THE PATENTABILITY OF HUMAN GENES IN ASIA: CHINESE LAW, COMPARATIVE ANALYSIS AND FUTURE DEVELOPMENT

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ABSTRACT

The patentability of human genes has long been a controversial topic around the world. The United States Supreme Court denied the patentability of isolated genes but acknowledged that of cDNA in the Myriad case. On the contrary, similar to the attitude of Europe, China grants patent protection to isolated genes upon satisfying certain requirements. However, the related provisions in the Chinese patent legalsystem are far from specific enough. This article introduces the major approaches in the most representative jurisdictions towards this question and their problems respectively. Then this article aims to provide suggestions for the future direction of China on this issue from the perspective of comparative analysis.

Keywords: Patentability, Gene, Myriad, Breast Cancer, Chinese Law, Patent Law, Comparative Law.

INTRODUCTION

Deoxyribonucleic acid, known as DNA, has been widely acknowledged as probably the most important substance in the human body to maintain normal physiological functions. In 1953, Watson and Crick found the structure of DNA in the double helix, which explains how DNA functions.[1] The basic units of DNA are four kinds of bases: A (adenine), T (thymine), G (guanine), and C (cytosine), and on each helix, the bases form different regions of exons and introns spacing; between the two helixes, A pairs with T, and C pairs with G through hydrogen bonds. [2] Generally speaking, DNA functions through the "central dogma" to produce proteins.[3] First, RNA (ribonucleic acid) polymerase breaks the hydrogen bonds between the helixes to expose the sequence on one helix. Then, a primary RNA is produced by base pairing with the exposed helix. Through splicing, the introns of the primary RNA are deleted, hence the mature mRNA (messenger RNA) only contains the exons of the DNA sequence. Next, with the help of ribosomes and tRNA (transfer RNA), mRNA is translated into amino acid chains. After modification and packaging, the amino acid chain becomes proteins, which productwill be distributed to all parts of the cell to serve different functions.

In scientific research, scientists usually want to know the sequence of a certain DNA. With the technology of reverse transcription, scientists are able to synthesize a cDNA (complementary DNA) sequence that is complementary to the mRNA.[4] As a laboratory product, cDNA differs from naturally existing DNA in that it only contains the exon parts of the natural DNA. Therefore, cDNA is not a substance originally exist in nature.

A gene is the entire nucleotide sequence required to produce an amino acid chain or functional RNA. Therefore, gene is seen as the basic unit that supports the structure of life. Because gene has the characteristic of carrying hereditary information, researchers have been trying to identify and isolate genes that bear key functions in the human body through the

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years. In this way, they are able to explore the development of diseases, and accordingly the diagnosis and treatment targeting the relevant genes. Such research activities lead to the question of the patentability of human genes. To be specific, the issues include the patentability of:

1. The naturally existing DNA;
2. The isolated DNA;
3. The cDNA complementary to the natural DNA.

Chinese lawmakers responded to this question not in laws or regulations, but in the Guidelines for Patent Examination (hereinafter as "*Guidelines*"). The *Guidelines* bear the authority as administrative department rules, and it is the standard of patent prosecution for the China National Intellectual Property Administration (CNIPA). In the *Guidelines*, China clearly distinguishes the patentability of natural DNA and isolated DNA. While natural DNA is categorized as non-patentable discoveries, isolated DNA, if fulfilling the requirements specifically stated in the provision, is treated as a patentable chemical substance.[5]

According to Article 52 of the Convention on the Grant of European Patents (also known as "European Patent Convention", hereinafter "EPC"), any invention is patentable if it satisfies the requirement of novelty, inventive step and industrial application.[6] Provisions regarding the patentability of gene sequences can be found in Part II, Chapter V, Rule 29 of the Implementing Regulations to the Convention on the Grant of European Patents (hereinafter as "Regulations to EPC"), which takes a very similar approach to China on this issue, and further specifies that patentability exists "even if the structure of that element is identical to that of a natural element."[7]

The attitude towards the patentability of human genes has gone through a great reversion in the United States. For over 30 years, the United States Patent and Trademark Office (USPTO) was used to granting patent protection to isolated human genes, which conduct fostered the research and development (R&D) of medical companies and helped the United States took monopoly in the "gene enclosure movement." Myriad Genetics, Inc. (Myriad) discovered the precise location and isolated the sequence of BRCA 1 and BRCA 2 genes, which genes are related to the development of breast cancer and ovarian cancer. Relying on the granted patents involving BRCA genes and related diagnostic uses, Myriad gained a market monopoly in this field. After several rounds of litigation, the Supreme Court of the United States (SCOTUS) finally held that the isolated BRCA genes were non-patentable while the cDNA is patentable in 2013. This landmark holding set up a new standard regarding the patentability of human genes in the United States.

This article first briefly introduces the litigation history of the *Myriad* case in part 2 and the rationale behind the holding of SCOTUS. Part 3 focuses on the Chinese policymaking and law interpretation and summarizes the approaches concerning this issue among several representative jurisdictions and analyzes the advantages and disadvantages of those. Then, part 4 discusses the patentability of human genes with the general requirements of patentability. On the ground of such, this article aims to provide an outlook for Chinese law making and interpretation regarding the patentability of human genes on the ground of comparative law analysis.

