

The Pharmaceutical Innovation and the Patent System After TRIPS in China --Using Developing Countries Cases to Analyze

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ABSTRACT

Due to the high technique intensity and large expenditure on R&D, patent always plays an important role in the developing of pharmaceutical industry. With the signing of TRIPS agreement, the new patent system shows a significantly effect to pharmaceutical innovation in developing country. In this paper, the author combined the economic theory and previous studies to indicate that the gradually improved patent system stimulates the incentive for pharmaceutical innovation in China. However, after analyzing the effect of TRIPS agreement to India and Brazil's pharmaceutical innovation, I conclude that the strict patent protection caused by TRIPS agreement actually could deteriorate the result of pharmaceutical innovation in India and Brazil. Since China faces the same situation with India and Brazil, this conclusion would also be found in China. At the end of the paper, the author provided some suggestions to Chinese government based on the cases happened in India and Brazil.

Keywords: *Pharmaceutical innovation, patent system, TRIPS agreement, developing country*

1. INTRODUCTION

Patent provides a law protection for intellectual property so that the owner of the patent could prevent others from using the inventions in the duration of the patent. To provide a better protection for the inventors and encourage the innovation in the country, the patent system was established in most countries of the world. The patent system could exclude the others from using the invention to create a monopoly circumstance for inventors in the duration of patent, thus stimulate the social incentive to innovate new techniques. According to the data from National Science Foundation, the research and development expenditure of US pharmaceutical industry was about 79.6 billion dollars in 2018, which was significantly high even comparing to the total GDP in US. At the same time, the pharmaceutical industry is the most innovative industry in US because of the high R&D intensity. Furthermore, Grootendorst (2009) indicates that the patent system has an important effect on the research and development investments in the pharmaceutical[1]. Therefore, it's critical to analyze the relationship between the patent system and the pharmaceutical innovation. With the signing of TRIPS agreement in 1994, the pharmaceutical patents are protected by the World Trade Organization Member States and the developing countries in WTO are facing a stricter patent protection especially in pharmaceutical industry. Because of that, researching and exploring the effect of the patent system after the signing of TRIPS to pharmaceutical innovation in developing countries would be significantly important.

In this paper, The first part will mainly discuss the general impact of patent system on pharmaceutical innovation. After that, the second part will discuss the effect of TRIPS to India and Brazil's pharmaceutical industry in order to assess the impact of TRIPS to China's pharmaceutical innovation as India and Brazil have the similar situation with China in WTO. Furthermore, the final part will provide some recommendations on patent system reform in China based on the conclusion.

1.1. Patent System and Pharmaceutical Innovation

Patent system is established to protect the intellectual property and encourage the inventors to do more innovation in the future. Ramsden (2014) shows that the patent system expanded as the industry's technology level advanced and the increase of nation wealth will lead to a proliferation of patent [2]. Since a drug patent could provide a monopoly power to the pharmaceutical company which owns this patent during the duration of the patent, we could use the Price-Quantity model under monopoly situation to theoretically analyze the impact of patent system on pharmaceutical innovation. In order to extract more profits for selling drugs, the pharmaceutical company with patent will act as a monopolist. By using the economic theory to analyze the optimal solution for monopolist, it's easy to get the benefit of an additional unit of good equals to the cost of and additional unit of good which is equation 1.

Equation 1: $\text{Marginal Revenue} = \text{Marginal Cost}$

From graph 1, by comparing the perfect competitive market case which is price equals to the marginal cost with the monopoly case, it's obvious to find the the price under monopoly is higher and the producer surplus which is the profits of the monopolist is larger than the perfect competitive market case. Therefore, the pharmaceutical company with patent would extract more profit in the duration of the patent. Since the new technique patent could increase the profit for the pharmaceutical company, the pharmaceutical companies would have more incentive to research and develop new drugs so that the number of pharmaceutical innovations will increase. Consequently, economic theory indicates that the patent system would stimulate the pharmaceutical innovation.

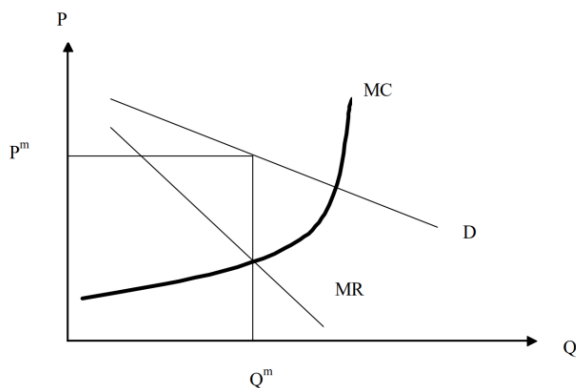


Figure 1 The Price-Quantity Graph under Monopoly Situation

There are some previous researches which show their authors' opinions about the relationship between the patent system and the pharmaceutical innovation. Lewis (1996) represents that for pharmaceutical industry, the intellectual property rights is a critical asset since the investment and R&D cost is significantly high in this industry. Therefore, the patent system could stimulate the pharmaceutical innovation especially for the developed countries such as US and UK [3]. By contrast, Leoni and Sandroni (2016) use game theory analysis to simulate all the conditions under patent system, they show that the patent system might delay the R&D investment in the pharmaceutical innovation due to the strong collusive behavior [4]. However, by analyzing a large number of pharmaceutical R&D and patents datasets, Gawel (2016) indicates that the patent system has a positive effect on pharmaceutical innovation in developed countries and the countries with high GDP. But Gawel also points out that the low-income countries still remain inconclusive since it's hard to determine whether the patent system has a positive effect or a negative effect to the low income countries' pharmaceutical innovation [5].

