Analysis of the Development Strategies of the Export of Chinese Active Pharmaceutical Ingredients

Zhou Yinhao, Dong Li*

(School of Business Administration, Shenyang Pharmaceutical University, Shenyang 110016, China)

Abstract

Objective To study the competitive advantages of Chinese active pharmaceutical ingredients by analyzing the international market situation and competition pattern of active pharmaceutical ingredient (API). **Methods** Through the analysis of the competition pattern of global API market, the advantages and shortcomings of China's APIs in the international market were found out, and some development strategies and suggestions were put forward. **Results and Conclusion** It is urgent for China API enterprises to adjust their industrial structure, improve their production process, and actively participate in international certification for more export.

Keywords: API; export; development strategy

According to the data released by Precedence Research, the size of the international active pharmaceutical ingredient (API) market in 2022 was 204.04 billion US dollars, and it is predicted that the global API market size will continue to grow at a CAGR of 6% from 2023 to 2032, reaching 363.7 billion US dollars in 2032 [1].

1 Overview of international API market

From the perspective of international scope, there are five main regions of API production in the international market, which are China, India, Japan, Western Europe and North America.

1.1 Western Europe

Western Europe is primarily composed of highly developed nations, and the biopharma industry in this region developed earlier than most countries in the world. Its production scale is huge, and it has a leading high-tech level of biopharma. Therefore, Western Europe is an important region of the export of API. According to relevant data, the total output value of Western Europe's API is about 3.6 billion to 4 billion US dollars, and the number of exports has reached more than four-fifths of its total output of API industry. The main export target countries and regions include the United States, the Middle East, South America, Southeast Asia, Taiwan, Hong Kong and Macao of China [2].

European Union has its own set of unique API registration standards. There are two ways to register APIs in the EU. The first is the active substance master file (ASMF) procedure. The second is to apply to enter the European drug market through the certificate of suitability (COS) recognized by the European authorities. If the imported APIs can be legally used by customers in the European market, the API products must obtain EDMF approval or

* Corresponding author: Dong Li, associate professor. Major research area: Pharmaceutical intellectual property research. Tel: 024-23986543, E-mail: sydongli@163.com.

COS, otherwise they will never be adopted by any biopharmaceutical enterprise in the EU member states.

1.2 North America

From a regional perspective, North America represent the world's largest market for APIs demand and is also the leading importing region. In terms of market share, North America has the biggest API market in the world with the largest market share. Due to its leading biopharma technology and strict environmental protection regulations, the level of competition in the API market in the United States has been high compared to that in other countries. The demand for biotechnological raw materials in the US market is huge, which not only intensifies the competition between global manufacturers of APIs, but also greatly promotes the rapid growth of market for APIs.

1.3 Japan

Japan's biopharma technology is in the leading position in the world. Besides, Japan boasts world's leading biotechnology and pharmaceutical manufacturing industries. Therefore, Japan's APIs are highly recognized in the international market, which occupy a large market share. However, most of the APIs produced in Japan are sold in the Japanese domestic market. In other words, the vast majority of Japanese APIs are produced and sold domestically. The reason for this situation is that the cost of APIs produced by Japan is too high. Compared with the APIs produced by China and India, Japan's APIs obviously lack market competitiveness.

1.4 India

APIs produced in India are exported to various countries and regions in Europe Unions and North America in large quantities every year. It can be seen that India's API industry is an "export-oriented industry" with clear characteristics. 80% of its API production is exported to other nations, but at the same time, India also imports a large number of Chinese APIs for its pharmaceutical production [3].

The Indian government attaches great importance to the development of the domestic pharmaceutical industry. It has not only formulated a series of preferential tax policies for better export of drugs (including patented APIs and nonproprietary APIs) but also granted tax relief to biopharmaceutical companies. For foreign investors, the attitude of the Indian government is strongly supportive, and the Indian government must have a holding rate of up to 75% in joint ventures. Such a move has greatly stimulated the enthusiasm of overseas investors to invest in India's biopharmaceutical industry [4].