THE MYRIAD CASE

The average American woman has a 12-13% risk of developing breast cancer, but for women with certain genetic mutations in BRCA 1 and BRCA 2 genes, the risk can range 50-80% for breast cancer and 20-50% for ovarian cancer.[8] The BRCA genes are known to the public to some extent due to the famous Hollywood actress Angelina Jolie. Because her mother died of ovarian cancer, Jolie did a gene testing and found she was also a carrier of

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mutations in the BRCA genes. She went through breast and ovary resection to prevent from developing cancer.[9]

After discovery of the precise location and sequence of BRCA 1 and BRCA 2 genes, Myriad applied for patents involving BRCA genes and related diagnostic uses in 1994, and obtained a number of patents related to BRCA genes in the United States. Relying on the important functions of the gene, between 1997 and 2013, Myriad sold around one million tests and generated $2 billion in revenue (Sherkow & Scott, 2014).[10] More importantly, Myriad obtained a market monopoly in this field by virtue of the patentright, which limited the research and development (R&D) of the gene by other companies and scientific research institutions.

In 2009, 20 plaintiffs including the Association for Molecular Pathology (AMP) jointly sued Myriad in the Southern District of New York, asking the court to revoke the patent right of BRCA genes owned by the company. The plaintiffs believed that BRCA genes were natural rather than artificial products, and were not patentable. Judge Sweet held that because the gene fragment obtained after isolation and purification is not significantly different from the original material naturally existing in the human body, the BRCA gene patents are invalid and revoked 15 relevant patents of Myriad.[11]

Myriad appealed to the Federal Circuit. Although the Federal Circuit finally upheld Myriad's BRCA gene patents by a 2:1 majority, the three judges actually expressed three different opinions. Judge Lorie believed that the chemical structures of the isolated BRCA genes have some difference with that of naturally existing human genes, and hence are patentable; Judge Moore upheld the patentability of human genes from a political perspective that USPTO has always believed that separation of gene fragments obtained after purification can be granted patent rights, which has formed a relatively stable patent system and business order; by contrast, the opposing Judge Bryson offered a similar explanation with that of Judge Sweet.[12]

Finally, this case goes to the SCOTUS. The Court sorted out two issues:

1. Whether a naturally occurring segment of DNA is patent eligible by virtue of its isolation from the rest of the human genome?
2. Whether the cDNA according with the above mentioned DNA segment is patentable?

The Court quoted 35 U.S.C. § 101 as the general rule of patentable inventions, which stipulates that "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 therefor, subject to the conditions and requirements of this title."[13] The *Mayo* case set up the precedent that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable."[14] Therefore, the Court was to decide whether Myriad's patents belong to "new and useful …composition of matter" under § 101, or they are just natural phenomena.

The Court then analyzed the features of Myriad's claimed patents. As to the isolated BRCA 1 and BRCA 2 genes, the Court decided that Myriad did not create anything of the encoded genetic information, regardless of the extensive effort the company paid. Although Myriad argued that the isolated genes severed chemical bonds and thereby created artificial molecules, none of the patent claims reflected this result. Therefore, the BRCA 1 and BRCA 2 genes isolated by Myriad are not patentable. On the other hand, the Court confirmed the patentability of the cDNA because it is not a "product of nature" and satisfies the requirement of § 101.[15]

This judgment is supported by the mechanism that DNA functions, in which the reverse-translated cDNA only contains the exons of the natural DNA and hence is a human made product. Genes and DNA sequences are special among other natural substances because they bear two characters at the same time: not only chemical compounds, but also

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carriers of genetic information. If the prosecutors focus more on the character of gene as a substance, they are more tend to grant patent protection to it when the isolated gene has certain difference in structure from its natural phase; however, if the informational character of gene is more valued, prosecutors would want to preserve it in the public domain for the sake of human- being and not grant patent. On this point, the Court seems to prefer to treat gene as an information carrier.

Moreover, there is a public policy reason behind the judgment. Before the *Myriad* case, because of the BRCA gene patents, other research institutions were forbidden from developing better genetic prediction and diagnosis technologies without paying Myriad extremely high royalties. At that time, USPTO gave broad patent protection to human genes to protect the leading position of the United States in the gene industry, by which method the prior technical advantages of the American gene industry can be protected to the greatest extent, and the latecomers can be blocked. However, such a system had increasingly shown obstacles to R&D activities and downstream industries. Beginning from the *Myriad* case, the United States has totally converted the attitude towards the patentability of human genes, which especially gives more freedom to the downstream R&D activities of the gene industry. As the Court demonstrated in the last part of the judgment, researchers like Myriad can claim patent protection is there is "an innovative method of manipulating genes" or "new applications of knowledge about the BRCA 1 and BRCA 2 genes."

THE PATENTABILITY OF HUMAN GENES IN CHINA AND IN OTHER JURISDICTIONS

China

Since the 2010 *Guidelines*, China has clearly specified that while naturally existing genes or DNA segments, in its original phase, are non-patentable, the isolated genes or DNA segments can be granted patent protection upon meeting certain requirements.[16] This rule has not been modifies in the following versions of the *Guidelines*.

