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Legal and Economic Analysis of Medicine Purchased Oversea

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Abstract

In recent years, the phenomenon of purchasing medicine abroad has gradually increased. In particular, it has resulted in major cases with great social influence, such as the case of "Lu Yong Selling Counterfeit Medicine". It has sparked an intense debate on the legality of oversea purchase of medicine. Although the treatment expense is greatly reduced for the patients, oversea purchase of medicine is suspected to undermine intellectual property protection. Finding a balance between "inspiring pharmaceutical companies to innovate" and "making it affordable to patients" is the key to solve the problem of oversea purchase of medicine. Based on the analysis of the positive and negative effects of overseas purchase of medicine, this paper proposes the principle of "consideration of protection and antitrust", which not only protects the intellectual property rights of the medicine, but also prevents companies from abusing intellectual property rights.

Key words: Legal and economic analysis; Medicine; Purchased oversea

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1. LEGAL ISSUE ON MEDICINE PURCHASED OVERSEA

Recently, domestic consumers have gradually increased their purchases of medicine abroad through traveling, overseas websites, and oversea procurement service. Among them, Chinese consumers is the largest group of purchasers. The purchases are generally made in India, Hong Kong, and other countries or regions. The State Food and Drug Administration has repeatedly reminded consumers not to buy medicines overseas due to safety purposes. However, the number of purchases made on medicine abroad has increased. The main reasons are: first, the approval process for new drugs in China is too long. The listing time of the same drug often differs by six or seven years between domestic and oversea. Many patients cannot wait that long for the drug to be listed in China; the second reason is the huge price gap between domestic and abroad, and these new drugs are not included in the scope of medical insurance reimbursement. While oversea procurement service of medicines has greatly reduced the cost, it has also caused controversy over its legality, especially by the case of "Lu Yong Selling Counterfeit Medicine" occurred in 2014.

1.1 Background on the Case

Lu Yong was originally a boss of a knitwear company in Wuxi, which was mainly engaged in foreign trade. In 2002, Lu Yong was diagnosed with chronic myelogenous leukemia. This disease does not cause sudden death like acute leukemia. As long as the patient takes the anti-cancer medicine, the disease can become stabilized. This "life-saving medicine" is an anti-cancer drug called "Glivec" produced by Novartis in Switzerland. This medicine can stabilize the condition, but it needs to be taken constantly. The price of this medicine is 23,500 yuan a box. A patient with chronic myeloid leukemia needs to take a box per month. The cost of medicine in addition to the cost of

treatment almost hollowed out Lu's family. In June 2004, Lu Yong accidentally learned the imitation of the "Glivec" anti-cancer drug produced in India, which only cost 4,000 yuan for a box. The comparison tests between the two Glivec produced in India and in Switzerland indicated that there was a 99.9% similarity. According to the Chinese law, even if these anti-cancer drugs do have curative effects and are indeed true medicine, they will be recognized as "counterfeits" since they have not obtained the sales license for Chinese imported drugs. On March 19, 2014, Lu Yong was released on bail for the pending trial. On July 21, the Qijiang City Procuratorate filed a public prosecution against Lu Yong for the crime of damaging credit card management and selling counterfeit drugs. The court of Minjiang City in Hunan Province was originally scheduled to open on November 28, 2014. He applied to extend the court opening due to health conditions. On January 27, 2015, the Qijiang City Procuratorate requested the court to withdraw the lawsuit, and the court made a ruling on the "withdrawal of the lawsuit" on the same day.

1.2 Legal Issue of the Case

The procuratorate and the court were facing a dilemma in this case. From the perspective of human rights, Lu Yong should be granted medicine after his arrest without violating his basic human rights; in addition, the procuratorate and the court must choose between the high-priced domestic drugs or low-cost generic drugs. From the perspective of intellectual property protection, if the sales of generic drugs or overseas procurement service are allowed, the innovation power of pharmaceutical companies will be cracked down; and if they are prohibited, a large number of patients cannot afford the treatment. Proper handling of such incidents requires the support from the government in terms of policies, as well as the improvement of relevant legislation in a timely fashion. Of course, because of the drug management system in China, some domestic generic drug manufacturers refuse to spend much on research and development and are suspected of abusing market dominance. As a result of this, the price of drugs is too high, and there is a lack of innovation incentives of new drugs.

