

Research on the Status quo of Anti-cancer Pharmaceutical Patents in China: Based on the Patent Analysis

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Abstract: Patent documents contain a large number of economic, technical and legal information, which is an important information source for technological innovation. The paper explored the patent information of pharmaceutical R&D based on data of anti-cancer pharmaceutical patents in China from 1986 to 2012, which help of search analysis of patent data, and drew the patent map of the R & D in the field. Therefore the main problems in the process of pharmaceutical R&D and related advice are put forward.

Introduction

Patent is the most effective carrier of the technical information. Based on the statistics of the World Intellectual Property Organization (WIPO), 90-95% of Research and Development (R&D) outcomes are covered in patent documents, in which 80% of published technical information is not disclosed in the technical literatures. More than 90% of inventions information all over the world is first found in the patent literatures. If the patent information which is utilized to the best advantage would likely shorten 60% R&D time and save 40% R&D cost [1]. At the same time, patents are useful sources of knowledge about technical progress and innovative activity [2], which, most importantly, are significant indicator for measuring the level of innovation capacity in a country or region. As a matter of fact, they will also have a profound impact on a country's national sovereignty and economic security. Having resort to the advantage in economic, technical competition, the developed country takes a strategy of expanding the coverage and layers to protect their patents, hoping to obtain more market share. While the developing countries are facing extreme pressure from developed countries having the patent competitive advantage of and more technical barriers.

Materials and Methods

The data source of this analysis is from the Chinese Patent Office's (SIPO) Patent Search and Service System (trial) [3], which retrieved in June 2012. That's to say, this analysis is based on the authorized announcement literature issued before June 2012; and there would be some delay on statistics of patent information, resulting in a floating of the number of patent applications which is for reference only.

Query for anti-tumor drugs

Application date: Jan. 1, 1986 - Jun. 1, 2012.

Keywords: (tumor AND cancer) NOT (health-care wine AND tea AND health-care AND pill box)

Query=①+②. Save the retrieval results in Excel file to the local computer, and then carry out data scrubbing which include two processes: (1) related screening of the patent literature retrieved and filing the patent literature meeting the requirement, (2) regulating the different writing on same concept to eliminate analysis inaccuracy resulting from different writing on same concept or item. On the basis of the above mentioned, patent data of this paper is finally coming out.

Results and Discussion

Overall development trend of application

Among 1986 -2011 year, the total patent applications of anticancer drugs in China are up to 7270. In whole process, it can be divided into three stages.

The first stage is from 1986 to 1992. During this period, the patent applications of anticancer drugs are rare, which is less than 100 ones. The main reason is that the patent of drugs, according to the Article 25 of Patent Law in 1985, could only be granted to methods of production rather than drugs themselves or substances obtained by using chemical methods. Consequently, it lacks of self-innovation drugs in China for people only imitate new drugs abroad in this period. People are not enthusiastic about application for its valueless.

The second stage is from 1993 to 2004. Here it can be subdivided into two parts: the first one is the stage from 1993 to 1999. China has modified "Patent Law" and bestowed patent protection to medical production in order to revitalize the pharmaceutical industry, advance medical technology, take the country on the road to innovation on the basis of absorbing foreign advanced technology as well as encourage medical technology inventors' enthusiasm, absorb investment and transfer new technology. In consequence, since 1993, the applications grow steady from 19 in 1993 to 96 in 1999. The second one is the stage from 2000 to 2004. In 2000, for complying with the requirements of China's market economy and international rules, China has implemented the second amendment to Patent Law, which further strengthens the efforts for patent protection, improves the judicial and administrative

Enforcement, at the same time simplifies and improves the patent approval and rights protecting program, safeguards the legitimate interests of clients. In this context, the patent applications of anticancer drugs get rapid development, increased from 119 in 2000 to 311 in 2004.

The third stage is 2005-2011. Given important position of China in the global strategy, a number of large international pharmaceutical companies have strengthened the efforts for patents layout one after another. On the other hand, in June 2008, the State Council issued the "National Intellectual Property Strategy Outline", which enhances the ability of Chinese anti-oncology drug patent creation, utilization, protection and management. It is of great significance in promoting the sustainable development of medicine industry. As a result, applications, witnessing a leapfrog development, achieve to 974 in 2011 from 528 in 2005. While anticancer drugs patent applications are still growing in trend.