As stipulated in Part II, Chapter 10, § 9.1.2.2 of the Guideline (2020 modified), a gene found in the nature and existing in its natural phase is a scientific research and thus is not patentable; however, if the gene is "isolated or extracted for the first time from the nature, its base sequence is unknown in the prior art and can be definitely characterized", the gene per se and the process to obtain it are patentable.[17]

Although there is no doubt that isolated human genes are patentable in Chinese law, China provides other rules to regulate such patents. According to Article 5, Paragraph 2 of the Patent Law, "no patent will be granted for an invention based on genetic resources if the access or utilization of the said genetic resources is in violation of any law or administrative regulation." Therefore, prior approval of the relevant administrative departments or the permission of the relevant right holders in accordance with the provisions of the relevant laws and administrative regulations has to be obtained before the acquisition or utilization of genetic resources including genes and other DNA segments.[18] Moreover, the *Guidelines* requires that for patent applications involving inventions of product related to genes per se, the specifications shall include the following contents: product confirmation, product preparation, use and/or effect of the product.[19]

After legal research on the PKULAW database,[20] no judicial decision in China was found to directly deal with the patentability of isolated genes. Because the Chinese patent law system clearly allows the patentability of isolated genes, the prosecutors are used to granting patents to such inventions. On the ZHIHUIYA patent database, 79250 invention patents and

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patent applications in China was searched out to include "gene" in title, and most of them claim the patentability of isolated genes. [21] Some of the examples are: phosphine resistance gene (CN88102798A), pyrimidine analog resistance gene DNA and its application (CN1035129A), cucumber mosaic virus coat protein gene (CN1040823A). Some of these patents date back to before 2010, which shows that China even recognizedthe patentability of isolated genes before the specific the *Guidelines* came into being.[22]

Europe

In addition to global international conventions such as Agreement on Trade- Related Aspects of Intellectual Property Rights (hereinafter as "TRIPs"), the sources of patent law in Europe mainly come from four aspects: (1) EPC, under which the patents granted by the European Patent Office (hereinafter as "EPO") canenter into force in the contracting countries designated by the applicant and are bound by the domestic patent laws of these contracting countries; (2) domestic patent laws of the member countries; (3) the European Patent Package, which aimsto promote the convergence of substantive and procedural patent laws within the EU; and (4) Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (hereinafter as the "*Directive*").[23] These legal sources all recognize the patentability of human genes to some extent.

In 1998, the *Directive* was introduced to regulate biological inventions in Europe, Article 5, Paragraph 2 of which stipulates that "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[24] Although this provision does not explicitly states genes or DNA sequences, they shall be included as elements "isolated from the human body or otherwise producedby means of a technical process."

In 2000, the requirements of patentability specified in Article 52, Paragraph 1of EPC include not only the common features of novelty, inventiveness and utility,but also that the patent application shall be based on a "technical invention".[25] In the Decision T272/95 HOWARD FLOREY INSTITUTE / Relaxin case, EPO granted patent protection on the isolated H2-relaxin gene based on the understanding that the isolated human genes contain technical information because"isolation" is the result of the technical procedures including identifying, purifyingand classification, which can be implemented by humans in a whole set of methodsbut cannot be completed by nature itself.[26]

At the level of national law, the patent laws of France and Germany are morestringent for human gene sequences (Cole, 2015).[27] For example, § 4 of the German Patent Act provides that "where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim." However, scholars argued that for human gene related inventions, European patents are more accessible than national patents, thus national laws like § 4 are no more than symbolic (Ann, 2006).[28]

Japan

Beginning from this century, Japan implement the strategy of "seizing biotechnology patents", in order to change its disadvantages in the biotechnology field and to defeat the monopoly of the United States.[29] Because there is no specific provisions regulating biotechnology products in the Japanese patent laws, anisolated human gene can be granted

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patent protection if it meets general patentability requirements.[30]

Although Article 32 of the Japanese Patent Law provides that "inventions liable to contravene public order, morality or public health shall not be patented", there are very few cases regarding public order or morality or public health raised in Japan (Restaino et al., 2003). [31] However, it is quite frequent for a gene patent application to be challenged of issues related to utility or having industrial applicability.[32]

Australia

IP Australia, the commonwealth agency that oversee all patents in Australia, used to officially state that "a DNA or gene sequence that has been isolated may be patentable" upon satisfying the other statutory rules of patentability, and isolated DNA patents are issued and valid in Australia currently (Mead, 2013).[33] In 2013, before the final procedure of the *Myriad* case in the SCOTUS, the Federal Court of Australia ruled in the *Cancer Voices Australia v. Myriad Genetics Inc.* case that isolated DNA and RNA are patentable because they are "manufactures" under §18(1)(a) of the Australia Patent Act (Vines & Faunce, 2013).[34] However, in 2015, the High Court of Australia finally decided that the patent application of invention satisfying a "manner of manufacture" must not only be a discovery, but also reach certain level of individualization, and Myriad's applications related to BRCA genes are not fully individualized compared to naturally existing genes, because they are the inherent and inevitable results of the according natural genes.[35] Since then, Australia takes a similar attitude with that of the United States in resisting the patentability of merely isolated human genes, although the rationales are different.

