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Analysis of the competitiveness of the biological pharmaceutical industry on the example of the United States

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Abstract. Since entering the era of bioeconomy, the biotechnology industry economy represented by the bio pharmaceutical industry is leading a new wave of technological revolution. China's strategic deployment for the bio pharmaceutical industry economy has achieved remarkable results, but there is still a large competitive gap compared with the United States and other biomedical powers. The goal of this article is to study the American biomedical market and find out the gap, so as to provide inspiration for the development of the biomedical industry in China and other countries. The Porter Diamond Model is used to build the theoretical research method analysis framework of the international competitiveness of the bio pharmaceutical industry. Taking the United States as an example, the paper analyzes its competitive advantages in six aspects: the elements of the biomedical industry, the enterprise structure and competition, the demand conditions, the relevant and supporting industries, the government and development opportunities. Based on this, the paper puts forward policy recommendations conclusions for China's development of the bio pharmaceutical industry, so as to provide reference value for the development of the pharmaceutical industry.

Keywords: bio pharmaceutical industry economy, biomedicine, China, USA, international competitiveness, Porter Diamond Model

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Анализ конкурентоспособности биологической фармацевтической промышленности на примере Соединенных Штатов

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Аннотация. С момента вступления в эпоху биоэкономики экономика биотехнологической отрасли, представляемая биофармацевтической промышленностью, влечет за собой новую волну технологической революции. Стратегическое развертывание Китая в сфере экономики фармацевтической промышленности достигло значительных результатов, однако по-прежнему наблюдается большой конкурентный разрыв по сравнению с США и другими биомедицинскими державами. Цель исследования — изучить американский биомедицинский рынок и выяснить существующий разрыв, оказывающий влияние на развитие биомедицинской индустрии в Китае и других странах. Для проведения анализа методов исследования международной конкурентоспособности фармацевтической промышленности в работе используется Алмазная модель Портера. Базируясь на примере США, анализируются конкурентные преимущества в шести аспектах: элементы биомедицинской промышленности, структура предприятия и конкуренция, условия спроса, соответствующие и поддерживающие отрасли, правительство и возможности развития. Исходя из этого, даются рекомендации, направленные на формирование политики, способствующей развитию биологической фармацевтической промышленности Китая.

Ключевые слова: экономика биофармацевтической промышленности, биомедицина, Китай, США, международная конкурентоспособность, Алмазная модель Портера

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Introduction

The United States' pharmaceutical industry based on biological science and technology. Biomedicine is a general term for drugs obtained from organisms or their tissues and cells for disease prevention, treatment and diagnosis by combining genetic engineering, cell engineering, enzyme engineering, protein engineering, fermentation engineering and other bioengineering technologies. They are widely used in the treatment of tumors, infections, metabolic and immune diseases, blood and mental diseases, and play an irreplaceable role. At present, the biopharmaceutical industry is leading a new wave of technological revolution in the pharmaceutical industry under the background of the biopharmaceutical economic era, and becoming one of the industries with the most development potential.

For the pharmaceutical industry especially in the biomedical sector, the United States and other major countries in the biomedical industry have made strategic plans. In 2012, the Obama administration issued the 'National Bioeconomy Blueprint,¹ setting strategic goals for the development of traditional biotechnology industries, including genetic engineering, DNA sequencing and automatic high-throughput of biomolecules, and new biotechnology industries, such as synthetic biology, proteomics, bioinformatics. The Chinese government also attaches importance to the development of the bio pharmaceutical industry. 'The 13th Five Year National Science and Technology Innovation Plan' issued by the State Council in 2016 and the '13th Five Year Bioindustry Development Plan' issued by the National Development and Reform Commission both emphasize the importance of developing the biopharmaceutical industry. Under the guidance of the bio pharmaceutical industry development plan, China's bio pharmaceutical industry has great development potential in the future.

In the global competition of bio industry economy, some developed countries are in an advantageous position in the international market competition of bio pharmaceutical industry by virtue of the advantages of production factors, strong scientific research strength, huge domestic and international market demand and efficient enterprise competition environment. Among them, the United States has become the most competitive country in the field of biomedicine. Since the 13th Five Year Plan, China's bio pharmaceutical industry has achieved remarkable development results, and has initially acquired strong international competitiveness. However, compared with the United States, China's biomedical industry still has a certain gap. Therefore, it is of great significance for China and other developing countries to analyze the development characteristics and competitive advantages of the American biomedical industry.

