IPR and Innovation Capability Building of Traditional Chinese Medicine (TCM) Enterprises

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Abstract

Traditional Chinese medicine (TCM) is a branch of medical science rooted in the Chinese traditional culture. It has great development potential in China. TCM is a high-tech intensive industry, relying much on the technology innovation. However, pure innovation will not bring the firm an exclusive right on the innovation profit or commercial success. Without the guidance and protection of Intellectual Property Right (IPR), the innovation may not be effective, or the competitor may easily imitate the innovation result. IPR is not only a protection system for the innovation activities, but also a management tool for the TCM firms to arrange its innovation projects. In one word, the IPR and innovation are related with each other, together creating the commercial value for TCM firms.

The TCM industry in China has a fast development, but the whole situation is still weak. The main reasons are low innovation capability, lack of self-innovated new medicine and lack of a systematic IP management. In this article, from the perspective of TCM firms, the outer environment will be analyzed, with the focus on the protection laws and systems for the medicine. After that, some feasible suggestions will be given for TCM firms to better use IPR as a management tool to guide the innovation.

Since the theories may be a little abstract, two famous cases of the TCM firms are selected to study. The Tongrentang Group and the Chengdu Di’ao Group are both famous TCM enterprises in China, but with very different innovation paths. Lessons may be drawn from them by other TCM companies.

The main conclusion of this article could be summed as several points: First, TCM firms need to stress the technology innovation to gain the market advantages. They should take a combination of different levels of innovation after analyzing themselves and finding out the most appropriate positioning. Second, they should try to choose the feasible research focus to develop modernized TCM products. There may be four paths for a modernized development, each with different requirements. Third, TCM firms are suggested to make use of IPR strategy in the whole process of its value chain in order to guide and protect its innovation results. The detailed suggestions are given in Chapter 5. Fourth, to guarantee the efficacy of the IPR strategies, it is of need to establish a special IPR management system. Finally, besides a protection and management tool, TCM firms may try to consider IPR as a profit source.

Key words: Intellectual Property Right (IPR), Traditional Chinese Medicine (TCM), Innovation, Strategy, Quality Control
1. Introduction

1.1 Background

Traditional Chinese medicine (TCM) is a branch of medical science rooted in the Chinese traditional culture. It has its special theory system and methodology, differing a lot from the western medical sciences. It has been used since thousands of years ago, and kept being developed from then on. Nowadays, the TCM is still proved to be the knowledge of high practical and commercial value, with the capability of self development and innovation. (16)

Nowadays, there are many biotechnology companies in China working on traditional Chinese medicine as their products. This is a typical knowledge- and technique-intensive industry, highly depending on research and development (R&D). Since R&D is a long-term and high-risk process, requiring multi-disciplines collaboration as well as high investment, it needs very good Intellectual Property Right (IPR) protection to give support and protection of the final product and the potential high profit.

Though there is lots of knowledge in this industry in manufacturing, there is more recorded in traditional textbooks, which are open to everyone. Therefore there is big dilemma in this industry. On the one hand, it needs much innovation to develop new drugs; on the other hand, it is not very easy to be protected by IPR. This dilemma makes the industry less innovative than expected. The revolution of biology gives TCM companies a good opportunity to catch up with western medical industry. This paper will try to find a new way to promote the innovation capability in this industry from the perspective of IPR management.

Intellectual Property Right also has been studied sufficiently since being brought out. It has been transformed from a pure law concept to a wider concept. Researchers have studied it from different perspectives, such like economics, politics, and enterprise management. This article will go further beyond the protection function of IPR, and try to study how IPR could be used as a management tool to promote the innovation performance of TCM enterprises.

1.2 Research question, purpose and content

The question I would like to give some answers to is: how could TCM enterprises upgrade their performance by putting efforts into the IPR and innovation management? Actually, there are four levels of studying the IPR management: the country, the region, the industry and the enterprise, while I choose the most microcosmic enterprise perspective to study it. (37)

The study will aim to give the TCM enterprises some feasible suggestions in making
use of IPR as a tool to upgrade their innovation performance. Several relevant research articles have been published on this topic previously. Therefore I will give a brief review of this literature first to introduce the important concepts and results. After that I will do some analysis of the outer environment of TCM enterprises, including the market, resource, culture, law factors, etc, followed by bringing forward some feasible suggestions to the these enterprises. Then I will give two Chinese famous TCM enterprise cases. In the last part, I will give a summary and some discussions. The structure of this article could be schemed as figure 1.

Figure 1: The structure of this article. There are five chapters, each focusing on one point. Chapter 1 will bring forward the studied question, Chapter 2 will give an introduction of the previous research on this topic, Chapter 3 analyzes the current environment that the TCM firms are now in, and Chapter 4 brings some suggestions for the TCM firms while the last chapter gives two cases of TCM enterprises.

1.3 Methods

Since I do not have a very systematic or solid background in the field of IPR and Innovation, but only the basic knowledge learned from master courses, I do this thesis project at a comparatively basic level. I use mainly two methods. The first is literature searching and reading, which includes both English and Chinese literature.
After reading large quantities of literature, I sum up relevant results together as a review article may do. The second is survey of two famous Traditional Chinese Medicine enterprises. I study these two cases, and do interviews with people from these companies. Although the successful experiences of these two companies may not be applicable to all others, they should have some directive significance.

2. Literature Review

2.1 The concept of Traditional Chinese Medicine

2.1.1 The concept of Traditional Medicine

Before studying the TCM related questions, there is a need of giving a clear definition of the traditional medicine. According to the website of WHO, traditional medicine refers to “health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.” 1 There is another definition from a WHO document, according to which “traditional medicine is the sum total of knowledge, skills and practices on holistic healthcare, which is recognized and accepted by the community for its role in the maintenance of health and the treatment of diseases. Traditional medicine is based on the theory, beliefs and experiences that are indigenous to the different cultures, and that is developed and handed down from generation to generation.” (41)

To enumerate its content, the traditional medicine may include a wide scope such as herbal medicine, acupuncture, massage/manipulation, heat/steam/sauna, diet, exercise (e.g. Yoga, Qigong), and spiritual/mental therapy and others. Among those the use of medicinal plants and the technique of acupuncture are the most important forms. (41) From the definitions we could understand that traditional medicine much relies on the natural medicinal material and handed-down experiences. Besides, the practices and forms of it are closely related with the indigenous culture, thus vary greatly from one region to another.

Before the establishment of the western medicine theory system in the modern years, it is traditional medicine that played the promotive, preventive, curative and rehabilitative role with varying emphasis in different countries. (41) It has been the main form of healthcare, and in many countries an alternative or complementary to the main form of the healthcare system.

2.1.2 The concept and principles of Traditional Chinese Medicine

Based on the above definition, Traditional Chinese Medicine could be simply defined as the medical science, practices and medicine uniquely used in China since 1 http://www.who.int/mediacentre/factsheets/fs134/en/, visited date 2009-01-22
thousands of years ago. (14) It is an important sort of the nature medicine or the herbal medicine. In a more detailed definition, it includes herbal medicine, acupuncture, moxibustion, massage, food therapy, and physical exercise, such as shadow boxing. (32) Although there are profound content in the TCM concept, due to the research purpose which focus on the enterprises rather than the TCM practitioners or hospitals, in this article, when TCM is mentioned, it refers to traditional Chinese drugs, while the medical science or practices is out of consideration.

During the past thousands of years, TCM has developed a school of its own in global traditional medicine for its exact curative effect and integrated system information. Most of the principles of TCM were regarded as derivated from the philosophical basis of Taoism and Confucianism. (3) Ancient Chinese scholars categorized all natural phenomena into two opposite, complementary, interdependent but exchangeable aspects: Yin and Yang. They also considered everything in the universe consisted of five basic elements: wood, fire, earth, metal, and water. In their opinion, all things in the universe were constantly changing towards a situation of dynamic balance and harmony. Based on such belief, TCM was developed to understand, prevent, and cure disease.

In the theory of TCM, Yin refers to the material aspects of the organism and Yang to functions. The organism was treated as a whole, with the circulation of Qi (energy) and blood linking every part. The organs work together by regulating and preserving Qi and blood through the so-called channels and collaterals. Pathogenic and climatic factors may disturb the balance of Yin/Yang and the harmony in the organs. In such cases, diseases occur. Drug or other treatment would aim to expel or suppress the cause and restore balance. (32) Besides, TCM also has its special diagnosis methods: looking, listening, asking, and touching.

2.1.3 Comparing TCM with the western medicine
Compared with western medicine, TCM has several distinctive features. First, it has different composition. While western drugs contain mostly chemical compounds with already known structure and function, most of the TCM are natural drugs or simple mixtures made from natural drugs, which are complex and with unknown composition. Natural drugs refer to the medicinal plants, animals and minerals that exist in the natural world and utilized by humans for medical use. (14) Second, they have different way of curing diseases. The active components in western drugs are one or several known compounds, which have clear targets in the human body. After assimilation, they will arrive at certain part of the body to a high concentration and play the curing role. On the opposite, there may be many kinds of active components in traditional Chinese drug, which are all unknown. They will influence different targets in the body to have a total cooperation effect. (32) Therefore, there’s a saying in china that the western drug always focus on the sick part while the traditional Chinese drug always focus on the whole body. Third, the prescription of western
medicine is the same for everybody. However, due to the complex composition and uncertain mechanism, when using TCM it is important to ask the doctors to help choose the right prescription and drugs. The TCM prescription is not definite, but varies a little among the patients even for the same syndrome.

Therefore, compared to western medicine, TCM does have some adverse effects. Since its uncertain prescription, the main adverse effect is possible inappropriate use of TCM. If using TCM without the doctor’s scientific guidance, the patient may be in the risk of taking the wrong prescription. This weak point could be avoided by more rigorous clinical trial, quality control and guided application in the modern years. The second weak point may be that it could not involve the field of surgery or public health. Besides, with fewer side effects, TCM has a slower effect than the western medicine does.

Though the adverse effects, there are still strong reasons to push the development of TCM in the public. First, it is more cost effective and affordable by the patients especially those in the small villages. Second, most of the patients have a cultural acceptance of TCM. They have the belief that when used properly, it is effective. Third, the treatment of TCM is based on natural materials and holistic approach, which is complementary to the western medicine, therefore may be used as the hypurgia of western medicine. Finally, it is safer and has fewer side effects, if taken in the correct prescription and concentration. Now the trend of medical practice has changed from disease treatment alone to the combined mode of prevention, treatment, recovery and health care. TCM is such a combined mode, with more and more population. (53)

In sum, western drugs have one known chemical compound as the active component, aiming to recover the ill organ, while the TCM is a complex mixture of natural plant, animal, minerals, aiming to adjust the whole body from the unbalance situation to the balanced situation. The aim of the western drug is to perish the disease, while the aim of TCM is to regulate the function of human body to a balanced state. The essential difference exists in the different culture of understanding the health and diseases. In spite of the big difference, both of them have been proved to be effective in counteracting diseases, therefore should be developed.

2.1.4 The modernization of TCM
Although having played an important role in China’s history, TCM was challenged by Western medicine during the late 19th century. Along with the development of modern science, Western medicine was given increasing emphasis because of its clear theory base and rigorous trial system. Besides, it had notable effects in surgery and public health, areas that had not been well developed in China until then. From then, the development of TCM was slackened until 1949, when the new Chinese government re-established the position of TCM. Since that year, TCM has been scientifically studied and gradually integrated with Western medicine. Biomedical
sciences also have made considerable changes to TCM.

The absence of scientific understanding has caused skepticism and criticism about TCM, although randomized clinic trials have confirmed the efficacy of TCM. Nowadays, there is advocate for developing modernized TCM, which was written in the Chinese “9th and 10th five year plans”. According to the plans, the modernization will be realized on several aspects. First, more TCM compounds which have confirmed efficacy and stable quality are encouraged to develop, and they may also enter the international market. Second, it is of need to establish and optimize the normative system for the TCM R&D and medicine standard. The GAP, GCP and GLP standards will be popularized in the TCM industry. Third, more TCM plant cropping bases, modernized TCM technology industry bases are encouraged to build. Large TCM groups are encouraged to develop the international competitiveness.

