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The Conflict Between Pharmaceutical Patent Right and Life Right and Its Resolution Mechanism: From the Perspective of Legal Philosophy

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Abstract: This paper explores the conflict between pharmaceutical patent rights and the right to life and its resolution mechanisms from the perspective of legal philosophy. It begins by discussing how the outbreak of COVID-19 has led to increased global demands for vaccines, temporary medical facilities, and public health controls, which in turn has sparked reflection on the relationship between pharmaceutical patents and the rights to life and health. The paper then analyzes several typical cases, including the Haiqing Ni counterfeit drug case, the Lu Yong case, and the Shanghai fake vaccine case, to illustrate the specific points of conflict between patent rights and the right to life. It also discusses the positive relationship between patent rights and the right to life, as well as the negative impact of the monopolistic nature of patent rights on the protection of the right to life. To resolve these conflicts, the paper proposes some existing measures, such as the application of the principle of proportionality and the compulsory licensing system, and suggests future possible measures, including the re-improvement of existing measures and the establishment of feasible new measures. In conclusion, while existing measures have alleviated the conflict to some extent, there are still difficulties and limitations in their implementation, necessitating further legislative and regulatory improvements.

Keywords: Patent right, the right to life, legal philosophy

1. Introduction

The outbreak of COVID-19 in Wuhan in 2019 has become a public health event sweeping the world in just a few months. As the virus continues to expand and even mutate, countries around the world have stepped up efforts to control its spread. The development of vaccines, the establishment of temporary medical institutions and the emergence of various public health controls have finally contained the novel corona-virus epidemic. In today's post-epidemic era, epidemics are characterized by high transmission rate, high fatality rate and variability. The formation of these characteristics inevitably makes us think more about the relationship between pharmaceutical patents and the right to life and health under such circumstances [1].

Patent right refers to a kind of exclusive right granted by the state to the inventor or creator within a certain period of time according to the legal procedure according to the application of the inventor

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or creator, in order to disclose the content of the invention and creation to the society, and the invention and creation have the interests stipulated by the law. Under the regulation of China's Patent Law, drug patents mainly belong to invention patents, and the patentee can be protected by the patent of the corresponding drug production method according to law.

The right to life and health, as the most basic rights of human beings, are almost included in the Constitution in the legislation of all countries. The Constitution of China stipulates the right of person and personality, which can be regarded as an inclusive statement of the right to life.

Article 5 of the Bill of Rights, as amended by the United States Constitution, states: "Any person...Shall not be deprived of life, liberty, or property without due process of law, "directly pointing to the importance of the right to life.

However, as the power effect of patent rights is to monopolize the method of drug production to a certain extent, in the current epidemic and other diseases, it inevitably poses a threat to the life and right to health of the public. Especially in developing countries where the development is unbalanced and sufficient, the high price of drugs makes it impossible for some people to afford them. Thus, the conflict between pharmaceutical patent rights and the right to life and health has been formed. How to balance the protection of patent rights for drugs and the public's life and right to health is an urgent problem to be solved, including how to regulate from the perspective of law and policy, and how to make changes under the influence of public health events such as the novel corona-virus.

In terms of research methods, this paper mainly adopts the form of literature and case analysis. This paper collected and listed the typical cases of disputes involving pharmaceutical patents and human life and right to health in China in recent years, and summarized the specific links and conflicts between pharmaceutical patents and life and right to health. Then continue to combine the literature of Chinese and foreign scholars, to solve the conflict between pharmaceutical patents and life and health rights, to find some existing and possible solutions in the future.

2. Related Case Analysis

2.1. The Case of Haiqing Ni Selling Counterfeit Drugs

Haiqing Ni , a quack practitioner in Jinhua, Zhejiang province, has no medical qualifications. He came across a secret recipe passed down by his family and based on it developed a Chinese herbal remedy for advanced cancer. He claims to have saved hundreds of terminal cancer patients with the secret formula. However, the Chinese herbal medicine tablets he developed did not have a manufacturing license or drug administration approval number, so they are legally considered fake.

