Science of Law Journal (2025)
Clausius Scientific Press, Canada

DOI: 10.23977/law.2025.040519
ISSN 2616-2296 Vol. 4 Num. 5

The Preliminary Discussion on the Legal Regulation of Gene Patents

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Keywords: Gene, Patent, Legal Regulation, Principle of Exhaustion of Rights, Creative, Protection Mode

Abstract: With the rapid development of gene technology, gene has become an important strategic resource for human beings. In order to seize the bridgehead of future gene projects, more and more genes are being patented by biotechnology companies, and the laws and regulations related to gene patent are constantly improving with the innovation of gene technology. However, there are still many loopholes in the practical application of gene patent laws and regulations. Because of the late development of our gene technology. compared with the developed countries in Europe and America, we are relatively backward. In terms of legislation, we learned from the legal systems of many countries with relatively mature gene technology, so the legal regulation of gene patent is in an advanced state, especially in the application of the principle of exhaustion of rights, the creative recognition of the patent right, and the selection of the mode of protection of gene patent. This article will analyze and study the disputes of our gene patent legal regulation on the basis of analyzing our existing gene patent legal regulation, unifies foreign relevant legal systems, and puts forward my opinions.

1. Introduction

1.1 Gene

A gene, which is a DNA segment carrying genetic information, is the complete nucleotide sequence required to produce a polypeptide chain or a functional RNA. Gene technology is a type of technology within bioengineering based on genes, involving various technical manipulations of genes. In this era of advanced science and technology, the level of gene technology has reached an unprecedented height. Today, fundamental gene technologies such as gene mapping, gene isolation, and gene recombination are quite mature. The gene technology revolution can be said to be another major revolution for humanity following the industrial and information revolutions. Therefore, the maturity of gene technology can, in a sense, be used to measure a country's technological level.

As the foundation of gene technology, genes naturally become the primary research subject for advancing gene technology. In practice, genes can be divided into natural genes and new genes obtained through gene technology (which are essentially genes). However, in research in non-biological professional fields, especially in interdisciplinary studies related to genes, many scholars conflate the latter with the concept of "gene technology." Many papers on "gene technology patents"

are actually about "gene patents." Of course, the reason for this loophole is that many scholars want to distinguish between natural genes and genes later processed through gene technology, thus equating "gene technology" with "genes processed through gene technology." This article adopts the topic "A Preliminary Discussion on the Legal Regulation of Gene Patents," focusing mainly on the patent issues of genes synthesized through gene technology.

1.2 Gene Patent

In the 1970s, during the seed wars, the United States enacted the latest amendments to the Plant Patent Act and the Plant Variety Protection Act, becoming the first legislation to extend patent rights to living matter. Soon after, the United States clarified the patentable scope and patent models for genes in the latest United States Patent Act. In 1998, the European Union also clarified the patentable scope and patent models for genes in the newly issued Directive on the Legal Protection of Biotechnological Inventions. In the early 21st century, the "Myriad case" caused a global sensation. In this case, which indirectly promoted the advancement of gene patent regulations, the United States further refined the legal regulation of gene patents. The latest Leahy-Smith America Invents Act provides detailed regulations on genetic testing research. With the refinement of gene patent legal regulations in Europe and America, many developing countries have also formulated corresponding gene patent legal regulations based on their national conditions and the development status of gene technology.

Compared with the relatively complete gene patent legal regulations in European and American countries, legislative debates in most developing countries regarding gene patents still linger on substantive requirements for patent applications (novelty, inventiveness, practical applicability), the determination of protection modes, and how to balance the resulting conflicts of interest. As a country where gene technology is just emerging, China has also exposed many problems in the legal regulation of gene patents, requiring further research, discussion, and improvement.

2. Current Status and Controversies of China's Gene Patent Legal Regulation

2.1 Current Status of Gene Patent Legal Regulation

According to Article 22 of the Patent Law, inventions and utility models granted patent rights must meet the three substantive requirements of novelty, inventiveness, and practical applicability. The granting of patent rights in the field of genes similarly needs to comply with these three substantive requirements. However, because genes possess the dual attributes of materiality and informativity, determining whether a gene meets the three substantive requirements differs from general inventions and utility models.

Novelty means that the invention or utility model applied for does not belong to the prior art before the filing date. In the field of genes, novelty can be judged by comparing the sequence listing in the specification with already published sequence listings of human genes or DNA fragments.[1]

Inventiveness means that, compared with the prior art, the invention has prominent substantive features and represents notable progress. In the field of genes, determining whether a gene possesses inventiveness involves judging whether an ordinary person skilled in the art of gene technology could easily conceive of the technical solution of the patent application.[2] If an ordinary technician could conceive of the technical solution of the gene technology, it lacks inventiveness; if not, it possesses inventiveness.

