

Patent Trend Analysis on TCM Intervention and Treatment Technology of Immune Diseases in China and Abroad

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Abstract: Traditional Chinese medicine, as an advantageous field of China with independent technology, has received increasing attention in the area of intellectual property right. Among them, TCM intervention treatment technology of immune diseases is an important aspect. However, it faces many problems in its intellectual property right developing process, such as low authorization rate, low technology content, foreign patent layout and competition from foreign enterprises. This paper analyzes patent status of TCM intervention treatment technology of immune diseases in recent years, focusing on the analysis of foreign patent status especially, and finally, puts forward some suggestions on the development of TCM Intervention and treatment technology of immune diseases from the aspect of intellectual property rights.

1. Introduction

Traditional Chinese medicine, according to the State TCM Administration, includes traditional Chinese medicine and traditional medicine of various nationalities, hereinafter collectively referred to as TCM. TCM is the precious wealth accumulated by the Chinese nation in the long-term struggling against diseases. It contains profound scientific knowledge, which makes an indelible contribution to the health and prosperity of the Chinese nation through its efficient practice along the history. It is an important part of the great culture of China.

With the development of modern medicine and immunology, people have realized that the disorder of body's immune system can not only easily cause infection and immune diseases, but also has a close relationship with many other diseases such as tumors, hypertension, diabetes and even mental illness. And generally, immune diseases are considered to be refractory diseases, which indicates that modern medicine still have no effective treatment methods on them yet. In addition, lacking of less-toxic and effective immunomodulatory drugs, many chemical drugs and immunosuppressants have large toxic and side effects, and may arouse drug-induced diseases.

However, traditional Chinese medicine has obvious advantages in this aspect. Many traditional Chinese medicine as well as its ingredients, TCM prescriptions and acupuncture methods have immunomodulatory effects, which can enhance the body's immune function and avoid excessive immune responses, thereby enabling the body to achieve and maintain an immunologic balance. After long-term application and practice, traditional Chinese medicine has been proved to be effective. Many of them have immunomodulatory effects. For example, scientists have found more than 100 kinds of TCM polysaccharides containing immunomodulatory activities.

2. Patent Data Source and Search Formula

The following data comes from the Innography database and Guangdong Patent Big Data Application Service System, among which foreign patent data is retrieved with Innography, and Chinese patent data is retrieved with the Guangdong Patent Big Data Application Service System.

The table below shows the retrieval results of foreign patents about TCM Intervention and treatment technology in immune diseases. Data retrieval date: April 14, 2016.

Table 1 foreign patents for TCM intervention and treatment technology of immune diseases

Item	Quantity of patent application	Quantity of patent authorization	Authorization ratio	Quantity of valid patent	Proportion of valid patent to authorized patent
TCM Intervention and treatment patent	1725	450	26.09%	340	75.6%

Note: the number of valid patents refers to the number of patents that have been authorized and are still in maintenance status as of the retrieval date.

As can be seen from Table 1, the total number of foreign patent applications for TCM Intervention and treatment technology in immune diseases is 1725, and the amounts of Authorized patents are 450, with a low authorization ratio of only 26.09%. Among them, the number of valid patents is 340, and the proportion of valid patents to authorized patents is 75.6%. The total amount of foreign patent applications in this field is low.

The following table is the search results of Chinese patents in the field of TCM Intervention and treatment technology in immune diseases. We download the Chinese patent publication number and import them into Innography for retrieval and statistical analysis. Data retrieval date: April 14, 2016.

Table 2 Chinese patents for TCM intervention and treatment technology of immune diseases

Item	Quantity of patent application	Quantity of patent authorization	Authorization ratio	Quantity of valid patent	Proportion of valid patent to authorized patent
TCM Intervention and treatment patent	12870	4135	32.13%	3020	73.04%

As can be seen from Table 2, the total number of Chinese patent applications for TCM intervention and treatment technology of immune diseases is 12,870, and the authorized amount is 4,135. The authorized ratio reaches 32.12%, of which the valid patent amount is 3020, and the proportion of valid patent to authorized patent is 73.04%.

The Chinese patents and foreign patents data above are summarized, and the results are shown in the following table.

Table 3 global patents for TCM intervention and treatment technology of immune diseases

Item	Quantity of patent application	Quantity of patent authorization	Authorization ratio	Quantity of valid patent	Proportion of valid patent to authorized patent
TCM Intervention and treatment patent	14595	4585	31.41%	3360	73.3%

It can be known from Table 3 that the total number of global patent applications for TCM Intervention and treatment technology of immune diseases is 14,595, and the authorized amount is 4,585, with a relatively low authorization rate of only 31.41%. Among them, the number of valid patents is 3360, and the proportion of valid patents to authorized patents is 73.3%. The authorized

patent is well maintained.

