Part II Supply: Strategy of Firms. Chapter 5 Innovation: Evolution and Motivation

Chapter 5

Innovation:
Evolution and Motivation

Firms depend on innovation for survival, development and excellence, especially in the increasingly competitive and rapidly changing market environment. This chapter focuses on introducing and then analyzing the current status, evolution processes, experiences, and issues of innovation in the Chinese pharmaceutical industry. We try to reveal the motivation behind the efforts being made in this field, and to help understand how Chinese pharmaceutical provision can be sufficient and sustainable.

5.1 Literature Review

First of all, we must distinguish the differences between Invention" and Innovation. According to J. A. Schumpeter's Innovation Theory, enterprise innovation is the introduction of a new combination (which consists of essential production factors and production conditions, and has never appeared before) into the production system, i.e. a new business success. Business innovation needs to go through a more complicated process and has many influencing factors (including a firm's interior factors and external environmental factors), requires the capability to cover the whole value chain and various areas of knowledge (science, technology, manufacturing, and the market). Invention focuses on creating knowledge, i.e. it is a scientific activity, while innovation is an economical activity which emphasizes the commercialization of scientific production.

Secondly, we must clarify the relationship between Innovation and R&D. There are five major patterns of innovation: product innovation (inventing new products), technology innovation (finding or improving new approaches in manufacturing), market innovation (developing new markets), resource allocation innovation (exploiting new supplies of resources), and organization innovation (utilizing new a organizational structure). All of these innovation patterns can be found in the Chinese pharmaceutical industry. In this section, we will focus on the first two, i.e. product and technology innovation, which also have reference to R&D. We should be aware that (1) innovation goes beyond R&D;

and (2) on the other hand, generic drugs are still the overwhelming majority of products in the Chinese pharmaceutical industry, and so some R&D resources are spent on the study of generic drugs. Therefore, R&D does not definitely mean or lead to innovation.

There are several mechanisms to promote innovation: patents, sales margins, research and development subsidies, bonuses for new inventions, contract research and development, and research and development by public institutions (*J. Lanjow, Lecture in 2005*). Researchers often point out that patent protection is effective at raising the profits from, and investment into, research and development among pharmaceutical firms. Okada (2006) conducted an empirical test, which showed that for a patent that is frequently referred to in a different patent's application, the subsequent sales of drug firms holding that patent increased by 30%. On the other hand, innovation heavily relies on human capital. It is difficult for managers, who do not directly engage in innovation, to control the innovation process. Thus the structure of governance is another noticeable, important and significant factor that affects firms' innovative activities. These two points are discussed in detail in separate chapters, however, and so we will only briefly introduce them as and when necessary.

5.2 Innovation in the Chinese Pharmaceutical Industry: a Survey

The pharmaceutical industry is closely related to civil health, society stability, and economic development. It is an economic colony that merges multiple disciplines with advanced technology and techniques, and requires and calls on innovation out loud. R&D is the most pivotal competence in the competition for pharmaceutical firms to survive and succeed. Moreover, as we see later, the pharmaceutical industry's technical innovation is a game characterized by huge investments, high risks, and a long time period.

5.2.1 Basic Information on R&D in the Chinese Pharmaceutical Industry

Generally speaking, low investment in R&D and lack of capability for innovation are two key factors that severely and directly restrict the Chinese pharmaceutical industry's development and advancement. The average ratio of investment in R&D to revenue is about 1.5% in the Chinese pharmaceutical industry, which is much lower than the average level among international advanced pharmaceutical giants. Tables 1-6 outline the overall status of innovation in the Chinese pharmaceutical industry.

Table 1: Distribution of Independent-Innovation Enterprises in the Chinese Pharmaceutical Industry (2005)

Industry	# of Enterprises with Independent-Innovation Activities	(%)
Raw Chemical Materials and Chemical Products	540	32.3
Medical and Pharmaceutical Products	423	55.1

(Source) NBSC

Table 2: R&D Personnel and Investment in the Chinese Pharmaceutical Industry (2005)

Industry	# of R&D Staff	R&D Investment (RMB 10,000)
Raw Chemical Materials and Chemical Products	46,334	846,315
Medical and Pharmaceutical Products	23,949	399,510

(Source) NBSC

Table 3: R&D Projects in the Chinese Pharmaceutical Industry (2005)

Industry	# of R&D Projects	# of R&D Project Staff	R&D Project Fund (RMB 10,000)
Raw Chemical Materials and Chemical Products	2,592	33,798	695,047
Medical and Pharmaceutical Products	2,546	17,401	325,519

(Source) NBSC

Table 4: Manufacturing and Sale of New Products in the Chinese Pharmaceutical Industry (2005) [RMB 100,000,000]

Industry	New Products' Value	Sale of New Products	
			# Exported
Raw Chemical Materials and Chemical Products	1,044	1,039	146
Medical and Pharmaceutical Products	512	469	71

(Source) NBSC

Table 5: Patent Application and Possession in the Chinese Pharmaceutical Industry (2005)

Industry	# of Patent Applications	# of Invention Patents	# of Invention Patents Owned
Raw Chemical Materials and Chemical Products	2,155	903	1,495
Medical and Pharmaceutical Products	2,708	1,659	1,134

(Source) NBSC

Table 6: Technology Acquisition (2005) [RMB 10,000]

