

An Empirical Study on the Patent Quality of Vaccine Technology from China, the United States and Japan

— Based on the Comparison of Legal Status, Maintenance Time and Citation Index of Vaccine Patents Granted in China

You kai-jie^{1, a}, Qiao yong-zhong^{2, b}

¹No. 422, Siming South Road, Xiamen University, Xiamen, China

²No. 422, Siming South Road, Xiamen University, Xiamen, China

^azizaishuiyifangyou@163.com, ^bqyzh1@qq.com,

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Abstract. Studying the patents granted in China in the field of vaccine technology, this paper conducts an empirical analysis on legal status, maintenance time and citation index of the vaccine patents from China, the United States and Japan. Based on a series of data, the paper draws the conclusion that: the vaccine patents from the United States are more stable and have higher technology maturity; the vaccine patents from Japan update with a quicker speed, and the patentees from Japan would like to take a short-duration patent strategy; as for vaccine patents from China, in general, the technology maturity, the update speed and the patent quality are inferior to those of the vaccine patents from the United States and Japan. Additionally, the Patent Citation Index of vaccine patents granted in China is quite low.

Introduction

Medicine technology is concerned with citizens' health, even the future of the whole country; therefore, it is a high priority of technological innovations. In the field of medicine technology, vaccine technology is a very important subdivision. Due to the determination of curbing infectious diseases and the change of mindset from *'treatment first, prevention supplemented'* to *'taking prevention primarily, treatment for auxiliary'*, in recent years, capital investment and research efforts have been increasingly put into in the field of vaccine technology. Correspondingly, there have been an enormous number of scientific and technological innovations and breakthroughs. Patent[Ⓞ], as a barometer of scientific and technological innovation and breakthrough, can reflect the development of vaccine technology.

According to the research conducted by the author of this paper, there are few studies, which are based on patents, on the development trend of vaccine technology in the past ; if any, the previous studies mainly focused on the number of vaccine patents and through the number of patents analyzed the distribution of patentees, R & D institutions, origin countries or regions and so on. For instance, Feng Yi et al. conducted an empirical study on the number of patent applications submitted to China to know the distribution of origin countries and provinces^[1]; Tian Zunming et al. analyzed the global market distribution in the field of vaccine technology, through the number of vaccine patents from various patentees, R & D institutions, and origin countries or regions^[2]; Gong Guan probed into the research capacity of China vaccine industry, by making statistical analysis on patent application date, technological classification, etc^[3]; Zhu Ping, through the number of vaccine patents, analyzed the current development status of A61K39 vaccine patents applied in China^[4]. Nevertheless, only analyzing the number of patents is insufficient to uncover the development level of vaccine technology objectively. In order to accurately grasp the development dynamics of vaccine technology, other relevant patent information should be dig deeper, and not only the quantity, but also the quality of vaccine patents should be taken into account.

[Ⓞ] In this article, patent refers to invention patent.

Therefore, this paper attempts to analyze the quality of patents in the field of vaccine technology owned by right-holders from China, the United States and Japan. The research is carried out from three dimensions of vaccine patents: legal status, maintenance time and citation index, aiming to know the level of innovation capability and the size of research and development potential in the field of vaccine technology in these three countries.

Data Collection and Variable Design

Data Collection. The data collected in this paper come from *Patent Search Column* of the official website of the *State Intellectual Property Office* of China. Since the technological intensity of design and utility model patent is weak, this article only consider *invention* patent; this article takes patents *granted in China* as samples, for the sake of putting the samples under roughly identical requirements or standards of application, examination and authorization and horizontally comparing the quality of the vaccine patents from different countries; this article selected the patents which were announced in public during 2003 ~ 2007, for the reason that after about 10 to 15 years the patents announced in these years, though have not wholly terminated, yet most of them have experienced various phases, such as publication, withdrawal/refusal/becoming effective, authorization, rights change, termination and other phases, and the data from these five years are large enough to ensure the abundance of the sample size as well as the reliability of the study (the sample size before 2003 is too small). According to the Strasbourg Agreement on International Patent Classification (IPC Patent Classification), the vaccine technology field belongs to A61K in the A (Living Needs) category, with subdivision A61K39/00 and A61K45/00.