3. Present Status Analysis of Patent Application

Analyzing the 14,595 patent applications retrieved according to their filing year, we can obtain the patent application trend of TCM Intervention and treatment technology in immune diseases in the past 20 years shown in Figure 1.

As can be seen from fig.1, patent applications amount for TCM intervention and treatment technology of immune diseases was relatively small in the 1990s but increased rapidly after 2001. Since 2005, the number of global patent applications has been more than 500 for each year. Although the number of patent applications declined from 2007 to 2009, the decline was small. After 2009, patent applications have been in a period of rapid growth, reaching 1,300 in 2012 and over 2,000 in 2014.

From the perspective of application countries, the relevant patent applications are mainly from China, with a total of 12,870. Chinese patent applications account for 88.18% of global patent applications, which reflects China's unique advantage in the TCM field.

Some patent applications in 2015 and 2016 have not been published yet and are not included in this analysis.

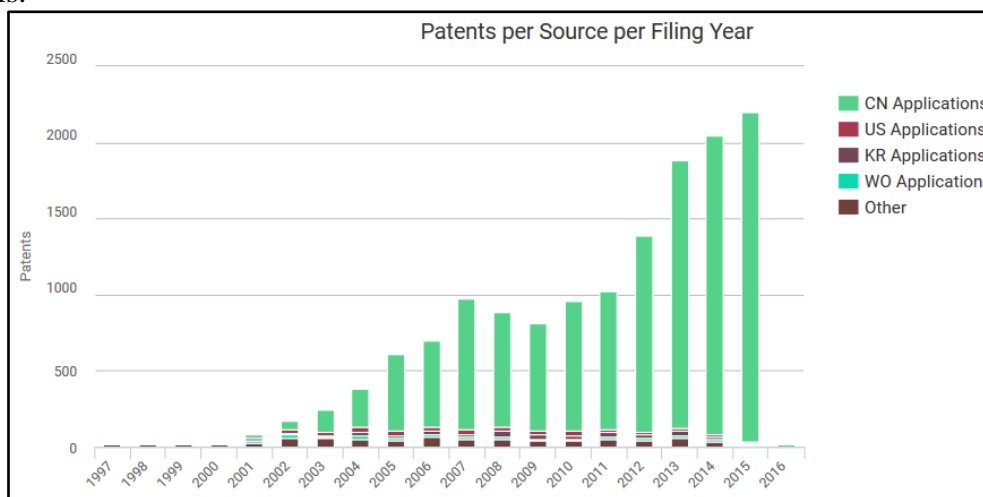


Figure 1 global patent application trend of TCM intervention and treatment technology of immune diseases

3.1 Analysis of Source Jurisdiction

Source Jurisdiction can indicate which countries or regions the patentees will protect their inventions in. And it also reflects the countries or regions where the invention may be used in the future. Through the analysis of Source Jurisdiction, we can find that the patent applications for TCM intervention and treatment technology of immune diseases are mainly distributed in China, which shows that China is a key applying country in this field.

3.2 Analysis of Inventor Location

Inventor Location can reflect the origin place of patent technology. Through analysis, we can find that relevant technologies are mainly derived from China, with a small number from South Korea (412), the United States (297), India (253) and other countries. Chinese inventors have a total of 12,985 patents, accounting for 88.97%, which shows that China is the main research country in this field.

We found that Israel is not among the countries applying TCM intervention and treatment technology, but there are 17 patent applications from Israel, which shows that although Israel conducts research in this field, relevant patents are all applied abroad. At the same time, we found that 253 patents in this field originated from India, but only 126 patents were applied in India, indicating that half of India's patents were exported and distributed in other countries, and India is

mainly a technology exporting country. Although there are only 11 patents from Australia, a total of 47 patents are applied in it, indicating that Australia also has application market, and most of the patents are produced by other countries. In addition, Japan is in the similar situation. Therefore, I suggest that patentees should not ignore the patent layout of key foreign applying countries or regions when making patent applications.

Since most of the patents in this field come from China, accounting for 88.18% of the total, the global patent application trend and technology distribution are similar to those in China. In order to better understand the current Chinese and foreign patent situation, we divide the patent in this field into foreign patent and Chinese patent for analysis.

4. Analysis of Foreign Patent Status

4.1 Foreign Patent Application Trends

According to the statistics of 1725 foreign patent applications retrieved with the Filing Year, we can obtain the trend of foreign patent applications for TCM intervention treatment technology of immune diseases in the past 20 years, as shown in figure 2.