Ni established the Haiqing Folk Herbal Medicine Research Institute in 2009 and obtained a national invention patent for herbal medicine tablets for tumor administration. However, he still cannot legally produce and sell the medicine because the product has not received legal approval. In October 2011, the Wucheng District Public Security Bureau in Jinhua city shut down his research institute, warehouse and outpatient department he worked with, and arrested Ni and his family. By this time, Ni had been diagnosed with advanced kidney cancer, but he chose to treat it with his own herbal medicine. After nearly a year and a half of treatment, his cancer was effectively controlled and turned benign.

Despite Ni's claim that his drugs worked and the willingness of many cancer patients to testify on his behalf, the court relied largely on the fact that he produced and sold unapproved drugs, rather than the actual effects of the drugs. The court held that it was illegal to produce and sell drugs without approval, regardless of whether they were effective.

Ni was sentenced to 10 years in prison for producing and selling fake drugs in a first-instance verdict handed down by the Wucheng District Court in Jinhua, Zhejiang province, on April 8, 2013.

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Although his drugs may help cancer patients to some extent, the law has strict regulations on drug production and sales, and any unapproved actions will be punished by law.

2.2. The Case of Yong Lu

Lu was diagnosed with CML in 2002 and needed to take Imatinib mesylate tablets, a cancer drug produced by Novartis of Switzerland, for a long period of time. However, the drug was expensive, and the monthly drug fee almost emptied Lu's family base, putting him under great financial pressure. It was in this difficult situation that Lu began to look for more economical ways to treat the disease.

In 2004, Lu learned that Imatinib mesylate tablets made in India not only had similar efficacy, but also cost about one-sixth of the original. He decided to try the generic version and found it worked well after taking it. So he began sharing this information with his fellow patients and helped others buy the generic drug. As the number of people in the group increased, the price of the group purchase further dropped, bringing benefits to more patients.

However, Lu Yong's behavior has caught the attention of relevant authorities. He was caught by police in connection with credit card purchases of generic drugs, and the Yuanjiang procuratorate prosecuted Lu to a Yuanjiang court on charges of "interfering with credit card management" and "selling fake drugs."

After going through a series of legal procedures, in 2015, the Yuanjiang procuratorate finally decided to withdraw the prosecution against Lu, and the court also granted the decision to withdraw the prosecution.

2.3. The Shanghai Fake Vaccine Case

After Ms. Zhou's child received the first dose of pneumonia vaccine in Australia, due to the shortage of pneumonia vaccine supply in China after returning to China, she finally chose to renew the pneumonia vaccine for her child in the Meihua outpatient Department after searching for many ways.

In order to solve the problem of vaccine supply, Meihua Outpatient Clinic purchased the vaccine from Singapore through illegal channels, and Jian Lihe and others from Taiwan brought the vaccine back to Shanghai for sale. However, the action violated drug administration regulations at the time, as drugs imported without approval and not inspected according to law were identified as fake. As a result, the Meihua outpatient department's behavior was investigated and the relevant personnel were held criminally responsible for the crime of selling fake drugs.

In this process, Ms. Zhou and other parents did not know, they just hope to vaccinate their children with safe and effective vaccines. In the first instance judgment, the relevant personnel of Meihua outpatient department were punished for the crime of selling fake drugs. However, as the case involved multiple levels and complicated legal issues, the Shanghai Higher People's Court ruled to revoke the original verdict and remanded it for a retrial. This means that the outcome of the case has not yet been finalized, and further legal procedures are needed to hear and adjudicate.

3. The Relationship between the Protection of the Right to Life and the Protection of Drug Patent Rights

3.1. Positive Relationship

3.1.1. The Goal of Pharmaceutical Patent Right and Life Right is the Same

Although patent rights are mainly characterized by their exclusivity and monopoly, it can be seen from the legislative purpose of intellectual property law in the Civil Code that the core goal of patent rights as rights is to protect the legitimate rights and interests of creators and achieve an incentive

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mechanism for innovation. Other international laws and other conventions have almost reached a consensus on this point. For example, Article 1, Section 8 of the US Constitution stipulates that Congress has the right to guarantee the exclusive rights of authors and inventors to their respective works and inventions within a certain period of time, so as to promote the progress of science and practical art. From the perspective of jurisprudence, Professor Peter Drahos' "instrumentalism" viewpoint is typical, which firstly denies the existence of intellectual property as a complete "exclusive right" or "monopoly right", but only regards such monopoly as a tool or a way to realize a certain moral value [2].