Industry	Expenditure on Introduction of Overseas Technology	Expenditure on Digestion & Assimilation	Expenditure on Purchasing Domestic Technology
Raw Chemical Materials and Chemical Products	195,478	43,023	46,610
Medical and Pharmaceutical Products	35,815	34,971	56,041

(Source) NBSC

Given the limited resources in the initial development stages and their weak innovation capability, Chinese pharmaceutical firms have to choose a down-to-earth strategy: "combing imitation and innovation together, while first imitating" has become the representative development mode of medicines in China. Nowadays, most chemicals in

China are generic drugs. Only several medicines (such as Qinghaosu, etc.) are admitted internationally as innovative drugs. Due to insufficient R&D and the lack of independent intellectual property rights (IPR), Chinese medical firms have to focus on producing generic drugs. Dependence on generic drugs, however, leads directly to tight competition, which prevents firms from enter into a well-ordered developing orbit, further limiting the development of the Chinese pharmaceutical industry.

Fortunately, we are pleased to find some promising firms (such as Kanion, Hisun, Fosun, DCPC, etc.) that are paying more attention to R&D and attach importance to innovation. The highest R&D investment ratio, which we knew through a field survey, reached about 12% (Kanion). The feature that all these firms have in common is that they have a good management infrastructure. These pioneers utilize specific APIs and R&D into new drugs as breakthroughs, and they benefit from differences in products, technology, and marketing strategies. They have already started to upgrade the Chinese pharmaceutical industry structure with the symbol of internationalization and innovation. We will discuss this type of firm in detail and introduce their developing experiences in case studies.

5.2.2 Basic Information on R&D in Representative Chinese Pharmaceutical Firms

In this section, we summarize the basic information on R&D in Chinese pharmaceutical firms that we visited between May and June 2007.

Investment by firm consists of physical capital and human capital. Of these two, innovation heavily relies on human capital. In order to invest physical capital, a firm must need capital. Speaking reversely, if you can finance, you can invest and acquire physical capital. However, human capital is something different: first, ownership of human capital is ambiguous. Though a manager or company pays a scientist’s salary, his boss can bring him to a laboratory, but cannot have him seriously engaged in research and development work. Secondly, innovation comes from ambiguous ownership, cooperation with research staff, or some type of interaction. Therefore, the allocation of decision-making rights related to innovation is very important in this field.

Table 7: Basic R&D Information From Visited Firms (May - June 2007)

No.	Firm	Sales (2006) (bil. RMB)	R&DExpenditure/Sales (%)	Who decided which drugs should be listed?	Who provided information on new drugs	Notes
1	A	2.40	10	Expert Committee	R&D Department	
2	B	1.51	8	Expert Committee	Market analysis, and consultation with an outside expert	
3	C	2.69	5-6	Decentralized by the size of investment	Technology Center and Marketing Department	
4	D	0.20	6	-	Research Institute and Information Department	
5	E	50	20	Headquarters in Japan	Shanghai Corporate	
6	F	1.42	8	Directors' meeting	R&D Team, Marketing Team, Expert Committee	Practically, the Chairman and management are a part of the R&D team. CTO
7	G	0.85	8-12	Chairman, Directors' meeting	R&D Team	
8	H	2.70	8-9	Expert Committee		
9	I	3.60	1.5	Directors' meeting or GM office(determined by the size of investment)	(1) Laboratory, (2) New Drug Research Center	
10	J	1.00	6	Expert Committee (Management + outside experts)	(1) Hospital, (2) R&D Team, (3) Sales	Limit of expected sales 0.5 bil / year
11	K	0.40	8	Directors' meeting in the company itself, not the holding company		
12	L	4.05		Chairman, Directors' meeting at headquarters	(1) Marketing and Sales, (2) R&D Team	

(Source) Author

5.2.3 Market, Resource Allocation, and Organization Innovations

Although the achievements made by the Chinese pharmaceutical industry's R&D is not so exciting, there have been some original innovations that are worth considering, primarily innovations in the market, resource allocation and organizational structure.

According to the "Decision of the Central Committee of the Communist Party of China and the State Council on Implementing the Outlines of Science and Technology Planning and Strengthening the Capabilities in Self-Innovation", China aims to establish a technical innovation system which involves "market-oriented, enterprises as the main body, and combing industry, universities, and institutes together to innovate". To be leading players in innovation and in order to provide sufficient, affordable, and effective drugs, Chinese pharmaceutical firms usually adopt the following methods:

1. Staying close to the market by means of strict market-oriented technical innovation. When market demand arises, it will be detected immediately (indeed, some demands are raised intentionally). The target product will be identified and its efficacy will be realized via a series of R&D processes and technical means, and be launched in the market quickly;
2. Due to conflicts of interest and a lack of complementary activity, cooperation among Chinese pharmaceutical firms is infrequent. However, there is a lot of cooperation between Chinese pharmaceutical firms and universities and institutes. In addition, Chinese pharmaceutical firms recognize that there is a large gap in the R&D of innovative drugs, compared with advanced international firms. They are aware that R&D must meet international standards, and they look to utilize international resources for technical innovation (such as improving their technical capability through international cooperation), in order to create an internationalized means for R&D and operation management;
3. Chinese pharmaceutical firms usually adopt a "multi-department cooperation" strategy for organizing R&D. Generally, R&D acts as the leading department, and the departments of Marketing, Finance, and Manufacturing take part in the project. This kind of organization innovation can efficiently accelerate the transfer of new products from R&D to production and then to the market.