According to figure 2, the total number of foreign patent applications for TCM intervention treatment technology of immune diseases is relatively small. In the 1990s, there were only a few foreign patent applications each year, mainly from Japan, South Korea, etc. In the United States, the research in this field is relatively late, and the application for related patents began after 2000. Since then, a small increase in patent applications could also be seen in other countries, but overall, the number of patents is small, with no more than 40 applications per year.

Some patent filed in 2015 have not been published and thus are not included in this analysis.

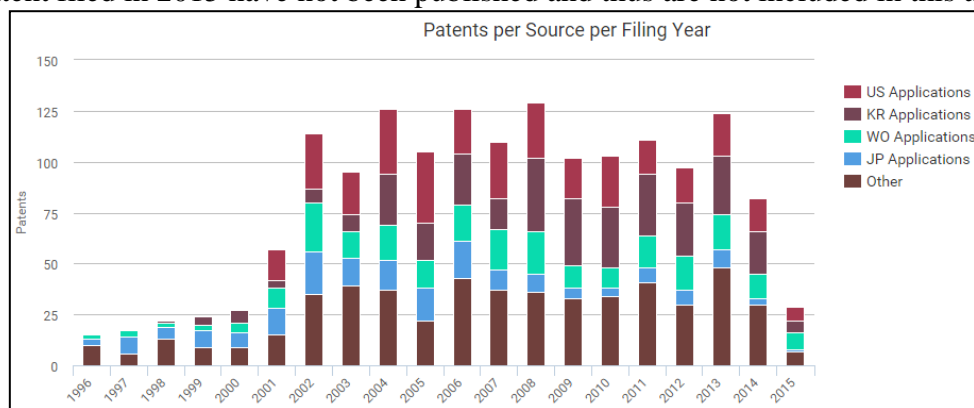


Figure 2 foreign patent application trend of TCM intervention and treatment technology of immune diseases

4.2 Analysis of patentees

In the field of TCM intervention treatment technology of immune diseases, the domestic company with relatively more patents applying abroad is Tianjin Tasly Pharmaceutical Co., Ltd., which has 25 patents abroad, indicating that Tianjin Tasly Co., Ltd. focuses more on foreign markets. If domestic enterprises want to export products to expand the foreign market, they need to pay attention to the layout of foreign patents. Foreign companies or universities with relatively more patent applications in this field include India's Piramal Healthcare Limited, Council of Scientific & Industrial Research, and Yale University. From Table 4, we can see that of the top five patentees with foreign patents, three are from India, namely Piramal Healthcare Limited, Council of Scientific & Industrial Research, and Sahajanand Biotech Private Limited, which shows that India is the main country studying in this field. India has abundant natural plant resources of traditional medicine. According to statistics, it has more than 7,000 kinds of traditional medicinal plants, supporting India to be one of the major technology producers in this field.

Table 4 list of the top 10 foreign patentees

Sequence number	Patentee	Quantity of patent application
1	Piramal Healthcare Limited	45
2	Council pf Scientific & Industrial Research	29
3	Tianji Tasly Pharmaceutical Co., Ltd.	25
4	Yale University	25
5	Sahajanand Biotech Private Limited	17
6	Procter&Gamble Company	16
7	Kyung Hee University	15
8	Korea Institute of Oriental Medicine	14
9	Tsumura & co	11
10	Amorepacific Corp.	11

4.3 Analysis of Inventors

According to statistics on foreign patent inventors in TCM Intervention and treatment technology of immune diseases, most of the top ten inventors are from enterprises, with only two inventors belonging to scientific research institutes in universities. And the top ten inventors are mainly from Piramal Healthcare Limited, showing that the company has relative advantages in TCM Intervention treatment technology of immune diseases.

Table 5 foreign patent inventors for TCM intervention treatment technology of immune diseases (TOP 10)

Sequence number	Inventor	Quantity of patent application	Affiliation
1	Somesh Sharma	30	Piramal Healthcare Limited
2	Shwu-Huey Liu	20	Yale University
3	Yung-Chi Cheng	20	Yale University
4	Paul Schulick	18	New Chapter, Inc.
5	Thomas Newmark	16	New Chapter, Inc.
6	Ashish Suthar	16	Piramal Healthcare Limited
7	Mi Won Son	15	Dong-A Pharmaceutical Co., Ltd.
8	Soon Hoe Kim	14	Dong-A Pharmaceutical Co., Ltd.
9	Parikshit Gaikwad	14	Piramal Healthcare Limited
10	Arvind Saklani	14	Piramal Healthcare Limited

4.4 Analysis of Technology Structure

Through analysis of IPC for TCM intervention and treatment technology of immunological diseases, we can see the categories of foreign technologies and the distribution of related patent applications in this field.