Above, pharmaceutical patent on the surface of the invention of drugs has a certain monopoly effect, but in fact, this monopoly is only a tool and way. Lawmakers hope that through this protection, the speed of drug invention into the public domain will be delayed, so as to stimulate the innovation willingness of researchers and pharmaceutical manufacturers, promote the progress of drug research and development, and thus provide protection for the life and health of the public. As for the right to life, without doubt, as the most basic and most important right in human rights, its purpose directly points to people's life and health protection, so it can be determined that the goal of pharmaceutical patent and the right to life is the same.

3.1.2. The Regulatory Approaches of Patent Right and Right to Life are Complementary

The complementarity of patent right and right to life is reflected in the nature of the two rights. Its essence includes the complementarity of upper law and lower law, as well as the complementarity of public law and private law.

First, the right to life is regulated in the Constitution. From the perspective of jurisprudence, it is "the law that regulates the law", that is, the upper law of all laws. As a superior law, the regulation of the right to life reflects a kind of program role. Ruiting Ma pointed out: "To ensure the realization of citizens' right to life and health is a solid cornerstone for the protection of drug patent rights, which promotes the rapid development of drug patent protection in the global scope, and effectively enhances the competitiveness of the pharmaceutical industry in the international market. As a lower law, the drug patent law more clearly puts forward a way to protect the right to life, making the programmatic provisions of the right to life no longer general, but also provides guidance for the judicial path and law enforcement [1]."

Second, the right to life, as a right regulated by public law, is usually mandatory and authoritative and implemented through the compulsory force of the state, while the patent law, as a private law, pays more attention to the autonomy of the parties and solves disputes through negotiation and mediation [3]. This kind of different regulation mode enables both to exert the maximum effect in their respective fields. From the perspective of legal value, public law realizes social justice and equity by limiting state power and guaranteeing citizens' rights while private law achieves economic benefits and efficiency by protecting individual rights and promoting market competition. They complement each other in the pursuit of value, and jointly promote the harmony and development of society.

3.2. Negative Relationship

Although it is mentioned above that monopoly in patent law are only tools to achieve the moral goal of public life and health, in practice, it is undeniable that such monopoly brings some adverse effects on the protection of life and right to health.

First, the regulation of drug patents slows down the large-scale entry of drugs into the public domain, and the arbitrary nature of the development method increases the scarcity of drugs, thereby raising its price in a disguised way. High prices limit the audience of drugs. On one hand, they exclude

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the possibility of low income or even middle and low income people to access treatment, and only open to high income people. Especially in the face of special diseases, the high price of drugs makes middle - and low-income families forced to give up or take negative treatment. Whether this artificially widening the gap between the rich and the poor has a negative impact on the equality of the right to life protection is a conflict that we need to ponder and solve. On the other hand, from a macro point of view, the regulation of drug patents makes some cutting-edge drugs concentrated in developed countries. Due to their strong scientific and technological level and the blessing of some monopolistic malicious national policies, developing countries need to spend a lot of costs to introduce these drugs into the public domain of their society. Therefore, from a global perspective, unbalanced and unequal protection of the right to life is also one of the manifestations of the conflict between patent rights and the right to life [4].

Furthermore, the establishment of drug patents makes it difficult to regulate the behavior of generic drugs in the judicial path. In the third part of the cases, whether it is the Haiqin Ni case as the first case of TCM prescription identification, the sensational Lu Yong case or the Shanghai vaccine case during the epidemic, they all reflect the same feature, that is, under the strict regulation of drug patents in China, generic drugs continue to emerge as a low-cost equivalent solution. Combined with the basic facts of the three cases, the research and development of generic drugs today is mostly motivated by the pursuit of the realization of the right to life, rather than the infringement of pharmaceutical patents alone, but it is in violation of legal provisions. In the case that the objective aspect of crime is true and the subjective aspect of crime is doubtful, how to regulate the distribution of generic drugs is the dilemma brought by the conflict of two rights.

4. Methods of Solving the Conflict between Pharmaceutical Patents and the Right to Life

4.1. Existing Measures

4.1.1. Application of the Proportionality Principle

The principle of proportionality is an important principle in jurisprudence. It is embodied in the principle of compatibility between crime, responsibility and punishment in the field of criminal law, which means the severity of punishment should be commensurate with the crime committed and the criminal responsibility borne by the criminal. This principle emphasizes the nature, circumstances and degree of harm of criminal acts, as well as the subjective malignancy and personal danger of criminals, as the main basis for determining the type and degree of punishment.

