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## Industrial value Chain: an analysis of medical biotechnology industry

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### ABSTRACT

Value Chain analysis is one of the most important research in industrial Analysis. The value chain analysis method is applied in the medical biotechnology. The research results indicate that bio-economic and relative industries is in great increasing. Value chain theory indicates that the core to increase competitive advantages of Chinese bio-medical industry is to increase internal operation efficiency of industry value chain.

### KEYWORDS

Industrial value Chain; Medical biotechnology industry; Operation efficiency.



Biotechnology started to transform from lab research to the industry since 1980s; with early completion of human genome project (HGP) in the 21st century, biotechnology industrialization process can be speeded up, with bio-medicine, bio-environmental protection, bio-agriculture and bio-energy and almost all the fields of human economic life involving biotechnology industrialization so as to make bio-economic vitality developing greatly. Bio-medical industry consisting of the most vital part in bio-economy is upsurging as the important impetus for bio-economic development.

### BIO-MEDICAL INDUSTRIAL FEATURES

Being different from other commodities or common biotechnological products, bio-medical products possess a complicated systematic research and development as a project.

Seen from industrial development, the industry is featured basically as follows <sup>[1]</sup>:

**High technology.** Bio-medical industry is a sort of emerging industry with high-concentration knowledge, high-content technology and multiple-subjects' comprehensive development and mutual penetration, as well as advantages in high knowledge assets and intellectual property rights.

**High income.** Average cost for development a new genome project medicine needs 0.1~0.3 billion dollars, and the investment on innovating a new product needs more, generally 0.3~0.5 billion dollars at least.

**High risk.** Investment on new medicine commonly spans a series of procedures from research before clinic, clinic study for human body, registration for listed company, mass production, and product quality guarantee to after-sales supervision, any of which may influence the success or failure of the investment.

**High return.** Bio-medical industry is of a sort of high-profit industry, whose products can obtain huge profits at the first time of launching on the market after successful development. Generally speaking, a new bio-medicine can recoup the investment after being listed for two or three years, especially, the enterprises with new products and patent products that form technological monopoly can get more than 10 times returns or profits.

**Long industrialization circle.** Biotechnological medicines possess a very long circle from research and development to product transformation, beside three essential stages for biotechnological products, namely theoretical studies, pilots and products' mass production, spanning a series of strict clinic experiments before being listed company and a longer audit procedure than the one of common commodities. It generally takes eight or ten years to invent a new medicine presently, shorter than before for ten or twelve years.

The basic unique features are the very sources of difference between bio-medical industry and others as well make the following extraordinary natures:

**High entrance barrier of the industry.** Bio-medical industry is of strong industrial barrier, mainly represented in six aspects involving technical barrier, factor barrier, capital barrier, governmental regulations, market structural barrier and patent right restriction, among which, patent right restriction is the largest barrier of the industry.

**Obvious spillover effect.** Research and development is one of the important parts of bio-medical product industrialization, with knowledge achievements, technical innovation or information as the main products, all of which possess the common features of public articles, namely non-competitiveness and non-exclusiveness, instead, technology leaders promote technical progress and productivity level of other enterprises with technological involuntary diffusion, which shall be considered as one of the external manifestations of economy.

**Huge external cost.** Bio-medical industry gets the external cost results from generation of external economy, added by exchange cost for capital specificity under the system of intellectual property rights protection, as well as the corresponding costs for the influencing factors including technical standard, regulatory barrier and market barrier, etc.

**Information asymmetry.** Information asymmetry exists in the real exchange activities, with one party withholding the information to seek the rent activities, making good use of information asymmetry to others having no knowledge at all. High asymmetry of bio-medical information resulted from high specialized biotechnology lifts the cost to obtain the information.

**Uncertainty.** Uncertainty of products development, market and environment exists in bio-medical industry. Take uncertainty of bio-medical products development for instance, some medicines may cause adverse effects, may be re-determined or influenced by other unpredicted factors. All the certainty increases investment risk and exchange cost.