5.2.4 Innovation Achievements in the Chinese Pharmaceutical Industry

Although the Chinese pharmaceutical industry currently has not seen as good results from innovation as we might wish, there are still several noteworthy achievements that we would like to highlight.

Above all, the Chinese pharmaceutical industry's efforts in innovation have ensured that people can obtain sufficient, affordable (although people complain that "it is difficult and expensive to see a doctor", they unanimously agree that "it is a problem with the system") and efficient drugs. Currently, China can independently produce a series of products of APIs, doses, biologics, Traditional Chinese Medicines, medical treatment instruments, and pharmacy machines, and has already set up a whole system including science and research, education, production, circulation and other assisting establishments.

Secondly, the government's efforts and assistance have significantly influenced pharmaceutical innovation in China. Most of the pharmaceutical firms we visited have received R&D funds (some more, some less), finance aid and/or preferential tax treatment from local and/or central government bodies. These favorable policies and measures provide a great incentive for firms to pay more attention to R&D. To the best of our knowledge, almost all innovative drugs which have independent IPR (admitted internationally) came from The National Key Technologies R&D Program (NKTRDP). National science and technology projects have achieved remarkable results and advanced the Chinese pharmaceutical industry's progress in R&D. For example, both Fosun's Artesunate (which possesses the No.1 certificate for a Class One New Drug in China) and DCPC's "Beijing Hypertensive No. 0", have benefited from NKTRDP. National R&D projects can utilize and unite social resources and power, concentrate to invest in and attack some key technical problems, and also promote science and technology's advancement and independent innovation in the pharmaceutical industry.

Finally, some ambitious and conscientious pharmaceutical firms are growing rapidly by relying on R&D. Through the pursuit of profit and efficiency, these firms continuously improve and innovate, reducing production costs, strengthening scientific management, and trying any way to meet the customer's demand. We believe that firms of this kind have a promising future and will see quick development, if their market exploration and expansion is not only limited to their home base, but also expands overseas (this requires internationalization talents in R&D, management, and global marketing, etc).

5.2.5 Development Phase and Basic Evaluation

The Chinese pharmaceutical industry's development, the degree of pharmaceutical patent protection and supervision of drugs, and the level of engagement in international affairs, all demonstrate that China is a large but not a powerful country when it comes to producing drugs. Most Chinese pharmaceutical firms are still relying on massive manufacturing, low resource costs and low labor costs to struggle and develop forward. The basic evaluation of the Chinese pharmaceutical industry's innovation is as follows:

1. The Chinese pharmaceutical industry is still striving in the primary stage of R&D. Most of its innovation takes place in the fields of technology, the market, resource allocation and organization. By and large, product innovation is very sparse and is still in the imitation-innovation stage.
2. China is in the upstream of the global pharmaceutical industry supply chain, playing the role of a manufacturer and a provider of APIs and raw materials.
3. Chinese pharmaceutical firms (especially chemical firms) mainly produce generic products and focus on the extremely competitive domestic market.

5.3 Evolution and Motivation of Innovation in the Chinese Pharmaceutical Industry

5.3.1 Major Innovation Patterns in the Pharmaceutical Industry

5.3.1.1 Characteristics of R&D in new drugs: greater difficulty, longer R&D periods, increasing investment, less marketable innovative drugs

Pharmaceutical R&D requires huge investments. In 2003, the average R&D cost of an innovative drug approached US$700-800 million, and only 34 innovative drugs were approved to enter market that year. Pharmaceutical firms need to invest at least US$150-200 million dollars in R&D annually in order to retain their innovative potential in the international market. In the US, the average time it takes for an innovative drug to go through all the phases, from R&D right through to being granted approval by the FDA to enter the market, is 12.5 years. The two most time-consuming phases are drug discovery (5 to 7 years) and clinical research (5 to 8 years). But

accompanying this huge investment and high risk, is the return of a tremendous monopoly on profits during the patent protection period (usually 20 years) if an innovative drug has been developed successfully. The detailed R&D flow of a innovative drug, and the values and risks associated with each phase, are set out in Figure 1.

