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Patenting Genes in China, the U.S., and the EU: How Does It Differ? Could It Get Out of Control?

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It is generally recognized that gene patents can be granted. However, one of the key points of contention in the international biotechnology field remains that there is no agreement on how to define the scope of specific gene patent protection. That said, there are considerable commonalities, since the scope of gene patent protection in all countries is fundamentally about gene sequence, gene technical methods, and products produced from a gene technical method.

GENETIC PATENTABILITY IN CHINA

Generally, a gene technical method can be granted as a process patent in China. However, there are some exceptions. For example, the technology of human cloning is not patentable if it changes the gene unity of the human reproductive system or animal genetic unity; biological methods are not patentable if they violate some traditional ethical concepts, such as research on human embryos; and the propagation of plants and animals for commercial and industrial purposes are subject to the invention-creation stipulation in Article 5 of China's Patent Law (CPL).

Genetic screening diagnostic methods for "the diagnosis or for the treatment of diseases," as set forth in Article 25 of the CPL, cannot become patentable subject matter. Transgenic animals or transgenic plants obtained through DNA and the biological technology of genetic engineering are not patentable because they pertain to the animal and plant categories under Article 25 of the CPL. As for transgenic microorganisms, because they belong to neither the animal nor plant categories, they are patentable under the CPL. It is considered a mere discovery when one finds a gene or a DNA fragment existing in its natural form, because such gene or DNA fragment is considered a "scientific discovery" subject to Article 25 of the CPL, and those are not patentable. However, when a gene or a DNA fragment, whose base sequence is not recorded in the existing technology and can be precisely characterized, is first separated or extracted from nature and is valuable to the industry, such gene or DNA fragment and the method producing it are patentable.[1]

GENETIC PATENTABILITY IN THE UNITED STATES

According to Article 101 of the Leahy-Smith America Invents Act, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore." In *Diamond v. Chakrabarty*, the U.S. Supreme Court held that except for the laws of nature, physical phenomena, and abstract ideas, "the Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[2] According to the holding, any transgenic animals, plants, and microorganisms may be patentable. Gene technical methods, including diagnostic methods or disease treatments, are patentable. Although the human body cannot be patented, products separated from the human body (including organs, genes, DNA sequences, cell lines, etc.) may be patentable. However, that landscape has changed significantly in the past few years, resulting in a narrower set of

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[1]Guidelines for Patent Examination, part II, ch. 10, § 9 (2010).
[2]*Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

patent-eligible subject matter than previously available to bio/pharmaceutical industries.[3]

In January 2001, the U.S. Patent and Trademark Office (USPTO) issued guiding regulations on patent examination, raising the bar on gene patent applications: it is now prohibited to grant a patent in the case that researchers cannot fully reveal the specific function of the gene. In June 2013, the U.S. Supreme Court held that a DNA fragment of natural origin was a natural product. On the one hand, such DNA fragments are not patentable just because they were separated from nature. On the other hand, complementary DNA (cDNA) was held patent eligible as non-naturally occurring.[4] Before the *Myriad* case, the main criteria for deciding the validity of gene patents was that the structure of a separated DNA sequence differed from that in the natural state. However, the final adjudication held that the difference between a separated DNA sequence and the natural DNA structure is not sufficient to support that it is a new artificial compound; however, cDNA is patentable because its structure is significantly different from that of the DNA sequence in the natural state. This indicates that the U.S. Supreme Court pays more attention to the gene structure than to the connotation and functions based on the gene.

GENETIC PATENTABILITY IN THE EUROPEAN UNION

The scope of protection of gene patents in the EU is mainly affected by the EU Directive on the Legal Protection of Biotechnological Inventions (Directive 98/44/EC, or "the Biotech Directive"). The purpose of this directive is to balance the protection afforded biotechnology patents and the welfare of the general public, establishing a more effective patent system. According to the directive, some gene technology methods are not patent eligible. The Biotech Directive indicates that "[w]hereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability[.]"[5] Also, the following shall not be patentable: plant and animal varieties; essential biological processes for the production of plants or animals; processes for cloning human beings; "methods of altering the gene unity of human reproductive system"; the "use of human embryos for industrial or commercial purposes"; and the like.

Although the Biotech Directive explicitly notes that plant and animal varieties cannot be patented, the concept of animals and plants has been recently redefined, deeming some plant and animal species (referring to any flora and fauna known as the lowest level of classification) patent eligible. If the technical feasibility of floristic and zoic invention is not limited to a particular species, then it may be patented.[6] Article 31 of the Biotech Directive clearly points out that flora characterized by a particular gene (but not the entire chromosome) cannot be protected by the Right of the New Plant Variety. Therefore, a plant is not unpatentable *per se*. Microbiological methods, other technical methods, or products produced through the above methods may be patent-eligible subject matter, unless such product is a plant or animal variety. As for gene sequences, the Biotech Directive clearly stipulates the formation and development of the different stages of the human body, as well as simple discovery of its elements (including a whole gene sequence or part), does not constitute a patentable invention. However, some elements separated from the human body or produced by the technical method (including a whole gene sequence or part) may constitute a patentable invention, even if the structure of that element is the same as its structure in nature. In practice, through cases like *Monsanto v. Cefetra*, the Court of Justice of the European Union (CJEU) has restricted the scope of protection for DNA sequence patents.[7] CJEU clearly points out the scope of protection for gene patents is limited to living biologic material, ruling out protection for processed, derivative products thereof. This establishes a purpose-bound protection for gene sequences rather than an "absolute" protection.