Seen from external influencing factors, it involves system innovation, capital market, intellectual property protection and medical ethical issues. Bio-medical industry possesses its own special regulations, to adapt to which, system innovation is the core and shall be applied in regulation of current policies and reformation of traditional system as well as promotion of bio-medical industry development. Due to long investment circle and great risk, bio-medical industry shall make good use of capital market to diversify the investors' risks, and risk investment shall play the role of engine for small and medium-sized bio-medical enterprises, meanwhile, effective capital operation shall be the foundation for success of bio-medical industry. Intellectual property protection shall include strategic decisions for maintaining technological advantages, protecting trade profits, improving competitiveness, and bio-medical industry developed by driving force of economy protected by intellectual property, so bio-medical industry relies on intellectual property protection more than other industries. Biotechnology, a double-edged sword, can benefit us and cause ethical issues that greatly influence development of bio-medical industry for biotechnology can change evolution species composition and inherited characters of human beings.

### CONCEPT AND FEATURES OF BIO-MEDICAL INDUSTRIAL VALUE CHAIN

The concept of "value chain" was proposed by Michael Porter in 1985. In Michael's opinion, the process of the value created by the enterprises makes up of design, production, marketing, delivery and a series of different economic activities assisting the product and associated mutually, all of them consists of value chain of the industry <sup>[2]</sup>. According to his value theory, industry value chain refers to distribution and association of the whole process in an industry from the original raw materials to roughing, then from fine processing to the consumers' products. Different industries have different value chains,

and taking the features of bio-medical products and industry into consideration, the author holds the idea that value distribution and association of bio-medical industry chain is related to technology flow, capital flow, information flow and material flow, and value activities involve biotechnology, bio-finance, bio-information, bio-market, bio-logistics, bio-exchange and bio-consumption in such a huge value chain. With deep development of industrial interior labor division, value activities of different types

in industry chain no longer is made of single activity as its agent, instead, instead, made of several agents, a series of different economic activities associated mutually consist of the whole industry value chain, and divide the chain into three links including upstream, midstream and downstream according to association relationships with each link relying on each other and closely related to each other.

Bio-medical industry value involves a great many aspects related complicatedly and consisting of a complex longitudinal industry chain, which is different from others mainly for long industrialization chain circle, high industrial association and refined labor division, etc.

Long industrialization chain circle. As mentioned above, it generally takes generally takes eight or ten years to invent a new medicine to medical audit, then the whole process of industrialization chain sometimes needs 10~15 years if added by certain period for mass production stage, market commodity stage and products circulation.

High industry association. High interior association of bio-medicinal industry is mainly reflected at two aspects. Firstly technological association. Gene project technology, recombinant DNA technology, PCR technology and protein project technology and other technologies are mainly applied in the research of bio-medical products, with development of genomics and related technologies, medical genomics and related technologies have been developed rapidly, and bio-medical further development is closely associated with computer, biochip, combinatorial synthesis, nanometer, high throughput screening and other new technologies; secondly is association with other industries, association with the upstream industries like bio-resources and related production materials, downstream industries mainly including biotechnological products application and supporting related industries, as well as health care food, apparatus, environmental protection industry and green agriculture.

Refined labor division. Bio-medical industry involves a great many technologies, so the industry chain can be refined into different fields, including specialty refinement, product refinement and market refinement. Specialty refinement of bio-medical industry technology is at high strength, as a high-tech knowledge system supported by multiple sciences, it involves not only biology, medicine, pharmacy, mathematics, statistics, computer and other natural sciences but also economics, management, sociology, ethnics, laws and other humanities and social sciences. Product refinement is mainly reflected at classification aspects of bio-medical products spanning biotechnological medicines, biotechnological nutritive health care products, biotechnological diagnostic reagents, devices applied for biotechnology and biotechnological informationization, among which, biotechnological medicines includes hormones, enzymes, cell factors, vaccines, therapeutic monoclonal antibody, nucleic acid, cell therapy and tissue project products etc. Besides, research of bio-medical products can be divided into different stages, with different intermediate goods at each stage. Due to various types of genes and diseases, market refinement is determined by non-exclusiveness of market competition. Product refinement results in market refinement and international labor division.

The whole industry chain can be divided into three links including upstream, midstream and downstream, with several different adaptive agents involved in each link. At the upstream stage university and college or research institutions are mainly taken as agents, the drug research departments of pharmaceutical enterprises participating in and risk investment organizations and contract research organizations (CROs) as the significant part of industry chain; at the midstream stage the enterprises start to intervention and clinic research is finished by medical organizations. At the downstream stage the enterprises are the main agents for a series of economic activities spanning production, operation and marketing, etc. The enterprises play an important role in economic social activities, and industrialization is only realized by enterprise finally; medical organizations are the main circulating channel and exchange places; the government supervises and coordinates the whole industrialization process, political favoritism and protection can accelerate industrialization process. Realization of industrialization chain process shall be based on social labor division of high efficient production method and effective integration. Obviously, complication of industry chain has increased investment risk as well as exchange cost and administrative cost.