In the face of problems involving pharmaceutical patent rights and the right to life, in the society where the management of generic drugs and other fields is not yet systematic and perfect, the application of the principle of proportionality is a common way to integrate judicial rationality and legal justice. The cases in the third part reveal the progress and changes in the application of the principle of proportionality between crime, responsibility and punishment by courts in China from 2013 to 2019. The parties involved in the Haiqing Ni, Yong Lu and Shanghai vaccine cases were all charged with producing, selling and providing counterfeit drugs, yet courts handed down increasingly lenient sentences in almost identical cases over the past six years. According to China's Criminal Law, those who produce or sell fake drugs shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also be fined; If serious harm is caused to human health or if there are other serious circumstances involved, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than 10 years and shall also be fined; If death is caused to another person or other especially serious circumstances are involved, he shall be sentenced to fixed-term imprisonment of not less than 10 years, life imprisonment or death and shall also be fined or sentenced to confiscation of property.

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In Ni's case, although the amount of money involved reached more than 500,000 yuan, there was no evidence to prove that his use of drugs was harmful to the human body, but he saved the names of many people. In the case of both mitigating punishment and serious circumstances, the reasonableness of the court's decision to sentence a person to 10 years in prison for serious circumstances without an accurate evaluation of the drug's efficacy is actually debatable [5]. However, justice is progressing. In the Lu Yong case two years later, the court's judgment of "sales" behavior and "significant and minor circumstances" reflected the perfect interpretation of judicial rationality in the case; Six years later, in the Shanghai vaccine case, although there was no verdict yet, the defense in the second instance first analyzed from the factual and moral perspective that the defendant's purpose was to assume social responsibility and the doctor's benevolence. Then clarified the defense that his behavior belonged to the legal circumstances, which also reflected the precise application of the principle of compatibility of crime, responsibility and punishment in the judicial field.

On one hand, the application of the principle of proportionality and the principle of compatibility between crime, responsibility and punishment can maintain the mandatory provisions of legal provisions on pharmaceutical patent rights in the accurate conviction. And on the other hand, it reflects the soft guiding instructions of the Constitution respecting human life and health rights in sentencing.

4.1.2. Compulsory License System

Articles 5 and 7 of the 1985 TRIPS Agreement provide: "In order to protect national security, public health and social welfare, the State may, in its public interest, have the right to grant a compulsory licence to the inventor of the invention to exploit his patent if a patent has been granted for an invention or a patent contained therein, and if the invention can be reasonably compensated for its reasonable exploitation." This article provides for the compulsory patent licensing system for the first time. The recognition by China, the United States and other WTO member countries shows the rationality and necessity of this legislation in the current era of increasingly serious global health problems.

The compulsory licensing system of pharmaceutical patent is based on the positive relationship between the patent rights of traditional Chinese medicine and the right to life and health in the fourth part, which provides another reasonable regulation path for the conflict between the two. In jurisprudence, the compulsory license system passes through the expression of "exclusive right" of intellectual property and becomes another "tool" to realize the moral value it hopes to realize. And back to the reality, based on the minimum standard provisions of TRIPS Agreement, countries have set up the laws and regulations of compulsory license system and its application restrictions. In the domestic scope, the application of compulsory license system under certain circumstances can enable the pioneer drugs to enter the market faster and more in the face of high-impact diseases, and the reduction of prices can guarantee the right to life of more middle and low-yielding individuals. Internationally, the application of compulsory license also avoids the monopoly of pioneer drugs in developed countries to a certain extent.

However, it should be pointed out that the current nationwide compulsory licensing system still reveals some problems that need to be solved urgently. In China, although there were provisions on compulsory licensing as early as 1992, it has rarely been implemented until now [6]. In the United States, generic drug regulation and the shortening of the time limit for pioneering drugs have discouraged pioneering drug invention, and compulsory licensing requires additional constraints [7,8].

It can be seen that there are some problems in the implementation and restriction of compulsory licensing system at present, and further legislative regulations are needed in the future.