With the several reforms after 1978, China's patent system has gradually improved so that the pharmaceutical patent has drawn more attention by the government. With the incremental patent law protection, China's pharmaceutical innovation has also improved in a significant level. According to the report by Wang (2009), the improved patent system has played a critical role in

the process of pharmaceutical innovation in China [6]. From graph 2, the data from China Statistical Year Book also shows that there is a nearly 10 times increase of the expenditure on R&D in Chinese pharmaceutical industry from 2002 to 2012.

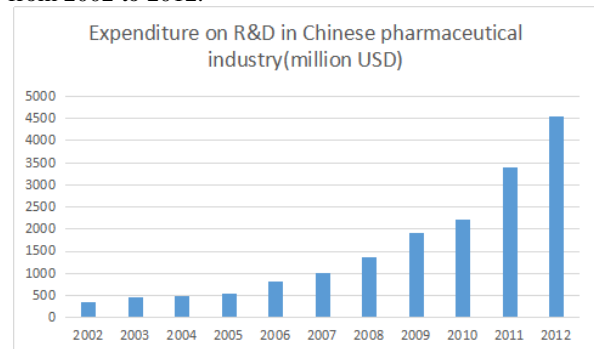


Figure 2 Chinese Pharmaceutical Industry Expenditure on R&D

This also indicates that the patent reform in China leads to a huge increase in pharmaceutical innovation. Consequently, from the theoretical analysis and the previous studies, I indicate that the well-organized patent system could stimulate the pharmaceutical innovation especially in developed countries. After combining with the patent system condition, it's obvious to see that with the reform of patent system in China, the incentive for pharmaceutical innovation has largely increased in Chinese pharmaceutical industry.

1.2. TRIPS and Developing Countries' Pharmaceutical Innovation

Trade-Related Aspects of Intellectual Property Agreement – TRIPS agreement is an agreement about the patent protection between the member nations in WTO. The purpose of this agreement is to protect the inventor's intellectual property in the international trade system between WTO member nations. Murthy (2002) shows that the TRIPS agreement could protect the patent, inspire the technological innovation and share information between the members in WTO so that the benefit could be collected by the providers and users [11]. However, Damodaran (2008) indicates that the initial version of TRIPS agreement is to enhance the developed countries' dominating status in global patent system. The developed countries in WTO extend the patent duration and weaken the compulsory licensing in order to protect the patent in their countries so that they could extract more profits from the patent to stimulate the pharmaceutical innovation in developed countries [7]. Even though, the Doha declaration has revised the TRIPS agreement to relax the restriction on pharmaceutical intellectual property, and the signing of TRIPS agreement still has a significantly impact on the pharmaceutical innovation in developing countries. Singham (2017) provides his opinion that the signing of TRIPS would harm the pharmaceutical industry

in developing countries and the innovation in pharmaceutical industry would slow down due to the agreement. This would lead to a net loss in global welfare and the current patent system still need to be reformed [8]. Since China is the biggest developing country in the world, it's crucial to analyze and assess the impact of TRIPS agreement to China. In the next part, the paper will analyze the impact of TRIPS on large developing countries' pharmaceutical innovation such as India and Brazil to assess the the impact of TRIPS to China's pharmaceutical innovation.

1.2.1. India

India has a rapidly growing pharmaceutical industry which has a significantly large size right now. According to the data from the India government, India occupies nearly 20% share of the generic medicine and support 62% vaccines for the whole world demand in 2020, which is a significantly enormous amount. In general, the India pharmaceutical industry mainly focuses on the export of generic drugs. At the same time, the report from FDA shows that Chinese pharmaceutical industry grows rapidly since the reform of market system and China occupies nearly 40% market share of active pharmaceutical ingredients which are the key parts of producing drugs. It's obvious to see that the Chinese pharmaceutical industry and India pharmaceutical industry are concentrated on the export of low patent protection pharmaceutical goods and they also have a significantly large size. Therefore, analyzing the impact of TRIPS to India pharmaceutical innovation would be important to analyze the impact of TRIPS to China. Firstly, Damodaran (2008) draws his opinion about the pharmaceutical innovation by comparing the patent law before and after the signing of TRIPS, he points out that the R&D investment increased in a rapid speed before the signing of TRIPS because of the vague patent system. After the signing of TRIPS, India's patent system is stricter than before so that the import of high-technique goods with patent has increased a lot in India. Hence, the incentive for India pharmaceutical companies has dampened so that the India government needs to reform the patent system and subsidize more on R&D spending in pharmaceutical industry [7]. Furthermore, Chaudhuri (2009) analyzes the pharmaceutical industry's R&D and number of new drugs data in India specifically, Chaudhuri concludes that the the spending of pharmaceutical industry on R&D in India has increased dramatically after the signing of TRIPS because the pharmaceutical companies has to put more effort on pharmaceutical innovation due to the patent protection. However, Chaudhuri also concludes that although the agreement leads to an incremental incentive to innovate new drugs, the result of pharmaceutical innovation in India after the signing of TRIPS is not significant enough since the number of new chemical entity drugs developed by the India pharmaceutical companies is quite small after the TRIPS. Furthermore, Chaudhuri points out that it's unfair to set a high patent protection for developing

