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Approaches for Industry Upgrade of Chinese Pharmaceutical Enterprises Based on Relevant Cases from Developing Countries

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Abstract

The purpose of this article is to provide suggestions regarding how to avoid possible problems during the process of entering international market and improving innovation ability. Based on collected cases of obstructions that some Indian producers encountered during the process of industry upgrade in recent years and reasons of these obstructions. Some suggestions for Chinese pharmaceutical enterprises were provided. It had been found that patent dispute, drug quality issue, inaccurate market positioning and uneven recourses distributions are four major obstructions for Chinese generic drug producers. It is suggested that Chinese pharmaceutical enterprises should cooperate with multi-national pharmaceutical companies regarding patent issue, pay attention to drug quality monitoring during drug manufacturing, focus on long-term aboard market share and balance resource distribution between imitation and innovation departments inside enterprises.

Keywords: Pharmaceutical enterprise；Industry upgrade；Developing country；China

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1. Introduction

Promoting technical innovations and breaking into international markets are two major directions in industry upgrade of pharmaceutical enterprises in developing countries. These enterprises will inevitably encounter many obstructions, which might profoundly undermine the effort of industry upgrade if not well handled. Therefore, pharmaceutical enterprises should realize opportunities and benefits as well as obstructions and risks during the process of industry upgrade. By collecting and analyzing some related cases, we hope suggestions in this article could be helpful for future development of Chinese pharmaceutical companies.

2. Analysis of obstructions of industry upgrade for pharmaceutical companies from developing countries

2.1 Great difficulties of patent challenge

Many pharmaceutical companies from developing countries now consider patent challenge as an effective method to enter into major drug markets, such as United States and European countries. Successful stories of Indian drug companies did prove this pathway to be valid to company's internationalization. They started from generic drug, utilizing rules from Hatch-Waxman Act to nullify patent threat from original patent holder, legalize their new drug applications and finally solidify their market share in developed countries. However, while their appreciating huge success should be appreciated, it is also very important to realize the risks of losing lawsuits of patent infringement. The case between Ranbaxy and Pfizer was a perfect example.

Ranbaxy is a leading pharmaceutical company in India, ranking second for total revenue in 2011. In March 2004, Ranbaxy took a legal action and claimed two patents (US 4681893 and US 5273995) related to Pfizer's blockbuster drug Lipitor were invalid. By challenging Pfizer's patents, Ranbaxy attempted to imitate Lipitor and market their generic version in America. But against its will, Federal court in Delaware rejected Ranbaxy's request and decided that Ranbaxy's behavior infringed Pfizer's patent therefore its product could not be marketed. Although Ranbaxy appealed and fought for more than five years, it still finally lost the case[1]. The result is that huge human, time and monetary capital invested into this program almost turned to be in vain.

It is not difficult to understand that as a local pharmaceutical giant, Pfizer obtained large advantage on utilizing patent law of the United States over Ranbaxy. As a matter of fact, because of the soaring cost to develop a new drug, in order to compensate R&D cost, innovative drug producers such as Pfizer and other leading drug producers have always fought hard on their drug patents to exclude competitors thus increase profit margin from market exclusivity. At the same time, for the purpose of protect pharmaceutical companies' enthusiasm on innovation, it has become an obvious trend for both international organizations such as WTO and individual countries (including India itself) to change their patent law systems, in order to provide better protection for drug patents. All these factors have made patent challenge become more difficult than ever before.

2.2 Drug quality accidents

Quality issue is another problem interfering the process of industry upgrade. While pharmaceutical companies in developing countries consider entering international market as an important pathway for industrial upgrade, quality of drugs, especially for generic drugs, has become one of the biggest concern at the process of obtaining marketing authorization. Several cases have already been widely reported in recent years.