By analyzing the national policies, we could see that the state holds a clear attitude for the TCM development. First, it stipulates the legal status of TCM, and encourages its independent development. Second, it encourages the innovation in the TCM industry rather than simple imitation. Third, it stresses the TCM quality control and pushes the GMP standard. A modernized TCM industry with these features will be the trend in the future.

2.1.4.1 The content of TCM modernization
From these plans, we could see that the modernization of TCM is “under the direction of traditional theory and experience of TCM, using the international medical standards and criterions for reference, making full use of modern science and technology theory, methods and means to produce the safe, high effective, stable, and controllable TCM products.” (55) Concretely, the modernization will be realized on four aspects as the picture may show. The essence of the TCM modernization will be the combination of TCM with modern technology especially the biotechnology, modern academic thoughts, and modern scientific culture. The goal of modernization will be development of medicine with guaranteed safety, effectiveness, consistency and scientificity.

2 The “five year plan” is one part of the Chinese national economic plans. They are plans mainly for laying out the important construction projects, productivity distribution and the important proportion relation in the national economy. Except for the period from 1949 to 1952, and that from 1963 to 1965, China has scheduled 11 “five year plan”, and the “11th five year plan” are carried from 2006 to 2010.

3 GAP, Good Agricultural Practices. GCP, Good Clinical Practice. GLP, Good Laboratory Practice.

4 “中药现代化研究与产业化开发”实施方案.
http://www.cintcm.com/lanmu/zhongyi_keyan/yanjiu_gangyao/xiandaihua.htm, visited date 2009-03-08
2.1.4.2 TCM modernization and analytic chemistry
Since the prescriptions are quantified and formulated by scientific authorities according to their clinical experiences but not the component structure study, to screen out those active components and analyze them is one of the major tasks for TCM modernization. Among the thousands of components contained in the TCM, only a few of them are responsible for the pharmaceutical or toxic effects. The basic method to study is to first separate and analyze the components by screening, followed by the pharmacology or mechanism experiments. (68) However, the existence of other components makes the screening and analysis of the bioactive components extremely difficult. Modern techniques especially the development of analytical chemistry and molecular biology contributes to these studies.

Now, with advanced analytical instruments, modern instrument analytic chemistry is widely used in the analysis of TCM for several purposes. The first is to help improve the speed and precision of the separation and purification of different components. For example, thin-layer chromatography (TLC), gas chromatography (GC), high-efficiency capillary chromatography (HECC) is widely used. The high speed countercurrent chromatography (HSCCC), supercritical fluid chromatography (SFC), high-performance capillary electrophoresis (HPCE), has also been used. (56-65) High-performance liquid chromatography (HPLC) is the most common method for the separation and preparation of active ingredients in TCM. The counter-current chromatography (CCC), with its liquid stationary phase, is one of the prime methods for isolating compounds from Chinese herbal medicines. (71) The affinity chromatography with immobilized bio-molecules as the stationary phases was introduced to screen and analyze the bioactive components from TCMs. Besides, the
micro dialysis combined with HPLC was developed to study the binding behaviors of drugs and metal ions to proteins in vitro, respectively. (79)

The second goal is to do precise analysis of the molecular structures of the components. For example, the GC-MS/NIR is a very precise method to analyze the molecular structure of the unknown component in TCM. The third goal is to help set the means for the standardization and normalization of the TCM products. These sensitive and reliable techniques could be used to pick the characteristic index of the standard components. Then when used in the quality control system these technique could analyze the TCM products and guarantee that the quality satisfying the standards. For example, the analytical methods like HPLC and HPCE can be used as the method of collection for the fingerprint database of TCM, which is used in quality control and differentiation of TCM .(69)

2.1.4.3 TCM modernization and molecular biology
The development of molecular biology works on other aspects. The first is drug effect research. The molecular biology could help extend the research of TCM mechanism from the traditional level of organisms and organs to the level of microcosmic cells and molecules. For example, many anticancer TCM is tested to be able to cause apoptosis of cancer cells and affect the expression level of related genes. In another case, many anti-aging TCM is found to increase the expression of some zymoprotein genes, resulting in activating some enzymes such as the antioxidants. (70) The second aspect the molecular biology contributes is to help the pharmacological screening. For example, high-throughput screening methods using receptors and specific enzymes as targets have been extensively used in the field of screening candidates from synthetic compound libraries. (78) Another aspect that molecular biology is working on is to provide many new research methods. The methods developed during molecular biology research could later be used in the TCM study, such as the DNA gel electrophoresis, protein electrophoresis, patch clamp, gene clamp, gene chip, fluorescent probe, TUNEL assay, in situ hybridization, and differential mRNA display, etc.

2.1.4.4 TCM modernization and other techniques
Other modern techniques especially the computer science also contributes to the modernization of the TCM. The development of computer science could help collect and process the TCM related information. For example, it is of importance to link to the international databases of the TCM, and find out useful information like the popular traditional prescriptions. It will also help if the firm could get to know the research achievements of the modern TCM at an early time.

2.2 The theories of technology innovation
2.2.1 The concept of technology innovation
The word “Innovation” was first brought out by J.A Schumpeter in 1912, and in 1939
he presented his economic theories in the Journal Business Cycles with the innovation as the core concept, namely the innovation theory. According to his opinions, the innovation may include: (1) Combination of new production factors, (2) Utilization and realization of new possibilities, (3) Breaking out the old tradition and create a new one, (4) The capability to deal with uncertainties, (5) The fundamental factor for economic changes. According to another simple definition, it is the process of using knowledge to solve a problem. (80) Innovation is a very broad concept, different from invention, which is the discovery of a new idea, but also including all new activities involved to solve a problem. (80) Schumpeter classified innovation into five categories: new products, new methods of production, new sources of supply, the exploitation of new markets and new ways to organize business. Daft put forward the two basic types of innovation, the technical innovation and administrative innovation.

After Schumpeter, Mansfield put forward the concept of “technology innovation”, which is an invention when used for the first time. In another definition, it is the use of knowledge to apply tools, materials, processes, and techniques to come up with new solutions to problems. (81) According to the Library of Congress in US, the technology innovation could be defined as the process from the creation of a new product or new craft idea to the marketing application of it. It includes the creation, research, development, commercialization, production, and diffusion of the new idea. The goal will be the commercialized application of the technology and the market success of the new product.

2.2.2. The importance of technology innovation
Technology innovation is extremely useful because of several reasons. (80) First, it is an important source of value creation. By innovation, the production of existing products or services could be done more efficiently. New products and services that meet needs that were not previously satisfied may also be created. Those changes could have tremendous economic impact. Second, new technology makes possible the formation and rapid growth of new companies and small companies. The leading companies without continuous technology innovation will only come to death. The technology innovation provides a mechanism for entrepreneurs and managers to create and preserve the competitive advantages.

2.3 A brief introduction to Intellectual Property Right (IPR)
2.3.1 The definition and main content of the IPR
“Intellectual property (IP)” is now a universal law term in the world. In the 17th century, the trademark and patent were called “Incorporeal Rights” in France, while on the founding conference of World Intellectual Property Organization (WIPO), the term “Intellectual Property Right” (IPR) was used for the first time by US scholars. There are two kinds of definition for IPR. The first is to generalize its features while the second is to enumerate its main content. For the first kind of definition, we could refer to the WIPO website: “Intellectual property refers to creations of the mind:
inventions, literary and artistic works, and symbols, names, images, and designs used in commerce.” On Wikipedia, Intellectual property is defined as “legal property rights over creations of the mind, both artistic and commercial, and the corresponding fields of law. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; ideas, discoveries and inventions; and words, phrases, symbols, and designs. Common types of intellectual property include copyrights, trademarks, patents, and trade secrets.”

For the second kind of definition, we could refer to the “Convention Establishing the World Intellectual Property Organization”, which was signed at Stockholm on July 14, 1967 and amended on September 28, 1979. According to the article 3 of this convention, intellectual property shall include the rights relating to:

1. Literary, artistic and scientific works
2. Performances of performing artists, phonograms, and broadcasts
3. Inventions in all fields of human endeavor
4. Scientific discoveries
5. Industrial designs
6. Trademarks, service marks, and commercial names and designations
7. Protection against unfair competition
8. And all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

According to another important IPR related treaty, the “Agreement on Trade-Related Aspects of Intellectual Property Rights” (TRIPS), the IPR could be divided into also eight categories:

1. Copyright and Related Rights
2. Trademarks
3. Geographical Indications
4. Industrial Designs
5. Patents
6. Layout-Designs (Topographies) of Integrated Circuits
7. Protection of Undisclosed Information
8. Control of Anti-Competitive Practices in Contractual Licences

According to a common used classification of IPR, the IPR mainly covers four main parts, the patent, the trademark, the brand, and the technology secret. From these definitions, we could know that the essence of IPR should be a series of rights, and the right owners could legally and exclusively make use of the creations of the mind, the commercial mark or other commercially valuable information. Research on Intellectual Property Right was done in many fields such as law, economics and

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management. In this article, I will choose the perspective of enterprise management and treat IPR as a series of rights, a kind of enterprise asset, and one means that enterprises could make use of to win the market competitions.

2.3.2 The features of IPR
IPR has many basic features differentiating it from other law concepts. As a summary of relevant literatures, those features could be generalized as four points. (52)

1. Exclusivity. There are two meaning for this. First, the right owner exclusively owns the knowledge asset and monopolies the use of it. Second, for each knowledge product, only one IPR is allowed to exist.

2. Able to be copied. IPR is a kind of immaterial knowledge asset, very easy to be copied and spread. The cost of copy and spreading it could be nearly ignored when compared with the cost of creating the IP. Therefore, IP could be used by different people at the same time, and create very high social value.

3. Regionalism. The IPR is derived by making application according to certain laws, thus its effectiveness could only work in the certain region where the law is effective. If a right owner would like its intellectual property also protected in other regions, he or she should make extra applications according to relevant IPR protection international convention, bilateral agreement, reciprocity principles, and the IPR law in that target region.

4. Timeliness. IPR is a kind of monopolization just for a limited period of time. When the stipulated protection time expires, the IPR no longer exists, and the protected knowledge product becomes the common asset of the whole society.

2.4 The linkage between IPR and the innovation capability of TCM enterprises
IPR is a law concept which is tightly related with the innovative organizations by endowing them a monopolization right. In the present world, IPR is more like a kind of asset, just like other capitals. Therefore, towards creating more and effective IPR, the firms should pay attention to the innovation process.

2.4.1 IPR protects and encourages the innovation
As I mentioned above, IPR is not only a law concept, but also has economic and social meanings. One of the original intentions of setting up the IPR regulation is to encourage invention and innovation by endowing the inventor a monopolization right for a certain period of time. Therefore it indirectly pushes the progression of the whole society.

According to the research by some scholars, since the knowledge product is very easy
to imitate, imitation with a low cost could harm the innovation enthusiasm, (1) but the IPR increases the imitation cost by endowing the inventor an exclusive use right. (21, 22) Therefore the IPR stimulates innovation by preventing imitation. In some other scholars’ opinions, the IPR could offer the inventors market advantage, and then attracted by the potential monopolization profit, the inventors try their efforts to do innovation work. (27, 30) In a study on the imitation time and imitation cost in the chemistry, medicine, electronics and engineering industry, it was found that if without the patent protection, about more than half of the patented technology innovation would not be started.

2.4.2 IPR works in different industries, especially medicine industry
IPR protects the knowledge product in different industries. In a famous study done by Taylor and Silberston from Cambridge University, they found that the effect of IPR on the R&D varies among different industries. (31) The medicine industry relies on the IPR protection the most, the chemistry industry the second, and the engineering industry the third. (31) In some later research, it was also found that in the medicine industry, patent is generally the most important and effective way of getting innovation. (5, 13) According to Cohen’s research, the effectiveness of patent on the product innovation is 50%, on the process innovation 36%, the number for chemistry industry was only 38% and 25%, while the average number for all industries was only 35% and 23%. (5)

The reason for this lies in the features of the medicine industry. First, to develop a new drug requires very high capital and time investment in the R&D period, but once the composition of the patented drug become known to others, the imitation cost is very low. It was estimated that the average cost for new drug, calculated with the price in 1990, is 8.4 Billion USD, in 2000 26.4 Billion USD. (49) Besides, the average time cost for a new medicine is 12 years. Therefore in the medicine industry, the patent system is especially needed to prevent unpermitted imitation. Otherwise few people would like to put effort into innovation on new drugs. Another reason is that the product and process of medicine industry are easy to be precisely codified, therefore convenient for transferring. (19) A clear and precise patent claim means that it is comparatively safe and reliable. (5) In a sum, the patent in the medicine industry generally contain a clear defined chemical composition, which means very high potential value and is difficult to be invented out. These patents are easy to sell for a high rent. As a result, these patents are considered the most effective.