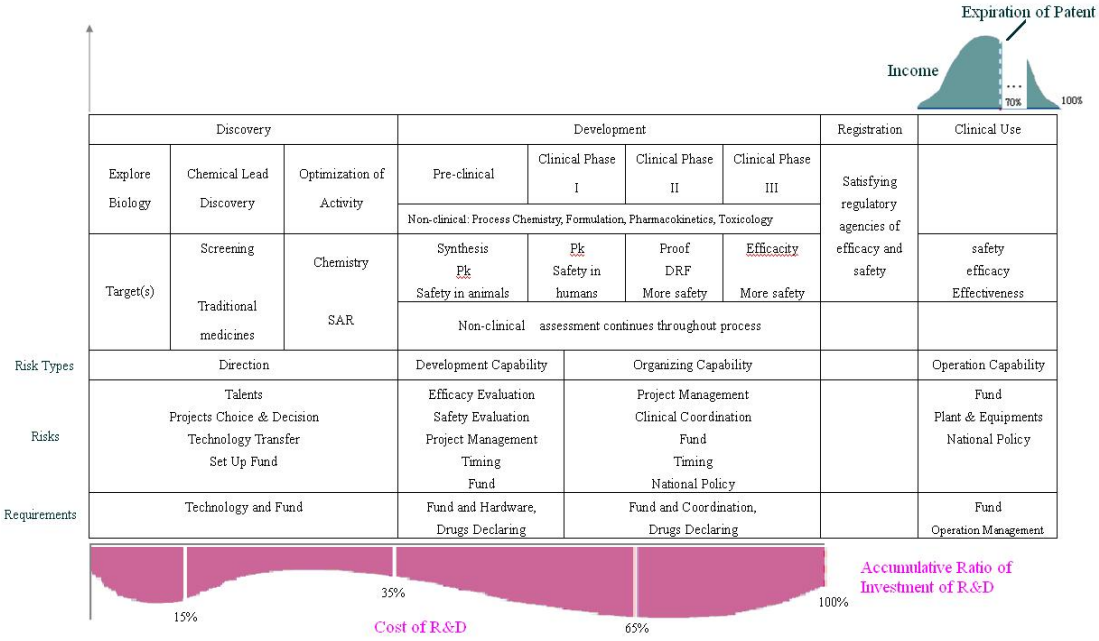


Figure 1: R&D Flow of an innovative drug, and the value and risks in each phase

Source: [1]

Figure 1 shows that the highest investment point appears in clinical phases I-III. The large numbers of patients and the history of the illness, along with the low costs and other favorable clinical examination conditions, drive more and more international R&D organizations to carry out clinical examinations of new drugs in China. This trend provides an opportunity for some Chinese pharmaceutical firms that have clinical drug resources and a strong capability for organization. The qualified firms can utilize the economic rules, their own abilities, and the advantage of being close to the market, to cooperate with international R&D organizations first in the clinical phase, and then gradually expanding to other phases.

5.3.1.2 Major patterns in pharmaceutical industry innovation: product and technology innovation

All five major types of innovation patterns (product innovation, technology innovation,

market innovation, resource allocation innovation, and organization innovation) can be found in the innovation processes of pharmaceutical firms. Of these, product and technology innovation are the two most prominent modes. Figure 2 details the processes of a pharmaceutical firm's technical innovation and the related factors within each period.

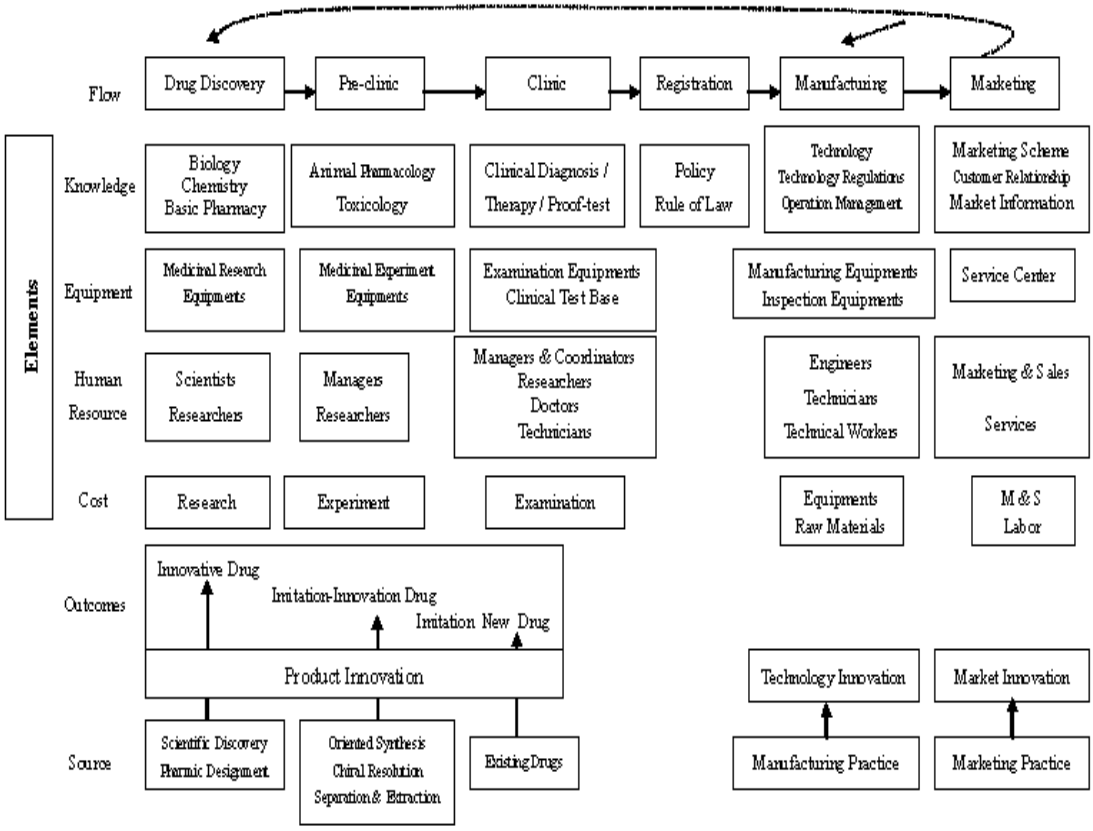


Figure 2: Model of Pharmaceutical Firm Technology Innovation Process

Source: [1]

Usually, pharmaceutical product innovation happens mainly during the Drug Discovery, Pre-clinic, and Clinic phases. The innovative results include innovative drugs, imitation-innovative drugs, and imitation new drugs (new forms of dosage and new indications developed from existing drugs).