Practical applicability means that the invention or utility model can produce some positive effect. In the field of genes, the applied gene technology patent needs to be able to solve problems existing in the prior art and be used in industry. Of course, when judging whether a gene patent can solve

existing problems and be practically applied, attention must also be paid to two situations lacking practical applicability: first, non-reproducibility, meaning it cannot be repeatedly implemented by an ordinary technician; second, products utilizing natural conditions of a contingent nature, such as some raw materials.

2.2 Controversies in Gene Legal Regulation

2.2.1 Controversies over the Determination of Inventiveness

China's judgment on patent inventiveness usually adopts a three-step approach. Step one: determine the closest prior art. The closest prior art refers to the technical solution most closely related to the claimed invention in the prior art, serving as the basis for judging whether the invention has prominent substantive features. Step two: determine the distinguishing features of the invention and the technical problem actually solved by the invention. In examination, an objective analysis should be conducted to determine the technical problem actually solved by the invention. To this end, the distinguishing features between the claimed invention and the closest prior art should first be analyzed, and then the technical problem actually solved by the invention should be determined based on the technical effects achieved by these distinguishing features in the claimed invention. Step three: judge whether the claimed invention is obvious to a person skilled in the art. In this step, starting from the closest prior art and the technical problem actually solved by the invention, it is judged whether the claimed invention is obvious to a person skilled in the art.

This "three-step" approach can be accurately applied in the field of general patents, but it has shortcomings in the field of gene patents. Because gene technology has strong ease of replication and the final review standard is judged by "people," how to avoid human subjectivity and establish as objective a standard as possible in the judgment of inventiveness has become a topic of discussion among many scholars.

2.2.2 Controversies over Gene Patent Protection Modes

There are two protection modes for gene technology patents: the product-type protection mode and the function-type protection mode.[3] The product-type protection mode refers to protecting gene patents through claims to the gene product. Protection of the gene encompasses both the gene itself and all its functions. The function-type protection mode refers to protecting gene patents through claims to the function of the gene. Protection of the gene encompasses only a specific function. Our country adopts the product-type protection mode.

The advantages of the product-type protection mode are obvious; this protection mode provides strong protection for genes. For countries with relatively developed gene technology, it is conducive to the development of gene technology, providing legal guarantees for their monopoly on research. However, since China's gene technology is relatively backward, whether adopting this protection mode and granting some biotechnology companies the opportunity for monopolistic research hinders the development of gene technology has become a controversial topic in gene patents in recent years.

3. Extraterritorial Experience in Gene Patent Controversies

3.1 Extraterritorial Experience in Determining Inventiveness

In U.S. patent law, inventiveness is also defined as "non-obviousness."[4] In the early days, the United States primarily had two standards for judging "non-obviousness": the Graham standard and the TSM standard. The Graham standard primarily examines the following questions when judging "obviousness": determining the differences and distinctions between the prior art and the new

technology; the ordinary skill level in the field; and other auxiliary factors for consideration. The Graham standard is the foundation for obviousness judgment but has obvious shortcomings, such as lag issues in judgment. Subsequently, the United States introduced the "TSM standard." The "TSM standard" means that if a person skilled in the art can obtain motivation from prior art documents to combine existing technologies to obtain the new technology of the applied patent protection model, then the creation lacks "non-obviousness." This examination method greatly reduces the subjectivity of examiners. However, this seemingly more objective judgment method still has loopholes. Many scholars believe that if the "TSM standard" is applied too rigidly, it may underestimate the level of ordinary technicians in the field, ultimately leading to the proliferation of gene patents.

3.2 Extraterritorial Experience in Protection Modes

Through the U.S. Patent Act and related case law, the United States adopts the product-type protection mode for gene patents. Of course, adopting this protection mode is also determined by the United States' own national conditions and the development status of its gene technology. U.S. gene technology is relatively leading, and its gene technology industry is developed. Adopting this monopolistic protection mode is more conducive to biotechnology companies making breakthroughs in specific gene technologies.

The U.S. Myriad case arose from the shortcomings of product-type protection. Although the core issue of this case was "whether genes isolated from the human body constitute an invention or a discovery," it also sparked discussions on gene patent protection modes.[5] Myriad Company is a famous U.S. biotechnology company that successfully isolated a gene called "BRCA1" in an experiment. Mutations in this gene are the primary cause of hereditary breast cancer. After isolating this gene, Myriad Company applied for a patent, obtaining exclusive research rights.[6] However, due to insufficient investment in related fields, the company's research on the "BRCA1" gene stagnated, while some companies with greater investment and more mature technology in related fields could not conduct research due to patent rights. This led to a stagnation in breast cancer research in the United States, affecting the treatment of many patients. After three trials, this case concluded that "genes merely isolated from the human body cannot be patented." Subsequently, the feasibility of product-type protection became a hot topic in the field of gene patents. As U.S. gene technology became more advanced, the product-type protection mode was accepted by U.S. scholars, and therefore this protection mode is still applied in the United States.