Variable Design.

Patent Legal Status. Patent, not only contains technical information, but also contains legal information, with high intelligence value.

After announcement, a patent may be withdrawn or given up by the applicant (deemed to be withdrawn) or rejected due to the weak awareness of patent right protection or not strong enough technical strength^[5]. Therefore, *the rate of being withdrawn or given up or rejected* can, to some degree, reflect patent applicant's awareness of patent right protection and the technical strength of the patent.

Patent Authorization Rate is the ratio of the number of granted patents and applied patents. The patent application can only be granted when it passed substantive examination, meeting the requirements of the novelty, creativity and practicability. Therefore, the patent authorization rate is an important indicator to measure patent quality.

Patent Existing Rate is the ratio of the number of still existing (until the data collection date) granted patents and all granted patents (including the existing patents and the lapsed patents). The termination of a patent is generally due to the reason that the patentee doesn't continue to pay the patent annual fee or the patent is found to be failing to meet the requirements of novelty, creativity and practicability. Commonly, the patentee will only continue to pay the patent annual fee to maintain the patent right only when the expected return of the patent is greater than the patent annual fee. Besides, the termination may also be caused by the patentee's weak awareness of patent protection or low level of patent management. Therefore, through Patent Existing Rate, we can know about the quality and technology maturity of the patent and the patent protection awareness of the patentee.^[6]

Patent Maintenance Time. *Patent Maintenance Time* is a period of time during which the patent is valid after authorization. To keep the patent valid needs to pay a certain amount of fee. One of the purposes of charging patent maintenance fee is to encourage the patentee to give up the patent which may be almost worthless and give it to the public for free use.^[7] Thus, based on economic rationality, the patentee will continue to maintain the patent right only if the expected benefit of maintaining the patent is greater than the cost of maintaining it. Consequently, Patent Maintenance Time can reflect the quality, market value and update speed of the patent.^[8] Additionally, apart from technical and institutional factors, patent maintenance time can also reflect the patent strategy of the innovator.^[9]

The object of analyzing the patent retention time covers the lapsed patents and the still existing patents (until the data collection date^②). Accordingly, *Patent Maintenance Time of the lapsed patent* is the duration between the authorization date and the termination day of the patent, and *Patent Maintenance Time of the still existing patent* is the duration between the authorization date and the data collection date.

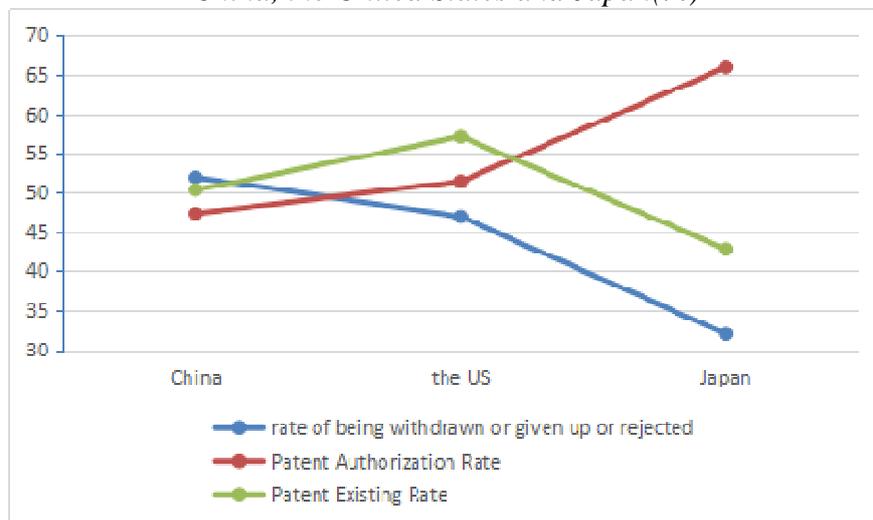
Patent Citation Index. *Citation index* refers to the number of times a patent is cited by subsequent patents. In general, more times the patent is cited, greater value the patent has. Why the patent citation index can reflect the value of a patent can be explained from two perspectives: first, since technological innovation is a continuous ongoing process, if a patent breaks a new path for the follow-up innovations, the patent plays a path-breaking role, and the cited times is the external expression of such path-breaking function^[10]; second, based on its legal function, the previous patent can limit the rights of the subsequent patent—therefore, more times a patent is cited, indicating that more times this patent is used as a technical reference, and greater limiting effect it takes on subsequent patents.