Literature review

Within the scope of the author's research, the author referred to the works and research of some relevant scholars, and attached some websites related to the biomedical industry and the official economic data of the United States.

Porter Diamond Model (Michael Porter, 1979) provided an important analysis idea in his book "National Competitive Advantage". This has been widely used in the competitiveness analysis of various industries. Based on this, the article constructs an analysis model of the competitiveness of the American biopharmaceutical industry. Chinese scholars revealed various shortcomings in the development of China's pharmaceutical industry in their research on the "Current Situation of China's Biomedical Development" (Shi Guang & Liu Fang Shu, 2016). Chinese Scholars also described the current status of China's biomedical development investment in his

¹ The United States released the National Bioeconomy Blueprint. Retrieved from www.most. gov.cn/gnwkjdt/201206/t20120612_94963.htm

article, pointing out that insufficient investment has led to insufficient research and development capacity (Guo Zhong Ping, 2020). At the previous year, there are also have some scholars respectively described the characteristics of the development of American biomedicine and the advantages of innovation ability in their articles "Research on the Competitiveness of American Biomedical" and "Analysis on the Innovation Ability of American Biomedical", which provided feasible ideas for the development of China's biomedicine industry (Zheng, 2011; Zhang, 2011). The specific research in this area used porter diamond model are Chinese scholars Zhao Bing and Zhang Dong Sheng (2011). They used the Porter Diamond Model to analyze the competitiveness of regional biomedicine industry in China. This provides ideas for the completion of this article.

Methods

This paper uses some scientific methods. In order to compare the specific differences and development differences between Chinese and American pharmaceutical industries, this paper uses comparative analysis, model analysis and induction. The Porter Diamond Model is used to specifically analyze the development elements of various aspects, and summarize the differences between the current medical development of China and the United States, so as to further draw a conclusion that in the face of the developed biomedical industry in the United States, it provides corresponding reference suggestions for the developing countries represented by China in the development process of biomedical industry and how to improve it.

Based on the Porter Diamond Model,² this article constructs a theoretical framework for the competitiveness of the biomedical industry, conducts an empirical analysis of the competitiveness of the U.S. biomedical industry, and recently compares the bottlenecks and problems in China's development of the biomedical industry. Finally, it puts forward relevant policy recommendations. This study has a reference significance for understanding the development model of biomedical industry in developed countries such as the United States, and also has a very important reference value for discovering the comparative advantages and disadvantages of the development of China's biomedical industry and guiding its development.

Competitiveness analysis framework based on Porter's diamond model

Porter's diamond model, also known as diamond model, is a commonly used model to evaluate the competitiveness relationship between countries and has been widely used in the competitiveness analysis of various industries. This model was first put forward by Michael Porter, an American strategic management

² Diamond model theory, also known as diamond theory and diamond model, was proposed by Michael Porter, a professor of Harvard Business School, in his representative work The Competitive Advantage of Nations.

scientist, in 1990. The theory of this model believes that the size of competitiveness is closely related to the four basic elements, production factors, demand factors, related, supporting industries, and competition in the same industry, as well as two auxiliary elements, chance and government. Based on this, an evaluation model for the competitiveness of the global biopharmaceutical industry was constructed (Figure 1).



Figure 1. Analysis framework of biomedical industry competitiveness based on Porter's diamond model Source: compiled by authors based on Porter's diamond model.

According to the Porter Diamond Model, the "factor conditions" provides the initial advantages of the development of the biomedical industry and is the basic condition for the industrial development, mainly including the human resources, biological resources, capital resources, etc. "Demand conditions" refer to the market demand for products or services provided by the biomedical industry; "Relevant and supporting industries" refers to the development of relevant supporting industries in the upstream and downstream of the biomedical industry from the perspective of the whole industry chain; "Competition in the same industry" reflects the concentration and market competition of the biomedical industry with biomedical enterprises as the main body; "Chance" is one of the uncertainties in the competitiveness of the biomedical industry. This paper analyzes the competitiveness of the U.S. biomedical industry through the division of labor in the international biomedical industry value chain and the novel coronavirus pneumonia epidemic; "Government" refers to the policy guidance of government departments on the biomedical industry. Including the supervision, guidance and encouragement policies for the bio pharmaceutical industry.