2.4.3 IPR's role in the TCM industry
In TCM industry, the following could be effectively protected by IPR. (1) Prescriptions and formulations;(2) Raw TCM material, including the planting techniques, packaging techniques, quality testing techniques, new medicinal positions, new utilizations; (3) Processing techniques; (4) Medicine production techniques, including the crafts, equipments, preparation accessories, automatic techniques, utilization of the medicine dregs, and the techniques to deal with the pollution; (5)
Techniques for quality control and safeguard; (6) Basic research, including the experiment animal model research, the working mechanisms of TCM, the pharmaceutical rule of compound compatibility, the research on active component and their pharmacology.

There is no systematic research on IPR’s role in the TCM industry. However, in the general opinions of the Chinese scholars, the IPR is not as effective in TCM industry as in the modern medicine industry. There are several reasons for this. First, IPR only protects the innovation products, while a classic prescription may be recorded in the ancient books hundreds of years ago and open to everyone, thus cannot satisfy the condition of innovation for applying a patent. If a prescription has been successfully used by a firm to produce medicine, then other firms could easily imitate. Second, the composition of TCM is complex and prescription often not definite; therefore it is difficult to give a very clear claim for the invention. Without a clear claim, the IPR loses its effectiveness since others could easily imitate by slightly changing the prescription. Finally, since TCM is a traditional industry, many people still do not have the awareness to protect the products by IPR.

Since it is different situation for IPR in the TCM industry, it is a challenge for the TCM firms to consider the IPR situations when they try to launch the innovation activities. From the perspective of the legislation organizations, there may be some omission in the IPR laws that need to be amended to better protect this special medicine industry, but from the perspective of the firms, they have to adapt themselves to the existing IPR systems.

2.5 Previous Research on IPR strategy

2.5.1 An introduction to the enterprise IPR strategy
Enterprises need to do plans and design for the companies in order to direct the business, which could be called the management and development strategies. According to the definition of Fred.R.David, the strategy is a kind of art and science to make, carry and evaluate decisions which could make the organization reach the goal. Due to the high significance of IPR in the TCM industry, IPR should be included as a part of the whole enterprise strategies. The IPR strategy could be defined as a series of strategies and means, which guide the enterprises on how to make use of the IPR systems with the purpose of protecting their own legal rights, gaining the competitive advantage, restricting the rivals and seeking the maximized economic profit. (19) From the definition, we could see that the main task of IPR strategy is to properly use IPR relevant law and policy as a tool to guide the company to create and operate the knowledge property in an optimum way.

The IPR strategy has been used a lot by large firms in developed countries, and they have a certain development trend. The first is internationalization of the IPR management. When the enterprises expand its business abroad, it needs
internationalized management, of which IPR management is an important part. The second is professionalism of IPR related staff. Along with the increasing position of IPR management, more and more enterprises set up specialized departments and staff to work on IPR. Their main task is to do thorough survey and study on the relevant IPR, to analyze the trend, and then setting up schemes for the R&D departments. Another trend is the technicalization of the management methods. Now faced with a more and more complex environment, enterprises need more effective management tools to help make wise and timely decisions. Examples of this kind of tool include mathematical analysis model, statistic method, electrommunication equipments, computer and internet techniques, etc. The fourth trend is that IPR management treated as a profit center. Different from a traditional function of assisting the R&D center in protecting the scientific result, now IPR more and more frequently work as an independent and profitable center. IPR is treated as an asset to administrate. (28)

2.5.2 Previous research on IPR strategy

Previous research on IPR strategy could be summarized in following categories: (1) the basic theory of enterprise IPR strategy, like the definition, the features, the principles of setting and implementing; (2) the correlation between the IPR strategy and the enterprise development; (3) the concrete type and means of IPR strategies; (4) the implementing environment of the IPR strategy; (5) the IPR strategy in successful cases in developed countries. (19)

There are different methods of classifying the IPR strategies, which could be summarized in the following table.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content of IPR</td>
<td>Patent strategy, trademark strategy, business secret strategy, copyright strategy</td>
</tr>
<tr>
<td>Way of implementing</td>
<td>Management strategy, utilization strategy, capital administration strategy, protection and control strategy</td>
</tr>
<tr>
<td>Utilization scope</td>
<td>Inside management and administration, outside management and cooperation</td>
</tr>
<tr>
<td>Certain modes</td>
<td>Offensive, Defensive, Information</td>
</tr>
</tbody>
</table>

The content of right on of the most frequently used criteria for classifying IPR strategy. According to this, there are patent strategy, trademark strategy, business secret strategy and copyright strategy, while the first three are the most commonly used in the TCM industry.

For another criterion, the IPR strategy could include the following types. (1) The offensive type, which means that the enterprise actively patents its new techniques and products or register the trademarks before the competitors do, so that it could be in advantage of monopolizing the market. (2) The defensive type, which means that
before doing research and production in a certain field, the enterprise launches a thorough survey on the IPR situation in this field and the IPR of the main competitors, so that it could make decisions on how to gain values on an existing market. (3) The information strategy, namely the way an enterprise utilize the patent information to serve its strategic decisions. (19)

2.6 Summary

Originating in ancient China, now the TCM as an industry still has its development potential. It is high-tech intensive but differs a little from the modern medicine industry. The differences make the application of IPR strategy in the TCM more complex than the modern medicine field. However, it still relies on the IPR to encourage and protect the innovation activities.

3. An analysis of the outer environment of Chinese traditional medicine enterprises

In order to give some feasible suggestions to the TCM firms in china, a comprehensive study on their operation environment is necessary, which may include a series of factors, like market, plant drug resource, consumer demand, R&D capability, relevant law and policy, etc.

3.1 The factors inside China

3.1.1 The health system for TCM in China

TCM originated in ancient China, and has always been given much attention by the Chinese government since long ago. Since modern years, Western medicine and TCM are the two mainstream medical practices in China. (72) The health prevention and delivery system includes hospitals, health centers, and clinics. Hospitals have the best facilities while the later two provide services and facilities for patients with common and non-severe diseases. 99% or the later two systems are located in the rural areas, and they play an important role in the Chinese healthcare industry. In each county there is a special county TCM hospital (altogether 1800 TCM hospitals). Besides, in most of the township health centers, there are both western medicine doctors and TCM doctors. (41) Some health workers at the village clinics are able to work on both western medicine and TCM. (42) In 2007, there are 298,408 health institutions in total, while 11.91% of which, namely 35538, are TCM institutions. (29) Now most of the hospitals are state-owned, but there are many private-owned clinics. The government has reduced the investment on health sector but owns the price-control right.

In 1986, the State Administration of Traditional Chinese Medicine was established with the function of performing legal supervision and fighting against illegal activities.
Besides, at each level of administration, like province, municipal, and county, there all established particular administrative institutions. Therefore there is a systematic administration network from the top to the bottom.

3.1.2 The education for the TCM
China is also stressing the TCM education. Historically, the knowledge of TCM was passed on to family members or students through the apprentice-master relationships. Now TCM has been integrated into the formal academic training. It was educated in TCM universities, western medicine universities and comprehensive universities. The time a student takes to get the degree of bachelor, master, doctor on TCM is 5, 8 and 10 years respectively. According to the data in 2007, there are 47 TCM universities with 86, 296 graduates, while there are another 89 medicine universities offering TCM major, with 14, 959 graduates, added by 134 non-medicine universities with 7, 129 graduates. (29) The fundamental TCM curriculum includes both TCM knowledge and the western medical science such as the physiology and molecular biology. However, there’s a trend that the TCM training is maybe too westernized with the course time ration to be about 6:4 or even 5:5 between TCM and western medicine. (72)

3.1.3 The resources for TCM production
An investigation of TCM resources was conducted in the 1990s (53), and results showed that there are 12,870 kinds of TCM resources (including taxon under species), including 11146 medicinal plants from 383 families and 2309 genera, 1581 species of medicinal animals from 11phyla, 33 classes, 141 orders, 415 families and 861 genera, and 80 different kinds of medicinal minerals. The statistic research also revealed that the most common 320 medicinal plants have an overall abundance of $8.5 \times 10^6$ tons. The normal output by cultivation is $3.5 \times 10^5$ tons, the normal volume of purchase yearly (including wild and cultivated) is $4.7 \times 10^5$ tons and the yearly requirement is $3.5 \times 10^5$ tons. Besides, of the 29 species of medicinal animals, 26 species have a total reserve of $2.3 \times 10^5$ tons. The output by feeding is 810 tons, while the total purchase amount is five times of that. We also have a rich reserve of the 13 kinds of medicinal mineral materials. (54) Besides, there are more than 600 TCM planting bases in China. The medicinal plants were cultured on a total area of about 3500 Km$^2$, with an annual output of 400,000 tons, which makes the balance between the provision and the demand. (15) However, there are also many problems concerning the use of resources, for example, the overuse of resources, pesticide residue in the medicinal plant materials, heavy metals over standard norms, instable product quality, etc.

What’s more, there are many TCM recipes, with total 300,000 secret recipes and proven recipes, among which 60,000 were recorded in the literatures. Therefore, China has a profound resource to develop the TCM industry.

3.1.4 The market for TCM medicine in China
The total number of TCM out-patient visits is almost 1.3 billion per year, which is about one third of the total outpatient visits in China. (76) Almost 40% of these TCM visits are delivered in village clinics/community health service centers, followed by 28% in TCM hospitals, 16% from health centers, 10% in other hospitals, and 7% from private clinics and others.

Along with the fast economical development and the high GDP growth rate, the medicine field has been given more and more attention. The consumption of medicine has a trend to increase. In 2005 the average medicine consumption was less than 10 USD per person, while it was 300 USD in the US. From 2001 to 2005, the medicine demand has an average growth rate of 12%. Now ratio of the average medicine consumption per person on the average GDP per person is about 2%. The people in the cities consume more medicine than those in the rural areas. Besides, the old people have four times more medicine consumption when compared with ordinary people. (51) As a result, since the aged people will be a larger proportion of the whole population, the increase of the medicine demand will be pushed. Another influencing factor is that the health system in the rural areas is always developing. Along with the increased income and improved life quality, the peasants in the rural areas will be a potential market for medicine. (51)

3.1.5 The national policy and regulation for TCM
Since the 1990s, the micro-economic situation in China is steady, with GDP growth rate around 9% or above. Compared with the western countries, China has a faster economic growth, therefore provides a good environment for firms to develop.

In the “10th five year plan”, modernization of the TCM was put forward as an important topic. According to the “11th five year plan” in the biology industry, the modern TCM projects should aim to increase the TCM industry innovation capability, to build the innovation platform for TCM herbal pieces preparation, TCM quality control and medicinal plant breeding. Large TCM group with annual sales more than 10 Billion RMB will also be encouraged. 7

Now as one of the two main medical practices, TCM is under the same registration and licensing procedures as is western medicine. From 1999, the medical professional licensing is required for the TCM practitioners. The doctors or pharmacist need to have special training, certain years of residency in a medical institution and to pass the license examination to get their licenses. (74)

3.1.6 The TCM practitioners
Though the government supports the TCM education and the development, the number of TCM practitioners experienced a drop due to the popularity of the western medicine. In health clinics, 50.3% of the total doctors do the work of western medicine.

medicine, 32.3% practice TCM/western integrated medicine, and only 17.4% practice TCM (75). Currently, about 12% of the licensed doctors are TCM doctors and only 6% of pharmacists are licensed TCM herbalists.

