specifications in order to satisfy specific requirements of Chinese designing standard, materials, process equipment and other conditions, it shall first obtain the written approval of ***.

4.2 In the event *** creates any improvements to the Technologies, Specifications or Technical Data reasonably necessary to the activities of JV, it shall deliver such improvements to JV ***. In the event JV creates any improvements to the Technologies, Specifications or Technical Data, it shall deliver such improvements to ***.

4.3 Any such improvements or modifications to the Technologies, Specifications or Technical Data developed by either party and/or the JV during the term of this agreement, shall be owned exclusively by Party B. Any new products and/or intellectual properties developed by the JV independent of *** Technologies shall be owned and controlled by ***.

Technology transfer agreement

https://www.sec.gov/Archives/edgar/data/352747/000119312508173428/dex103.htm

Case Study

- Problem: IPR holders have difficulty to enter the Chinese market without the help of local companies, but seeking help means losing IPR.

- Foreign Investment Law (2019) as a solution?

Article 22 The State protects the intellectual property rights of foreign investors and foreign-invested enterprises, protect the legitimate rights and interests of intellectual property rights and related rights holders; infringement of intellectual property rights, strictly in accordance with the law to pursue legal liability.

The state encourages technical cooperation in the process of foreign investment based on voluntary principles and commercial rules. The terms of technical cooperation by the parties to the investment in accordance with the principle of fairness and equal consultation to determine. Administrative organs and their staff shall not use administrative means to compel the transfer of technology.
（国家鼓励在外商投资过程中基于自愿原则和商业规则开展技术合作。技术合作的条件由投资各方遵循公平原则平等协商确定。行政机关及其工作人员不得利用行政手段强制转让技术。）

- **Not particularly helpful**

Case Study

- Problem: IPR holders have difficulty to enter the Chinese market without the help of local companies, but seeking help means losing IPR.

- Technology Import and Export Management Regulations （2020）as a solution?

Article 24 The technology import contract of the transferor shall ensure that the technology provided is complete, error-free, effective, and can achieve the agreed technical objectives.

...

Article 26 After the expiration of the technology import contract, the technology transferor and the transferee can negotiate on the continued use of technology in accordance with the principle of fairness and reasonableness.

- **Not particularly helpful**

Case Study

- How to understand the opening up of China’ s market is a gradual process and not accomplished in a short time ?

- How to understand the interplay of government and enterprises as well as law and contracts in capturing foreign technology ?

Compulsory licenses

- Patent compulsory licensing is a legal mechanism that allows a government to grant a license to a third party to produce, use or sell a patented product or process without the permission of the patent holder

https://www.cnipa.gov.cn/col/col1510/index.html

强 制 许 可 请 求 书

① 请求人	姓名或名称			电话		
	邮政编码			地址		
② 联系人	姓名			电话		
	邮政编码			地址		
③ 专利代理机构	名称			机构代码		
	代理师(1)	姓名		代理师(2)	姓名	
		执业证号			执业证号	
		电话			电话	

④ 根据专利法 ☐第 53 条 ☐第 56 条 规定请求给予实施下述专利的强制许可

专利号 _____ 申请日 ____年____月____日

专利权人 _____

发明创造名称 _____

⑤ 请求强制许可理由

⑥ 附件清单

☐请求人具备实施条件的说明材料

☐未能以合理条件与专利权人签订实施许可合同的证明文件

☐

⑦ 请求人或专利代理机构签字或者盖章	⑧ 国家知识产权局处理意见
____年____月____日	____年____月____日

100019
2022.10

Compulsory licenses against no use or monopoly

- **Article 53** Under any of the following circumstances, the patent administrative department of the State Council may, upon the application of an eligible entity or individual, grant it or him a compulsory license to exploit the patent for an invention or utility model:
- (1) The patentee, after the lapse of 3 full years from the date when patent is granted and after the lapse of 4 full years from the date when a patent application is filed, fails to exploit or to fully exploit its or his patent without any justifiable reason; or
- (2) The patentee's act of exercising the patent rights is determined as a monopolizing act and it is to eliminate or reduce the adverse consequences of the said act on competition.

Compulsory licenses for national emergency or public interest

- **Article 54** Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the patent administrative department of the State Council may grant a compulsory license to exploit the patent for an invention or utility model.

Compulsory licenses of semi-conductor technology for public interests or against monopoly

- **Article 57** Where the invention involved in the compulsory license is a semi-conductor technology, the exploitation of the compulsory license shall be limited only to public interests and the circumstance as described in Article 53 (2) of this Law

- …(2) The patentee's act of exercising the patent rights is determined as a monopolizing act and it is to eliminate or reduce the adverse consequences of the said act on competition.

Compulsory licenses for public health

- **Article 55** For the purpose of public health, the patent administrative department of the State Council may grant a compulsory license for a patented medicine so as to produce and export it to the country or region which conforms to the provisions of the relevant international treaty to which the People's Republic of China has acceded.

Compulsory licenses for cumulative innovation

- **Article 56** Where an invention or utility model for which the patent was granted has seen any major technical progress of prominent economic significance when compared with another invention or utility model for which the patent has been granted earlier, and the exploitation of the later invention or utility model depends on the exploitation of the earlier one, the patent administrative department of the State Council may, upon the request of the later patentee, grant a compulsory license to exploit the earlier invention or utility model.
- Where, according to the preceding paragraph, a compulsory license is granted, the patent administrative department of the State Council may, upon the request of the earlier patentee, also grant a compulsory license to exploit the later invention or utility model.