Results

As a leading development level in the world, the biomedical industry in the United States has its own unique development advantages. We can draw a conclusion by using the Porter diamond model. In terms of funds, the United States has high investment and strong research and development investment, which provides a solid economic foundation for the innovation of biomedicine; Pay attention to the utilization of talents. In the biomedical industry, almost 90% of the employees have high education; In addition, it is also crucial to attach importance to venture capital and establish a dynamic competitive atmosphere for enterprises. Finally, the government must also participate in it. The establishment and improvement of supportive policies and reasonable tax provisions conducive to the biomedical industry also provide essential support for the development of the entire pharmaceutical industry.

Analysis on the Development and Competitiveness of American Bio Pharmaceutical Industry

Factor conditions

Strong $R\&D^3$ and innovation strength. In response to the increasingly fierce international scientific and technological innovation competition, large international biomedical enterprises have rushed to increase scientific research investment. At present, the U.S. biomedical industry has established international advantages in the world, with R&D strength and industrial development leading the world. The United States ranks first in the world in terms of the number of biomedical related papers, the number of bio pharmaceutical patents, the number of bio pharmaceutical drugs under research, and the number of bio pharmaceutical enterprises. Graul reported that 65 % of the newly launched biological agents in the world in 2018 were developed by American companies. According to the 2019 Ranking List of 'Global Enterprises R&D Investment' released by the European Commission, five of the 10 biopharmaceutical companies with the highest R&D intensity in the world in 2019 came from the United States, of which Merck ranked second in the world with a R&D investment of 9.8 billion euros. The number of innovative enterprises in the field of biopharmaceuticals in the United States has a significant advantage in the world. According to the List of the 'World's Most Innovative Companies in 2019' released by Fast Company, all the 10 companies in the biomedical field that were included in the list came from the United States, while only 7 American biomedical companies were included in the list in 2018. High intensity R&D and innovation have brought prosperity to the biomedical industry in the United States. According to the 'Global Top 25 Biotechnology Companies in 2019' released by Gene Engineering and Biotechnology News (GEN) magazine, among the top 10 biomedical companies ranked by market value in 2019, American companies accounted for 6 (Table 1).

³ Research and development.

Table 1

Ranking	R&D		Innovation		Market value	
	Company	Nation	Company	Nation	Company	Nation
1	Incyte	US	Foundation Medicine	US	Amgen	US
2	Vertex Pharma	US	Arterys	US	Novo Nordisk	DK
3	Celgene	US	Alnylam	US	CSL	AUS
4	Bristol-Myers Squibb	US	Flatiron Health	US	Gilead Sciences	US
5	UCB	BE	Amgen	US	Celgene	US
6	AstraZeneca	UK	Viz.ai	US	Allergan	IE
7	Merck	US	Velano Vascular	US	Herui Pharma	CHN
8	Daiichi Sankyo	JPN	Berkeley Lights	US	Biogen	US
9	Eisai	JPN	T2 Biosystems	US	Vertex Pharmaceuticals	US
10	Roche	СН	Catalog	US	Amgen	US

Ranking of R&D industry, innovation, and market value of global biomedical companies in 2019

Source: compiled by authors based on Gene Engineering and Biotechnology News and Fast company website. Retrieved December 1, 2022, from www.genengnews.com/a-lists/top-25-biotech-companies-of-2019/; www.fastcompany.com/most-innovative-companies/2019

Abundant biomedical talent resources. According to the QS World University Ranking released annually by Quacquarelli Symonds,⁴ 56 of the top 200 universities in the OS World Ranking of Biosciences in 2020 are American universities, while only 23 universities in the UK are ranked second. Scholar Lindburg and others pointed out that the employment demand of the US biomedical industry was strong. As shown in Figure 2, the number of biomedical jobs increased gradually from 2010 to 2013, and there was a significant growth in 2015. Although there was a decline after 2015, the number of jobs released in 2017 was still higher than that in any year from 2010 to 2014. Technical posts in the biomedical industry (excluding sales accounting, etc.) also followed a similar trend, peaking in 2016, and then declining slightly in 2017. It is worth noting that, contrary to the declining trend of the overall number of biomedical posts in 2015–2017, the proportion of technical posts in the total number of posts rose from 17.6% in 2015 to 20.3% in 2017. This shows that the demand for technical talents in the biomedical industry is growing year by year. In addition, technical posts have high requirements for education. The number of employed people with bachelor's degrees is the largest (62.2%). 15% of the technical posts require the practitioners to have a postgraduate degree, and less than 1/4 of the technical posts can be obtained through a low degree.