Relevant Data Analysis on Vaccine Patents Owned by Rights Holders from China, the United States and Japan

In the field of vaccine technology, China announced 1640 invention patents from 2003 to 2007 in total. Among them, the number of patents from China, the United States, and Japan respectively accounted for 39.2%, 21.6%, and 20.5%; and the patents from any other countries accounted for less than 3%. Therefore, this article selected vaccine patents from China, the United States and Japan announced in China from 2003 to 2007 as research subjects, adding up to 1334 patents in all, which is a large enough sample size.

Comparison of Patent Legal Status in the Field of Vaccine Technology. According to the statistical analysis conducted by the author of this article, among the vaccine patents announced in China from 2003 to 2007, 643 patents are from China (of which, 334 patents are withdrawn or given up or rejected, 325 patents are granted, and until the data collection date, 153 patents are still valid); 354 patents are from the US (of which, 166 patents are withdrawn or given up or rejected, 182 patents are granted, and until the data collection date, 104 patents are still valid); 337 patents are from Japan (of which, 108 patents are withdrawn or given up or rejected, 222 patents are granted, and until the data collection date, 95 patents are still valid). To convert the above numbers to percentages, we can draw Figure 1 below.

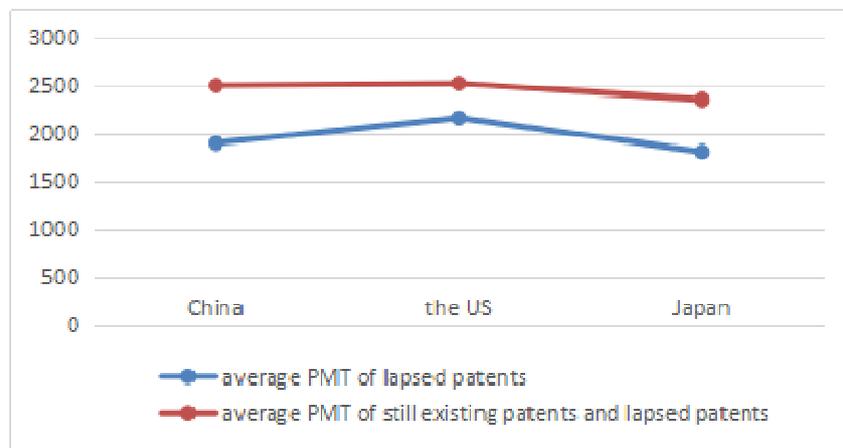
Figure 1 Legal Status Related Variables of Vaccine Patents Owned by Rights Holders from China, the United States and Japan(%)



Known from Figure 1, the patents owned by right holders from china had the highest rate of being withdrawn or given up or rejected(51.9%), followed by patents from the US (46.9%), and the patents from Japan had the lowest rate (32.0%). As for Patent Authorization Rate, the patents from Japan had the highest rate (65.9%), followed by the patents from the US (51.4%), and the patents from China had the lowest patent authorization rate (47.3%). In addition, by the data collection date, the patents from the US had the highest Patent Existing Rate (57.1%), followed by the Chinese patents(50.3%), and Japanese patents had the lowest rate(42.8%).