The tree diagram in figure 3 shows the statistics of IPC involved in foreign patents for TCM intervention and treatment technology of immune diseases. In the figure, each region represents an IPC group, and the area size represents the number of patents contained in the IPC group. Regional colors represent the total number of global patents. The redder the regional color, the more the total global patents are, and the bluer regional color, the less the global patents are in this field.

As shown in the figure, the IPCs in this field are mainly the A61K subclass of A part (medical, dental or cosmetic preparations), which are specifically concentrated in the A61K36 group (drug products with undefined structures from algae, mosses, fungi or plants or their derivatives, such as Semi-finished traditional herbs product). The rectangular area of this graph is the largest, indicating that the patents analyzed are mostly concentrated here. In addition, the patents in this field also include the A61K9 group (such as: external preparations for treating immune diseases, Chinese medicine capsules, Chinese medicine pills and other pharmaceutical preparations characterized by

special physical shapes) and the A61K31 group (for example, pharmaceutical preparations with effective components such as flavonoids, saponins, polysaccharides, etc.). Other technology types had fewer patent applications.

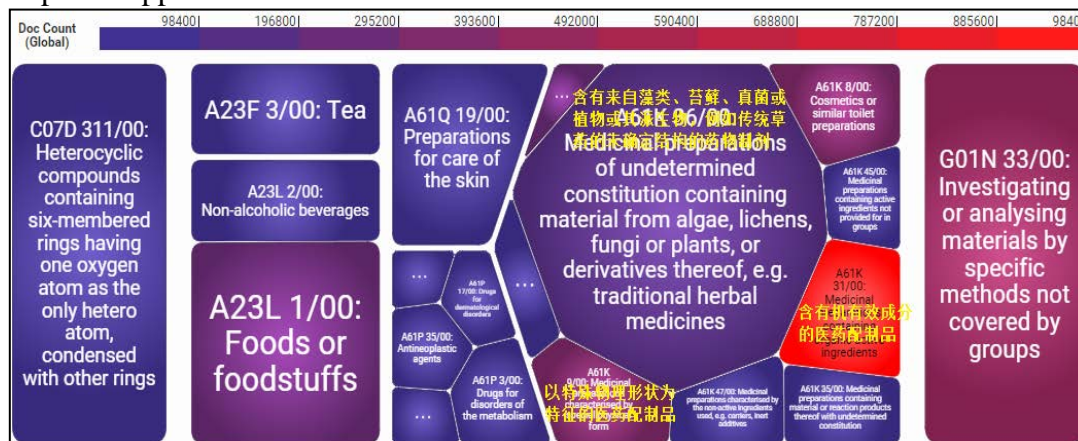


Fig. 3 distribution analysis of foreign patented technologies

4.5 Competitiveness Analysis of Patentees

Through the competitors bubble chart from Innography, we analyze the competitiveness of foreign patentees in this technical field. The statistical dimensions include bubble size, abscissa and ordinate.

The larger the bubble is, the more patents the patentee has.

Through comprehensive statistical analysis of three key indicators, patent quantity and quality, patent classification and patent citations, the horizontal axis of the bubble chart can objectively and comprehensively reflect the technical strength of each patentee. The higher the statistical value, the stronger the technical strength of the patentee is in this technical field.

Through comprehensive statistical analysis of three key indicators of patentee, annual revenue, the number and location of R & D centers, and legal litigation, the vertical coordinate of the bubble chart can objectively and comprehensively reflect the overall strength of each patentee. The higher the statistical value, the stronger the overall strength of the patentee is.