India

Although § 3(c) of the Indian Patents Act (1970) prohibits patenting a discovery of a living or non-living thing found in nature, it does not answer the question of the patentability of isolated genes. In the *Monsanto Technology LLC. v.Nuziveedu Seeds Ltd.* case, the Division Bench of the High Court of Delhi held that gene sequences providing genetic traits to genetically modified plants are not patentable subject matter in India, but this decision was set aside by the Apex Court of India due to the complexity of issues, and no concluding remarks were later made by the Supreme Court, which further obscures the Indian position on the matter.[36]

ISSUES AND PROBLEMS REGARDING PATENTABILITY OF HUMAN GENES

As can be seen from the above, the approaches taken by different jurisdictions towards the patentability of human genes can be divided into two distinct categories: either granting patent protection to isolated human genes, subject to general or specific legal requirements of patentability, or resisting patentability of such inventions. Either of the two approached is related to the development stage of the biotechnology industry in the certain jurisdiction, and has its advantages and disadvantages.

Public Policy and Choice of Approach

Whether certain jurisdictions choose to grant patent protection on human genes has a definite relationship with public policy, in particular with the development of scientific research and the biotechnology industry.

Take the reversion of the attitude in the US patent law as an example. Over decades

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before the final judgment of the *Myriad* case, USPTO widely accepted the patentability of isolated human genes. After gaining the leading position in the biotechnology market, US was aware of the shortcoming of such a policy to hinder further application of the genes. Regarding such, the decision of the *Myriad* case shows the change of direction by the United States.

Comparing the attitude of the United States and Australia with the approaches of other jurisdictions like China, Europe and Japan that generally allow the patentability of isolated human genes, it can be seen there is a tendency to grant human gene patent when the jurisdiction want to develop biotechnology and win over other countries in the field. This is the strategy of "pre-emptive patenting", which is acquisition of patents to prevent potential rivals from entering the market.[37]

Nevertheless, just as it is still controversial about the advantages of the patent protection system, it remains to be seen whether granting patent protection or not in fact helps or hinders the development of the biotechnology industry. There are several issues and problems related to each approach.

ISSUES AND PROBLEMS OF THE PATENTABLE APPROACH

Whether Patents Actually Foster R&D

Recital 18 of the Directives states that the rationale underpinning it is that: the patent system provides insufficient incentive for encouraging research into the production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, [and] the Community and the Member States have a duty to respond adequately to this problem.

While in fact, it is questionable whether such regulations actually function as being designed for. Even with this presumption since 1998, investment in the biotechnology industry in Europe has been in decline, and American medical companies are now acquiring ownership or control of European companies (Palombi, 2003).[38]

Further, it remains uncertain whether product patents are even needed to induce the discovery of genes. Studies show that a significant portion of the research of isolated human genes are done in academic and non-profit research institutes, which means that public institutes are capable of successfully undertaking such research (Ghosh, 2012).[39] Besides, even without the protection of product patents, the researchers can still patent processes covering new uses of the genetic sequences as the incentive of R&D activities.[40]

How to Define the Nature of Isolated Human Genes

In the Chinese patent law system, the Guideline defines that "no matter it is a gene or a DNA fragment, it is, in substance, a chemical substance." Similarly, in Europe, while Article 5.1 rules that parts of the human body including the sequence or partial sequence of a gene are non-patentable, Article 5.2 provides that the isolated element including the sequence or partial sequence of a gene are patentable even if the structure of that element is identical to that of a natural element, which also treat isolated human genes as a chemical compound (Calvert & Joly, 2011).[41]

However, it is doubtful whether suitable to categorize isolated human genes as chemical compounds. Unlike a chemical compound, the function of which is specifically related to its structure, the diversity of gene expression means that there is no specific relationship between a gene and its functions in an organism. [42] Especially due to mechanisms like epigenetics, a single gene or DNA segment may produce several different kind of proteins serving different functions. Therefore, the practice of treating isolated genes as

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chemical substances and accordingly grantingpatents lack support.

Conflict with the Requirements of Trips

As Article 27.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter as "TRIPs") provides that "patents shall be available for any inventions", the first criterion before an alleged invention is granted patentprotection is that it shall be an "invention", or in other words, it shall be a patentable subject matter.[43] However, the Regulations to the EPC provides that "an element isolated from the human body …may constitute a patentable invention, even if thestructure of that element is identical to that of a natural element."[44] The Directive also mandates that the patent laws of member countries presume that "biological material" be an "invention". However, the isolation technique and the isolated human gene are two different items, and cannot be mingled as the same subject matter. Treating isolated human genes as patentable "inventions" has the problem of blurring discoveries with inventions, which constitutes a direct violation of Article 27.1 of TRIPs.

ISSUES AND PROBLEMS OF THE NON-PATENTABLE APPROACH

Isolated Genes are not Identical to That of Nature

Jurisdictions that recognize the patentability of isolated human genes focus more on the characteristic of DNA as genetic information carriers. Nonetheless, information-bearing capacity is not the sole important characteristic of isolated human genes. Just as Judge Lorie who supported the patentability of the isolated BRCA genes in the *Myriad* case stated, the structure of the DNA sequence has beenmaterially changed through human intervention, so that it can be better used for applications in therapeutics and diagnostics that native DNA cannot (Schilling, 2011).).[45] Therefore, compared to the claimed invention in the *Funk Brothers* case involving merely a mixture of naturally-occurring bacteria performing the same functions they performed in nature,[46] isolated human genes are more similar to the bacteria in the*Chakrabarty* case which had been altered to enable their use in breaking down crude oil.[47] Thus, it is untenable to decline the patentability of isolated human genes based on the reasons that no new creation exists (the rationale of the United Statesin the *Myriad* case) or not individualized (the rationale of Australia).