One of the most obvious case is Ranbaxy's drug quality crisis. In 2008, FDA issued a warning letter to Ranbaxy, indicating that its two facilities in India had serious quality problem. In May 2009, FDA issued the second letter accusing one of its factories in India falsified data to obtain marketing authorization in United States. This time, FDA did not only banned Ranbaxy to export its products to US, but also suspended reviewing all marketing application from Ranbaxy[2]. Since US is the largest oversea market for Ranbaxy, these punishment affected its performance immediately. After the warning letter went public, Ranbaxy's stock price plummeted 5% in one day. At the third quarter of 2009, the sales volume dropped 53% in US and 30% in developing countries. Although Ranbaxy made a lot of efforts[3], since the damage caused by quality problem was so huge, Ranbaxy still hasn't fully recovered from this incident.

2.3 Inaccurate market positioning

In addition to mature markets, such as United States and European countries, many drug enterprises are also looking for positions in emerging markets, which were ignored by international pharmaceutical giants for a long time because of people's limited purchasing power. In this case, with the advantage of low cost compared with NMCs, low price is usually a sharp weapon for enterprises from developing countries when entering a new market. However, if price advantage cannot combine with proper market strategy, one still might not be able to survive in a new environment thus lost the chance of industrial upgrade. The failure of Cipla encountered in Africa is a good example

Cipla is the largest pharmaceutical company in India in 2011 for total revenue. In 2001, Cipla marketed its cocktail anti-HIV drugs in Africa with the price of only one US dollar for one person per day[4]. This price is lower than one tenth of pioneer drug. Considering the obvious price advantage and huge HIV population in Africa, the company expected sizable sales volume could be achieved in several years. However, Cipla did not realize that in Africa, especially some countries in sub-Sahara area, healthcare consumption for one person in one year is two dollars. Not many HIV patients countries could afford these drugs even the price was already much lower than before. Finally Cipla had to withdraw from African market[5]. Therefore, in order to enter into a new market, it is essential for an enterprise to overcome the traditional low-price method, find suitable market and establish appropriate price strategy.

2.4 Uneven recourses distributions between imitation and innovation departments

Transition from imitation to innovation is an inevitable progress for industry upgrade of a pharmaceutical company. During this process, enterprises usually obtain both imitation and innovation programs. Many enterprises invest on their innovation programs with profit earned from imitation drug programs. It is expected that once brand drugs are market, the high sales volume would be able to compensate the huge cost of R&D activities. And by gradually altering the importance of imitation and innovation branches, an enterprise might be able to realize industry upgrade from a beneficial cycle. The problem is that the risk of marketing a whole new drug is much higher than marketing a generic one. Once the sales volume is less than expected, the enterprise may suffer from the setback of unsuccessful innovation program. The beneficial cycle might turn to be a vicious one.

Dr. Reddy's Laboratories (DRL) is the third largest drug producer in India. In 2004, Indian pharmaceutical company Dr. Reddy's Laboratories (DRL) decided to promote its R&D ability on new drugs. They appropriated 8% of sales income for R&D activity, aiming to market blockbuster drugs. However, five years later, new products were still not on the market for many reasons such as unsuccessful clinical trials. And large investment during the last five years cannot be made up. In 2009, DRL had to reduce its investment on R&D activity and closed its research center at Atlanta. The aftermath of this failure is serious: the ambitious innovation program stops. Meanwhile, since large amount of resource was invested into innovation program, the traditional imitation branch is also profoundly weakened, resulting in DRL's overall declination[6] [8].

3. Advices on Chinese pharmaceutical companies

As enterprises in developing country, Chinese pharmaceutical companies face the same technique and market circumstance as their Indian counterparts do therefore might encounter the same obstructions. Chinese pharmaceutical companies may use problems mentioned above as lessons, avoid or reduce impact of these challenges, and find their own pathways for breakthrough.