4. Suggestions for Improving China's Gene Technology Patent Legal Regulations

4.1 The application of the obvious-to-try principle

China's Patent Examination Guidelines have preliminarily established substantive examination standards for gene patents.[7] Although there are detailed descriptions of the examination standards for inventiveness, there are still shortcomings in some aspects. Combining the "Combined Molecule Case," we can identify a drawback in patent inventiveness judgment: when the prior art belongs to a conventional solution in a certain field, specific product technologies in that field do not lose "obviousness." This phenomenon is particularly common in the field of genes because gene technology work is highly imitative; different genes may be turned into corresponding gene technologies using similar methods. For example, after referencing conventional techniques for replicating DNA and cDNA, replicating a specific DNA and cDNA does not lose "obviousness." This could easily lead to the proliferation of patent rights. Although China's judgment on inventiveness in gene technology patents reduces the subjectivity of examiners, restrictions must be added to prevent gene technologies from being too easily granted patents, causing a proliferation of gene technology

patents and affecting the field of biotechnology.

Therefore, in legislation, we can learn from the U.S. "obvious-to-try principle" to avoid excessive rigidity in inventiveness examination.

4.2 Selection of Protection Mode

According to the current development status of China's gene technology, China's gene technology is still in a developmental stage. If biotechnology companies are allowed exclusive research rights, it may occur that a company owning the patent for a gene sequence experiences lagging research due to technical reasons, while companies capable of research cannot do so due to patent restrictions.[8] This will inevitably slow down the development of China's gene technology.

Although the "function-type protection mode" may lead to the emergence of patent thickets and hinder breakthroughs in gene technology, China's current level of gene technology is unlikely to cause "patent thickets" to appear at this stage. From another perspective, applying the "function-type protection mode" in China brings more benefits than drawbacks.

In summary, China's gene technology patent protection mode should adopt the function-type protection mode rather than the product-type protection mode. China's gene technology is still in its initial stages. If biotechnology companies are granted monopolistic rights to research gene technologies, it will inevitably lead to excessively slow development of certain gene technologies. However, to prevent the possible future emergence of "patent thicket" phenomena, certain measures also need to be formulated for prevention.

5. Conclusion

Through this article's analysis of China's existing legal regulations and controversies regarding gene technology patents, it is not difficult to see that China's gene technology patents have shortcomings both legislatively and technologically. Of course, due to immature technology and advanced legislation, there are many controversies in judicial practice. This article mainly discusses and analyzes currently typical controversial topics. Some controversial topics may seem unsupported by relevant cases, but by comparing extraterritorial judicial practices in gene technology patents and judicial practices in similar fields in China, if China's gene technology makes huge breakthroughs one day, legislative defects will become particularly obvious, and related controversial cases will continuously emerge. As the world's largest developing country, we should adapt to the Fourth Industrial Revolution in advance, combine China's national conditions and future gene technology development trends, and establish a gene technology protection mechanism with Chinese characteristics to safeguard the development of China's gene technology.

References

[1] Ou Shaomiao. Research on China's Human Gene Technology Patent System[D]. Shantou University, 2021. DOI: 10. 27295/d.cnki.gstou.2021.000488.

[2] Yi Haoran. Research on the Patentability of Human Genes and the Balance of Interests[D]. North China University of Science and Technology, 2019.

[3] Liu Xin. Issues, Controversies, and Responses to the Patenting of Gene Technology[J]. Electronics Intellectual Property, 2021(08):4-17.

[4] Li Zhao. Research on Issues in Gene Patent Application and Examination[J]. Heilongjiang Science, 2020, 11(08): 145-147.

[5] Ming Yang. Comparative Study on the Patentability of Genes[D]. Shandong University, 2020. DOI:10. 27272/d. cnki. gshdu.2020.004291.

[6] Wang Tun. Analysis of Issues Related to Gene Patents——Starting from the U.S. Supreme Court's "Human Gene Patent" Case[C]//Department of Treaty and Law, State Intellectual Property Office. Patent Law Research (2014). Patent

Law Research (2014), 2017:156-164.
[7] Wu Juan. Research on the Scope and Limitations of Gene Patent Protection[J]. Legality Vision, 2017(24):188-189.
[8] Michael A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," Harvard Law Review 111, no. 3 (January 1998): 621-688.