Influence on the Granted Valid Patents and Future Patent Drafting

When rejecting Judge Lourie's rationale for the patentability of isolated human DNA based on different structures, SCOTUS pointed out in the opinion that the molecules in the BRCA patents are not claimed in terms of severed covalent bondsand thus are not considered in the trial.[48] This leaves the room for patent drafters to wonder whether the outcome of patentability would be different if the patent claims describe the covalently truncated 5' and 3' terminal structures of the isolated DNA segments (Burk, 2013).[49] Since the draft of patents might greatly influence the result of patent prosecution, this remains a question for jurisdictions which decline patentability of isolated human genes and DNA sequences.

Studies show that among the 72,052 granted US patents (up to 2013) associated with nucleic acid sequences, 8,073 currently in force contain simple nucleic acid molecules with natural sequences that are most likely to be invalidated influenced by the *Myriad* case (Graff et al., 2013).[50] But it is hard to tell the scope of patents that the *Myriad* case would affect as to decide issues including how closely could the claimed sequences match natural sequences; whether single-site mutations or polymorphisms would change the result; how to

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decide when does a sequence become "markedly different" from naturally existing sequences; and what if a variant synthesized in the laboratory today turns out to be identical to a naturally existing sequence that would be discovered at some point in the future?[51] These are all issues that the *Myriad* case fails to resolve.

Influence on the Biotechnology Market

As has been mentioned above, Myriad achieved a market monopoly with the BRCA genes and charged high license fee from other researchers and patients, which became an obstacle to the industry. Studies show that before the final decision of the *Myriad* case, many biomedical giants including top universities raced in obtaining patents related to human genes, but while such patents covered almost 20% of human genes, many patentees did not actively implement the exclusive rights brought by patent rights.[52] Scholars also raised concerns that patentability of human genes would make scientists spend time in gaining more territories in the gene map rather than dig into mechanisms behind genes.[53]

The actual extent of the influence of the *Myriad* case on the biotechnology industry is unknown because there are no studies on the economic benefit of isolated DNA patents compared with cDNA patents.[54] However, giants in this industries like Myriad have been trying to reduce the impact. For example, Myriad has announced to phase out BRCA gene examinations by mid-2015, marketing instead a more comprehensive test panel for 25 genes, which may become a new issue of patentability.

THE CRITERIA OF PATENTABILITY OF GENES IN CHINA

Article 22, Paragraph 1 of the Chinese Patent Law provides that "an inventionor utility model for which a patent is to be granted shall be novel, inventive and practically applicable." Therefore, in order to be granted patent, a claimed patent has to meet the requirements of: (1) novelty, (2) inventiveness, and (3) practical applicability. This standard is also applicable to inventions involving isolated human genes. The *Guidelines* provides further criteria for the prosecution of such inventions.

Novelty

According to Article 22, Paragraph 2 of the Chinese Patent Law, novelty means that the invention is not an existing technology, and prior to the date of application, no application for the identical invention has been filed and recorded after the said date of application.[55] Part II, Chapter 10, 9.4.1 of the *Guidelines* further provides that if a protein itself has novelty, the invention of the gene encoding the protein also has novelty.[56] This provision is generally rough.

Inventiveness

As stipulated by Article 22, Paragraph 3 of the Chinese Patent Law, inventiveness means that, comparing with the technology existing before the date of application, the invention has prominent substantive features and represents a notable progress.[57] The revision of the *Guidelines* in 2021 happens to amend specified provisions regulating the inventiveness of gene inventions:

If the protein encoded by a structural gene has different amino acid sequences and different types of or improved performance compared with the known proteins, and the prior art does not give the technical teaching of the above performance changes caused by the

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sequence difference, the gene invention encoding the protein has inventiveness.

If the amino acid sequence of a protein is known, the invention of the gene encoding the protein does not have inventiveness. If a protein is known and its amino acid sequence is unknown, the genetic invention encoding the protein does not possess inventiveness as long as those skilled in the art can easily determine its amino acid sequence when submitting the application. However, in the above two cases, if the genehas a specific base sequence and has an unexpected effect compared with other genes encoding the protein and having different base sequences, the gene invention has inventiveness.