Generally, innovative drugs and imitation-innovative drugs are more difficult to generate than imitation new drugs. On the other hand, highly-technical R&D is also required for high-level imitation new drugs. The development of imitation new drugs is characterized as integrated innovation.

Pharmaceutical technology innovation usually happens in the manufacturing phase by introducing new manufacturing technology and new methods of quality control to produce existing drugs. Technology innovation makes production easier by making it less time-consuming and less energy-consuming, while at the same time obtaining a better quality of product.

A pharmaceutical firm's market innovation is usually market-oriented, continuing to develop new markets and creating new marketing mechanisms. Resource innovation, meanwhile, means to optimize allocation of pharmaceutical resources in order to improve the efficiency of the utilization of resources by setting up a global integrated mechanism and channels. Generally speaking, organization innovation in pharmaceutical firms refers to building an innovative strategic alliance or cooperative R&D organization.

5.3.2 Innovation Patterns in the Chinese Pharmaceutical Industry

Although Chinese pharmaceutical firms' capability for innovation is relatively weak, their investment in the R&D of new drugs is severely insufficient, and there are very few local innovative drugs, nevertheless, some representative Chinese pharmaceutical firms have carved out their methods of innovation with individual characteristics. We have summarized the most typical and impressive patterns of innovation as follows: (1) product innovation for R&D into new drugs; (2) technology innovation to improve production efficiency and capacity; (3) marketing innovation in promoting the brand and improving the firm's status; (4) organization innovation to improve the efficiency of R&D, manufacturing, and market development.

5.3.2.1 Product innovation for R&D into new drugs

In this section, we introduce several shining examples of product innovation in the Chinese pharmaceutical industry, although they are a rarity. As we discussed earlier, national R&D projects played an important role in this field.

Qinghaosu, a world-renowned chemical product that was independently developed by Chinese scientists in 1971, and its derivatives, Artesunate, which has the characteristics of low toxicity, swift time to effect, high effectiveness, and low recrudescence, is the only effective water-soluble derivative of Artemisinin and was given an award as the

“most effective” antimalarial drug by the WHO and was listed among the essential antimalarial drugs in 2000. It is also the first product to possess the First Class New Drug Certificate issued by China’s Ministry of Health. Favorable reviews noted that Artesunate had taken a pragmatic step forward in the exploitation of the international market as a finished product with Chinese independent IPR.

Case Study: Fosun Pharmaceuticals -- Innovation for Good Health

Fosun Pharmaceuticals (Fosun Pharma) was founded in 1994 and grew to become a leading pharmaceutical enterprise in China. Its businesses cover pharmacy, clinical diagnostic and therapeutic products. It has the largest drug retail and distribution network in China and is aiming at the global market. It is listed on the Shanghai Stock Exchange with a market capitalization of about RMB12 billion.

The Anti-malaria drug Arteannuin, which was developed by Guilin Pharmaceuticals (a subsidiary company of Fosun Pharma), has been recommended by the WHO as the most preferred drug for treating malaria. This is the first Chinese pharmaceutical ingredient with an independent intellectual property right that has reached the global market. In 2005, Fosun Pharma passed the WHO's direct supplier qualification authentication, and became China's only direct supplier to the WHO to date. Arteannuin was the first drug approved and has obtained the No.1 Certificate of the First Class New Drug in 1987. The form of Arteannuin for injection possesses the No.2 Certificate.

Fosun Pharma actively encourages product innovation, and allocates 5-7% of its annual revenue to innovation, especially R&D. Fosun Pharma has established an R&D innovation team lead by world-class scientists, who have established platforms for the world's leading technologies such as dry powder precision nasal spray, gradual controlled release, liposome, etc. By December 31st, 2006, Fosun Pharma had obtained a total of 54 patents, with 184 still in the application process. In the treatment of malaria, diabetes, hepatic diseases, and gynecological diseases, Fosun Pharma has developed leading products such as Arteannuin, Insulin, Huahong tablets, and Atomolan. Fosun Pharma's production lines for major active pharmaceutical ingredients and some drugs have passed American, EU, WHO and GMP authentications. The company has received the necessary eligibility for entering the international mainstream markets.

Strengths:

- Leading products in various market segments: Arteannuin, Insulin, Huahong tablets, Atomolan.
- Strong research and development platform:
    1. R&D team: a national-grade technical center with over 500 researchers, including experts in the pharmaceutical industry with R&D experience in world-class pharmaceutical enterprises and GMP experiences.
    2. Products: currently, there are around 200 medicines in various stages of development, with more than 10 being included in key clinical research projects scheduled for 2007. The new products cover treatments for malaria, diabetes, gynecological diseases and hepatic diseases.
    3. Patents: 54 patents have been acquired and 184 are still in the application stage.
- China's largest Medicine Distribution and Retailing Network
- Strength in scalability and M&A capabilities: achieved rapid growth in revenue and expansion through M&A.

Strategies:

1. Discover, cultivate and develop heavyweight products.
2. Establish the largest pharmaceutical retail and distribution network in China.
3. Actively explore opportunities in the overseas markets, increasing the awareness and recognition of Fosun's brand among international audiences.
4. Actively seek opportunities for M&A, and expand the business scale.

