Advances in Economics, Business and Management Research, volume 212
7th International Conference on Economy, Management, Law and Education (EMLE 2021)

Analysis on the Development of Chinese Biopharmaceutical Industry

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ABSTRACT
Known as the "never ending sunrise industry", the biopharmaceutical industry is one of the most important strategic emerging industries in China. Entering the 21st century, with the rapid development of science and technology, the biopharmaceutical industry has also witnessed tremendous rapid development. Bioengineering pharmaceutical technology combines the advantages of biology, medicine and microbiology. Biotechnology is widely used in various fields of pharmaceutical engineering, including genetic engineering, cell engineering and fermentation engineering. From the current state of development, although China's biopharmaceutical industry has made significant progress, there are still many areas that need to be improved and strengthened, especially in terms of innovation. First, many companies lack incentives and thus lack innovative talents. Second, most biopharmaceutical companies have little awareness of voluntary innovation and invest a large amount of capital and human resources in high-yield, low-risk, low-cost generics. Finally, the domestic market of pharmaceutical companies appears to be characterized by being small, scattered and disorganized, thus leading to an uneven development of core technologies. Based on the statistical analysis of recent years, some suggestions for changing the status quo and achieving innovative breakthroughs are proposed to elaborate the further innovative development of biopharmaceutical enterprises in the future.

Keywords: *Biopharmaceuticals industry, Pharmaceutical engineering, Development trend analysis, Innovation.*

1. INTRODUCTION

The biotechnology industry is a high-tech industry that emerged for application in China around the mid-1970s, and is a technological product that brings together the best of chemistry, science, pharmacology, microbiology and many other disciplines. The development of biotechnology has never stopped, and according to the current stage of development, biotechnology has great application value, mainly in genetic engineering, cell engineering, fermentation engineering, etc [1].

With the development of biotechnology, China's biopharmaceutical industry has been developing rapidly, but it is still lagging behind compared with some European and American countries [2]. In recent years, the development of biopharmaceutical industry has also gradually encountered bottlenecks and new challenges. Through the current data, it can be found that China's biopharmaceutical industry is currently facing the situation that there are not enough talents, insufficient innovation awareness and ability as well as mostly small, chaotic and scattered companies. Through the statistical analysis for recent years, people can find the solution for the current situation, so as to further promote the sustainable development of China's biopharmaceutical industry, or even the high-speed development.

2. CURRENT SITUATION OF BIOPHARMACEUTICAL DEVELOPMENT

According to statistics from Evaluate Pharma, global biopharmaceutical sales increased from US$181 billion in 2015 to US$258 billion in 2019, an increase of 42.5% [3]. The size of China's biopharmaceutical industry continues to grow, with the market size exceeding RMB 370 billion in 2019

[4], according to the data. Meanwhile, the proportion of biopharmaceutical production value in the pharmaceutical industry continues to rise, with the number of domestic biopharmaceutical INDs growing from around 5.2% of chemical drugs in 2011 to 14.3% in 2019 [5]. With the strong support of national policies, China's biopharmaceutical industry has shown a trend of continuous expansion in industrial scale, increased investment in research and development, accelerated development of new drugs with intelligent technology and industrial clusters.

As shown in "Figure 1", in the field of biopharmaceuticals, the United States has the largest number of patent applications worldwide, followed by China and Japan, accounting for 14.28%, 9.49% and 8.65% of the global total, respectively. In terms of applicant nationality, US applicants accounted for 49.49% of global patent applications, while Japan and China accounted for 9.60% and 9.07% respectively [6].

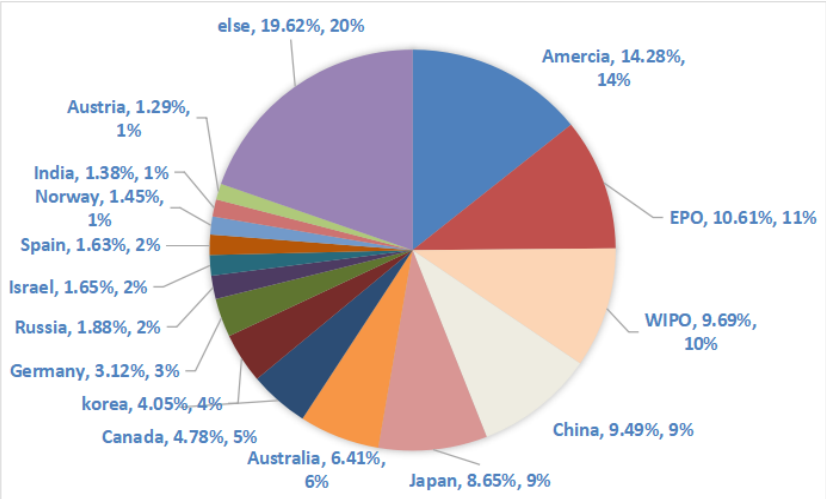

Figure 1 Global Distribution of Biopharmaceutical patent applications.