3.1.7 The public opinions for TCM

TCM originated in China. The theory and principles of TCM is closely related to the Chinese traditional culture, therefore the TCM is accepted by the Chinese population. The efficacy of TCM has been confirmed by the cases of past thousand years. Especially nowadays, there is a trend among the people that they prefer natural materials to the artificial products, thus they more and more prefer the nature herbal medicine to the chemical medicine.

However, there are still a small portion of Chinese people that prefer TCM treatment to western medical treatment (72). A survey of 1161 out-patients revealed that 19% of the respondents have never had any TCM treatment. 25% of them have TCM treatment because of chronic conditions while another 17% have TCM treatment because western medicine failed to cure them. (77)

In another survey of 42,819 Chinese people in both urban and rural area, it was showed that 54% of the people prefer western medical treatment, 25% prefer TCM/western integrated treatment, 12% prefer TCM treatment, and 5% chose western medicine for acute conditions while TCM for chronic conditions, and 1% prefers western medicine for diagnosis while TCM for treatment (78). The reason that the people prefer TCM treatment is: their belief in TCM (50.7%), its good clinical outcome (21.5%), its treatment of the cause (11.2%), frequent adverse-reaction of western medicine (8.7%), and inexpensive price (6.8%). Besides, people with less than a grade school level of education and those with higher than college are more likely to use TCM.(72) Females, people who live in urban areas, and people with professional occupations are also more likely to use TCM.(72)

3.1.8 The academic research of the TCM

Currently, there are about 800,000 references and abstracts to literature on TCM in the Traditional Chinese Medical Literature Analysis and Retrieval System (TCMLARS).(72) However, very few of them are regarded as “rigorous” scientific evidence of efficacy and safety of TCM treatment based on western medical methodology, such as randomized clinical trials (RCT).

There are now about 30 disciplines related with TCM. On the common diseases especially the cardiovascular diseases, malignant tumors, immunology diseases and infectious diseases, the research of TCM has got well progress and clinic effect. In 2007, there are 90 TCM research institutions with 12984 working people. There are 9 national TCM research institutions, 49 province level institutions and 32 at municipal level. (29) The academic research of TCM focuses on several different aspects. The first is the research on the drug processing techniques of the TCM, which improves
the convenience and the curing effect. The different processing techniques and experiences for 500 common TCM have been systematically compiled. The mechanism has been explained how the medicine get rid of toxicity and increase the efficacy by the processing techniques. The second research point is on the dosage form. Now there are about 40 different dosage forms for the TCM, including the injection, capsules, drops, etc. The study on the pharmacology of TCM could be summed as the third point. Research on the planting of medicinal materials is also progressing well. Besides, there are studies on the theory base of the TCM. For example, the meridian systems have been studied a lot. The national new medicine (TCM) clinical experiment research center has been established in Beijing and Guangzhou, which will assume the task of research on TCM. From 1978 to 2000, there are 78 TCM projects results won the national level awards. A quality standard was set for 220 most common TCM materials. (15)

3.1.9 The protection system for TCM in China
There are different levels of legislation and administration on TCM from the state constitution to local laws in provinces and municipalities. In the State Constitution, the legal status of TCM is stipulated. Regulations on TCM have different focus, such as medical administration, production and trade, technology and education, personnel and labor, international cooperation and drug control laws. (41) From the perspective of the firms, there are two different kinds of protection system for the TCM. One is the IPR law system and the other the administration system. Some of them are applicable to all kinds of medicine while some are special for the TCM. Here I will give a brief introduction to both.

3.1.9.1 The IPR related laws for TCM
The main forms for the IPR protection in the TCM industry include patent, trademark, commercial secret, copyright, and new plant species.

(1) The patent protection.
The patent law was first put into force in China in 1985, and from 1993 medicine can be protected by the patent law. There are three types of drug patents: the active component, fraction or prescription of the medicine, the production craft, and the utilization patent. (12) The basic requirement for application of a drug patent is novelty, creativity and utility. The effective period for a patent is normally 20 years, with the application date as the beginning, and the period cannot be extended. In more detailed words, it should never be opened to the public by any means, should be advanced compared with existing techniques or products, and should be able to be utilized for an active role. Since there is a processing time after the application sent in, generally during the R&D process for a new medicine, the time after animal experiments and before the clinic trial phase is the proper time for application of a patent. (48)

(2) The trademark protection
The trademark law was first put into operation in China in 1983. The trademark is a visual mark used to differentiate the medicine for administration or sales. The registration requirement is that no one else has ever registered the same or similar trademark in the same or similar merchandise. The effective period for a registered trademark is 10 years, which is extendable, with the authorization date as the beginning. In a broad sense, the trademark involves five different marks, the trademark, the service mark, the manufacturer name, the commodity source mark, and the source area mark. According to the Trademark Law in China, for all human-used medicine there should be a registered trademark, otherwise it cannot be sold on market.

(3) The commercial secret and copyright protection.
Different from the patents and the trademark, the commercial secret and the copyright are automatically generated, when appropriate to the legal standard, without any special application. The commercial secrets protect the important information in the production and administration process, such as the key formulation, production crafts and methods. The requirement for the information to be a commercial secret is that it should be kept secret, commercially valuable, and be protected by the right owners with certain measures. The copyright protects the published articles, instruction books, databases and software, with an effective period of 50 years.

3.1.9.2 The administration protection system for TCM
The main forms of administration protection for TCM include the new medicine protection and the TCM variety protection. There is another medicine administration protection which aims to protect the medicine registered before 1993 when the patent law started to protect the medicine, and I will not consider it in this article.

(1) The protection of the new medicine
In China a new medicine is defined as a medicine that has never been produced in China. A medicine that has been patented abroad, as long as it has not been produced in China, could still be treated as a new medicine. It could be divided into three categories, namely the TCM, chemical medicine and biological products. The protection for new medicine was stipulated in the “drug administration law”, which was first put into force in 1984 by State Food and Drug Administration (SFDA), with two complementary regulations “provisions for new drug approval” and “regulations for the new medicine protection and the technology transfer” issued later. According to these documents, in each new medicine category, there are five levels of new medicine, with varied protection periods: type I 12 years, type II and III 8 years, type IV and V 6 years. In 2002, the protection period was canceled, replaced by the 5 years new medicine supervision period. The requirements for a new medicine certificate are high quality, security and good clinical trial results. Different from the patent protection, which aims to protect the innovation, the aim for such protection is to set criteria on the new medicine R&D and guarantee the medicine quality. (48)
Although the new medicine protection is not the IPR protection in law terms, it also endows an exclusive production right for a certain period, therefore actually protects the benefit of the right owners, and widely accepted by the TCM firms. Generally, after successfully completing the clinical trial phase, the firms apply for the new medicine certificate from the SFDA. After the certificate has been issued, during the 5 years supervision period, the SFDA cannot authorize other firms to produce or input the same kind of new medicine. (47)

(2) The variety protection for TCM
This is also an administration system that protects the varieties that are produced in China and have been listed in the State Medicine Standard. The requirement for issuing a TCM variety protection certificate is that the medicine should have significant effect on certain diseases, and the product quality and standard should accord with certain requirements. The aim is to guarantee the quality of the TCM variety, protect the human health and standardize the medicine market. (48) The TCM variety that has been authorized to be protected could only be produced by those firms that own the TCM variety protection certificate.

3.1.9.3 The medicine standard
Since the comparatively complex and uncertain feature of TCM, there are state quality standards to regulate on this, such as the Chinese Pharmacopoeia, Ministerial Drug Standards and Pharmaceutical Standards of SDA. The standardization of TCM includes requirement of the name, source, identification, description, extract, processing, assay, characteristics and channel tropism, action and indication, usage and dosage, precautions for use and conditions for storage. Modern analytical methods are used in quality control. For example, thin layer chromatography can test a crude drug and liquid chromatography can be used for single crude drugs or for patent medicines consisting of several compounds. (41)

3.1.9.4 The difference between patent protection and the medicine administration protection
Now there are two collateral protection systems for medicines, each with different focus and features. First, the IPR protection is completely exclusive, but the administration protection system may provide protection for more than one manufacturer, who may not be the original inventor. Second, the IPR protection focuses on the novelty and encourages innovation, while the later focuses more on the quality and effectiveness, encouraging the medicine quality control but not innovation. (17) The new medicine certificate is a prerequisite for a medicine to be on the market, but patent is not. (7) Third, the IPR has a longer effective period, and protects more than concrete medicine but also the techniques and crafts. The new utilization, production methods, and the exterior design for the medicine are all patentable, but the administration protection only covers the medicine itself. Fourth, the IPR protection is stipulated in the law thus with higher protection strength. Before the new medicine certificate issued, the SFDA will check to ensure that the applicant does not
infringe other’s patents. If there is any confirmed infringement, even already issued new medicine certificate could be invalidated. (47) Therefore, the patent protection has a priority over the new medicine administration protection. Besides, the IPR is also internationally accepted therefore better for the firms that would like to do international business. (47)

From their differences we could see that both patent certificate and new medicine certificate are needed. They are differently focused but complementary to each other.

3.2 The factors relative to worldwide trade

3.2.1 The international IPR policies

About IPR, there are many related agreements in the international market, which influences whether TCM could be effectively protected in the international market.

(1) TRIPS. In the famous TRIPS agreement, the geographic mark is defined as the mark that could differentiate a commodity from others by claiming that it comes from a certain country or region. The quality, fame and other features of the commodity could be mainly attributed to the geographic source. Therefore, the geographic mark if of great importance to mark the product quality.

(2) “Convention on Biological Diversity”. It is a law document established by the United Nations Environment Program (UNEP), which aims to protect the sustainable biological and genetic resources, and also the first global agreement on protection of the biological diversity source. Besides bringing forward the goals of protecting and sustainably utilizing the bio-diversity sources, this document also for the first time proposed an idea, that the traditional knowledge is a kind of knowledge asset and should be given equal and urgent protection.

WHO also encourages the Member States to establish a national system of traditional medicine evaluations and formulation. It supports the integration of traditional medicine with modern medicine and the cooperation between both.

3.2.2 The international market for TCM

According to a statistic result of WHO, there are 4 billion people using herbal medicine to cure diseases. In more than 130 countries, herbal medicine is used, and in more than 120 of them there are herbal medicine research institutions. Now the trade of herbal medicine is 30 billion USD, which still grow at annual rate of 20%. (12) For the TCM, there is an international market for export, including the Asia, North America and Europe. Now the four main TCM markets are Southeast Asia, Japan and South Korea, the Western, and the Africa and Arabic market. 

There is a big market outside China for TCM, such as Europe and especially Germany. In 1997, the Institute for Demoscopic Research Allensbach conducted a survey to study the use of natural medicines in Germany. According to the study result, 65% of the German population was users of natural medicine. While in 1970, only 52% of the population was in the group. (41) 80% of the population believed that the risk of natural medicines is low, whereas 47% and 37%, respectively, of the population considered the risk of western or chemical medicines as medium to great. (41)

According to the United Union statistic, the worldwide herbal medicine market could reach 60 Billion USD every year, which is 20% of the total medicine market. In recent years, US gradually recognized the TCM as the medicine rather than the dietary supplement. In 2005, the NIH of US together with the NCCAM, brought a plan of developing the plant medicine. In 2004, FDA issued the “guidelines for plant medicine research”. The requirement for plant medicine is slightly different from chemical medicine. The standards requirement for pre-clinic research techniques is looser, and the mixture of plant medicine could be treated specially. (51)

3.3 The basic situation of TCM industry in China

In China, the TCM industry is categorized into three groups: the raw herbal medicine, sliced herbal medicine, and patent medicine. (72) The sliced herbal medicine is the herbal medicine that has been processed. There are basic processing method such as slicing, steaming, and drying. Besides, some other raw herbal material is processed with ginger, honey, licorice, and sulfur. The major purpose of these processes is to reduce toxicity, to sanitize and increase the efficacy. The patent medicine is the herbal medicine formula that has been standardized, with patent or not.