1.5 China

China and India are both major producers of APIs in the world. So far, China has become the first producer and exporter of APIs in the world. The scale of China's API industry is huge, and the types of APIs are rich, up to 1,500 kinds, and the output of APIs accounts for about one-fifth of the market share for world's APIs [5]. China's API industry has formed a high concentration of industrial belt. In addition, China's API industry has the agglomeration effect. From the perspective of enterprise scale, small and medium-sized enterprises are mainly distributed in the south of Jiangsu, Zhejiang, and Shanghai. Due to the geographical advantages in the southern coastal cities, the logistics industry is highly developed, and the degree of integration with the international market is high. The large scale enterprises are mostly distributed in North and Northeast of China, and most of them are state-owned enterprises with more production and high degree of industrial industrialization.

2 Analysis of the international market competition pattern of APIs

2.1 Declining competitive advantages of nonproprietary APIs in Europe and North America

Most of the internationally famous pharmaceutical

enterprises in Europe and the United States have transferred the source of their APIs from local production to overseas purchase. As to the production of nonproprietary APIs, due to their low price and low value, more developed countries in European Union and the North America give up their own production and choose overseas procurement. Only a few high value-added bioengineering APIs for new drug are produced by themselves for fear of technology leakage.

Taking North America as an example, due to the implementation and gradual improvement of environmental protection laws, the API industry in North American countries has suffered a considerable impact. Many APIs that cause serious pollution in the production process and affect the local environment have been banned from production. Therefore, they have to rely on imports from overseas, so the production advantage of nonproprietary APIs in Europe and the United States is fading.

With the aggravation of the global population aging trend, the demand of drugs for senior citizens will become large. The demand of drugs in European Union, North America, Japan, South Korea, Singapore and other developed countries and regions will increase the market size of the international APIs, thereby promoting the increase of the sales of generic drugs in the international market. Therefore, China and India, which have advantages in labor cost and large scale of API production, have become the main suppliers and competitors of APIs in the international market.

2.2 China and India becoming the dominant players in the international API market

The cost advantage of China's API industry is obvious. The cost of producing APIs in Chinese pharmaceutical enterprises is generally about one-fourth lower than that of overseas companies. The difference in production cost also leads to great competitive advantages in market price, so it enhances the competitive advantages in the market of APIs of our country. At the same time, the state has always maintained a supportive attitude towards the development of the API industry. China's government has introduced various relevant policies and regulations to promote the development of API industry.

The strong competitive advantages of China and India in the international API market are closely related to the low labor cost and imperfect environmental protection system. 60% of the APIs produced in India are exported to the international market [6], and they have successfully passed the API certification of European Union and countries in North America. Therefore, India has become the main competitor of China's API industry in the international market. The International API classification and its characteristics are shown in Table 1.

Table 1 Classification and characteristics of APIs

Classification	Bulk APIs	Specialty APIs	Patented APIs
Definition	APIs corresponding to drugs for a long time after the patent protection period	APIs corresponding to the first generic drug APIs, APIs corresponding to drugs for a short period of time after the patent protection period	Drugs in the preclinical and clinical research stages and APIs corresponding to drugs within the protection period of marketed patents
Usage	Thousand tons/Ten thousand tons	Ten tons/Thousand tons	Only used by original manufacturers
Business model	Self-production and self-sale	Self-production and self-sale/ Contract customization	Self-production and self-sale/Contract customization
Changes in demand	The demand is basically stable	The demand is growing fast	The demand is growing fast

(to be continued)