⁴ Quacquarelli Symonds. The QS World University Rankings. Retrieved December 1, 2022, from https://www.topuniversities. com/university-rankings/university-subject-rankings/2020/biological-sciences







Figure 2. Employment situation of biomedical industry in US during 2010–2017 (*a*)Total job postings (*b*)Total technical job postings (*c*)Technical job postings degree requirements *Source:* compiled by authors. Retrieved December 1, 2022, from www.ceicdata.com/zh-hans/indicator/unitedstates/employed-persons

Developed venture capital. The biopharmaceutical industry has the characteristics of long R&D cycle and high investment risk, which requires the support of developed capital markets. The United States is one of the most active countries in venture capital, and venture capital is the main capital source for the entrepreneurship and development of American biomedical enterprises. During 1998–2000, the venture capital in the biomedical field in the United States rose from 1.4 billion dollars to 4.39 billion dollars. After 2000, although the economic growth of the United States slowed down, the proportion of innovation and investment funds in the biomedical industry in the total funds increased significantly. It reached 4.63 billion US dollars in 2004. Since the third quarter of 2006, the investment of American venture capital in life science has surpassed that of IT industry for the first time, becoming the largest industry of venture capital. This trend continued in 2007, with the total amount of venture capital reaching 5.71 billion US dollars. Among the top 10 venture capital events with the largest amount in the global biomedical industry in 2019, the United States accounted for 5 enterprises. According to the annual report of Ernst & Young,⁵ the total amount of risk financing in the US biopharmaceutical market hit a record high in 2015 and 2016, reaching US \$9.8 billion and US \$8 billion respectively. The average annual risk financing amount from 2001 to 2015 was only 4.5 billion US dollars, which shows that the US biomedical risk financing continues to show a strong momentum.

Enterprise structure and competition

Highly clustered industrial clusters. In terms of spatial layout, highly concentrated industrial clusters are an important feature of the development of the biomedical industry in the United States. Many states and regions regard the development of biotechnology industrial clusters as an important development strategy. At present, five biotechnology industry clusters have been formed in San Francisco, Boston, Washington, North Carolina and San Diego. Among them, Silicon Valley biotechnology industry employees in San Francisco account for more than half of the U.S. biotechnology industry, and enterprise R&D investment accounting for 57 % of the U.S. biotechnology industry, and enterprise R&D investment accounting for 59 %. Its sales are growing at a rate of nearly 40 % every year.

Dynamic enterprise market competition. In 2019, Stoke, Springworks,⁶ BioNTech and other innovative biomedical companies submitted their applications for listing on NASDAQ, which successfully attracted the attention of many investors. The meeting report of JPMorgan Chase in 2020 pointed out that the average annual biopharmaceutical IPO index of the United States in 2019 was 31 % higher than the market benchmark index by 24 %. According to the analysis of "HBM Pharma/Biotech

⁵ Retrieved December 1, 2022, from https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/ topics/life-sciences/life-sciences-pdfs/ey-biotechnology-report-2017-beyond-borders-staying-the-course1.pdf

⁶ Retrieved December 1, 2022, from https://springworkstx.com

M&A⁷ Report 2020" released by HBM Partners in 2020, the US biopharmaceutical industry is very active in M&A, including 18 private enterprises and 16 listed enterprises with M&A value of more than US \$100 million; In Europe, only 9 companies have reached this level in terms of M&A value. In 2015, after the M&A volume of the US bio pharmaceutical industry declined for four consecutive years, the peak of M&A activity reached USD 171.02 billion in 2019 (Figure 3).



Figure 3. US biomedical industry M&A amount in 2010–2019, million US Source: compiled by authors based on HBM. Retrieved December 1, 2022, from www.hbmpartners.com/media/ docs/industry-reports/HBM-Pharma-Biotech-M-A-Report-2020.pdf.