"Figure 2" illustrates that 67.77% of the regional patent applications in China in the biopharmaceutical field were filed in China and 32.23% were filed in China by foreign applicants. Foreign applicants have a strong interest in China's biopharmaceutical market, most notably the United States, with 13,800 patent applications filed in China, surpassing Shanghai, which tops the ranking of Chinese provinces and cities. In "Figure 3", Shanghai by far accounts for the largest number of domestic patent applications in China at 10.48%, followed by Beijing at 9.03% and Jiangsu Province at 6.92%.

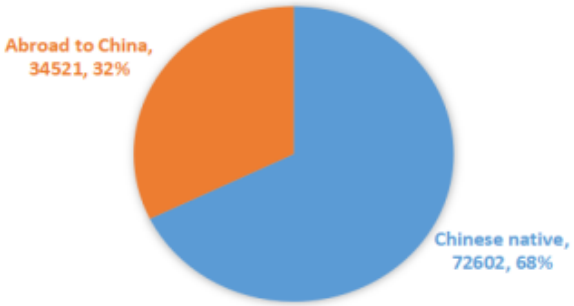

Figure 2 Share of regional patent applications in China.

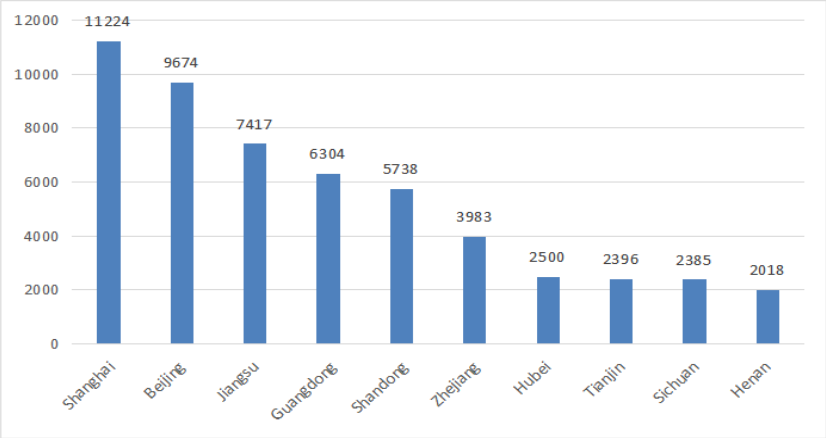

Figure 3 Number of patent field by region in Chinese native.

3. PROBLEMS IN BIOPHARMACEUTICAL DEVELOPMENT

3.1 Lack of Innovative Talents

Although the quality of academics continues to improve, there is a shortage of innovative talent in biopharmaceuticals in China compared to overseas, resulting in a lack of innovation in major companies. In 2014, the annual average number of employees in China's pharmaceutical industry was about 2.16 million, of which 180,000 were R&D personnel, accounting for only 8%, of which 54,000 were researchers [R&D personnel with intermediate titles or PhD degrees], accounting for 3% of all R&D personnel. The number of researchers [R&D personnel with intermediate titles or doctoral degrees] is 54,000, accounting for 3% of all R&D personnel [7]. However, the proportion of R&D personnel in pharmaceutical companies in developed countries is no less than 30% of the total workforce.

The following reasons are responsible for the shortage of talent. First, the systems and programmes of many domestic biopharmaceutical companies have an impact on the introduction of talent, such as the lack of incentive mechanisms. Many domestic pharmaceutical companies are currently underinvesting in biopharmaceutical engineering innovation and research, resulting in more young people not receiving the treatment and research and innovation support they desire. Next, the current human resources situation is not optimistic, and more and more fresh graduates, including undergraduates and postgraduates, are a bit over-ambitious in their job search intentions. They are always rejecting the low level positions and low salaries offered by large companies, but do not want to go to small companies that they do not see. As a result, there is a shortage of new blood in the biopharmaceutical industry, which has led to a bottleneck in the improvement of biotechnology.