Currently there are 561 herbal resource centers that produce raw herbal medicine, 1500 manufacturing sliced herbal medicine and 684 producing patent medicine. (73) Developing and Producing TCM drug is the core affair of these TCM companies. Some big enterprises have their planting base themselves, but the most of them need to buy the materials from providers. In general, this is a typical knowledge- and technique-intensive industry, highly depending on the research and development. The value chain of one typical enterprise could be described using a linear model:

![Figure 3: the value chain of a typical TCM enterprise.](image)

3.3.1 R&D of TCM firms

There are four different types of R&D of TCM. (Table 2) The first is separation of single chemical compounds from the medicinal plants, and then development of new medicine based on activity screening experiments, pharmacological and toxicological
tests. This is very similar to western medicine R&D. The second is preparation of the effective fractions of the medicinal plant, which then could be used for new drug development. The famous Chengdu Di’ao group is mainly doing this type of R&D. The third, namely the most traditional and common type, is Chinese herbal medicine compound preparation based on the traditional TCM theory and prescriptions. The main composition of such drugs is crude extract of natural plants, and the relevant compound should satisfy the quality index. The famous Tongrentang Group is the leader in this type of medicine production. The fourth type is development of functional food and beverage based on the standardized crude of plant drug. (15)

Table 2: Four types of TCM new medicine R&D.

<table>
<thead>
<tr>
<th>Type</th>
<th>Main content</th>
<th>Strength of IPR for protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1</td>
<td>Separation of the single chemical compounds</td>
<td>+++++</td>
</tr>
<tr>
<td>Type 2</td>
<td>Preparation of the effective fractions of medicinal plant</td>
<td>++++</td>
</tr>
<tr>
<td>Type 3</td>
<td>Preparation of mixture of the crude extract of natural medicinal plant</td>
<td>++</td>
</tr>
<tr>
<td>Type 4</td>
<td>Development of functional food and beverage</td>
<td>+++++</td>
</tr>
</tbody>
</table>

Considering the protection content of the IPR, I simply differentiate the IPR protection strength of each type, which of course needs more scientific survey to confirm. For the TCM R&D which is similar to the western medicine research (type 1 and type 2), IPR works well. However, different from the modern medicine field, IPR may not be as effective in the traditional type 3 (Preparation of mixture of the crude extract of natural medicinal plant). The main reason is that IPR only protects the innovation products, while a classic prescription may be recorded in the ancient books hundreds of years ago and open to everyone, thus cannot satisfy the condition of innovation for applying a patent. If a prescription has been successfully used by a firm to produce medicine, then other firms could easily imitate. A second reason is that the composition of TCM is complex and prescription often not definite; therefore it is difficult to give a very clear claim for the invention. Without a clear claim, the IPR loses its effectiveness since others could easily imitate by slightly changing the prescription.

3.3.2 Production step of TCM firms

For the production step, in the past TCM was made by handwork or by simply mechanized lines. Now, due to the state emphasis on the medicine quality control and the demand of the production efficiency, such production mode is no longer applicable. Since the 1980s, China started to push the system of GMP (Good Manufacturing Practice) among the medicine producers in order to guarantee a secure and controllable production of the medicine. More and more TCM firms have passed the GMP confirmation. Scholars studying on the modernization of the TCM industry also call for advanced production lines with quality control system and high
manufacturing efficiency so that this medicine could satisfy international standards and be on the international market.

3.3.3 Marketing of TCM firms
Marketing is another important step of the TCM firms. Their clients are mostly hospitals and drug stores. Although China pushes the development of retail drug stores, now hospitals are still the main clients for the TCM firms. An efficient marketing network and a group of talents with the ability of opening and keeping the market is the prerequisite for success. In sum, a well operation of the chain signifies well development of a firm.

3.3.4 Features and trends of TCM industry
In recent years, the TCM industry has a fast development, with annual growth rate of sales 15% and that of profit 7%. In 2004, there were 5605 medicine production enterprises, of which 2412 produce the TCM. After the GMP put into operation, many TCM enterprises stop or changed their business. Up to 2006, there were 5801 medicine production enterprises, of which 1752 produce TCM. The industry economy is more than 100 billion RMB, with about 9000 TCM varieties and more than 40 dosage forms.

There are certain features for the TCM industry. The first is small scale. About 90% of the TCM firms are small scaled. They have a dispersive distribution, with little communication with each other. In 2001, among the 500 Chinese large firms only 25 are TCM firms. According to a statistic, in 2001 only two medicine firms have annual sales of more than 5 billion RMB. The second feature is that there are a large number of TCM firms, but with very similar products. For example there are about 150 firms producing the Bezoar Antipyretic Tablets, and 200 firms producing Isatis tinctoria. Therefore the provision is much more than the demand. Another feature is that the products are low in techniques, which is due to lack of the R&D investment. On average, only 2% of the sales are used for R&D investment. Fourth, most of the firms stress marketing much more than the IPR creation. The core patents for a firm are few. Besides, a normative innovation system has not been formed. The TCM industry should be a whole industry chain, requiring the cooperation of the capital, technology, marketing, etc. however, the cooperation between these parts has not been formed. Finally, the innovation environment in the state is also not good. In recent years, the drug price has been lowered by the national policy.

Now along with the advocate for modernized TCM development, more and more TCM firms invests in the research of the chemical medicine mode. They try to use modern molecular and protein technologies to look for effective fractions or compounds to develop new drugs, but neglect the fact that TCM is different from chemical medicine. It has its special feature and advantages. Modernization of TCM

is not to simply change it into chemical medicine. 

3.4 The opportunities and challenges
After analysis of all the environment factors that may exert influence on the TCM enterprises, including the infrastructure, resources, market, culture, protection laws and regulations, we could see that there are both opportunities and challenges for the TCM industry to develop.

On one hand, there will be an increasing market for the TCM industry, along with the demand of the population and the support from the government. The profound TCM resources and talent reserves guarantee the well development, while the continuous research on TCM provides the basis for the development towards a modernized future.

On the other hand, there are more challenges to face. First, TCM has had a slackened development in modern years, therefore is hard to adapt into the modern healthcare and R&D. Many consumers still regard the TCM as less developed and far behind the western medicine. (72) Besides, the knowledge and concerns about the adverse effect of western medicine is much less than that for TCM. Although the TCM principles is an important part of the Chinese culture, as a sort of medical science its theories and methodologies still need to be confirmed by modern science. For example, it is of need to explain clearly the matter foundation for Yin, Yang and Qi. It is the most effective method for the TCM industry to fight against the skepticism.

Second, most of the firms are small scale, without advanced equipments and production techniques. The variety of dosage forms and products are low. Third, there has not been formed a system to ensure stable quality of the medicinal materials and the manufactured medicine. Fourth, although supported by the government, there are still skepticism towards TCM because lack of scientific theory base. Therefore the TCM firms should have a clear understanding of the outer environment, to seize the opportunities and meet the challenges.

4. Suggestions for Chinese TCM enterprises
Considering all the factors analyzed above, TCM enterprises in China need to choose innovation and IPR as their development focus in order to meet the requirements of TCM modernization. Innovation gives TCM firm competitiveness, and IPR guarantee their competitiveness.

4.1 The R&D or production value chain
The operation of a typical TCM firm could be described by figure 4. A project is
firstly pushed by the market demand. If the feasibility and potential profitability of this project get confirmed, it goes into two collateral chains. The first chain describes the progression of the project, and the second chain describes the flow of the created Intellectual Property (IP). There is a correspondence between each step of the upper chain and that of the lower chain. The R&D step solves the technique problems for drug production, which at the same time creates new knowledge asset for the company, namely the Intellectual Property. In the production step, drug is manufactured by certain production methods, and such core methods should definitely be protected by IPR, so that unpermitted imitation could be prevented. In the commercialization step, the firm prepares the drug for the market. They choose the right market positioning, look for proper sales opportunities, etc. In other words, they try to administrate their knowledge asset, changing them from pure techniques into profit. When the project ends, it goes again into the market.

These two value chains make up the core of a TCM firm. By market survey and scientific research, the firm understands the market demand, and then it aims to satisfy such demand by running the two value chains. A proper running requires good management strategies and methods; innovation and IPR strategies are important parts of this. In all steps of the value chain, there are appropriate strategies. First the IP creation strategy or innovation strategy, then the IP protection strategy, which could be divided into the defensive mode and the offensive mode, followed by the IP administration strategy. Besides, to ensure a good IPR management, there are other auxiliary IPR management strategies.

4.2 TCM firms need to stress Self-innovation

The R&D is a long process. Only continuous innovation on the R&D step could endow TCM firms with core competitiveness. Take the R&D for an innovative drug
for example, which could be divided into 7 phases: preclinical research which covers the basic research and the research on the pharmacology and toxicity, then the three steps of clinical trial phase, followed by the pre-registering research which covers the information analysis, compiling and writing. After the drug has been registered at SFDA and a new medicine certificate issued, it could be finally pushed into the market. (43)

There are different types of innovation. Scholars divided the innovation activities into:

1. Product innovation, which provides customers complete and concrete new products or services.
2. Process Innovation, which provides new methods or procedures for developing and manufacturing the products.
3. Procedure Innovation, namely the way that the products and the process integrated into the organization operation. There are other dividing ways for the innovation activities, but generally classification of them into the product and process innovation is very common. In the TCM industry, product innovation means the development and improvement of new medicine, while process innovation means improvement of the production methods of establishment of a production line. Both of them are important and complementary to each other. The goal of the innovation is not pure innovation, but to create patents of high quality, which is high-tech, and with great profit potential. If the investment for innovation is unaffordable for the firm, it could consider import new techniques by patent permissions or other ways.

For another classification criterion, there are different levels of medicine innovation: the completely innovative medicine, partly innovative medicine, and the medicine with application way changed. The completely innovative medicine requires the most investment, a long cycle, and high difficulty, therefore only large firms with sufficient capital could perform this type of development. The partly innovative medicine is the new medicine but developing of which is based on the already known medicine information, like the working mechanism, the chemical structure, the pharmacology and the clinic effect. The development is more like an optimization or expansion of the original research result, without totally innovative discovery. This type of research has a clear development goal; the techniques and methods are comparatively mature, therefore it’s more possible to succeed. The third type may include several situations: imitation with already set state standard, the imitation of medicine which is already on the foreign market but changing its administration route, the acid radical/base group or the dosage form, imitation of the medicine with a nearly expired patent, production of the medicine by patent permission, imitation of the medicine which has not been on the market but the R&D work has already almost completed. (2) No matter which innovation level to choose, the firm needs to have to clear positioning of it.

4.2.1 Product innovation—Four paths for development of new medicine
As I mentioned above (page 29), there are four types of new medicine R&D. The firm has to analyze its own resources and advantages to decide which type of R&D to do.
For the type 1 and 2, namely the research on single compound or effective fractions, the research relies on the modern techniques and equipments very much. Therefore, the firm should establish its advantage in the modern physics, chemistry, biology, electronics, etc, and develop mature techniques to precisely and accurately extract or separate the chemical composition of TCM. Generally, research could be done to establish a quick activity screening method, which suits the requirement of the TCM features. After the screening result confirmed, the extraction and separation methods should be decided to get the compound of fractions with pharmacological activity. It is also of need to establish an information database which covers the chemical fingerprint and effect activity of the standard extracts. (15) The research focus should be on getting the standard compound and its testing methods and establishing the information database of the standard extracts.

For the traditional type 3, namely the research on the compound prescription, the research should focus on getting the recognition of the market including the international market. On one hand, the firm has to collect effective prescriptions; on the other hand, scientific data is needed to explain the efficacy and mechanism of the prescriptions. The scientificity should be proved, and a standardized production line is more needed for this type of drug development. Since it may be difficult to study the exact effect of each compound in the prescription, it is suggested to study the process how the whole medicine be assimilated, distributed, metabolized in the body. (15)

4.2.2 Process Innovation-Establishment of a steady and controllable production line
Since TCM is complex and unknown in composition, now the requirement on its quality is more and more strict. TCM firms need to ensure that the production process is very steady and controllable to meet those standards. Besides, when a new medicine developed, it is of urgent need to develop a production line for it. The process innovation is as important as the product innovation.

The standardization is a key research point of process innovation, which means the establishment of a standard process to systematically study the TCM on aspects of the medicinal materials, preparation, extraction, purification, and production of the dosage form. The technology platforms may be established, and help the firm to form its own sustainable R&D capability.