2. ANALYSIS ON THE PROS AND CONS OF GENERIC DRUGS PURCHASED OVERSEA

2.1 Pros

There are four main ways to purchase Glivec and generic drugs for patients with chronic myelogenous leukemia in different countries: one is to purchase the regular medicine in a hospital or from a pharmacy; second is to purchase a generic drug produced by domestic enterprises through a formal route in a hospital or from a pharmacy; third is to purchase imported Indian generic drugs through formal channels in hospitals or from pharmacies; last one is to purchase Indian generic drugs through informal channels such as overseas procurement service. There is a huge difference in the price. Lu Yong purchased the regular anti-cancer drug "Glivec" imported from Switzerland from Chinese hospitals at a unit price of 24,000 yuan/month. In September 2004, Lu Yong purchased generic drugs produced in India from Japan through individual oversea procurement service, and the unit price was only 4,000 yuan/month. Later, Lu Yong directly contacted the Indian anti-cancer drug distributor, India Sino, to buy and help other patients to purchase "Glivec" generic drugs. Due to the large quantity of purchases, the unit price dropped to 200 yuan/month. The main advantages of medicine purchased oversea is the low price and the moderate quality.

2.2 Cons

The drawback of oversea purchasing of medicine is mainly the damage on the innovation power of pharmaceutical companies. Swiss pharmaceutical company Novartis claims that the main reason for the high price of patented drugs such as Glivec is because of the huge cost of research and development and the extremely low success rate. It also means that the research and development of Glivec took 50 years and 5 billion US dollars. In order to encourage pharmaceutical companies to develop new drugs, the United States, China and other countries have a 20-year patent protection period. The problem is that patent protection also gives monopoly power to pharmaceutical companies, leading to the emergence of "astronomical priced medicine." In addition, domestic patients are exposed to risks when purchasing drugs overseas, such as scammers and counterfeits drugs. However, they are not left with many choices when their lives are in jeopardy. China introduced a new policy of "zero tariffs on anti-cancer drugs" in May, but the cost of medicine saved per patient is very limited, and these drugs are not covered by medical insurance. Thus, purchases of oversea medicines, especially Indian generic drugs, are still increasing, and it has spawned the gray interest space of a hundred billion yuan.

3. THE INSTITUTIONAL CAUSE OF OVERSEA PROCUREMENT SERVICE OF MEDICINE

Patients in China and the United States have become the largest consumer groups for overseas purchasing of medicines. This has a lot to do with the legal system of drug patents in China, the United States and India. In general, China and the United States have stricter

intellectual property rights protection for pharmaceutical patents, where in India it is relatively loose. The large price gap in medicine is also caused by the difference in their intellectual property protection system.

(a) Stricter Protection Policies for Patents in the United States, China, and Other Countries

In 1962, the US Congress officially passed the "Kefauver-Harris Drug Amendment", which greatly increased the approval threshold for drugs, requiring longer and broader clinical data (it usually takes a decade from research and development to clinical adoption) and more evaluation, even for generic drugs. This has led to an increase in the cost of research and development for pharmaceutical companies. In 1983, Bolar Company conducted a research trial before the expiration of a patent for the original drug of Roche Pharmaceuticals. The court ruled its results infringe. This became the last straw to takedown generic companies. In the second year, only 35% of the original patents that were expired were imitated, and generic companies, frightened by cost and supervision, voted with their feet. More than 150 original drugs were not imitated after the expiration of their patents. During the 1980s, three dark clouds shrouded the US medical industry: high drug prices made medical insurance funds severely tight, low profits weakened pharmaceutical companies' enthusiasm, and shortage of drugs caused increasing in number of deaths of patients. How to encourage pharmaceutical companies to develop "safe and effective" drugs that are affordable to the public? In 1984, Congressman Hatch and Waxman proposed the Hatch-Waxman Act, which simplified the original drug application process and introduced a patent connection system, including patent extension, market monopoly, and other terms improving the profitability of the original drug after its successful development. On the other hand, the bill adjusted generic drug certification standards, reduced the time and expense of R&D and market entry, and increased the probability of generic drugs. The FDA established a patent challenge system within the next few years. It allowed the generic drug company to challenge the patent in the patent period of the original drug. The first generic drug succeeded the challenge will have a 180-day market exclusivity (other generic drugs cannot be listed), and It could be sold at the price of 50~80% of the original drug. Since then, the proportion of US generic drugs in prescription drugs has soared from around 10% in 1981 to 86% in 2013. However, later, some patented pharmaceutical companies used complex patent law formation strategies to extend the life of patented drugs and to delay the use of generic drugs. These strategies included reverse payment (or "delay payment"), authorized generics, product hopping, bribing the rivals, monopolizing anti-cancer undeveloped markets, and so on. The situations in China and the United States are similar. The Chinese Patent Law stipulates that pharmaceutical formulas are patents and provide strict protection for drugs. Although the Chinese Patent Law also stipulates a "compulsory licensing system", it has not been implemented in practice.