Market demand

According to the United Nations Commodity Trade Statistics Database, the United States is the world's largest importer of biological agents. Its total import amount of biological agents in 2019 was 42.89 billion US dollars, accounting for 21.7 % of the world's total imports; In contrast, the US exported biological agents in 2019 with a trade deficit of up to US \$170.3 and a trade volume of US \$25.86 billion. This shows that although the US is a strong country in the biomedical industry, there is still a large market demand gap in its market; Compared with other countries and regions, the United States leads the world in medical and health care, with its recurrent health expenditure accounting for 17.1 % of GDP, ranking first in the world; In addition, the high level of economic and social development in the United States has led to the problem of population aging. According to the data of the World Bank, the proportion of people over 65 years old in the United States is as high as 15.8 %, while that in China is only 10.9 %, which also provides a strong demand market for the biomedical industry.

⁷ Mergers and acquisitions.

Development of relevant industries

The overall scientific and technological industry level of the United States is in the leading position in the world, and the industries related to the biomedical industry are also quite developed, such as the manufacturing industry of research equipment and production equipment, information technology industry, related professional services, drug sales, etc., which has formed a complete biomedical industry chain, providing strong support for the development of the biomedical industry in the United States. In recent years, new technologies such as artificial intelligence and big data have injected new vitality into the development of the American biomedical industry: machine learning methods such as support vector machines, artificial spiritual networks, and deep learning are increasingly being applied to fields such as biological drug discovery and design. In addition, the biomedical material industry based on biosynthetic technology and nanotechnology also provides support for the biomedical industry. On the one hand, nanotechnology, surface modification technology, 3D printing technology, stem cell technology and other cutting-edge science and technology are closely integrated with biomaterial manufacturing and clinical transformation; On the other hand, biomimetic material preparation technology inspired by biology has also become the frontier fields of biomedicine, such as drug delivery, tumor targeted diagnosis and treatment, molecular imaging, etc. Founded in 1975, the Society for Biomaterials (SFB) is one of the earliest biomedical materials research institutions in the world. At present, the United States is still the world leader in the biomedical materials industry.

The role of government

Advanced regulatory system. Since the first cell and gene therapy industry guidelines were issued in 1998, the US Food and Drug Administration (FDA) has successively issued 30 guidelines. Some guidelines have been updated and improved, and some guidelines have been withdrawn because they are no longer applicable. The FDA of the United States has formed a relatively complete regulatory system for cell gene therapy products, and constantly updated it according to the development of technology. It provides guidance to enterprises from all aspects of product research and development, and boldly approves the listing of products with mature processes and high risks and benefits. This approach is in the forefront of the world and is worth learning from. The United States controls the evaluation standards of the world's drugs. The highest authority for drug approval in the United States is FDA. In terms of drug innovation achievements, the new drugs (new molecular entities and biotechnology products) approved by FDA every year are taken as the guidance for comparison. Since 1950, Merck has been the most approved new drugs, with a total of 56 new drugs approved; Next, Lilly was approved with 51 new drugs, and Roche was approved with 50 new drugs. From 1950 to 2018, FDA approved 1577 new drugs in total. According to the public data of US FDA in 2020 (Figure 4), in 2018, FDA approved 59 new drugs, breaking the historical record of 53 new drugs approved in 1996.



Figure 4. Number of new drugs approved by FDA in 1995–2019 Source: compiled by the authors from FDA. Retrieved December 1, 2022, from www.fda.gov/news-events/fdavoices/innovation-new-drug-approvals-2019-advances-patient-care-across-broad-range-diseases.

Optimized policy environment. The United States has formed a multi-level threedimensional system at the policy level to strengthen support for the biological industry: at the administrative level, the President of the United States and Congress have set up special biotechnology committees to track the development of biotechnology, study and formulate corresponding financial budgets, management laws and tax policies; At the level of laws and regulations, the United States strengthened cooperative biotechnology research by enacting laws to encourage invention and innovation and promote biotechnology transfer; In terms of capital support, the United States has established a variety of financing channels for the biomedical industry, including federal government grants, state government grants, large companies, foundations, loans, venture capital; In terms of integrated development of production, learning and R&D, the United States has formed a joint biomedical R&D and production mechanism consisting of the federal government, state governments, enterprises, scientific research institutions and universities.