4.3 Innovative TCM firms need to stress the IPR
TCM firms have different sizes. A small firm may just involve the development and selling of TCM drugs, a medium firm operates all products that made from TCM drug, while a large firm covers all products or intangible knowledge that use TCM as the resource. (15) In this article, the business of the small firms will be studied, which should also be included in the core business of medium or large firms.
As I mentioned in the previous chapters, TCM is a high-tech intensive industry, therefore innovation is very important. As a result, the firms need to find ways to encourage and guide the innovation activities. Besides, they have to administrate the R&D results profitably. Therefore, to manage the IPR should be one of the main tasks of the firms.

The investors’ confidence with a TCM company may also be proportional to the patent quality and quantity owned by the company. Patent ownership often helps the company get competitive advantage by endowing it with exclusivity. Besides, when negotiating the technology transfer or arranging cooperation, the company with many patents will be on an active position.

From another perspective, the trend for TCM industry development is more standardized research and production. The quality control system and large scale production capability will be more and more important. They may also would like to do the international business. For all these, the IPR is important.

In sum, only with patented technologies of high quality could the TCM firms have its technology and market advantage, and guarantee their sustainable development. This chapter will give some feasible suggestions how a TCM firm could make use of the IPR to encourage, guide, protect, and administrate its R&D activities.

4.4 IPR strategy is an important part of the enterprise strategy

The IPR strategy from the perspective of enterprises, should work with other strategies together, aiming to enhance the core competence of the company in the long term. For a TCM enterprise, the goal of the IPR strategy may be to effectively open, occupy and monopolize a market. Concretely, it involves how the enterprise makes use of certain IPR laws and policies to create, manage, administrate and protect its knowledge asset. IPR strategy is one aspect of the enterprise administration capability and level.

The IPR strategies should be set by a group of people from different positions including the decision maker, the market experts, the IPR experts and the technology experts. The decision maker understands the goal and mission of the company well and will coordinate the strategy towards realizing the enterprise goal. The market experts know the current market situation and potential of the patented products. The IPR people could extract useful information from the IPR literatures. Familiar with the technology and crafts of patents, the technology experts will be able to assess the R&D feasibility. (44)

4.4.1 The IPR protection strategy

Although there are two different ways of protecting the TCM, the IPR and the administration, the IPR is of greater importance since it guarantees a complete
exclusivity. Generally just after the pre-clinical experiments the application for patents could be sent. Then after the clinical trial phases, the new medicine certificate is applied for, which is a prerequisite for the medicine production and sales. Since IPR has a strategically significance but the administration protection does not, here only IPR protection will be considered.

The basic function of IPR is to protect the knowledge and product from being imitated. To meet this purpose, much work should be done. As mentioned in the second part of this article, there are two different types of patent strategy. A more detailed strategy could be as following.

4.4.1.1 The offensive mode
Application for patent as soon as possible
Since the patent law always protect the first applicant of the invention, it is important to apply for patent after finishing the research. There may be more than one firm doing the same research, therefore a preemption attitude for application of the patent is important to guarantee that the result of R&D get protected.

The core patent application strategy
The core patents protect the core techniques or results of the basic research in a field. Later research in this field always goes around these core techniques, which lead to many improvement patents or supplement patents. Core patents often involve some epoch-making or leading core techniques, with potential of wide use and great economical profit. Therefore, owning core patents could endow a firm great advantage in struggling for monopolization position in the technique competitions.

Patent network establishment
This is one of the most commonly used offensive patent strategies, also called peripheral patent strategy. After obtaining the patents for core techniques and products, in order to further prevent competitors from rounding the few patents to make any commercially valuable innovation, the enterprise could try to patent many relevant techniques to form a dense network. The existence of such a patent network could make the competitors unable to use relevant techniques unless with permission, therefore effectively prevent them from sharing the market.

In the TCM industry, when the patent for the new medicine has been authorized, the peripheral patents network may be constructed, which includes the prescription, the crude extract, the effective fractions, the preparation methods and equipments, and the utilization. These peripheral patents could make the firm be able to work in this field to develop more related medicine and extend the effective period of patent protection. For example, the Tianshili group has the compound Dan Sen Drop as the core medicine, based on which they did research on its composition, the effective fractions extraction, the improvement of the production process, and extended the utilization of it from curing the coronary heart diseases and anginapectoris into curing
the micro-circulation disturbance and inflammatory response caused by the chronic alcoholic uptake. All these subsequent patents could expand the market area where Tianshili has the exclusive right on the core techniques, and could extend the period of the exclusivity on the market.

**Response strategy of patent infringement**
The firm should always study the competitors on the market. All business sectors including R&D, new drug production, product sales and product exporting should all be surveyed. Once its patented techniques or trademarks are used by other enterprises, the firm could take proper measures to stop that infringement and get compensation.

4.4.1.2 Defensive Mode

**Patent compromise strategy**
If warned because of infringing other’s IPR, the firm should try to negotiate with the IPR owner to fight for an opportunity of having patent permission agreement and paying the charge for use. This strategy could help the firm avoid being sued, and continue using the patent, but the charge will be higher than ordinary permission fee.

**Patent invalidation strategy**
If a firm plans to do R&D in a field where other firms already have got core patents or even patent network, or in case that a firm is sued of infringement, the firm could try to find evidence to invalidate the patents. If the invalidation is announced by the court or patent bureau, the firm could use techniques in that field without any infringement. This strategy helps guarantee a legal use of techniques by properly use of the patent law and policy. For example, the Shanghai Sanwei company has developed the new medicine of hydrochloride rosiglitazone, which help treat the type II diabetics. At the end of 2002, it successfully completed the clinical trial phase. However, when it intended to apply for the new medicine certificate, it found that the GlaxoSmithKline has already applied for several patents about the hydrochloride rosiglitazone, one of which has been authorized. A similar medicine has already been on the market. Therefore, with the GSK’s IPR existing there, Sanwei will never be able to produce this medicine even it get the new medicine certificate. However, by a careful analysis of the literatures, Sanwei found that before GSK’s application for the patents, relevant articles are published in a non-patent literature, which makes the patent lose its novelty. With this information, Sanwei successfully invalidated GSK’s patent and got the right to produce and sell hydrochloride rosiglitazone. (35)

**Patent utilization strategy**
If there is a patented medicine with the patent expire date approaching, the firm could consider working on the expired patent medicine, since it will not result in any infringement.

**Rebuilding of patents**
For the unpatented medicine of which the techniques have been open, the firm could
do further research based on the existing techniques. If there is any optimized prescription, preparation methods, effective fractions, new formulations, new utilizations found, the firm could patent them and re-gain the market exclusivity.

**Publication of the literature**
In case the firm does not think that there is any worth of patenting a research result, but at the same time, if the competitors patent on this, its own development will be limited. In such situations, the firm may choose to publish the research result in the research articles or in other way. As a result, other firms cannot patent on this because the information has been opened.

### 4.4.2 The IPR administration strategy
Besides having the protection function, IPR department more and more commonly plays the role of profit center. As an intangible capital, IPR need scientific and proper administration and management to be transferred into the profit. Many multi-national firms treat IPR as a profit source, such as IBM and Siemens. By being transferred to other firms, the patents could bring extra profits.

There are two kinds of transferring: the ownership transferring and the use right transferring (namely the patent use permission). The later is used more commonly. In order to make more profit, or share the international market, sales channel, assistant facilities of the permitted enterprises, the firm could consider allowing other firms to use the patent techniques. When the firm does not have any plans to develop in the field where it has patents, it could consider selling out the patents and the ownership for capital, which could be used for investment in new R&D.

### 4.4.3 Auxiliary IP management systems
#### 4.4.3.1 Building of a special IPR department
In order to ensure that the IPR strategies carried on well, it is of necessity to build a special IPR management department, which includes staff working specially on IPR, technique research, law affairs, management and marketing. Actually, this is what many multi-national enterprises do. For small scale TCM companies, a special department may not be needed, but there should be special staff working on this.

#### 4.4.3.2 Setting a systematic IPR management regulation
A systematic IPR management regulation should be set inside the company. The regulation should stipulate the management mode, the working procedures, the supervision on any infringement, the protection methods, the performance appraisal and the education. For example, when there is any technology input or transfer, there should be special survey procedures on the relevant IPR situations. When there are any cooperation or commission in the R&D, there should be clear regulations on the IPR ownerships.

#### 4.4.3.3 IPR information management system
An IPR information management system is also needed, so that the firm could track its and the competitors’ IPR application, transfer, permission, controversial, etc. For a TCM enterprise to better use the patent strategy to direct and support the R&D, information of the existing patents in this industry is necessary to be collected and analyzed. Only after these steps, the enterprise could understand the current situation of its own IPR. They should be aware whether these patents could effectively protect the medicine and restrict opponents in certain ways. By analyzing the IPR advantage and blank of the competitors or potential competitors, the enterprise could be able to make wise decisions on how to obtain more patents by investing in R&D, without repeating work in the field where others already have got patents. The work of such information gathering and analyzing could be summed as the IPR information strategy.

The useful information to be collected includes both the situation of the enterprise itself and that of its competitors as well as the targeted market. Concretely, it should include the following work: analysis of current research and production techniques of the enterprise itself, the development trend of the technology, the life cycle of the technology, the current technology situation and development trend of the competitors.

After gathering those data and analyzing patent or non-patent articles, the enterprise may be able to extract the following useful information.
(1) The kind of product which worth research and development (if the patent application increase sharply and the inventor is a large company or large research institution, then it may be the high-tech or high-invested products)
(2) The turn point of products (when there was a steady patent application, then followed by a sharp decrease, then a sharp increase, there may be a turn for this products)
(3) The development trend of the product market (the time needed for a product from patent application to being on the market, for medicine, it may be around 10 years)
(4) The dynamic situation of the technique patents.
(5) The main competitors and their strength. (the main competitors my the enterprises with the most patents or the patents with a wide covering range)
(6) The possible strategy of the competitors.
(7) The possible cooperation partners.
(8) The market or region where the existing patent could not cover.
(9) The law and technology barrier for our products. (44)

Therefore, it should be a comprehensive work involving the data collecting, drug patent database searching, literature reading as well as scientific statistics and analysis. (4) The IPR information strategy should be done as everyday task. People should always keep an eye on the general movements of the technology in certain fields, and communicate with the R&D department on this. Besides, the IPR information strategy should be performed in the early steps of R&D. Before a project launched, much
4.5 Summary

No matter what IPR strategies the TCM firm may take, it should suit the development of the company. There are several principles of applying these strategies. First, the IPR strategy should be in accordance with the whole enterprise strategy. IPR strategy is a tool for the firm to reach its development goal. In different situations, different development phases or with different goals, different strategies need to be taken. Second, the traditional role of IPR is protection, but a good IPR strategy needs to be taken from the beginning of the value chain to the end. Besides protection, it also guides and contributes to the innovation. Third, the IPR strategy should be a holistic system, with concrete measures complementary to each other. The patent strategy is the core. (6)

5. Case study of two famous TCM enterprises

5.1 The Chengdu Di’ao Group

5.1.1 History of Di’ao Group

The Di’ao group was founded at August 18, 1988 by researchers from the Chengdu Biological Institute of the Chinese Academy of Science (CAS), who had successfully solved the problems of large scale production of the natural product dioscin. Those researchers borrowed the initial capital of 500,000 RMB, and named the group “the pharmaceutical factory of Biological Institute of the Chinese Academy of Science”, which was later changed into “Chengdu Di’ao Group” in 1994. Since the establishment, Di’ao group expanded its production scale unremittedly and the sales reached 138 Million RMB in 1992.

As an enterprise incubated from a research institute, in the early stage of development Di’ao kept a very tight cooperation relationship with the CAS Chengdu Biological Institute. The institute had the ownership of the company, with the task of setting the development goal, creating a good environment for the company operation, and coordinating its connections with the government and related social organizations. At the same time, the Di’ao took the administration right to realized the set goal by self-production and self-sales. It assumed the sole responsibility for its profits or losses, with no capital intercourse with the institute. During the R&D stages there was much mutual support on talents, techniques and equipments, which formed a benign circle.