(b) More Lenient Protection Policies for Patents in India

The concept of "generic drugs" is not invented in India, but in the US, where the implementation of the first patent strategy taken place. The United States has consistently spent every effort to promote patent policies and to maintain and to consolidate the advantages of its technological powers. It constantly improves the patent system to meet the needs of the development of the country, society and the times. In 1984, about 150 commonly used drugs in the United States had expired. According to the regulations at the time, if other manufacturers wanted to produce these drugs, they must apply for new patents according to the new drug standards. At this time, the "Hatch-Waxman Act (drug price competition and patent period compensation law)" was proposed, and the new manufacturers only needed to prove that their "generic drugs" products were equivalent to the biological activity of the original drugs. Royalties were unnecessary, the cost of clinical trials was reduced, and the application procedures were simplified. The average price of "generic drugs" was only 20% to 40% of the patented drugs, and some even differ by more than 10 times, which greatly benefited the well-being of the lower classes of society. Through the ingenious use of regulations on generic drugs, the Indian Patent Law states that "the entire production techniques and procedures are protected, but if the techniques and procedures change, the corresponding product is no long subject to the original patent". As a result, Indian companies have adopted "reverse process technology" to slightly modify the Western patented pharmaceutical technology, or add some so-called active ingredients, and obtain the patents that India calls "concise new drugs", which are sold globally at low prices. Institutional easing has enabled the rapid expansion of generic drugs in India, and India has become a major manufacturer and supplier of low-cost, high-quality drugs worldwide. At the end of the 20th century, more than 50% of Indian medicines were exported, becoming the world's third largest pharmaceutical producer and a global drug exporter, most of which were generic drugs. The pharmaceutical industry has not only become an important factor for India's economic growth, but also a better choice for poor African countries that cannot afford to buy expensive patented medicine. India is known as the "Third World Pharmacy".

4. MANAGEMENT OF GENERIC DRUGS PURCHASED OVERSEA

According to the 2017 China Cancer Registration Annual Report released by the National Cancer Center, China had

4.29 million new cancer cases and 2.81 million cancer deaths per year, which is equivalent to an average of 12,000 new cancers per day and 7,700 deaths from cancer. As a country with a high incidence of cancer, the needs of national medicine for cancer treatment is enormous. The main drugs purchased by patients for the treatment of cancer are patented drugs and generic drugs. From the perspective of product definition, the pharmaceutical industry can be divided into three grades of products, namely, pharmaceutical patents, patented drugs and generic drugs. Different law enforcement methods and policy combinations should be adopted for different products.

4.1 Market of Pharmaceutical Patent Should Focus on Intellectual Property Protection

Pharmaceutical patents belong to the original innovation and should be the object of legal protection. However, due to the attributes of their products sharing, it is easy to produce problems such as "jungle of patents". Therefore, the government should adopt a strategic combination that emphasizes intellectual property protection. Under the WTO framework agreement and the relevant TRIPS regulations, the "patent compulsory license" and other means should be adopted in a timely according to the national conditions, especially when patented pharmaceutical companies trying to extend their patent period by slightly modifying the technology. The biggest role of intellectual property rights protection is to encourage invention and creation. Inventions and creations require venture capital, especially for drug inventions. Investment of a large amount of manpower, material resources and capital, time, and creative labor is required just for the possibility to succeed. Once a new drug is developed, others can imitate it at will, and the inventor will gain nothing return. This will seriously diminish the inventors' enthusiasm, and no one wants to actively develop new drugs. The patent system gives the inventors a certain right to monopolize the market for a certain period of time. They can be rewarded with great returns, not only to recover the investment in research and development, but also to obtain certain benefits, so as to continuously carry out new invention and creation activities. This further promotes the development of science and technology and the refinement of products.

4.2 Market of Patented and Generic Drug Should Focus on Antitrust Law Enforcement

For the market of patented drug and generic drug, the degree of innovation is far lower than for the market of pharmaceutical patent. In this area, a "consideration of the protection and antitrust" policy combination should be adopted, balancing the relationship between intellectual property protection and the prevention of intellectual property abuse. Intellectual property protection should have certain limits, and it shall be suspected of monopolistic behavior once the limits are exceeded. Whether it is the antitrust law in the United States, in the European Union, or in China, companies with market dominance are prohibited from using intellectual property rights to sell goods at unfairly high prices. To define the definition of an excessive pricing is a more complicated process, especially for intellectual properties. In fact, in the pharmaceutical industry and all other industries, antitrust law enforcement agencies rarely have cases of unfair and high-priced terms that resulted in punishing operators who abuse market dominance. So far, the National Development and Reform Commission has announced four cases of abuse of excessive market dominance, one of which involves the medical field. This implies that antitrust law enforcement agencies have not eased on the supervision and punishment of such abuses because of the difficulty in determining excessive pricing violations. In addition, in the patent drug market, more attention should be paid to the issue of administrative monopoly. The fair competition review system should be used to regulate this administrative monopoly behavior.

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