Comparison of Patent Maintenance Time in the Field of Vaccine Technology. Having obtained a patent after application just means that the right holder gets qualification to use the particular invention or creation exclusively, while keeping the patent valid is the beginning to make the patent come into play.^[11]

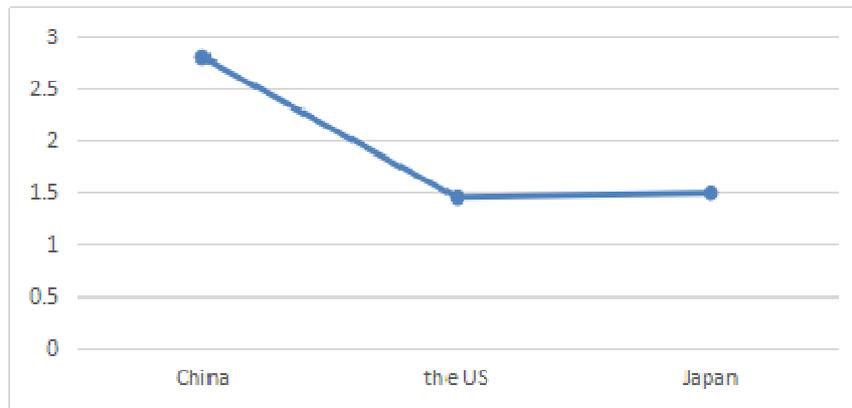
Figure 2 Average PMT of Lapsed Patents and Average PMT of Granted Patents, including Existing Patents and Lapsed patents(day)



According to the statistical data conducted by the author of this article, among the already lapsed patents granted in China in the field of vaccine technology, the patents from the US had the longest average maintenance time(2163 days), followed by that of patents from China(1901 days), and the average maintenance time of the patents from Japan is the shortest (1813 days). However, as of the date of data retrieval, there are many patents still in the validity period. Therefore, the still existing patents need to be incorporated into the study subjects, and the Patent Maintenance Time of the still existing patent begins at the authorization date, till the data retrieval date. The final statistical result shows that the average maintenance time of the patents from the US is the longest (2521 days), followed by that of patents from China (2500 days), and the average maintenance time of the patents from Japan is the shortest(2357 days), which is consistent with the order of average Patent Maintenance Time of the lapsed patents.

Comparison of Patent Citation Index in the Field of Vaccine Technology. According to the statistical data, among the vaccine patents announced in China, the average citation index of vaccine patents from China is 2.80; the average citation index of vaccine patents from the US and Japan are 1.45 and 1.49 respectively.

Figure 3 Patent Citation Index of Vaccine Patents Owned by Rights Holders from China, the United States and Japan(times)



From Figure 3 above, whether the vaccine patents from China itself, or from the US or Japan, the number of times that the previous vaccine patents have been used as technical references is quite low.

Conclusions

Among the patents granted in China in the field of vaccine technology, the patents from Japan had the lowest rate of being withdrawn or given up or rejected, from which it can be inferred that the patent applicants from Japan have stronger awareness of patent protection to vaccine. At the same time, the patents from Japan possessed the highest Patent Authorization Rate, which suggests that the quality of vaccine patents from Japan is generally high. Moreover, the patents from the US had the highest Patent Existing Rate, which indicates that the stability of vaccine patents from the US is better, and the vaccine technology is more mature.

From the above statistical analysis result, we can see it is the vaccine patents from the US that possess the longest average maintenance time, and the vaccine patents from Japan have the shortest average maintenance time. The average maintenance time not only reflects the patent quality of the patent and the patent protection awareness of the patentee, but also suggests the update speed of the patent and the patent strategy adopted by the patentee. According to the above analysis on patent legal status, we have drawn the conclusion that the patent applicants from Japan have stronger awareness of patent protection for vaccine and the quality of vaccine patents from Japan is generally good. Therefore, it can be speculated that the update speed of Japan's vaccine patents is fast, and the patentee would like to take a short-duration patent strategy.

Through the statistical analysis of the patent citation index above, it is obviously to see that, in China, the number of times that previous vaccine patents used as technical references by later vaccine patents are quite low. In other words, the usage of path-breaking role of previous vaccine patents in China is quite inadequate.

To sum up, among the patents granted in China in the field of vaccine technology, the patents from the United States are more stable and have higher technology maturity; the patents from Japan update with a quicker speed, and the patentees from Japan would like to take a short-duration patent strategy; as for vaccine patents from China, in general, the technology maturity, the update speed and the patent quality are inferior to those of the patents from the United States and Japan. Additionally, the number of times that the previous vaccine patents have been used as technical references is quite low in China.

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