Discovery of Qinghaosu

Qinghaosu (ARTEMISININ) was originally developed in 1971 in China (the Chinese Institute of Material Medicine) from the plant Artemisia annua L (sweet wormwood), and it is the active ingredient in Qinghao, a Chinese herbal tea that has been used for over 1000 years to treat malaria and haemorrhoids. Project “523” (the Chinese antimalarial drugs cooperation research, a project cooperated on at a national level) for developing new antimalarial drugs was established in 1969. By analyzing traditional prescriptions, the research group screened over 200 herbs and 380 abstracts from them by using the malarial models of mice or monkeys.

Enlightened by the classical remedy "immerse a handful of Qinghao in two liters of water, get the juice and drink it" (*Ge Hong: The Handbook of Prescriptions for Emergencies, circa. 340 AD, Eastern Jin Dynasty*), researchers studied the antimalarial effect of Qinghao. The treatment was understood when temperature, enzymolysis, solvents, species, portions and the season for collecting the herb were systematically considered. A new antimalarial drug was developed in 1971, illustrating the scientific picture of Qinghaos antimalarial nature for more than 1000 years. The new compound isolated from Artemisia annua L. is entitled Qinghaosu.

Sources:

(1) Interview with the Mangers of Fosun Pharma in December 2006, May and June 2007, respectively.
(2) http://www.fosun.com.cn

5.3.2.2 Technology innovation to improve production efficiency and capacity

Innovations are not only inventions but also adoptions. They come in many types and vary greatly in complexity and scope. Companies attempting to make a profit cannot continue to operate for long periods without innovating. It is also an without doubt that different companies take different approaches to the use of innovation in an attempt to improve their performance, depending on the company's strengths and weaknesses, and the opportunities and threats presented by the firm's environment.

In the Chinese pharmaceutical industry, "Technology Introduction - Digestion & Assimilation - Re-innovation" is a prevalent pattern of innovation. Within this pattern, technology innovation as a means to improve production efficiency and capacity is frequently observed. For example, DCPC invested more than RMB338 million between 1978 and 1997 to implement technology reconstruction and introduction, which in turn helped it take the lead over its competitors in production capacity, technical equipment and its manufacturing environment. Furthermore, DCPC set up 3 joint-venture pharmaceutical firms between 1992 and 1994 in order to introduce overseas equipment, technologies, and patent products, which greatly improved the standards of its manufacturing technology and quality management. Through all these tactics, DCPC successfully improved its products' technology, quality, production capacity, and sales. By means of technology reconstruction and improvement, in particular focusing on technology innovation and re-innovation after technology introduction, DCPC smoothly

promoted its technology reconstruction and upgrades. For instance, DCPC independently invented the “Two- step VC Fermentation” technology, which was awarded the 2nd Prize for National Inventions in 1983.

Technology introduction is one efficient and important approach to narrowing the technology gap between developed countries and developing countries. If Chinese pharmaceutical firms can successfully assimilate and then exert more efforts in switching from technology introduction to technological innovation, then perhaps they can explore the evolution process of re-innovation and enjoy the advantage of a late move from imitation to innovation. Within this process, contributing the accumulated input of R&D to the imitative innovation project may be of significance. Continual R&D input should be the key to triggering a situation where the “second mover” has an advantage over those who moved first.

5.3.2.3 Marketing innovation in promoting the brand and improving the firm’s status

Being market-oriented is perhaps one of the most essential keys to an organization’s success in highly competitive and rapidly changing markets and technology environments. This requires the integration of innovation with the corporate development strategy, to ensure that R&D works effectively with other functions - like marketing - to generate new innovations that are relevant to customer.

Pharmaceuticals rely heavily on their marketing policy, but the marketing strategy greatly affects pharmaceuticals as well. Pharmaceutical firms need to spend large amounts on advertisements and other forms of marketing (1) for the purpose of brand cultivation, product perception, and to raise the customer group; and (2) to drive bad pharmaceuticals and un-qualified firms out of the competition.

Many new and innovative products that have great potential fail, not because of technical problems, but due to the lack of an innovative business model. A notable phenomenon in the Chinese pharmaceutical industry is that another focus of firms is on marketing innovation. The major activities in this field include:

1. Close cooperation with hospitals in order to serve consumers better; paying more attention to clinical distribution and knowledge-marketing to increase the consumer group;

2. Marketing innovation by means of applying E-business technologies to the enterprise's logistics and marketing systems;
3. Efforts to develop international and other diverse subdivision markets.

5.3.2.4 Organization innovation to improve the efficiency of R&D, manufacturing, and market development

The organizational form of technological innovation activities in pharmaceutical industry has a wide scope, and there are different points-of-view in both academia and the industry. Usually, Chinese pharmaceutical firms' organization innovation method is to build a strategic innovation alliance or cooperative R&D organization, and to emphasize the importance of internal multi-department cooperation.

(1) Joint innovation with external partners to build strategic networks of technological innovation. The main objective of this kind of organization form is to utilize the complementary core-competences of different firms to maximize the benefit of their cooperation. Frequently-observed joint-innovation organization forms in the Chinese pharmaceutical industry are summarized as follows:

- Industry, University, and Institutional players cooperate to innovate;
- Horizontal cooperation with international giants;
- Vertical cooperation with hospitals and other organizations in the value chain.