The analysis of technology life cycle

The technology life cycle could be drawn out by gathering statistics on the variety of related patent applications and applicants in a technology. Generally speaking, the development of a technology may go through several stages such as embryo, growth, maturity, recession and recovery. In the embryo stage, manufacturer is not enthusiastic about the investment in the technology. Patent applications and applicants are in a small number but surging in growth stage. After it becomes mature, neither most companies willing to keep investment in research and development save a few manufacturers, nor new manufacturer wish to step into this area. And the growth of patent applications and applicants gradually slow down in this period. However, during the recession, the development and research of industry technology is grinding to a halt for either technical barriers hard to break through or over-maturity on industrial development, bringing the decrease in patent applications and applicants. At last in recovery period, Companies find blank sites of the technology toward a new technical direction which bring sharp increase in patent applications and applicants. Figure 2 is about technology life cycle of anti-tumor drugs patents. As it is shown, the research of anti-tumor drugs is in embryo stage from 1986-1992. And the patent applications (66) and applicants (88) are not so many. Then patent applications rise rapidly to 847 from 19 while applicants to 432 in 2009 from 57 in 1993 in the growth stage 1993-2009 year, which maintain on a stable level as applications rising 886 in 2010 to 974 in 2011 and applicants dropping to 249 in 2011 from 368 in 2010.

The analysis of key areas in technology development

The IPC is a tool for classification of patent literature from each country. It's designed as a retrieval tool for assuring the novelty and creativity including evaluation on advancement and practical value for Patent Office or other users. Users could obtain technical and law information in convenience as well as evaluate the development after analyzing the existing level in a technology.

The dominant one is A61K, which is up to 3760. Next comes the C07 (1845). These two patents numbers achieve to 5605 in total which account 77.1% of all patents numbers. In terms of the origin and structural features of anti-tumor drugs, it can be divided into three categories as chemical, Chinese and biological medicine. Currently, the key area of anti-tumor is chemical pharmaceutical. The mechanism of anti-tumor drugs taking effects is mainly preventing the synthesis of DNA, RNA and protein or targeting these macromolecules, resulting in the death of cancer cells from inhibiting the division and proliferation of them. Some drugs could be used for inhibiting tumor growth by altering hormonal balance. Anti-tumor drugs mainly include alkylating agents, antimetabolites, plant alkaloids and natural drugs, antibiotics for cytotoxin and related material and other anti-tumor drugs. From the point of this view, it matches well for patent application layout to current overall shape of technology development in anti-tumor drugs.

The highest portion shows in 2006, which is up to 68.5%, and the lowest in 1996 to 14.3%. On the other hand, the portion of C07 in all is to 25.4%, this data is also surpassed respectively in 86, 88, 90, 91, 92, 00, 02, 03, 04, 07, 08, 09, 10 and 11 year. Among that, the highest portion shows in 1988 which is up to 46.7%, while the lowest is in 1987 only to 0%. The portion of C07 in all is to 25.4% which is surpassed in 96, 98, 00, 01, 02, 03, 05, 08, 09 and 10 year. The highest portion to 18.9% shows in 2001 while the lowest to 0% in 1986. Furthermore, the above mentioned higher and lower growth rate do not come from the same year, implying there is a problem where something added to one side has to be subtracted from the other in patent IPC structure of anti-tumor drugs, that is to say the applicants apply for different technology areas in different years.

Statistics from international comparison

The research of anti-tumor drugs mainly focuses on A61K which possesses the biggest portion 59% in China. The country ranking from 2 to 10 respectively is the U.S. (53.2%), Canada (48.1%), UK (46.2%), Korea (44.4%), Germany (41%), France (40.1%), Switzerland (40.2%), Italy (39.2%) and Japan (33.5%). The biggest portion of C07D achieves to 28.8% in Italy, C12N 22.1% in Canada; C07K 22.9% in Germany, C12Q 8.5% in the U.S., G01N 12.7% in France, C07H 4.8% in Korea, C07C 7.9% in Switzerland, C07J 3.1% in China, C07F 3.8% in UK. From these data, it can be seen that research in anti-tumor drugs gets rapid development all over the world in recent years. Each country has its own interests and key areas, which will bring breakthrough in tumor treatment. With the progress in molecular biology, foreign applicants focus on the new anti-tumor drugs taking effects on tumor producing process and different tumor target, which is mainly embodied on C07 and C12. This kind of drugs has the characteristic of high pertinence and efficiency, which change the way of traditional chemical drugs engaging all the rapidly dividing cells and process the treatment against gene mutation and abnormal gene expression of tumor cells. Thus it has the advantage of more efficient drugs absorbing, less side effects, better bioavailability and treatment effect.