3.2 Some Enterprises Lack the Awareness of Independent Innovation

At present, the number of patent applications in the field of biopharmaceuticals in the world has reached 112,849, and the number of biopharmaceutical patent applications in China is 107,123, accounting for 9.49% of the world total. On the other hand, shows that China's patent system started later than that of western countries, and the patent technology strength of biopharmaceutical field is still relatively weak compared with western developed countries. In spite of more than 20 years of national support and local efforts, the relevant enterprises lack a sense of great innovation. For example, genetic engineering is the core of China's biomedical engineering technology, and through the research and development of related fields and the necessary industrialization, the development of genetic engineering has been materialized and applied to the medical field, but how to stimulate the important innovation consciousness of related enterprises and how to improve the incentive mechanism of innovation and development How to improve the incentive mechanisms for innovation and development remains a difficult problem to solve.

As of 30 April 2021, among A-share and Hong Kong-listed companies, R&D investment was RMB100 million or more (RMB300 million or more was 70 companies), of which RMB1 billion or more was invested by 17 companies; 56

pharmaceutical companies' R&D investment was 10% or more of sales, and 9 companies' R&D investment was 100% or more of sales. "Table 1" shows the data comparing the R&D investment intensity of the world's top pharmaceutical companies and some Chinese companies. The data shows that there is a large gap between the R&D investment intensity of domestic companies, with some companies exceeding 100%. However, compared to global pharmaceutical companies, the R&D investment intensity of major Chinese pharmaceutical companies is much lower than that of major foreign global pharmaceutical companies.

Table 1. R&D in global pharmaceuticals versus Chinese pharmaceuticals

Global Pharmaceutical Companies	R&d investment intensity/%	Chinese Pharmaceutical Companies	R&d investment intensity/%
Pfizer	22.4	Hengrui Medicine	18
Roche Group	22.2	Fosun Pharmaceutical	9.22
Merck	28.3	Simcere	25.3
JNJ	14.7	SinoBiopharmaceutical Limited	12.1
Novartis	18.2	CSPC	11.6
Bristol-Myers Squibb	26	BeiGene	419.2
GlaxoSmithKline	16.1	Innovent	48.17
Eli Lilly and Company	24.8	Joincare Pharmaceutical	7.93
Sanofi	15.3	Mindray	8.89
Abbvie	14.3	Sichuan Kelun Pharmaceutical	9.28

a Note: From FierceBiotech.

3.3 Generally Small Pharmaceutical Business Size

Due to the high degree of uncertainty in the research and development of new drugs, relatively large companies have an economic and human resource advantage in the research and development of new drugs and can better bear the risks associated with research and development. On the other hand, small and medium-sized enterprises have no economic name in R&D and production due to the constraints of their conditions. At present, the threshold for companies in the Chinese pharmaceutical industry is still low and the market structure is not fully developed [8], for example, the exit mechanism. As the pharmaceutical market expands, more and more pharmaceutical companies are interacting with each other, and by 2020, as shown in "Figure 4", the number of pharmaceutical companies in China has reached 7665. From 2015 to 2020, the number of pharmaceutical companies in China has been increasing, totaling 549 companies in six years, which is a growing trend. By 2020, the number of pharmaceutical manufacturing companies in China has reached 7,665, a year-on-year increase of 3.8%. However, there are only 22 pharmaceutical companies with a market capitalisation of more than $10 billion, which indicates that China still has a large number of small, dispersed and disorganised pharmaceutical companies with low market concentration, no obvious competitive advantage in the market and no formed economies of scale. The difficulty in forming economies of scale and scope has led to a dispersed use of resources, excessive competition between companies and low profit margins, which in turn limits companies' investment in research and development of new drugs.

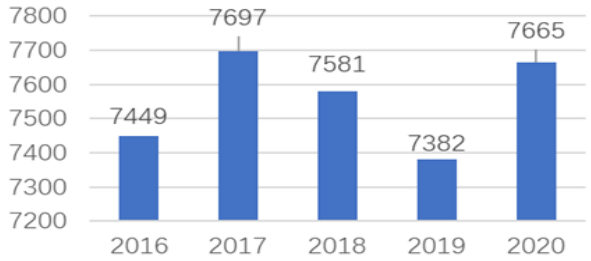

Figure 4 Statistics on the number of pharmaceutical companies in China, 2016-2020.

4. TRANSFORMATIVE APPROACHES TO BIOPHARMACEUTICAL INNOVATION

4.1 Enhancing Independent Innovation Capabilities

In the process of innovation and development of China's biopharmaceutical industry, the most important thing is to improve the ability of independent innovation. Companies can enhance their biotechnology capabilities and master key core technologies to improve their competitiveness. In general, this is because many companies will raise the level of China's biopharmaceutical industry to an infinite level while improving their independent innovation capabilities. Therefore, Chinese biopharmaceutical companies should continue to innovate and develop new technologies of their own, while drawing on other advanced technologies and effectively integrating resources around their independent innovation capabilities, so that biopharmaceutical companies can take more initiatives in competition.