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4.2. Suggestions for Future

4.2.1. Re-improvement of Existing Measures

Although the previous part of the review, the existing measures have reflected the balance between medical patent rights and the right to life and health, it is still a new attempt, whose imperfection is mainly reflected in the restrictions of compulsory licensing system. In part 4.1, it has pointed out the problems of compulsory license system in judicial practice, mainly focusing on the restrictive conditions of compulsory license system. According to the TRIPS Agreement, the restrictions of the current compulsory patent licensing system are very strict, covering the number of licenses, licensing procedures, one case, one discussion and many other aspects of restrictions, and it should be noted that such cumbersome restrictions in the TRIPS Agreement are only set up as "minimum standards".

As an international minimum standard, this is obviously unreasonable. Although in some countries, such as the United States, pioneers in pharmaceutical research and development are at a disadvantage, there is a need for more restrictions on compulsory licensing, but in more countries, compulsory licensing is only a legal text, and it is difficult to implement. In this regard, the research of Jared Mullowney and Neil Harris reflects a reasonable simplification of the restrictions on compulsory license system: (1) A license is granted in good faith and a national emergency is declared; (2) a compulsory license may be granted only if the patentee is unable or neglects to take adequate measures for its rights on its own; (3) the government compensates the patentee; (4) the compulsory license is granted until the national emergency is no longer declared [9].

In the outbreak of public health problems, the number of necessary licenses is actually difficult to count, and the cumbersome licensing procedures will undoubtedly have an adverse impact on the public right to health, so the simplification of these issues in the "minimum standard" is reasonable [10]. As for the specific implementation of different countries, it can make more regulations on the TRIPS Agreement according to national conditions, more flexible and operable.

4.2.2. Establishment of Feasible New Measures

While we continue to focus on the establishment of measures on top of the existing patent system, these measures can not help but overlook some problems in the patent system itself. Jowa Chan argues in his essay that in today's legal practice, the establishment of pharmaceutical patents is certainly not the most effective way to recover R&D costs [11]. In this paper, it can also be explained from the nature of patent rights: As mentioned above, the process of patent rights to achieve the ultimate goal of public interest is indirect. In this indirect process, many drug companies maliciously raise the price of drugs and take advantage of the opacity of the price to infringe the interests of consumers. This leads to the dilemma that the legislative purpose of patent law is contrary to judicial practice

In this case, it is urgent to introduce a new incentive mechanism. Australia's HIF is already leading the way, with a health-funding scheme based on the impact of drugs. Under this scheme, drug developers would no longer benefit from the licensing of patents, but instead from the impact of a drug once it reaches the market. The impact of a drug is assessed through research on factors such as how many copies it sells and how well patients are cured after it is launched. The government gives developers administrative incentives based on the results [11].

In this system, the R & D goal of the R & D developer is directly connected with the ultimate goal of "protecting the life and right to health of the public". The audience index to consider the influence of drugs also makes the R & D and drug companies have to consider the cost of drugs in order to obtain the high influence brought by low cost and high sales. This index also enables developers and drug companies to further consider the quality and safety of drugs. Above, the establishment of the new incentive mechanism is different from the patent law. By directly connecting with the public

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interest, the research and development company focuses on the comprehensive innovation of reducing cost, increasing utility and ensuring quality. Although it is only a concept and has not been implemented in any country, it is indeed a regulatory method worth considering.

5. Conclusion

By analyzing the typical cases involving disputes between pharmaceutical patent rights and human life and right to health in China in recent years, and combining Chinese and foreign scholars' literature, this study draws the following conclusions: There is a positive relationship between pharmaceutical patent right and life and right to health. The protection of patent right aims to stimulate innovation, and the ultimate purpose is consistent with the protection of the right to life. However, the exclusivity and monopoly of patent right do cause adverse effects on the realization of life and right to health in practice. Although the existing measures to resolve the conflict have alleviated the conflict to a certain extent, there are still difficulties and limitations in implementation. In this regard, this paper found a new conceptual incentive mechanism that has not been implemented in the literature, which directly links the incentive with public welfare, combined with the improvement of the existing measures, can provide coordination for the conflict between pharmaceutical patent rights and life and health rights.

In today's post-epidemic era, research on the relationship between the two will certainly continue, in-depth analysis of different countries and regions in dealing with the conflict between pharmaceutical patent rights and life and health of the policy and legal framework, compare their effects and feasibility, propose new solutions, and imagine the formation of a community of human destiny to this issue, better coordination between the two.

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