UTILIZATION OF INTELLECTUAL PROPERTY RIGHTS IN SYNTHETIC BIOLOGY BASED ON CASE OF JUDGMENT OF GENETIC RECOMBINATION TECHNOLOGY

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Abstract— Biotechnology is moving toward the creation and synthesis of artificial life forms that do not exist in nature. However, the development of synthetic biology has been hampered. Humans have engineered gene sequences to combine biological components to produce synthetic cells.This problem has therefore begun to be discussed among legal experts.Filnally, United States Supreme Court ordered the Association for Molecular Pathology v. Myriad Genetics.The ruling redefined the criteria for 'products of nature' in terms of presenting patent eligibility criteria for 'genes isolated from human bodies'. Therefore, it is time for the Korean government to implement and implement policy, legal and institutional support plans with the will to support and nurture synthetic biology.

Key word- Synthetic Biology, Gene Patent, Patent

I. INTRODUCTION

Biotechnology has been steadily developed since the double helix structure of DNA was discovered by Watson and Creek in the United States in 1953. Biotechnology is moving toward the creation and synthesis of artificial life forms that do not exist in nature. Already, we are now able to access biotechnologies such as genetically modified organisms (GMOs), DNA tests and stem cells. Furthermore, synthetic biology technology will be developed and direct genes will be able to be produced directly, and it will be possible to apply it to industry.(Seung, 2010) The background of synthetic biology is bioinformatics and nanotechnology, which are IT technologies in the field of biotechnology. As these technologies evolved, they led to the commercialization of gene sequence analysis and synthesis. Methods such as computer and mathematics and statistics were used to analyze this. Finally, synthetic biology laboratories were first opened in January 2003 at MIT by researchers in biology, electrical and computer engineering.(Kim, 2016) However, the development of synthetic biology has been hampered. Humans have engineered gene sequences to combine biological components to produce synthetic cells. This problem has therefore begun to be discussed among legal experts. In this study, compare DNA patent management clauses in Genetic Engineering and Synthetic Biology.

Ⅱ. SYNTHETIC BIOLOGY

1. Concepts of Synthetic Biology

Synthetic biology aims to produce and synthesize the genomes of synthetic cells. It is a new science that first appeared in the early 2000s. Synthetic biology is a conceptual biology that synthesizes DNA that performs a useful function to control the behavior of cells, introduces them into actual cells, and performs predictable functions.(Kim, 2016) To create artificial life forms, DNA sequences or genomes must be computerized. In order to realize this, there is a need for a technique for artificially synthesizing genes by analyzing DNA base sequences. Using these techniques it is possible to artificially synthesize part or all of the DNA of a small cell and then insert it into another adjacent cell to make an artificial cell. Craig Venter, who succeeded in this technique, completed the human genome map in 1995.(Seung, 2010)

Synthetic biology differs from existing genetic engineering and bioinformatics in manipulating genes.(Kim, 2016) It can be thought of similar to genetic engineering. However, the main difference is that DNA fragments are directly synthesized and used as components.(Seung, 2010) Synthetic biology is modularized to analyze and design biological systems.(SBS CNBC, 2010)

Ⅲ. LEGAL ISSUES RELATED TO DNA RECOMBINANT TECHNOLOGY

1. Gene patent

1) MYRIAD sentence

In June 2013, the United States Supreme Court ordered the Association for Molecular Pathology v. Myriad Genetics. Until the verdict was issued, the US Supreme Court's Diamond v. Supreme Court ruled that the DNA "separated from the human body" and

"everything made by man" was subject to patent protection. Based on the Charkrabarty judgment, the patent eligibility has been recognized.(Kim, 2009)

However, a recent ruling has distinguished DNA isolated from the human body as "naturally occurring DNA separated from the human body" and "DNA synthesized from mRNA"(cDNA). In addition, the court ruled that only the cDNA is patentable. As a result, it will be difficult to acquire patents on 'DNA isolated from human bodies' in the future.(Kim, 2009)

The ruling redefined the criteria for 'products of nature' in terms of presenting patent eligibility criteria for 'genes isolated from human bodies'. Therefore, it is meaningful that the principle of 'product of nature' can be applied as a criterion for determining patent eligibility.(Kim, 2009)

2) Opposition

Critics of the granting of patents to genes and DNA have made the following claims. First, granting of exclusive rights to human DNA is to grant patents to those already existing in nature, contrary to the fundamental aim of the patent system to grant exclusive rights to the results of human creative endeavors. Second, granting patents to genes and DNA is a hindrance to medical research.(Lee, 2013)

3) Acknowledgments

On the other hand, the arguments of the supporters are as follows. First, patents are essential for technological innovation and research promotion. Second, the development of drugs and diagnostic products requires long research and development, clinical period and investment. If the investment cost can not be recovered stably, it is worried that the technology development will not be achieved.(Lee, 2013)

4) Sinter

"Patent" is an independent product that is traded independently and generates revenue. There are a lot of stakeholders involved, but if one is overly stressed or shrunk, the overall balance will collapse, and the collapsed structure will not bring sustained fullness to anyone. The issue of gene ownership is constantly being raised because industrial biology is one of the fastest growing industries in the industry.(Lee, 2013)

2. Gene patents stemming from synthetic biology

In the case of synthetic biology, since the researchers design and genetically synthesize the whole genome of an organism, the DNA that is produced has a distinctive distinctiveness from that of the cloned DNA.(Kim, 2012)

In addition, synthetic DNA and synthetic cells may have functions and characteristics distinct from their corresponding counterparts in nature. Even if they have the same functions and characteristics, they can be distinguished from each other. Thus, synthetic DNA made from synthetic biology technology is likely to be recognized as an original work of creativity.(Kim, 2012)

CONCLUSION

DNA isolated from living organisms can not be protected by copyright because it is merely a duplication of what exists in nature through recombinant DNA technology.(Kim, 2012) On the other hand, synthetic DNA, which is an invention based on synthetic biology, is expected to have no difficulty in acquiring a patent because it has a characteristic distinct from that of a natural counterpart. In addition, researchers may designate DNA sequences and synthesize them chemically, so that synthetic biology may assess the possibility of copyright protection for DNA.

Therefore, in order to be competitive in the synthetic bioscience market, it is necessary to acquire intellectual property rights for synthetic DNA and technologies related to DNA synthesis and sequencing. The technological gap between developed countries and Korea is not so great as not to catch up. Therefore, it is time for the Korean government to implement and implement policy, legal and institutional support plans with the will to support and nurture synthetic biology.

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