## VALUE SYSTEM OF BIO-MEDICAL INDUSTRY VALUE CHAIN

Bio-medical industry value chain consists of technology chain, capital chain, information chain and material chain as a value system. Each composition of this system is an organic entirety and a value transfer process with exchange relationship of technology, capitals, and information and material aspects between each link<sup>[3]</sup>.

### Technology chain

Technology chain starts from research and development, transfers science into technology, and then realizes the upstream, midstream and downstream technology chained development with experiment/test, clinic state and production and processing stage, etc. Knowledge innovation is the source of industry chain, while the market is the end of industry chain. Bio-medical industry chain is of double significant driving forces from technology pushing and demands pulling. Based on market-oriented, all organizations and systems are effectively combined so as to promote upstream, midstream and

downstream technical spreading or transferring, reduce industry chain circle and related cost and fees of the industry, as well, increase industry value added.

### Capital chain

Capital chain takes government, enterprises and capital market as the capital supplier, finishes transformation from resources to the capital through capital flow and operation so as to earn benefits. According to American experiences, capitals needed by an biotechnological medical products is 1:10:100 in upstream, midstream and downstream percent in the process of industrialization<sup>[4]</sup>. Revitalizing the deposit capitals through flow and operation in capital market so as to improve capital utilization, reduce administrative cost, obtain resources advantages and earn benefits.

### Information chain

Information chain is a process of information flowing and knowledge transferring. Interior knowledge production can reduce exchange cost. Bio-medical industry is featured significantly by highly intensive knowledge with talents as main carrier, so it needs a great many specialized technical talents. Share of intermediate service system, information and knowledge platform can reduce learning cost.

### Material chain

Besides of procurement of raw materials and circulation of intermediate products, material chain includes drug procurement, package and storage, distribution, wholesale and retail and after-sales service, and the process to send drugs to consumers through marketing, namely drug supply chain logistics system. It is the key of strengthening the industry and prolonging the industry chain and mainly finished by medical circulation enterprises and medical organizations. Logistics and information flow can be accelerated by virtual technology, network service platform and other marketing channels so as to reduce related industrial costs and fees and improve its market share.

All compositions consisting of bio-medical industry value chain are not independently existing, but associated, restricted and relied on mutually. Medicines from research and development to delivery to the consumers is a process of associated chain of technology chain, capitals chain, information chain and material chain, where knowledge innovation and marketing channel are the core of the industry value chain, and taking a long term advantageous position in a certain product or industry only with holding the chain core of research and development and marketing channel. Technology chain, information chain and material chain are associated mutually and with capitals chain closely. Effective integration of all factors of value system can optimize the integrated benefits of industry chain.

Different adaptive agents in the industry chain possess the relative competitive advantages, which rely on whether value chain link operate well or not and then determine the amount of the enterprises' profits. Competition of the industry is the competition of value chain indeed; the one mastering the key technology of the industry can have the powerful core competitiveness, the maximum profits from the industry, and accordingly obtain the competitive advantages. The features of bio-medical industry, including but not limited to high research and development expenditure, long industrialization circle, complex industry chain, long patent protection period and high risk, make industrial barrier high and the whole industry value chain vertically and highly integrated. With deepening and expanding international labor division and economic globalization process, the industry chain gradually expands to other countries, embedded transnational value chain of world production network, driven by profits, bio-medical industry structure shows the new development trend like mergers and acquisitions, reorganization and association.

## MAIN PROBLEMS EXISTING IN CHINESE BIO-MEDICAL INDUSTRY VALUE CHAIN

Presently, complete and independent bio-medical industry chain is unavailable in China, so no matter technological level, scope or output value and benefits lag behind some developed countries. Although our government has increased investment on each link, various problems or restrictions during the development still influence the development of the industry chain.

Supporting policy is unavailable and systematic innovation is not enough. Presently, effective bio-medical industry supporting policy is unavailable in related government authorities; there is no special coordinating institution or organization to integrate the industry value chain, which results in separated industry chain and scattered resources, with traditional mechanism and system still restricting the industry from rapid development to a great extent.