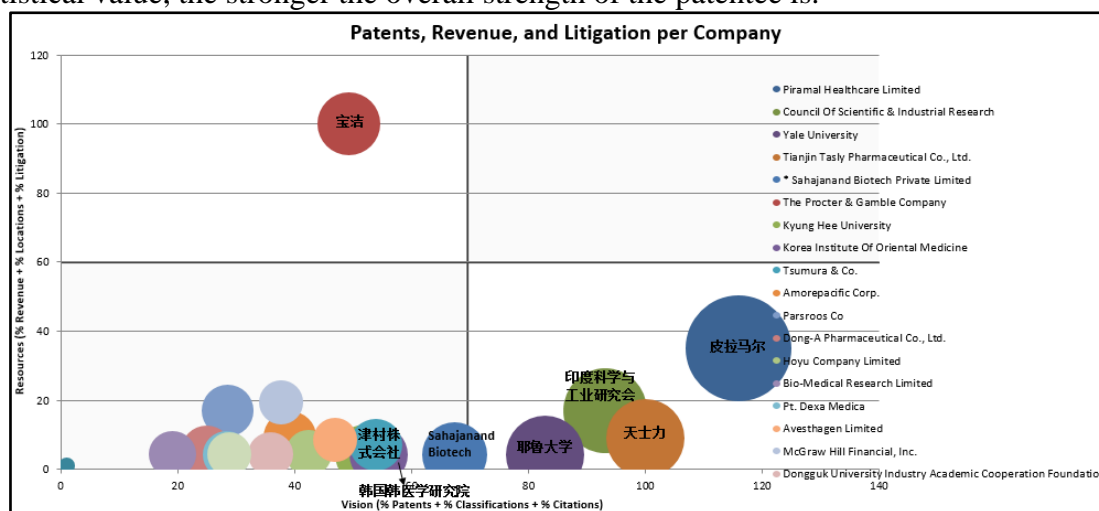


Figure 4 competitiveness analysis of foreign patentees for TCM intervention treatment technology of immune diseases

First, the distance of the bubble from the origin can indicate the technical strength of each patent applicant. Piramal Healthcare Limited's bubble is at the forefront of the abscissa, indicating that its technical strength is ahead of other patentees in the picture. In addition, the technical strengths of the Council of Scientific & Industrial Research, Tianjin Tasly, and Yale University among foreign patentees are also strong.

The position of the bubble can reflect the overall economic strength of the patentee. The higher the bubble height, the stronger the overall economic strength of the patentee is. As can be seen from the figure, P&G is the only company at the top of the picture. It shows that the economic strength of this company is relatively strong, but it lacks certain technical strength in the field. We suggest that the company can cooperate with technology leader companies to enhance its overall strength.

5. Conclusion

By analyzing the search results, we can know that the patent authorization rate in TCM intervention treatment technology of immune diseases is low. The reason may be that the current pharmaceuticals patent system is mainly designed for Western medicine, and the patent examination standards for originality, creativity and practicability are required precisely and strictly. However, due to the particularity of TCM, it is difficult for it to obtain the complete guarantee and fundamental protection from the current patent system. At the same time, there are many non-service patent applications in Chinese medicine. Many TCM technology inventors do not consider the possibility of authorization and industrialization, and some inventors even apply for patent just for honor. Therefore, many traditional Chinese medicine products have considerable limitations in clinical validation and test methods, which results in a low authorization rate.

Traditional Chinese medicine is an advantageous field of China with independent intellectual property rights. It has a far-reaching influence on southeast Asia, Japan, South Korea, India and other countries and regions. Moreover, in recent years, the Chinese medicine industry has gradually attracted the attention of the United States and many countries and regions in Europe and Australia. These countries and regions compete with China in the TCM market. One of the main means competing with Chinese company is to make full use of the patent system for TCM patent distribution, and to build a patent barrier to Chinese TCM industry. Meanwhile, in the field of TCM Intervention and treatment technology of immune diseases, Japan and Australia are relatively important technology applying countries. However, many patents in these countries are produced by other countries' inventor. Therefore, I suggest that patent applicants should not ignore the patent applications in key foreign countries or regions when applying for patents.

From the aspect of technology types, the main research of TCM Intervention and treatment technology of immune diseases in foreign countries include A61K36 group, as well as A61K9 group (for example, external agents, traditional Chinese medicine capsules, traditional Chinese medicine drop pills and other pharmaceutical preparations with special physical shape for the treatment of immune diseases). However, Chinese patents mainly focus on the prescription or extraction of TCM herbs, but relatively few on TCM compound or proprietary Chinese medicine. In addition, the dosage forms of TCM patents are mainly about conventional dosage forms such as pill, powder, paste, capsule, granule and oral liquid, while the researches on new dosage forms are relatively few. Conventional dosage forms of TCM use ordinary manufacturing methods, which are not difficult and are relatively low in technological innovation. This is mainly because of the different concepts and perspectives between TCM and modern medicine, which set great barrier for TCM to fix modern medicine standards and to expand the international market, and it also put forward to new requirements for the innovative and development of traditional Chinese medicine.

We should usually pay attention to the status of patent applications in important markets such as the United States, South Korea and Japan, and apply major patents in important markets. For example, we can pay attention to patent applications in diabetes, skin diseases, cancer and other fields in the above countries and make corresponding arrangements of patents.

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