If the structural gene claimed in an invention is a naturally availablemutated structural gene of a known structural gene, and the structural gene required to be protected is from the same species and has the same properties and functions as the known structural gene, the invention doesnot have inventiveness.[58]

This amendment adds the general criteria for the inventiveness judgment of structural genes, gives the creative situation, and reflects the applicable way of "three-step" test in the inventiveness judgment of structural genes.[59]

In judicial practice, inventiveness is the element challenged mostly for the patentability of inventions related to isolated genes in China. In the *Erasmus University Rotterdam Medical Center v. CNIPA* patent adjudication dispute appeal case, the court decided that those skilled in the art have no motivation to replace "camelized V gene fragments" with "naturally occurring V gene fragments derived from humans" to prepare antibodies only containing heavy chains, and thus the application has inventiveness.[60] And in the Chinese Academy of Agricultural Sciences Institute of Crop Science v. CNIPA patent adjudication dispute appeal case, because the claim 1 "A protein consisting of the amino acid sequence shown in SEQ ID NO: 1" has no inventiveness compared with prior art, the court ruled that the claim 2 "The gene encoding the protein of claim 1" has no inventiveness, either.[61]

Practical Applicability

Practical applicability means that the invention or utility model can be made or used and can produce effective results.[62] In the biotechnology field, the Guideline stipulates that some inventions have no industrial applicability because they cannot be reproduced, and thus are not able to be granted patent protection.

Other Requirements

Human genes are within the scope of genetic resources because they are materials containing hereditary units, hence are subject to provisions regarding the regulation of genetic resources.[63] Article 26, Paragraph 5 of the Chinese Patent Law requires that for an invention based on genetic resources, the applicant shall state the direct source and the original source of the genetic resources in the application documents.[64]

From the above rules, it can be seen that in order to maintain the general key of allowing the patentability of inventions involving isolated human genes, China has established a broadly sound framework based on the national conditions, but the details of the regulation remains to be improved.[65]

THE FUTURE DIRECTION OF THE PATENTABILITY OF ISOLATED HUMAN GENES INCHINA

Given all of the above comparative law analysis and summary of the related present

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Chinese patent regulations, this article holds the opinion that allowing the patentability is the proper measure suitable for the national condition of China, yetthere are several suggestions for the improvement of Chinese gene patent regime.

China Shall Still Recognize the Patentability of Isolated Human Genes

The national conditions of China in the biotechnology field is more similar to the conditions of Europe, compared to that of the United States: China has achieved remarkable progress in the gene technology industry in the past few decades, someleading enterprises like BGI have emerged, and the research of top universities andinstitutes have reached the world-class level; but the biotechnology industry of China in whole is still weak, and some of the key techniques are still in the hands of foreign companies (Ho, 2005).[66] At this stage, allowing to gain some exclusive rights with patents would encourage domestic biomedical researchers and companies to devotemore effort into R&D related to human genes.

Specially, China is a vast country with 56 ethnic groups, which indicate that China has extremely rich genetic resources remaining to be exploited. At the same time, as a developing country, China is facing the "biopiracy" by Western countries,which means taking genetic resources and associated traditional knowledge from biodiverse developing countries without permission, and patenting related inventions, not sharing any of the resulting commercial profits.[67] Granting patentsto domestic researchers is a practical method to protect the abundant genetic resources of China from flowing away.

SUGGESTIONS TO THE IMPROVEMENT OF THE PATENT SYSTEM RELATED TO HUMANGENES

Specify the Prosecution Standards of Gene-Related Patents, Especially the Detailed Requirements of Novelty and Practical Applicability

Although the *Guidelines* includes provisions to regulate the novelty, inventiveness and practical applicability of gene patents, respectively, the contents are far from being specific enough to guide prosecution. For example, the *Guidelines* provides that the novelty of a claimed gene is viewed from the novelty of protein it encodes, but not from the sequence of the gene itself. And the present regulations do not answer the questions like whether a claimed gene has novelty is part of its sequence has been enclosed by prior art before application.[68] As to the inventiveness standard in the Guideline, even after the recent amendment, the criteria still include too many subjective elements and are not easy to handle. Moreover, the *Guidelines* does not provide a direct standard for reviewing the practical applicability of a claimed gene invention.

In order to better serve the principle of recognizing the patentability of isolatedhuman genes, the patent prosecution standards of such inventions need to be specified. Especially important, China could take advantage of the practical applicability criterion to prevent patent applications that are not intended for industrial use but monopoly. In patent prosecution, the applicant could be asked tooffer a practical industrial scheme and examples that can are repeatable.

Provide a Profit Balance between the Researchers and the Genetic Resource Providers

In line with the Convention on Biological Diversity, many countries include benefit-sharing principles of genetic resources in legislation.[69] It remains controversial whether such

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principles should be set down as provisions or left to party autonomy. However, regarding the national conditions of China, providers of genetic resources are usually in the weak position compared to big biomedical companies and institutions, and it is hard to rely on provides like farmers to protect their legal rights by contracts. Therefore, it is reasonable for China to include such provisions in legislation to provide a profit balance between the researchers and the genetic resource providers.

Globally, there has been four gene patent benefit-sharing types: INBio-Merck model, ICBG model, Shaman model, and NCI model.[70] In the INBio-Merck model, Merck pays $1 million US dollars and shares according to the subsequent economic benefits of the patent to the Costa Rica National Institute of Biodiversity in exchange of genetic resources; in the Shaman model, Shaman shares the profits out of the patent with genetic resource providers; and the ICBG model, similar to the NCI model, offers patent license fee and technical training to the genetic resource providers.[71] China should learn from the successful international experience, and choose an appropriate benefit-sharing model for gene patents.