(2) Internal cooperation and mutual support among the R&D, Manufacturing and Marketing departments. Generally, the R&D department acts as the project development's "engine" while the Marketing, Finance, and Manufacturing departments also participate in the project's development. Since the Marketing and Manufacturing departments take part in the project during the early stage of R&D, the marketing people have a deeper understanding of the project's indications and clinical application, while the Manufacturing department can prepare itself properly for any technology and equipment requirements, and for quality control. Feedback and suggestions from these departments also helps the R&D department to improve its own work. This kind of innovative organization form, which combines manufacturing technology and quality management, adequately utilizes the advantages of market development and extension, and it can certainly efficiently speed up the transition to production and the new products subsequently being introduced to market successfully.

5.3.3 The Evolution of Innovation in the Chinese Pharmaceutical Industry

By considering the characteristics of pharmaceutical technical innovation and its flow, and integrating this with the current status of Chinese pharmaceutical R&D, we would like to give a brief introduction to the evolution of innovation in the Chinese pharmaceutical industry.

Table 8: Evolution of Innovation in the Chinese Pharmaceutical Industry

Stage	Representative Product & Technology, and Milestone
Independent R&D and Deferred Imitation (~1978)	Insulin Synthesis Qinghaosu Sodium Dimercaptosuccinate
Technology Introduction and Reformative Innovation (1978～1990s)	"Two- step VC Fermentation" Technology
Digestion, Assimilation & Re-innovation (1980s～1990s)	Industrialization Projects of Series of Vitamins Technology innovation in Dexamethasone Interferon Spray
Imitation-Innovation (Mid 1980s~Present)	Various "me-too" drugs
Independent Innovation (Late 1990s ~)	Polydatin Injection Tongxinluo Capsules Containing Attritive Powder Guizhi Fuling Capsule Shen Yi Capsule

Source: Author

Prior to the reforms in China, Chinese researchers practiced R&D independently and achieve several important results, such as the synthesis of Insulin and the discovery of Qinghaosu. During this period of self-sufficiency, China's pharmaceutical industry produced a series of basic drugs, which were usually older generic products, for the people's healthcare.

During the stage of "Technology Introduction and Reformative Innovation (1978～1990s)", Chinese pharmaceutical firms focused on upgrading their production facilities

and capacity, reconstructing and improving the technology flow by introducing new technologies and learning from leading international companies.

During the stage of "Digestion, Assimilation & Re-innovation (1980s～1990s)", most Chinese pharmaceutical firms carried out a great deal of development research and, after digestion, assimilated the key elements after introducing overseas patented technology. This activity greatly improved their technical capability.

At the stage of "Imitation-Innovation (Mid 1980s~Present)", Chinese pharmaceutical firms are now able to provide abundant drugs for people's healthcare, although most of them are generic drugs. Some pioneers, however, have started to pay more attention to independent R&D and are try to provide innovative products.

Since the late 1990s, in keeping with the national "independent innovation" development policy, more and more Chinese pharmaceutical firms are attaching increased importance to innovation, and some innovative firms and their own innovative products are starting to emerge.

5.3.4 The Chinese Pharmaceutical Industry's Experiences and Issues

The innovation of the pharmaceutical industry requires that enterprises be vast enough to bear the weight of increasing R&D costs and the huge risks involved. If they are not able to, then they need either a mechanism to share the risks or a suitable form of organization for their R&D.

We would summarize some of the experiences the Chinese pharmaceutical industry has seen during its development as follows: (1) gradually developing in a proper sequence based on self-competence. For example, a process of gradual accumulation from imitative innovation to integrated innovation, cooperative innovation, and finally independent innovation, according to the enterprise's strength; (2) the rapid development of the domestic market has provided a favorable space for Chinese pharmaceutical firms to grow; (3) the vision, force and leadership of ambitious entrepreneurs.

Analysis of Chinese pharmaceutical industry's development also suggests that, in order to guarantee rapid development, we need to enhance competence in the following areas:

(1) an effective and flexible strategy of pharmaceutical intellectual property protection; (2) a powerful national R&D organization infrastructure. (As we discussed in Section 5.2.4, National Science and Technology projects and other public sector R&D programs play an important role in the development of the Chinese pharmaceutical industry); (3) an integrated innovative system that consists of large-scale enterprises with independent innovation capabilities.

Case Study: Hisun Pharmaceutical -- Innovation Theory of "Fish"

Zhejiang Hisun Pharmaceutical Co., Ltd. was established in 1956 and has evolved into one of the largest bulk Active Pharmaceutical Ingredient (API) manufacturers in China. Hisun ranks among the top 20 Pharmaceutical companies in China as well as in the top 500 Chinese companies overall.

The Group's principal activities are developing, manufacturing and selling chemical raw material medicines, chemical intermediaries, medicinal preparations, biological medicines, Chinese patent medicines and medicine auxiliaries. Other activities include researching and producing necessary raw materials and importing machinery and equipment, apparatus and spare parts. The Group has distribution networks not only in China but also in the United States, Germany, Austria, Belgium and the United Kingdom. Its products are available in more than 30 countries and regions around the world.