The analysis of patent application date

There are two obvious trends could be observed. The first one is that the most obvious growth trend could be seen in China, which is out of nothing from the variation curve. In fact, there is a small amount of patent applications no more than 20 every year in 1986-1992. Afterwards, it is poised to increase and possess an average annual growth rate of 16.8% in 1993-2001. From 2002 to 2006 comes the rapid growth stage, in which the applications increase from 259 in 2002 to 660 in 2006, multiplying 2.5 times over 5 years and getting an average annual growth rate of 26.3%. At last, it gets a decline of 379 in 2011, falling back to the 2004 levels. The whole process is inverted U-shape. The second one is that the applications in other countries remain steady. The

patent applications in China, for example, of American companies maintained a steady state before 1992 and increased from 1993 to 2004. After that, it presented the trend of decreasing year by year. We supposed a reason for patents development trend “rising before decreasing” in different countries as Chart 6 show. As for the reason for rising, it’s been described above at macro-level, while at medium and micro-level, the main reason is that it undergoes sweeping change in worldwide pharmaceutical market, and region of the research on anti-tumor drugs shift obviously.

Patent application region analysis

It’s seen that the patent applications recently increase greatly in China, taking over the leading role in anti-tumor drugs. Meanwhile, it embodies enterprise research institution’s idea of attaching great importance to anti-tumor drugs domain and reflects great advance of science and technology level in China. Among the years in statistics, there are 5510 patent applications in China, comprising 78.5% of total. The U.S. are ranking the second with 714 applications up to 9.8%. Next come to Japan with 212 applications up to 2.9% of total. The fourth to tenth rank respectively is Switzerland (1.8%), Germany (1.5%), Canada (1.1%), France (1.0%), Korea (0.9%), Italy (0.7%) and the UK (0.7%). At present, the multinational pharmaceutical companies make more investment in China, showing the new characteristics and trends. Besides introducing their anti-tumor drugs to China, the companies bring the anti-tumor treatment health management innovation scheme together.

Conclusions

Good development trend of patent applications

In short, the number of patent applications of anti-tumor drugs is in the rapid development stage which could be roughly divided into three stages: the incubation stage in 1986-1992, the initiative stage in 1993-2004 and the development stage in 2005-2011. In fact, the above mentioned variation in different stages is related to previous amendments to Patent Law, policy adjustments in state innovation development and the evolution of international pharmaceutical markets that always alter or replace each other. From recent development trend, the applicants and applications of anti-tumor drugs in China would be on a stable level.

Different key areas of technical development

From characteristics of techniques, A61K, C07 and C12 take top 3 states, which account 89.2% in all patents. This patent numbers layout fits the overall develop pattern of recent anti-tumor drugs techniques very well. From the time series statistics, the year is not same about higher or lower rise rate of A61K, C07 and C12 showing up. In this level, it could be seen that IPC constitutions of anti-tumor drugs always alter or replace each other. From the international comparison statistics, besides studying the anti-tumor drugs in the traditional pharmaceutical field, abroad applicants focus on the new anti-tumor drugs taking effects on tumor producing process and different tumor target with the progress in molecular biology, expecting better treatment results. From the domestic comparison statistics, the main concern is in the field of chemical drugs in Shandong, central and western region where main forces of this research lie. On the other hand, it gets obvious progress in studying anti-tumor drugs from non-chemical drugs in Beijing, Shanghai and other region in eastern areas.

An obvious distinction among patent application regions

The number of patents in anti-tumor drugs is closely related to development level of the economic, technology, culture in applicants’ location. From international comparison, Besides China, in which the application number is large since this paper is based on Chinese statistics, top 10 are all from developed countries. From domestic comparison, the application numbers within different regions in China are greatly different, giving a trend of “high in east and low in west”. Shanghai, Beijing and Shangdong, as members of the first group, apply 44.8% in all domestic

application. The second group mainly including eastern and western regions takes 38.1% applications while the third group consisting of Central and western regions takes 17%.

While in the process of anti-tumor drugs research, the patent information is much more important. From technical aspect, it could know the status of development of a patent technique and divide the areas of technical development into technique-intensive area, forbidden area, unexplored area and profitable area. Also, it should check the patents number of each technique domain in all competitive companies, thus inferring the ability and distribution of the main technique as well as tracking the technique just as the saying said “Know yourself and know your enemy, you will win every war”, thereby laying a foundation for the future patent strategy in pharmaceutical enterprises. For that, it should strength the patent information analysis in enterprise or institution researching anti-tumor drugs. Based on patent retrieval, Studying with multi-angle and multi-way on the method of analyzing patent information not only is the essential element in applying patent competition information but also an important way to commence patent administration and implement patent strategy in pharmaceutical enterprises and institutions.

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