Such cooperation model had once promoted Di’ao’s development, but not quite suitable for its development in modern years. In 1988, Di’ao took the stock reform, and the CAS Chengdu Biological Institute became one of its share holders.
Quick expansion and large scale production let the Di’ao group accumulate much profit, but also some problems on the management system. From 2001, Di’ao began the administrative structure reform and internal integration, as well as searching opportunities to invest the cash in fields other than the medicine R&D. In 2003, it started to change in a diversified development model. That year, considering the high capital density and low technology intensity, it decided to invest in the energy industry, including the coal industry and the nonferrous industry, which were proved to be very profitable, with annual sales more than 100 Million RMB. Such income supported Di’ao’s high R&D investment in the medicine development. Besides, considering that it is difficult to integrate acquired pharmaceutical firms, Di’ao only has two acquisitions during development.

The annual sales of Di’ao group since its establishment were described in the picture. From it we could see that from the beginning to 2000 was a quick development period, followed by an adjustment and steady period. Actually in 2003, there issued new policies for new medicine, and the registration procedures for new drug has been changed three times during 2003 to 2006. These situation influenced Di’ao’s development in different degree.

![Figure 5: the annual growth rate of Di’ao Group](image)

### 5.1.2 Current situation

Now the Di’ao group is one of the leading pharmaceutical enterprises in China, doing research in fields of natural drug, genetically engineered drug, synthesized drug and new preparation of the medicine. It is also the largest production enterprise for steroidal saponins and high purity thymosin in the world.

The constitution of Di’ao group could be shown by figure 6. It owns 11 companies
with occupied area about 400*667 square meters: four drug production companies, one cosmetics production company, two drug sales companies, one healthcare products (including cosmetics) sales company, one pharmaceutical chain sale company, one mining and energy company, one real estate company.

After a quick development of 20 years since establishment, now the group has net asset more than 4 billion RMB, 8000 times of the original investment, and an annual sale 1.6 billion RMB. It has been in a leading position of paying taxes for 11 years continuously, and the first position of economic benefit in the TCM industry in Sichuan province.
The Di’ao group has been awarded a series of honors, like the “State Innovative Enterprise”, the Excellent TCM enterprise, the excellent enterprise in Sichuan province, etc. Diao has been awarded as the state famous trademark.

The main product of Di’ao group is the Di’ao Xin Xue Kang Capsule, used for prevention and curing of coronary heart disease, angina pectoris, etc. It is the state II level new medicine, state basic medicine, the protected TCM products, and the special production techniques was firstly witnessed in the world. Among the similar drug, Di’ao Xin Xue Kang Capsule has been ranked the first on sales quantity and the second on sales volumn.

5.1.3 The IPR management
When asked the secret for success of Di’ao group, the management people used the “accurate positioning of enterprise” as this key for success. According to his opinion, as an enterprise incubated from a research institution like CAS, Di’ao has a clear positioning of itself. The goal of the firm would never be publishing scientific articles or gaining academic awards but having the optimum market benefit. Therefore, Di’ao pays much attention on the market demand. The frame I mentioned in the third part of this article could well describe its development model. On one hand, it invest much in the R&D, on the other hand, it keeps its attention on the market demand of the drug and establish its sales network. The work mode is just similar to the shape of the dumbbell. The two ends are just R&D and marketing, while the middle part corresponds to a good management system of the company. Di’ao’s success should be attributed to many reasons, for example the sales. Di’ao has its sales network covering 29 provinces or regions in China. 11% of the sales people have a master degree, while 99% were with at least junior colleges education background. These sales people have their talent in exploring and keeping the market. However, in this article I will only focus on its innovation strategy and IPR management, which is also one of the important factors for its success.

5.1.3.1 The Innovation of Di’ao Group
Unremitted R&D on new drug is a prerequisite for Di’ao’s success. The pharmaceutical industry requires very high investment in the R&D, with the feature of high investment, high risk, high profit and long life cycle. According to Di’ao’s management people, the life cycle for Di’ao’s research on new drug is about ten years, similar with ordinary chemical drug. Therefore, Di’ao always stresses the R&D, having an annual investment between 60 to 80 Million RMB.

Such investment has contributed to Di’ao’s leading advantages in TCM industry, including advantages on modern techniques, production equipment, capability and quality control. In 1992, Di’ao established its own research institution on new drug, now with 7000 members, including 1634 technicians. The group has a modern
production area of more than 50,000 m², production lines with GMP confirmation, and advanced production systems.

Di’ ao has the capability of natural drug extraction, active fraction separation and purification, biochemical medicine extraction and purification as well as large scale production of genetically engineered medicine and chemical synthesized drug. In each field, it has special laboratories. Besides, it has the state natural drug engineering center, the drug screening center, the animal experiment center, the pharmacology and toxicology assessment center, the analysis and testing center as well as the post-doctor science research workstation. It has bought the 600M nuclear magnetic resonance apparatus, high resolution mass spectrometer (MS), liquid chromatography (LC), LC-MS, gas chromatography (GC), etc. It also has international advanced equipments like high-throughput full-automatic semi-preparative high resolution LC and dual-arm automatic screening work station. All R&D activities occupy a total area of 20,000 m².

Di’ao group could process 16, 400 ton of TCM medicinal materials, and 100 ton of biochemical drug raw materials. It has the annual production capacity of 3.5 Billion capsules, 4 billion pills, 100 million soft capsules, 80 million little capacity injection, 15 million lyophilized powders, 10 million eye drops, 100 ton of granules, 60 million oral liquid, 20 million bottles of large volume infusion solutions. Corresponding with its high production capacity, the Di’ao group takes very strict measures on quality control to guarantee the drug safety and stability. It has international advanced testing equipments as well as special staff working on quality testing and controlling. The group has its own enterprise standards to control the drug quality, which is higher than the state standard.

As I mentioned above, there are four ways of doing TCM development. Di’ao has chosen to focus on the active site or active fraction of natural drug, which is between developing pure natural drug and pure chemical compound. It is a TCM research model, but better to be controlled on the drug quality. Now Di’ao brings forward about two or three new medicines every year, from which comes half of the sales. 40% of the sales come from Di’ao Xin Xue Kang Capsules. Now it has already developed 10 new drugs with its own IPR, and 30 R&D projects on the way.

Di’ao has its mature procedures and standards for new drug research, so that the projects could run successfully. Generally, the R&D projects are brought forward based on understanding of the market demand. After that, exterior experts will be invited to help fully confirm the feasibility of the projects and choose the right projects to go on. In the real development process, the group stresses its cooperation with research institutions. When the R&D period finishes with certain results, related state department or hospitals will be consigned to continue the pharmacological and clinic research.
5.1.3.2 The IPR protection
Di’ao group knows that the core technology is its success key, therefore always stressing the techniques protected as the technology secrets. Besides, for medicine and crafts, it takes both patent protection and state administration protection. Up to Sep, 2008, it has applied for 112 self-innovation patents of which 30 have been authorized, and 8 PCT patents. For example, around the famous medicine Di’ao Xin Xue Kang Capsules, which has an annual sale of 600 Million RMB, Diao has applied for 9 patents, with the key crafts protected as the business secrets.

5.1.3.3 The IPR administration
The patent should be more than a protection method for the core techniques of the firm but also work as a profit center. In 2000, IBM got a profit of 8.1 Billion USD, 21% of which, namely 1.7 Billion USD were gained from the patent permission fee of the 2881 registered patents. The Shell owns 90% of the world petroleum patents, and the technique permission has been an important profit center for it. (45)

5.1.3.4 The trademark and other IPR related systems
Di’ao cherishes its R&D talents very much. On one hand, it absorbs talents and establishes its own post-doctor work station. On the other hand, it put efforts in the management and encouragement of these talents. The innovative encouragement system has been set to link the personal stipend of R&D staffers with the enterprise benefit. After a product brought to the market, the R&D people will be awarded 3%-5% of the product profit. Therefore, the high the benefit, the more the R&D people will be paid as a reward.

Besides, there set a “special patent research section” and a systematic IPR management system, which covers the whole process of patent invention, writing, auditing, applying, answering, and tracking. The CEO Li Bogang is directly responsible for this research section. The goal of it is to encourage technology innovation, to own the IPR, to respect and protect the IPR.

5.1.4 A summary for the Di’ao’s success
Pharmaceutical industry is different from other industries in that the products, which may be took by millions of different people at different occasions, are in close relation with human body health. Therefore, the drug should be very steady in the quality. Even only little percentage of the medicines cannot satisfy the quality standard, the consequence is hardly imagined. In a traditional meaning, TCM medicine is low in the quality stability. However, in most cases the prescriptions are given discriminatingly by doctors after considering the individual situation of each patient, which makes up for that deficiency in the quality stability. Now if a TCM enterprise would like to go out of the traditional doctor-prescription-drug mode, and realize the large-scale drug production, it has to guarantee a good control of the production process and the final product quality, no matter which specific way it chooses to develop. It is more difficult to realize the quality control of compound mixture natural
drug than that of the active fraction or chemical compounds, because the former has very complex and unknown constitution. This is one of the reasons why d’ao chooses the R&D focus on the effective fractions. In order to ensure the quality control, Di’ao has put 30% to 40% of the R&D investment in the process control and process optimization. Besides, it stresses the cooperation with the medicine equipment production enterprises to develop new equipments that could meet their expectations.

5.2 The Tongrentang Group

5.2.1 The history of Tongrentang Group

Tongrentang is a famous TCM brand in China, founded early in 1669 in the Qing dynasty (the 8th year of Emperor Kangxi's reign) by Xianyang Yue, who was an expert in distinguishing medicinal herbs, and devoted all his life to TCM. The word Tang means Pharmacy, while the words Tong and Ren were derived from the Book of Changes, one of Confucian classics, with the meaning “harmonious and selfless” and “treating others equally” in Chinese. These two words may reflect Xianyang Yue’s wish for his pharmacy.

Just after establishment, Tongrentang pharmacy became famous throughout the capital Beijing. In 1723 (the 1st year of Emperor Yongzheng's reign), Tongrentang was designated by this emperor to be exclusively responsible for providing patent medicine for the Qing royal court, and then had possessed this privilege from eight generations of Qing emperors for 188 years. During past dynasties, Tongrentang staffers always remembered their handed-down pharmacy commandment, translated as “neither manpower nor raw materials is to be saved at the expense of consumer's interests” or “no manpower was to be spared, no matter how complicated the procedures of pharmaceutical production were, and that no material was to be reduced, no matter how much the cost”. This motto was first written by Fengming Yue, Xianyang’s son, in the preface of the book “pill, powder, ointment and small pill ancestral feeding know-how of the yue's family”. From this we could see that Tongrentang has the tradition of stressing the medicine production techniques, the good morality, sincerity and faith. They guaranteed the medicine quality by strict compliance with high standards. By doing so, Tongrentang indeed got continuous trust and confidence from countless consumers of different ages.

In the modern years, the development of Tongrentang is greatly supported by the Chinese government. In 1954, it changed from a nationwide private enterprise into a joint state-private ownership. Songsheng Yue, the 13th descendant of the Yue family, served as the manager of Tongrentang that time. Being a business wise entrepreneur, he was granted an interview by Chairman Mao and President Zhou, elected as vice-mayor of Beijing and deputy director of the All-China Federation of Industry and Commerce.

Under his guidance, during the 50s-60s, Tongrentang had been through a quick development by choosing the way of setting up shops and expanding the group size. It put effort into increasing equipment and renovating production techniques of TCM. In 1957 it became the first developer and manufacturer of the new dose form of traditional Chinese medicine, such as Niuhuang Jiedu Tablet. In 1966, it was transferred as state-owned enterprise, and the brand became the national property.