Increase Protection on Human Rights in the Gene Patent System

Article 1009 of the Civil Code of China provides that "medical and scientific research activities concerning human genes and human embryos, among others, shall be carried out according to the laws and administrative regulations, and relevant provisions issued by the state, without endangering human health, violating moral principles, or damaging public interests." This provision is regard as response to the He Jiankui event involving manipulation on the genome of human embryos. In the research on human genes, the protection on human rights should be paid special attention to. To what extent are such studies allowed? How to protect the rights of privacy of the genetic resource providers? What are the legal consequences of violating human rights in gene patent applications? These are all questions remain to be solved.

Set up Restrictions to Human Gene Patents

Human gene patents have a strong connection to the public welfare. Legislation should balance the benefit among patent right holders, following researchers, genetic resource providers and the public. Using the patents to achieve market monopoly should be prevented. Besides, scholars suggest that a mandatory licensing mechanism specifically for genetic inventions be implemented in situations that involve public health and policy (Du, 2018).[72]

CONCLUSION

The debate on the patentability of human genes has continued for decades around the world. Different jurisdictions take distinct approaches towards this issue. In consideration of the monopoly caused by gene patents, the United States finally rejected the patentability of isolated human genes but still recognized the patentability of cDNA in the decision of the *Myriad* case. Australia holds a similar attitude with that of the United States, although the rationales are different. On the opposite, Europe, Japan and China acknowledges isolated human gene patents.

Either approach of this issue has its rationales and problems. At this stage, sticking to allowing isolated gene patents is suitable to the national situations in China. China has included general and specific reviewing criteria for the gene patent applications in legislation, but the provisions are far from detailed enough. This article provides some practical suggestions to improve the patent system of isolated human genes. China should try to balance

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the benefit related to gene patents among parties, provide a better R&D environment for the biomedical industry, andcontribute to the public welfare.

END NOTES

[1] See Georgina Ferry, The Structure of DNA, Nature (Oct. 09, 2019), https://www.nature.com/articles/d41586-019-02554-z.

[2] See DNA Is a Structure That Encodes Biological Information, Scitable by Nature Education, https://www.nature.com/scitable/topicpage/dna-is-a-structure-that-encodes-biological-6493050/ (LAST VISITED June 04, 2022, 2:10 PM).

[3] See What is the "Central Dogma"?, Yourgenome, https://www.yourgenome.org/facts/what-is-the-central-dogma (LAST VISITED June 04, 2022, 3:34 PM).

[4] See cDNA Definition & Meaning, Merriam-Webster, https://www.merriam-webster.com/dictionary/cDNA (LAST VISITED June 05, 2022, 10:02 AM).

[5] See Guidelines for Patent Examination Part II, Chapter 10, § 9.1.2.2, Jan. 2010, modified in Dec. 2020.

[6] See the Convention on the Grant of European Patents, Article 52, Dec. 2007, currently 17th edition, published in Dec. 2020.

[7] See the Implementing Regulations to the Convention on the Grant of European Patents Part II, Chapter V, Rule 29, July 1 2020.

[8] See Assn. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 583 (2013).

[9] See Jolie's Decision Sheds Light on BRCA Gene, Importance of Genetic Counseling, PBS (May 14, 2013), https://www.pbs.org/newshour/health/angelina-jolies-decision-and-the-devastating-brca-gene.

[10] See Sherkow, J. & Scott, C., CASE STUDY: Myriad stands alone, 32 Nat Biotechnol 620, 620 (2014). https://doi.org/10.1038/nbt.2944

[11] See Assn. for Molecular Pathology v. U.S. Pat. and Trademark Off., 702 F. Supp. 2d 181, 222 (S.D.N.Y.2010).

[12] See Assn. for Molecular Pathology v. U.S. Pat. and Trademark Off., 689 F.3d 1303, 1341 (Fed. Cir. 2012).

[13] 35 U.S.C § 101 (2012).

[14] See Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 70 (2012).

[15] See Assn. for Molecular Pathology, 569 U.S. at 595 (2013).

[16] See Guidelines (2020) Part II, Chapter 10, § 9.1.2.2.

[17] Id.

[18] See Guidelines (2020) Part II, Chapter 1, § 3.2.

[19] See Guidelines (2020) Part II, Chapter 10, § 9.2.2.1.

[20] https://pkulaw.com/case/.

[21] Applying the function of advanced search, the search conditions are limited to invention, China, patent or patent application, and gene in title.

[22] See Ou Shaomiao, On the Patent System of the Human Genetic Technology in China, Shantou University, 26 (2021). DOI:10.27295/d.cnki.gstou.2021.000488.

[23] See Zhao Hengyu, the Dilemma and Prospect of Gene Patentability Controversy, 6 Legal System and Economics 64, 67 (2021).

[24] Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, Article 5, Paragraph 2, adopted in 1998.

[25] See Zhao Hengyu, supra note 24, at 68.

[26] See T-272/95 Relaxin/HOWARD FLOREY INSTITUTE. 2002. Decision of European Patent Office Technical Board of Appeal 3.3.4 of 23 October 2002. Available at http://www.epo.org/law-practice/case-law-appeals/pdf/t950272eu2.pdf.

[27] See Paul Cole, Patentability of Genes: A European Union Perspective, 5 Cold Spring Harb Perspect Med 1, 2 (2015).