Slow technology diffusion and separated research and development from technology result in disconnection of upstream industry chain and downstream industry chain, as well as low rate of transformation. The current rate of achievements' transformation is lower than 0.5% in China<sup>[5]</sup>, especially engineering link in industry chain is very weak, mostly tracing and imitation, so the industry chain is at the low-end level and lacks downstream specialized enterprises, essentially, there is no effective industry chain at all.

Lack effective capital chain, narrow capital financing channel, low capital utilization rate and high administrative cost. Due to information asymmetry, uncertainty and long investment return circle of the industry, hard financing cause unstable earnings from risk investment; limited capital operation capacity, scattered resources investment, unbalanced investment proportion and overinvestment on infrastructural research, to some extent, cause separation of technology and capitals, restrict all links from technology transfer, knowledge diffusion and logistics development, and result in low rate and influence competition of the industry. For example, Beijing Keyu Union Stem Cell Biotechnology Co., Ltd. has launched storage stem cell reagent at low temperature and cell sales together with partner Oxford University, U.K., obtaining some achievements, but industrialization is not as successful as prediction of the CEO of the company Dong Ziping. Dong has analyzed various problems and considered lack of mature and effective capital operation as the largest pity. So far, risk investment mechanism is not sound enough in China, especially effective quit mechanism for normalized biological risk

investment, so international risk funds are unwilling to investment bio-medical industry in China, and accordingly in some sense influence international competitiveness of China at the very aspect.

Blocked information chain, low information share and high learning cost. Current domestic enterprise lack knowledge on knowledge capitals and their protection consciousness on intellectual property is very weak; bio-medical industry features decide the large demand for specialized technical talents and administrative talents, but current talents policy and incentive mechanism are still lacking, resulting in separation of talents and capitals and innovation talents shortage; added by unsound and lacking of supporting industries' service system and supporting products' safe technological standard, the new product registration and audit and other laws and regulations as well as supervision system are not sound enough, lacking of honest cultural atmosphere in the market, and lastly influencing industrial innovation capacity and competitiveness.

Material logistics system is undeveloped and circulation market is not standardized. Logistics was paid no attention in the past, and medicine tender procedure is not normalized with great rebate, all of which result in high circulation profits and reduction of profits of the medical organizations and enterprise; as well, current medical insurance system and health management system reform is not good enough, all of the above issues cause the problems existing in the end market of Chinese bio-medical industry.

## **SUGGESTIONS ON DEVELOPMENT OF CHINESE BIO-MEDICAL INDUSTRY VALUE CHAIN**

It is essential to integrate industry value chain in order to increase competitiveness of bio-medical industry, which is not finished by any institution or organization and unit; even the leading industrialized enterprise cannot take effect of integration for the value system. The author thinks that government support is the only way to develop the current Chinese bio-medical industry immediately. Aim to the main problems existing in the industry value chain, some suggested countermeasures are brought up as follows:

### **Strengthen system innovation strength and perfect industry policy system**

First of all, the governmental authorities shall establish the sound system adapting to rapid development of Chinese bio-medical industry, break through the traditional system restriction and mechanism barriers and consider system innovation as the important lever in promoting bio-medical industry development. Establish the special bio-medical industry organizations or coordinating institutions to coordinate the relationship between the industry and the government, promote effective implementation of related industry policy so as to coordinate the development of all links in bio-medical industry value chain and promote synergy effect among the factors in the value system. For example, the U.S. white house and congress set special biotechnology committee to study and institute the corresponding financial budgeting, administration regulations and taxation policies, as well as trace the development of biotechnology; furthermore, biotechnology industry organization (BIO) and other non-government organizations can help the government with institution of polices good for biotechnology research, development and industrialization development. Must normalize effectively the functions of all adaptive agents, take anti-commercial bribery as the long-term policy, continuously optimize the current system environment, further perfect the legal protection system and supervision system for intellectual property, technical transfer and technical diffusion, etc., establish the stereo policy system combined institution, laws and supervision and go on finding and creating new value so as to establish the complete industry value chain and further drive the whole industry to the rail with virtuous circle.