In 1992, the Beijing Tongrentang group was founded. In 1997, Tongrentang further transferred its ownership into a shareholding system. In that year, the Beijing Tongrentang Group Co., Ltd was established, and listed on the Shanghai Stock Exchange. In 2000, there founded Beijing Tongrentang technologies development Co., Ltd, and were listed in the Hong Kong stock market. Now “1032” could sum the constitution of Tongrentang. It has ten companies, two production bases, one institute, one hospital and two centers. (Following table)

Table 2: the structure of the Tongrentang Group

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<tr>
<th>Companies (10)</th>
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<td>Beijing Tongrentang Technologies Development Co., Ltd.</td>
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<td>Beijing Tongrentang Commercial Investment Management Co., Ltd.</td>
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<td>Beijing Tongrentang Pharmaceutical CO., Ltd</td>
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<td>Beijing Tongrentang Pharmaceutical Development Co., Ltd.</td>
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<td>Beijing Zhongyan Tongrentang Medicine R&amp;D Co., Ltd</td>
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<td>Beijing Tongren Shiji Advertising Co., Ltd</td>
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<th>Production bases (2)</th>
<th>The production bases of Beijing Tongrentang Co., Ltd. (Beijing)</th>
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<td>The production bases of Beijing Tongrentang Technologies Development Co., Ltd. (Hong Kong)</td>
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<th>Institute &amp; Hospital (1+1)</th>
<th>Beijing Tongrentang Institute of TCM</th>
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<td></td>
<td>Beijing Tongrentang Traditional Chinese Medicine Hospital</td>
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<th>Centers (2)</th>
<th>Tongrentang Information Center</th>
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<td>Tongrentang Training Center.</td>
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In 1933, it set up its first oversea shop in Hong Kong in the way of brand authorization. The first shop in Europe was set in 1994 in London. It has over 400 domestic pharmacies including franchise drug retailers, branch pharmacies and shops, and 20 overseas joint ventures or TCM pharmacies within 13 countries and regions.

5.2.2 Current operation situation
At present, Tongrentang has a steady annual growth rate of 20 percent or more. By 2005, Tongrentang's total assets had reached 7 billion RMB, with annual turnover
approximately 5.4 billion RMB.

Tongrentang continues the tradition of stressing the medicine production techniques and capabilities. It has five production bases around Beijing, 41 production lines, capable of producing 26 medicine form and 1000 products. Now all production lines have been awarded GMP certificates by China SFDA, while 10 production lines have been awarded with Australian GMP certificate. The production lines in the Hong Kong production base have also passed the GMP verification.

Tongrentang could really be called the TCM industry leader in China. Tongrentang Co., Ltd. has been among China's Top 50 Listed Companies with the Greatest Potential for Development for five year running, ranking first in 2001 and 2002. Tonrentang Technologies Co., Ltd. Is one of the best performed stocks in the Growth Enterprise Market of the Hong Kong Stock Exchange.

From the official website of Tongrentang, we could see that its enterprise goal is: “by means of developing green medicine brand with high technology, high culture added value and high market share, to become a large-scale pharmaceutical group with strong international competitiveness”, which in short is called “three high and one strong”.

5.2.3 Tongrentang IPR management
Since Tongrentang positions high technology and high culture added value as its enterprise goal, they should have their IPR management system corresponding with the focus on technology. Besides, Tongrentang is recognized as one of the most successful TCM enterprises, and I would like to study on its success experiences. Another reason that I choose Tongrentang as a case is that there are comparatively more materials about it than other TCM enterprises.

Tongrentang brand is the first Chinese trademark registered under “Madrid agreement concerning the international registration of marks” and “Paris convention for the protection of industrial property”, therefore protected by the international related organization. It has also been registered in more than 50 countries or regions worldwide. It is the first trademark from the Chinese mainland to have been registered in Taiwan. The famous brand of Tongrentang is a valuable and intangible asset for this TCM group.

5.2.3.1 The innovation activities
Tongrentang put much emphasis on independent R&D. Most of the R&D in Tongrentang is done independently, while cooperation in the R&D period is less common. In 2006, the Research Institute of Tongrentang was founded by combining the research departments of Beijing Tongrentang Co., Ltd. and Beijing Tongrentang Technologies Development. Co., Ltd. This new institute now directly belongs to the whole Tongrentang Group, and is responsible for the R&D tasks of all subsidiary
companies.

Tongrentang invests about 10 Million RMB in R&D every year, not including the fee for government projects. The R&D people include the research institute staffers and the technicians for all production lines, therefore difficult to estimate. One of the R&D focuses of Tongrentang is the production techniques. According to the stipulation of the state, the drug must be produced in airtight pipelines, which needs large scale capital investment and Tongrentang works well on that. For example, in a project finished in 2008, Tongrentang established the first production line for pills in China, which transferred the manual production model in the past into the real airtight production line operation. This result will reduce the cost for wax and increase the production efficiency.

In Tongrentang there are two kinds of R&D projects: the new drug development and the second-time research, which actually are the product innovation and process innovation respectively. The second-time research includes production technique improvement, quality enhancement, production efficiency elevation, etc. Both are stressed by the group, and carried unremittingly according to the need of the enterprise.

All of the researches of Tongrentang are based on the present experienced prescriptions, which have never been recorded in ancient books. Although the effectiveness of ancient prescriptions has been confirmed by countless cases, they are not applicable for modern enterprise research for several reasons. First, the constitution of the herbal medicine mixture needs to be adjusted a little according to the different situation of different individuals. Therefore, they can not be applied as an ultimate product to the patients. Second, this uncertainty makes it difficult to put them into large scale production, which needs steady quality. Third, the ancient prescriptions were recorded in the ancient books, so not patentable.

Before establishing a project, Tongrentang will do very detailed searching work. It traces the progress of projects and patent application in related fields. Normally, R&D will be done in a field where some previous research has been done, but not further enough.

5.2.3.2 The IPR protection
I did a search on the internet\(^ \text{12} \) and there are 114 patents for Tongrentang. Among them are 36 invention patents, 7 utility model patents and 71 product design patents. Most of the invention patents are about new compound pharmacy and the preparation methods of certain materials.

Most of the patents of Tongrentang are applied inside china. In general cases,

Tongrentang does not apply for patents in other countries. For example, in a project on the production line in 2008, Tongrentang applied for many patents at different stages. This project was in cooperation with the Heilongjiang Dier Pharmacy Machine LTD. It was stipulated in the agreement that both parts would own the IPR. Tongrentang would first apply the patented techniques into production for a certain period of time. When the production in Tongrentang had reached a certain scale, Dier could sell the patented techniques and machines for profit after discussion with Tongrentang. However, Tongrentang itself cannot transfer or sell the machines.

For one successful project drug development, Tongrentang will apply for different patents at the same time: the prescription, the production techniques and the application range. Generally, just after the project finished Tongrentang registers the medicine in the drug approval section in the government to get the approval license number and new drug certification, so that it could start the production. After the supervised period of 5 years, when the production has been on a large scale, Tongrentang began to apply for patents. There are two advantages of this time planning. First, patent application means publication of all details of the key techniques. Application at a time when the production has reached a certain scale could prevent other enterprises from spiteful infringement. At the time when tongrentang has already occupied the market, it would be difficult for other enterprises to gain profit by doing the same business, even if they take the risk of infringement. The second advantage of this time planning is that the period of patent validity has actually been extended. According to the interviewee, there are not much infringement problem about the protection of new medicine.

Tongrentang also has its own brand management department to deal with the infringement lawsuit affairs, which also is a secondary unit directly belonging to the group, just like the research institute. In the interviewee’s opinion, during the development process of a famous brand, IPR lawsuit problems are unavoidable, but generally only small firms infringes others’ IPR with the purpose of profit. Similarly, it is small firms that infringe trademarks abroad. Large firms like Pfizer will not infringe others’ IPR.

In the way of exporting, many countries have lowered the standard for TCM drugs, therefore there are not so much barriers in the international trade. However, Tongrentang will not consider establishing a production base abroad, since the saved transportation fee could not offset the high cost for establishment.

5.2.3.2 The IPR administration
Unexpectedly, according to the interviewee, Tongrentang seldom cooperate with other TCM enterprises because of the competition relationship between them.

5.2.3.3 Other IPR related systems
The IPR related work is assumed by staff at the technology management department,
which belongs to the Tongrentang research institute. They are in charge of the project application, project finishing, IPR application, and related affairs, not having any role in the R&D itself.

5.2.4 The lessons from Tongrentang
As I summed, in modern years, the development of Tongrentang has several features. (1) Stressing the administration of the brand. (2) Owning various products and high market share. (3) Expanding to the oversea market and developing the international competitiveness. By setting shops abroad, Tongrentang establishes a worldwide sales network, which contributes to the brand publicity. However, due to the large difference between TCM and western medicine, at present the targeted market is still ethnic Chinese people. (4) Developing products of high-tech and high culture added value. (5) Developing its own clinics. (6) The operation is a coordinated process, from the planting, to production to the sales.

5.3 Summary
By a simple comparison between Tongrentang and Chengdu Di’ao, we could find that there are many similar features between them. First, both of them have a high investment in the R&D, higher than the average level in the TCM industry. In order to support the high investment in the R&D, they also both take a various development mode to gain profits by investing in other fields. Di’ao invests in the energy field while Tongrentang has its own investment company. Second, both of them have a famous brand, which is invaluable asset for the group. Third, both of them have good consciousness of patent application, so that the R&D result could be well protected. Fourth, they have established the special IPR department working on related affairs to support the R&D.

They also have some differences. The main point is that they have chosen different R&D focus. Tongrentang mainly develops the TCM prescriptions while Di’ao works on the effective compound or fractions of the TCM. A second difference is that the main client of Tongrentang is the drug retail stores, while hospital is still the main clients for Di’ao group.

However, as far as I see, there may also be some points that they are not doing so good. The main function of IPR is still protection for the medicine, and the IPR department belongs to the research institute. The function of IPR as an administrable profit center seems to have been neglected. Due to the fierce competition in the TCM industry, the companies may not want to cooperate with others by means of patent permission. Second, most of the patents they applied are inside china, while the international market is neglected. According to a statistic data, China only has 3% of the TCM international market, much less than Japan and South Korea.

6. Conclusion
After literature reading, analysis of the outer environment for the TCM enterprises, and case study, some conclusions could be given. First, TCM firms need to stress the technology innovation to gain the market advantages. Innovation is the trend for a modernized TCM industry. Only those with advanced techniques could have core competitiveness. Advantages on marketing, advertisement, enterprise management could all be easily imitated, while technology is the real determinant of the strength of a company. Based on this, they have to find out the more appropriate innovation direction. They should take a combination of different levels of innovation after analyzing themselves and finding out the most appropriate positioning. Large firms may focus more on the completely innovation medicine, which requires the longest time but also the highest profit. Small firms may focus more on the medicine with only application way changed, which gives comparatively low profit, but also requires the shortest cycle.

Second, they should try to choose the feasible research focus to develop modernized TCM products. There may be four paths for a modernized development, each with different requirements. A modernized TCM industry calls much for the development of path 1 and 2, namely separation of single active component and preparation of the effective fractions of the medicinal plant, because they more suit the requirement of scientificity of the modern science. On these two paths, it is important to develop the research capability on modern sciences especially the analytical chemistry and molecular biology. Cooperation with universities and research institutes on projects may be a good choice. At the same time, herbal medicine compound preparation, the traditional way of TCM research, is also important in the modernized industry. However, in a new era and environment, development of this type of drugs requires stable quality, standardized production, and more evidence to prove its scientificity. Finally, for every launched new medicine, second time R&D could be done to improve the medicine or the production efficiency.

Third, TCM firms are suggested to make use of IPR strategy in the whole process of its value chain in order to guide and protect its innovation results. They have to develop protection strategies to protect their own benefit, the administration strategies to administrate IPR as a kind of capital and profit source. What’s more, a systematic IPR management regulation is also suggested to establish in order to ensure the strategies implemented. The detailed suggestions are given in Chapter 5.

However, I am aware that this article has several limitations. First, operation of a firm is complex, concerning not only innovation and IPR management, but also marketing, manufacturing, human resource management, financial management, etc. This article gives some suggestions just from the standpoint of innovation and IPR, which is a small part of the whole business affair of a firm. Second, this article has done two case studies, but since the firms tend to protect their IPR related things as commercial secret, it is not easy to get sufficient information. The two cases are both large firms, while actually I am more concerned with medium and small TCM firms who need
suggestions more. Therefore the cases may not be representative enough to cover the whole situation of the TCM industry, but as they are comparatively successful, lessons could be drawn from them. Finally, as the time for this project is short, I don’t have the capability to do the questionnaire study or much further study of the literatures. Further study on the IPR data of TCM firms, questionnaires of their innovation and IPR situations, and other further research, will result in more scientific conclusion.
Acknowledgement

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Reference


Press.


41. World Health Organization-Regional Office for the Western Pacific