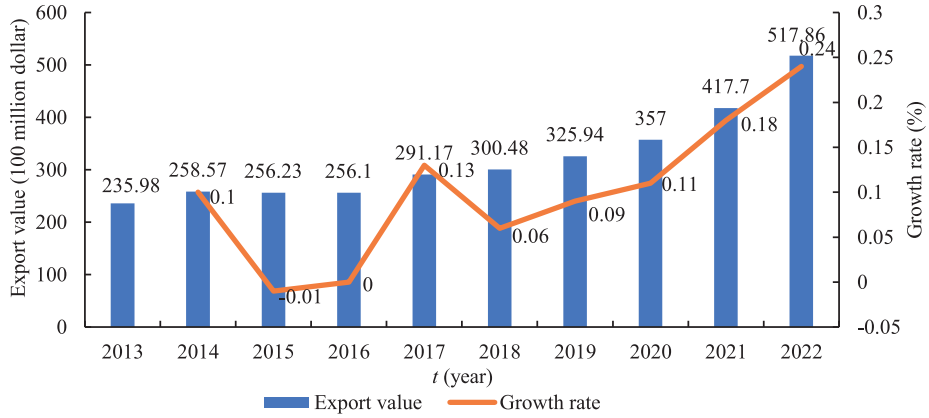
Continued Table 1

Classification	Bulk APIs	Specialty APIs	Patented APIs
Technical barriers	Low, high market competition incentive	High, only a few manufacturers can produce	High, only the original research enterprise or its commissioned enterprise production, low sensitivity to cost
Product added value	Low	Relatively high profit	High profit margins
Customer viscosity	Low	High	Extremely high
Core elements	Cost control ability	Enterprise first copy/grab copy ability	Research and development ability

3 Analysis of China's export status of APIs

3.1 Increasing trend of China's export of APIs year by year

According to the data from 2013 to 2022, the export volume of China's APIs had shown an overall growth trend. In 2022, the export volume reached 11.94 million tons, an increase of 8.74% year-on-year. Data released by the China Chamber of Commerce for Import and Export of Medical and Health Products showed that China had been the world's largest producer and exporter of APIs for many years (as shown in Fig. 1 and Fig. 2).



Source: China Chamber of Commerce for Import and Export of Medicines and Health Products

Fig. 1 China's export revenue of APIs from 2013 to 2022 [7]

Source: China Chamber of Commerce for Import and Export of Medicines and Health Products

Fig. 2 China's export volume of APIs from 2016 to 2022

The two largest target markets for China's export of APIs are India and the United States. In 2022, export of APIs to India accounted for 12.77% of the total exports, up 7.54% year-on-year. The US market accounted for 10.39% of total exports, up 8.74% year on year.

3.2 Main export varieties of amino acids and their derivatives

The superior products of China's pharmaceutical industry are mainly reflected in the categories of APIs for Western medicines. Therefore, export of APIs become the advantageous products. For a long time, the main products of APIs exported by China included penicillin, hormones, vitamins, antipyretic and analgesic, cephalosporins, aminoglycosides, lincomycin, cardiovascular system drugs, tetracycline, amino acids and their derivatives, anesthetic drugs, and central nervous system drugs. Among them, amino acids and their derivatives accounted for the highest proportion of total exports, accounting for 35.27%, followed by vitamins, accounting for 28.05%, and then hormones, accounting for 8.21%.

4 Analysis of the problems in China's export of APIs

4.1 Low added value of products

In the international pharmaceutical market, vitamin products produced in our country still occupy the main market share, but most of the raw material pharmaceutical products with a certain market competitiveness are low-end old products, including some products that will bring serious environmental pollution and low added value in the production process. Because there is still a big gap between China and overseas advanced high-end chemical raw material production technology, there is no obvious production advantage in high-end raw material medicine products.

4.2 Insufficient international certification

At present, as to international certification, the API industry in China still faces insufficient certification. Since the API trade is extremely susceptible to the influence of national tax policy and political and economic environment, the market risk undertaken by API industry is very large. Taking the United States as an example, China's API manufacturers for export need to apply for registration with the US Food and Drug Administration and then submit the required relevant documents and materials or supplementary documents to it. A drug management file, the DMF certificate issued by the US Food and Drug Administration should be submitted in accordance with the relevant regulations and requirements [8].