### **Enlarge investment strength and strengthen capital operation capacity**

The government shall enlarge the investment strength, increase the investment on infrastructural research funds and scientific development funds within budgeting, set national funds for industry development, special funds for bio-pharmacy enterprises' development and risk investment funds, etc., and strengthen the vertical investment of the whole industry chain, allocate the limited capitals according to the related policies and regulations, change the overinvestment on infrastructural research, strengthen resources allocation for midstream and downstream industry chain, and make full use of agglomeration effect of the limited capitals. Further perfect business investment and financing system of bio-medical industry, especially the quit system of biotechnology risk investment, which is the most important capital foundation for bio-medical industry, establish the real independent bio-medical growth enterprise market separating from Shenzhen main board market and promote the development of SME bio-medical enterprises. At the same of creating good capitals environment and solving bottleneck problems of industry capitals, strength the operation of capital market, promote effective capital chain and improve industry competitiveness with capital strength.

### **Establish innovative organization system and optimize industry structure and layout**

According to the demands for bio-medical industry value chain, perfect the current organization structure, accelerate the construction of the main public technology platforms like gene chip technology platform, GLP security evaluation center, GCP clinic test center, animal test center and bio-engineering center, and reduce the cost and risk based on scientific data, instruments and apparatus and special technical service and other resources share. Quicken construction of innovation organization system, develop the intermediary organs engaged in biotechnology medical industry information consultation and technical evaluation (including bio-safety, patent, investment and financing and other evaluation systems), establish the organizations and institutions in accordance with demands for industrialization development like CRO contract organization, strengthen the construction of the current bio-medical industry base, make full use of agglomeration effect of technology, capitals, talents and information and exert the driving force of the system and radiation. Meanwhile, through the related industrial structure policy adjustment, continuously optimize industry structure and allocation so as to improve resources allocation, promote effective flow of technology chain, knowledge chain and capital chain as well as actively promote the development of industry value chain. Although presently China lacks coordinated research and development capacity of innovative medical industry chain, but we can establish the innovation system and strengthen the research and development

of some bio-medical products or the relative advantages of some medicines in production links. For example, Tianjin Smithkline Beecham Co., Ltd. seizes up certain market share in gene project hepatitis b vaccine market through joint venture. The enterprise successfully obtains the advantageous conditions that cannot be obtained in U.S.A. through integration activities of value added effect, and reinforces the original competitive advantages as well as seizes the high end of industry chain with research and development advantages or technical strength. Shall actively guide and encourage the merging, reorganization and association of the enterprises, promote globalization strategy, strengthen strategic association and improve innovation capacity and international competitiveness of bio-medical industry in China.

### **Reinforce knowledge service concept and create good operation environment**

The current knowledge economic society is featured by “minimization of knowledge cost and dematerialisation of capital”. Government authorizes of bio-medical industry shall strengthen their knowledge service concept, pay attention to the construction of the information share platform and focus on the operation environment improvement of information circulation, construct the information network center including resources, technology, information, market, trade and laws and so forth, promote communication of technology and market supply and demand information and reduce learning cost so as to form into a good information chain and socialized production pattern. Further strengthen talents mechanism and incentive mechanism, go on reinforcing talents cultivation and intellectual introduction and realize capital personalization; strengthen standardization and procedure of industry value chain administration system, strengthen the construction of cultivation industry support system, intermediary service system and market system and perfect intellectual property exchange mechanism, supervision system and credit system so as to reduce administrative cost and improve non-price competitiveness; further establish operation mechanism adapt to the development of bio-medical industry, make good use of advantages to strengthen the research and development of self medicines, make China possess more core technologies of independent intellectual property and lead the future bio-economy.

### **Rectify circulation system and improve market operation mode**

Adjust market mechanism with governmental inference and rectify the market failures resulted from information asymmetry; reorganize medicine circulation system, standardize market competition order, rationalize the relationship between manufacturer, sellers and hospitals, reject rebate and solve the end market problems existing in the development of bio-medical industry; fully promote the reform of health management system and medical insurance system and change marketing channel so as to reduce circulation cost, obtain the benefit difference from circulation links, achieve the target of value added service and solve the problem of “expensive medicines” of common people.

## **CONCLUSION**

Value chain theory indicates that the core to increase competitive advantages of Chinese bio-medical industry is to increase internal operation efficiency of industry value chain, however, the key of which is macro-adjustment and policy support of the government. Shall strengthen technical management, knowledge management, capital management and logistics management, promote self flow of technology chain, capital chain, information chain and material chain of bio-medical industry value chain and effective integration of all factors, help the best choice of all adaptive agents, and accordingly form the core competitiveness of the industry and promote bio-economy develop rapidly in China.

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