3.1 Patent cooperation instead of patent challenge

Indian pharmaceutical companies frequently challenged MNC's patents, but seldom succeeded. The reason behind it is complicate. One of them is that these pioneer drug producers protect their products with very careful patent arrangement. The space left for patent challenge is already quite limited. Plus these law cases are often happen in developed countries, whose law systems are already familiarized by these pharmaceutical giants, which made patent challenge even more difficult. Considering more and more countries ratify TRIPs and exert high standard for patent protection, it is expected that the strategy of patent challenging would be less and less effective.

The truth is that, even the enterprise can win the law case, the overall conclusion is not necessarily beneficial for the winner. In a short term, enterprises may market their low-price products and profit from it. However in a long term, they may lose the precious chance for cooperation. Under the circumstance that the main stream international drug market is still largely controlled by NMCs, it would be wise for Chinese enterprises to seek cooperation. Compared with NMCs, the biggest advantage for Chinese enterprises is the low-cost on manufacturing and human resource, whereas NMCs are more advanced on R&D and management. It is totally possible for both sides to cooperate rather than confront each other and include patent issue into negotiation, so that patent dispute can be avoided. By doing so, Chinese pharmaceutical companies may not only further elaborate their traditional advantage, but also spare huge time and labor cost on patent challenge, therefore enter into international market in an easier way. The cooperation between MSD and Simcere is a very good example[7].

3.2 Pay attention to high standards of drug quality

Ranbaxy's severe setback because of quality issue was mentioned above. As a matter of fact, Indian pharmaceutical companies that suffered from the same issue were definitely not limited to Ranbaxy. From year of 2000 till now, nearly each and every Indian leading drug producers, such as Lupin, Sun Pharmaceuticals and DRL, received warning letters from FDA. The content of these letters were seldom about the quality of products, but detailed issues in the process of manufacturing, such as archive preservation, internal monitoring and facility management.

From 1st March 2011, China has formally implemented the new version of GMP (Good Manufacturing Practice). Compared with the old version published in 1998, the new GMP enhanced the requirement of sterile products and personnel quality, added some important content such as quality risk management and deviation handling. Besides, it is also vital to notice that even the new GMP is much more advanced than the old one; it still has a long way to go to reach the standard of GMP in developed countries. Under this circumstance, Chinese pharmaceutical companies should always consider quality as their first priority, follow high standard and pay more attention to process control in addition to management for quality of final products. It is not only important for companies' development inside China but also an essential requirement for entrance of international market.

3.3 Market planning based on market research

The failure Cipla encountered showed that when enterprises enter into a new market, they should not makes price strategy based on experiences in homeland but careful market research. Especially for developing countries such as African countries which have low purchasing power and imperfect legal systems, Chinese pharmaceutical need to obtain accurate and comprehensive information before marketing their products. Low price is great. But it can't be all.

3.4 Reasonable division of resources between different departments

As mentioned above, many enterprises consider enhancing innovation ability as the development strategy. It is true that innovative drugs can bring much more profit than generic ones. However, inappropriate division of resources between innovation and imitation program could also bring a lot of problems. The case of DRL is a perfect example. For enterprises that wish to transform into branded drug producers, it is vital to coordinate resource distribution between imitation and innovation departments. If resource is overly invested into innovation departments, survival of the company might be threatened as long as the new drug cannot be marketed or well sold. Enterprises should pay attention to potential risks brought by industry upgrade after realizing benefits from it, which requires pre-arranged plan for possible problems. Only reasonable resource distribution that considers both benefits and risks could provide sound and solid safeguard for enterprise' development.

4. Conclusion

The uprising of pharmaceutical companies in developing countries is important force changing the structure of international pharmaceutical industry. Chinese pharmaceutical companies have huge space for development and can play important role. However at the time, this circumstance needs enterprises to pay attention to potential risks and obstructions. Under current structure of global pharmaceutical

industry, Chinese pharmaceutical enterprises should cautiously map out their strategic plans, improve quality of drug manufacturing and cooperate with other companies to further enhance the ability to innovate.

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