4.2 Strengthening Support for Research in Terms of Funding and Talent Development

Biopharmaceutical engineering in China has developed significantly, but due to the impact of the market economy and the lack of investment caused by the epidemic, many biopharmaceutical companies have chosen to locate their research and production centers in more profitable, lower-cost generic drugs. This current state of development has hindered the improvement of biopharmaceutical technology in China in several ways. Firstly, the relevant government departments need to increase their support for biological research units. For example, financial and policy support should be provided to some universities and research institutes to encourage research in biopharmaceutical technology. Also relevant government departments need to improve the implementation of human resources and training systems, such as the establishment of corresponding human resources incentive mechanisms, support for some of the researchers, so as to improve their quality of life. At the same time, some enterprises need to shift their production focus to the principle that innovation is the primary productive force, and expand the funds and personnel invested in research units. Adopting a strategy of 'experienced people leading newcomers' is also an important means of addressing the lack of innovation and experience in companies.

4.3 Forming a Normative Development

For the healthy and orderly development of the biopharmaceutical industry, in addition to focusing on human resource development and technological innovation, greater attention must also be paid to the protection of intellectual property rights. In the pharmaceutical industry, the research and development of new technologies and medicines requires a large investment in the early stages, with no prospect of a return on investment and great risk, so many companies are not willing to take great risks to invest in the development of new products and technologies. Therefore, the protection of intellectual property rights is an important safeguard for the development of the biopharmaceutical sector in China, and also an inevitable requirement for innovative research and development. Regardless of whether a drug has been researched and developed in the past or has just been developed, the importance of intellectual property rights should be taken seriously and protection strengthened to ensure the orderly and prosperous development of the biopharmaceutical industry.

4.4 Use of Advanced Information Technology

In the process of innovation and development of the biopharmaceutical industry, we should make full use of the rapid development of Internet information technology, strengthen the integration and utilization of resources, expand more channels, and at the same time, through the use of some big data management and other advanced Internet technologies, on the one hand, to promote the innovative development of biopharmaceutical engineering, and on the other hand, to promote the industrial upgrading of biopharmaceutical engineering. Through this way, in order to better enhance the comprehensive strength of China's biopharmaceutical industry innovation and development.

5. CONCLUSION

In the current global environment, the level of the biopharmaceutical industry is gaining widespread attention. Since the birth of

biopharmaceutical engineering in China, a number of new biopharmaceuticals have been developed in the country, solving the problems of high cost, high risk and insufficient technical capability. The improvement of the level of China's biopharmaceutical industry can promote the diversification of the national economy and enhance the country's scientific and technological strength on the one hand, and provide protection for people's health on the other. During the Kovac-19 outbreak in 2020, several Chinese companies invested in the research of Kovac-19 nucleic acid for testing and Kovac-19 therapeutic vaccine regardless of the cost, which enabled the country to control the spread of the outbreak as early as possible and ensure the health of the people.

Although China has made great progress in the past 20 years, there is still much room for development. With the increase in social demand and the intensification of competition in the market economy, most biopharmaceutical companies still need to improve their research and innovation capabilities by strengthening support for research in terms of funding and human resource development, raising awareness of independent innovation, using advanced information technology, and implementing standardized management to promote the progress and development of the industry as a whole.

Given that China's economy will continue to grow at a medium to high speed in the future, the disposable income of residents will continue to grow, the aging process of the population will accelerate, and people's health awareness and consumption ability will continue to increase, China's biopharmaceutical industry will continue to grow at a medium to high speed in the longer term. From the perspective of the entire pharmaceutical industry, the proportion of biopharmaceuticals is also increasing, with sales of biotech drugs accounting for 14% in 2006, up to 22% in 2013, and expected to account for more than 25% in 2020. In addition, biotech drugs already account for seven of the top 10 best-selling drugs in the world. In the long run, biotech drugs will dominate the entire pharmaceutical industry in the future.

AUTHORS' CONTRIBUTIONS

This paper is independently completed by Pengfei Ji.

ACKNOWLEDGMENTS

First of all, I am very grateful to Prof. J. Axel Zeitler and Mrs. Wang. Both teachers made guiding comments and recommendations on the research direction of my thesis, promptly pointed out the difficulties and doubts I encountered during the writing of my thesis, made many useful suggestions for improvement and invested superb efforts. I am also very grateful to my classmates who attended classes with me, supervising and helping each other in the learning of pharmaceutical knowledge, and spending an unforgettable and happy time together. In addition, I would also like to thank my classmates for providing me with some inspiration and encouragement in the writing of my thesis. Finally, I would also like to thank my parents who have supported me in my research in pharmaceutical engineering.

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