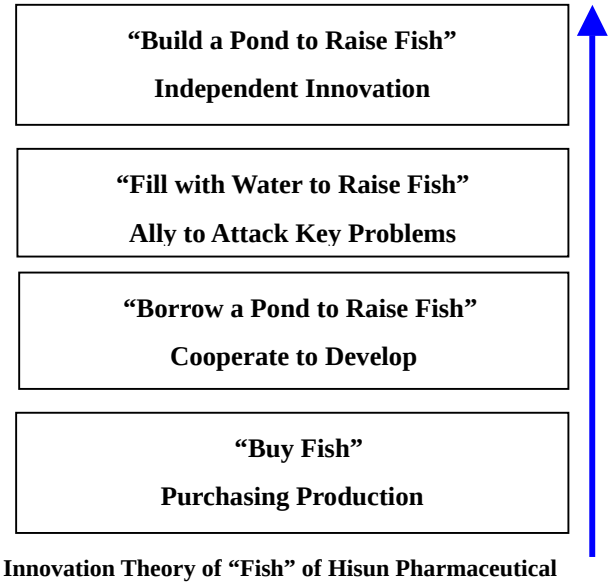
Hisun exports 80% of API production to North America, Europe, South America, and Asia. Hisun has had 9 successful FDA field inspections since 1992. Currently, Hisun has 15 FDA product approvals, 11 EDQM (CoS) approvals, and 73 products registered throughout the major pharmaceutical markets worldwide.

Hisun's new state-of-the-art Pharmaceutical Research Institute was established in 2001. It focuses on improving the core competency of producing cGMP quality active pharmaceutical ingredients through organic synthesis and fermentation. Depending on this institute, Hisun will develop new R & D projects, including biologicals, and joint R & D projects and contract research with multinational pharmaceutical companies.

Hisun's technical strength includes Fermentation and Organic Synthesis. Hisun is one the largest Chinese producers of Anti-Infectives, Oncologicals, Cardiovascular, and Animal Health Drugs. In addition, Hisun is producing finished dosage products, including tablets, capsules, and injectables.

Hisun has invested over 10 million USD over the past five years in plant renovation and new construction. Key process parameters are computer controlled. Hisun utilizes various drying technologies in its production including lyophilization, rotary drying, spray drying, filter drying, and conical mixing drying. In addition, Hisun filtration technologies include press

filtration, cermanic membrane filtration, reverse osmosis, nanofiltration, and ultra filtration. Hisun has established long-term relationships with more than 20 world class Chinese research institutes. These relationships provide Hisun with an additional source of R & D projects for new and existing molecules as well as Traditional Chinese Medicine.



Innovation Theory of "Fish" of Hisun Pharmaceutical

Sources: *(1) Interview with Mangers of Hisun in November 2006 and June 2007, respectively.*
(2) http://www.hisun.com.cn

5.5 Summary

We can summarize our observations of the Chinese pharmaceutical industry in this section as follows:

(1) Under the constraints of limited resources and infirm innovative capabilities, it is a feasible choice for Chinese pharmaceutical firms to adopt a policy of imitation-innovation during the current stage. For those firms that have been qualified in GMP, and have both a solid technical foundation and some R&D capability, if they can learn from the successes and failures of leading innovators and improve on this basic tenet – to invest their main resources in the middle and later stages of innovation, such as in the fields of technology design, quality control, cost control, production management, and marketing, in order to produce more competitive products with better

performance, higher quality, and lower price - it is quite possible for them to take the advantage in competition. Once these firms have won dominance in their competition, then they can pursue further development while continuing to grow, taking care of both their short-term objectives and their long-term vision and strategy. Thus they can aim at improving their independent innovative capability via imitation, in order to achieve the ultimate goal of Innovation in development and growth.

(2) The lack of talents in every field (R&D, Management, and Marketing) is another problem facing the Chinese pharmaceutical industry, and we believe it is the key factor limiting the industry's development. The Chinese educational system must be aware of this factor and must try its best to attract more talents to work in the pharmaceutical industry. This may lead to a permanent cure, helping the Chinese pharmaceutical industry to transition from imitation-innovation to independent innovation.

(3) An effective patent protection system should developed in phase with international regulations to promote Chinese pharmaceutical firms' innovative capabilities. On the other hand, it should also reflect the reality of the Chinese pharmaceutical industry's development. A patent protection strategy that brings "gradual progress in the proper sequence" and "accords with the current stage of national development", may be more suitable for the development of the Chinese pharmaceutical industry.

(4) National innovation-encouragement policies have begun to have a positive effect on the Chinese pharmaceutical industry. The State Development Reform Committee (SDRC) has established "Guidance for the Eleventh Five-Year Development Plan of the Pharmaceutical Industry", which emphasizes that the government will increase its support of R&D projects in the pharmaceutical industry and will work to realize the industry's industrialization through effective taxation and financial measures, and so on. Together with other supporting policies and detailed rules, we believe that the innovation capacity of enterprises will improve significantly in the coming years.

To better understand how that Chinese pharmaceutical industry did in terms of innovation and how it will develop over time, several un-discussed issues require further study in detail:

1. Detailed analysis of the development background (market and system environment) of the Chinese pharmaceutical industry;

2. Detailed analysis, evaluation and forecast of development trends in the Chinese pharmaceutical industry;
3. Comparison study of the development of the Indian pharmaceutical industry; and also the development experiences and lessons of other international pioneers in the pharmaceutical industry.

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