The patent law of the EU and China is more concerned about specific functions of gene sequences, which means the focus on gene patent protection has put particular emphasis on the specific function of a gene sequence, while their U.S. counterpart is

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[3]Weisun Rao and Fang Xie, *Patenting Bio/Pharma Inventions: A Comparative View of the Patent Systems in the U.S. and China*, 33(4) BIOTECHNOLOGY L. REP. 145–153 (2014).

[4]*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2109 (2013).

[5]Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 313) ¶ 35 and art. 4, § 1.

[6]Reference to Directive 98/44/EC, art. 4, § 2.

[7]Robert Fitt and Edward Nodder, *An Uncertain Future for Gene Patents: The View from Europe*, 29(6) BIOTECHNOLOGY L. REP. 615–622 (2010).

more concerned about gene structure. In the U.S., before the *Myriad* case, the main criteria for patentability of gene patents was that the structure of the separated DNA sequence differed from those under its nature state. However, the final adjudication still agreed that cDNA may get patent protection because the structure of cDNA obtained by reverse transcription of messenger RNA is obviously different from the DNA sequence in its natural state, while the rejection of patentability for separated DNA sequences stands because the differences between separated DNA sequences and natural DNA sequences are insignificant. It is clear that the functional difference is that the U.S. is using a different standard. As such, would the "absolute" protection be replaced by the following statement? Is it possible, because the patent examination of the EU and China is widely affected by the United States, that the trend will be to have a unified standard that approaches the standard in the United States?

CONCLUSION

In the comparison of the scope of patent protection among China, the U.S., and the EU, the U.S. and the EU allow patent protection for transgenic plants, animals, and products produced through microorganism methods, while China only allows protection for transgenic microorganisms. In the matter of gene technical methods, China, the U.S., and the EU all prohibit patents on the human body based on the requirements of bioethics, but the scope of China and the EU's protection is much narrower than that of the U.S.: for example, diagnostic methods, treatment of diseases, and the use of human embryos for commercial and industrial purposes (just to name a few) cannot be patented in China or the EU. In the matter of gene sequences, both China and the EU acknowledge gene sequences separated from nature as invention under certain conditions. This is entirely different from the standard set forth by the U.S. Supreme Court. As for the close attention to the structure of gene, all three regions are more concerned about the specific functionality of the gene sequence: the protection of gene patents is particularly focused on the specific scope of functions towards the gene sequence. Although the EU gives patent protection for separated gene sequences, in actual practice, there has been a tendency to weaken such protection.

Apparently, the patentability of genes is indeed a legal battle royale. One controversy is whether it is invention or discovery if the products derive from a gene sequence. However, if we delve deep into the essence of these controversies, it is easy to discern that such controversies are caused by local ethical factors—particularly the level of local biotechnology development. Patentability and scope of gene patent protection, in fact, is the secondary distribution between upstream gene patents and downstream monopoly rights of the biotechnology industry. A broad scope of gene patent protection means that patent policy has been tilting towards the upstream gene patent innovators, while a narrow scope of gene patent protection is more conducive to the development of the downstream biotechnology industry.

Currently, the vital issue is to balance interests between patentees and the general public, while the conflicts between patentees' monopolies and the downstream gene researchers can only be considered as secondary issues, because right now, gene patent owners tend to monopolize related methods and final products. However, in reality, the conflict between patent holders and the general public interest is more fiercely contested, since the gene patent holders want more monopoly on related technical methods, final products, and services. Since there are still some gaps in the level of biotechnology development between China and the Western countries in general, the scope of gene patent protection in China is narrower than the scope of protection in the EU and the U.S. That is the reason for transgenic animals and plants not getting patent protection in China.

In terms of the heatedly discussed gene sequences, whether the technical methods are low cost and inventive should be particularly emphasized, and a gene sequence discovery possessing practical value should be granted patent protection. When techniques become more developed, the potential for certain technological advances to reduce certain costs, such as the potential negative impact brought by monopoly, should be more worthy of concern. Developing countries tend to narrow the scope of protection of patents to close gaps with developed countries. Therefore, it is not difficult to understand that China, as a developing country in genetic research, will closely follow new standards from the U.S. to strictly control new gene sequence patents.

Although nowadays, the authorization standards of gene patents in various countries are different, they are far from coasting out of control. The most important reason is that the change of standards in gene patentability in the United States will profoundly affect the standards of other

countries and exert pressure for them to adapt to it. Currently, the United States is taking a leading position in global gene technology in innovation, marketization, and legal and ethical self-examination. In addition, globalization also amplifies the influence of the U.S. As for the EU and China, as well as other prominent gene technology countries, the now-different subjective criteria of gene patentability will become more-and-more similar as the development level of biotechnology in these countries enters the same stage.

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