Opportunities

The arrival of the bioeconomy era has enabled the United States to maintain its competitive advantage in the information economy era and occupy a favorable position because of the leading biotechnology; Some developing countries also attach great importance to the development of biological industry. Their relatively low R&D costs, labor costs, and clinical trial costs provide a good foundation for the United States to transfer some production and R&D links; The growth of some emerging markets also provides opportunities for the United States to further increase its market share by virtue of its innovative advantages. In addition, the 2019 novel coronavirus pneumonia (COVID-19) epidemic has attracted the attention of countries all over the world to the development of the biomedical industry, and has also promoted the innovation of the biomedical industry in the United States, such as the development of biomedicine, vaccine development, and biological testing.

Suggestions to current issues

China's bio pharmaceutical industry has the advantages of rich natural resources, sufficient labor force and perfect infrastructure. However, the innovation level of China's biopharmaceutical industry is not high. On the one hand, the research level of basic biological science is not high, and on the other hand, breakthroughs in the field of biotechnology cannot be well applied to actual production. There is a gap between theory and practice. In this regard, China should improve the level of biological science innovation, strengthen the theoretical research of basic biological science, further deepen the reform of the technical system, establish a technology innovation system with biotechnology enterprises as the main body, bio industry market as the guide, and deeply integrate technology innovation. At the same time, as an emerging economy in the world, China's capital market maturity lags behind that of developed countries such as Europe and the United States. Some medium-sized and small biomedical enterprises are often difficult to obtain financial support. In the future, we should strengthen personnel training in the biomedical industry and further optimize the financing mechanism of the biomedical industry.

China should further create a competitive environment for pharmaceutical enterprises. Rely on the existing 12 national biological industry bases to cultivate more biomedical industry cluster parks; At the same time, mergers and acquisitions, technology transfer and other activities among biomedical enterprises should be encouraged; Relax the access to the biomedical industry market, and introduce more high-quality pharmaceutical enterprises to compete with Chinese biomedical companies; We will improve the market allocation of biopharmaceutical industry elements and fully mobilize the competitive activities of biopharmaceutical enterprises.

China should further deepen the supply side structural reform of the pharmaceutical industry. Guide the high-quality development of the pharmaceutical industry with market demand; At the same time, we should vigorously develop the national medical and health construction, so that the development achievements of the biomedical industry can better serve the people. In terms of the construction of related industries, China should improve the construction of the pharmaceutical industry chain, coordinate the regional coordinated development of the pharmaceutical industry, achieve a new pattern of complementary advantages and common development of the national pharmaceutical industry, and promote the combination of the pharmaceutical industry, especially the emerging industries such as biomedicine and artificial intelligence, big data, cloud computing.

In terms of policy support, China should accelerate the establishment of a modern pharmaceutical capital market, develop securities market financing and venture capital, encourage private investment in the biomedical industry, and provide financing support and other preferential policies for medium-sized, small and micro pharmaceutical enterprises. The listing system of biotechnology companies should be optimized to improve the delisting efficiency of unqualified enterprises; Further actively expand the opening up of the pharmaceutical industry, improve the policy and service system for promoting investment in the pharmaceutical industry, and increase the international market share.

Conclusion

In conclusion, the United States is currently one of the countries with the strongest international competitiveness in the global biomedical industry. In terms of production factors, the United States has strong R&D and innovation strength, rich biomedical talent resources and developed venture capital; From the perspective of enterprise structure and competition, the American biomedical industry is highly concentrated, and the enterprise market competition is full of vitality; From the perspective of market demand, there is still a demand gap in the US biomedical industry due to the developed medical and health level and the aging population; From the perspective of the development of relevant industries, the relevant supporting industrial chain of biomedicine in the United States is perfect; From the perspective of the role played by the government, the United States has formed an advanced biomedical regulatory system and optimized the policy environment of the biomedical industry; Finally, the United States seized the opportunity of development and took a leading position in the international market of the biomedical industry by virtue of its competitive advantage. China's biopharmaceutical industry has developed rapidly. At present, it has become a global biopharmaceutical industry power with comprehensive competitiveness second only to the United States. However, there is still a large development gap between China and the United States.

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