countries since the developed countries only adopt the pharmaceutical patent protection system after they reached a high-level in pharmaceutical technology [9]. From other aspects, Schuren (2012) focuses on the pharmaceutical innovation system after the signing of TRIPS in India. Schuren indicates that the pharmaceutical innovation system in India focuses on the drug export and the growth of innovation in pharmaceutical industry in India mainly focuses on the export drugs [10]. Consequently, by analyzing the impact of TRIPS to India pharmaceutical innovation, I find that the expenditure of pharmaceutical R&D and the incentive for pharmaceutical innovation might be increased for the developing countries but the result of the innovation might not be success for the developing country due to the strict patent protection by the developed countries which hold a large number of pharmaceutical patent. Since China's pharmaceutical companies face the similar situation with the pharmaceutical companies in India, the impact of TRIPS might be the same for the pharmaceutical innovation in China.

1.2.2. Brazil

Brazil also has a huge pharmaceutical industry across developing countries. By contrast to India pharmaceutical industry which mainly focuses on the generic drugs and drug export, Brazil pharmaceutical industry is mainly focused on the medicines which could improve the domestic health level. The data from Brazil government showed that the healthcare expenditure is 193.09 billion US dollar in 2010 and the revenue was mainly extracted by the private sector which mean pharmaceutical companies. The report from World Bank indicates that the healthcare expenditure occupies 5% of GDP in China which is an extremely high number and the expenditure is used to help the domestic drug production so that the accessibility of drugs would increase. Since the China and Brazil implement the similar policy on domestic healthcare field and domestic pharmaceutical production field, analyzing the effect of TRIPS to Brazil's pharmaceutical innovation would be really helpful for us to assess the effect of TRIPS to China's pharmaceutical innovation. According to the research conducted by Schuren (2013), the Brazil pharmaceutical innovation is largely affected by the signing of TRIPS. After signing of TRIPS, the general incentive for pharmaceutical innovation in Brazil has dampened and the concern of pharmaceutical innovation in Brazil has changed to domestic market since most of the pharmaceutical companies in Brazil focused on the supply of domestic generic drugs and the trade deficit of drugs in the post-TRIPS period is nearly 3 billion USD [12]. From the pharmaceutical innovation condition after the signing of TRIPS, it's obvious to see that TRIPS agreement really could hinder the pharmaceutical innovation in Brazil. Consequently, from analyzing the impact of TRIPS agreement to India and Brazil's pharmaceutical innovation, I find that the stricter patent protection caused

by TRIPS agreement really could hinder the pharmaceutical innovation in developing countries even if the incentive of pharmaceutical innovation might be proliferated. Therefore, I conclude that the Chinese pharmaceutical innovation might also be hindered by the signing of TRIPS. At the same time, India and Brazil cases also give us some inspirations about the future of pharmaceutical innovation in China.

2. CONCLUSION

By using the economic model to analyze the effect of patent system to pharmaceutical innovation, the theoretical analysis part indicates that the well-established patent system could stimulate the pharmaceutical innovation. At the same time, the previous studies about the pharmaceutical innovation also show that the patent system could increase the pharmaceutical innovation especially for developed countries. However, these studies also show that the pharmaceutical innovation might not increase in the developing countries and long-duration patent might hinder the pharmaceutical innovation. After combining the theoretical analysis and the previous studies, it's easy to conclude that the incentive for pharmaceutical innovation in China has largely increased since the patent system has gradually reformed. After that, by analyzing the cases in India and Brazil to assess the impact of TRIPS agreement to China's pharmaceutical innovation, it was obvious to conclude that the pharmaceutical innovation in China might be hindered by the strict patent protection caused by the TRIPS agreement even though the reform of patent system could stimulate the incentive for pharmaceutical innovation in China. Furthermore, according to the development of pharmaceutical industry in India and Brazil, the conclusion suggested the Chinese Government to significantly increase the subsidy of pharmaceutical innovation for domestic companies and control the duration of patent to provide a proper driving force to the pharmaceutical innovation.

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