It is a clear that the production and supply center of APIs is shifting to the Asia-Pacific region. Although the application number of API products in China has doubled in the past 10 years, there is still a big gap compared with that in India. According to Claricate statistics, in recent years, the number of DMF applications in China has been between 100 and 150, while India has been more than 300. China's annual declaration number of CEP is between 50 and 60, while India's is more than 100.

4.3 Strict environmental protection supervision

China's supervision of API companies is also becoming strict. The newly revised "Drug Administration Law", implemented on December 1st, 2019, has put forward strict requirements for all aspects of drug production, such as on-site inspection, product and flight inspection, which have received more attention. In addition, the valsartan incident has also attracted more attention to the detection of genotoxic impurities in drugs in China. Documents such as "Review of Guidelines for the Control of Genotoxic Impurities" and "Technical Guidelines for the Research of Nitrosamine Impurities in Chemical Drugs (Draft)" put forward higher requirements for the production of APIs [9].

In December 2019, the "Guidance on Promoting the Green Development of the API Industry", jointly issued by the Ministry of Industry and

Information Technology, the National Medical Products Administration and other four ministries and commissions, clarified that in the future, the development of high-end APIs had to be accelerated, backward technologies and products would be eliminated in accordance with laws and regulations, and the industrial layout would be more optimized. It indicated that greater pressure was put on environmental protection for API enterprises that produced a large number of pollutants in the production process. Enterprises had to speed up the improvement of their production processes, which also meant that the future API industry would focus on green production. The production mode of high pollution and high environmental damage in the past must be abandoned and eliminated.

5 Countermeasures to promote the export of Chinese APIs

5.1 Strengthening international certification

International certification is helpful for Chinese API enterprises to strive for more market space and better market opportunities because their products are more competitive in the market. Since 2009, the number of applications of drug master file (DMF) and certificate of suitability to monograph of European Pharmacopoeia (CEP) from the United States and European Union by China's API enterprises has overtaken the number of certificates applied by other countries and regions, which means that Chinese enterprises are accelerating into the international standard market. India has maintained a leading position in the normative market by virtue of its perfect patent protection environment for generic drugs and its understanding of the regulatory laws and regulations in the European and American markets. Therefore, only through strict international certification, China's API enterprises can smoothly enter the European and American markets with higher profit margins and larger export volume, which enables API products to have more long-term development prospects [10]. It is vital for China's API industry to strengthen international certification in the future.

5.2 Improving the product production process

At present, China's API industry is facing more stringent supervision and higher environmental protection requirements at home and abroad, and the improvement of production technology is an imperative trend. In addition, the profits of the internationally regulated markets in European Union and the United States are much higher than those of the unregulated markets in Southeast Asia. In order to better comply with the norms of international standards, China's API enterprises should have a high level of product quality and a better production process. To improve their product quality standards, it is necessary for these enterprises to produce in accordance with international regulations. India's API industry is in the leading position in the international market just because its product quality standards are in line with international standards. In recent years, India's export of APIs has maintained rapid growth, and its superior product quality is one of the important reasons [11]. Therefore, in the future, China's API industry must strengthen modernization, improve product quality standards, and strive to transition from domestic GMP standards to international standards to meet the strict requirements of international API market, which can help them to obtain more growth space and more market competitive advantages.

5.3 Adjusting the industrial structure

At present, the advantage of China's low labor cost is decreasing year by year, domestic environmental protection laws and regulations are strict, and the standards for pollutant exclusion and treatment are high. These complicating factors require China's API industry to transform their industrial structure. Take India, the most powerful rival in the international market, for example, now the Indian pharmaceutical industry has shifted from the focus of the production of generic drugs to the research

and development of new drugs, realizing the purpose of extending the industrial value chain and further promoting its industrialization [12]. Combined with China's national conditions, China's APIs industry should refer to India's transformation model and method, adjust their industrial structure to realize the upgrading of industrial structure.

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