[28] See Ann C., Patents on human gene sequences in Germany: on bad lawmaking and ways to deal with it, 7 German Law Journal 279, 291 (2006).

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[29] See Yang Zebin, Analysis and Enlightenment of Gene Patentability in China and Abroad, 18 Legal Expo 165, 166 (2018).
[30] Id.
[31] See Restaino L G et al., Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?, 7 UCLA JL & Tech. 1, 12 (2003).
[32] Id.
[33] See Mead K M., Gene patents in Australia: a game theory approach, 22 Pac. Rim L. & Pol'y J. 751, 758 (2013).
[34] See Cancer Voices Australia v. Myriad Inc. [2013] FCA 65, available at: http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/FCA/2013/65.html (LAST VISITED June 8, 2022, 4:20 PM).
[35] See D'Arcy v. Myriad Genetics Inc. [2014] FCAFC 115, available at: http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/FCAFC/2014/115.html?context=1, (LAST VISITED June 8, 2022, 4:34 PM).
[36] See Ankita Sabharwal, The Indian IP office's approach to DNA patenting reveals grey area around gene patents, IAM (Dec.16, 2020), https://www.iam-media.com/article/the-indian-ip-offices-approach-dna- patenting-reveals-grey-area-around-gene-patents.
[37] See Harris C. & Vickers J., Patent races and the persistence of monopoly, 33 The Journal of Industrial Economics 461, 461 (1985).
[38] See Palombi L., Patentable subject matter, TRIPS and the European Biotechnology Directive: Australia and patenting human genes, 26 UNSW LJ 782, 790 (2003).
[39] See Ghosh S., Gene patents: Balancing the Myriad issues concerning the patenting of natural products, 27 Berkeley Tech. LJ 241, 267 (2012).
[40] Id. at 269.
[41] See Calvert J & Joly P B., How did the gene become a chemical compound? The ontology of the gene and the patenting of DNA, 50 Social Science Information 157, 165 (2011).
[42] Id. at 166.
[43] See the Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27.1, effective Jan. 1995, amended in Jan. 2017.
[44] See Palombi L., supra note 38.
[45] See Schilling S H., DNA as patentable subject matter and a narrow framework for addressing the perceived problems caused by gene patents, 61 Duke LJ 731, 753 (2011).
[46] See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948).
[47] See Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).
[48] See Assn. for Molecular Pathology, 569 U.S. at 593 (2013).
[49] See Burk D L, Are human genes patentable?, 44 IIC-International Review of Intellectual Property and Competition Law 747, 749 (2013).
[50] See Graff G D et al., Not quite a myriad of gene patents, 31 Nature biotechnology 404, 406 (2013).
[51] Id.
[52] See Ge Miao, On the Patentability of the Rights of Discovery of Human Genes, 10 Administration and Law 108, 112-13 (2018).
[53] See U.S. Dept. of Health & Human Serv., Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (2010).
[54] See Gostin L O., Who owns human genes? Is DNA patentable?, 310 JAMA 791, 792 (2013).
[55] See Copyright Law of the People's Republic of China Article 22, Paragraph 2, Mar. 1984, amended in Oct. 2020.
[56] See Guidelines (2020) Part II, Chapter 10, § 9.4.1.
[57] See Copyright Law of the People's Republic of China (2020) Article 22, Paragraph 3.
[58] Guidelines (2020) Part II, Chapter 10, § 9.4.2.1.
[59] See Interpretation of the Amendment of Part II, Chapter 10 of the Guidelines for Patent Examination, CNIPA, https://www.cnipa.gov.cn/art/2021/1/11/art_66_156156.html (LAST VISITED June 10, 2022 3:27 PM).
[60] See Final Decision of Second Instance, No. (2019) Zui gao fa zhi xing zhong No. 127, dated Dec. 6, 2019.
[61] See Copyright Law of the People's Republic of China (2020) Article 22, Paragraph 4.

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[62] Article 26 of the Detailed Rules for the Implementation of the Patent Law of the People's Republic of China (2010 Revision): The term "generic resources" as mentioned in the Patent Law refers to the substances which are taken from human bodies, animals, plants or microorganisms, which contain hereditary units and have actual or potential values.

[63] See Copyright Law of the People's Republic of China (2020) Article 26, Paragraph 5.

[64] See Ming Yang, the Comparative Research of Gene's Patentability, Shandong University, 33 (2020). DOI:10.27272/d.cnki.gshdu.2020.004291.

[65] Id.

[66] See Ho, Cynthia M., Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies, 39 U. Mich. J. L. Reform 433, 435 (2006).

[67] See Yi Haoran, Research on Patentability and Benefit Balance of Human Genes, North China University of Technology, 33 (2019).

[68] See Wu Yanling, Gene Patentability Research, Chongqing University, 23 (2015).

[69] See Jin Qingwei, Research on Benefit-sharing System of Gene Patents, 16 J Southeast University (Philosophy and Social Science) 27, 29 (2014).

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[71] Civil Code of the People's Republic of China, Article 1009, May 2020.

[72] See Du Li, Patenting human genes: Chinese academic articles' portrayal of gene patents, 19 BMC medical ethics 1, 5 (2018).

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