

On the Patentability of Human Genes: Based on the Principle of Equal and Shared Benefits

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Received 21 April 2024; accepted 1 June 2024
Published online 26 June 2024

Abstract

In the Myriad case, the US Supreme Court considered the BRAC gene to be a “natural product”, thereby denying its patentability, but in reality, it did not resolve the debate over whether the gene was “discovered” or “invented”. To avoid such unnecessary debates, the recognition of human gene patents should not blindly adhere to the traditional recognition model of patent objects. It should be examined from the perspective of the purpose of the patent system and balancing the interests of all parties, avoiding the excessive cutting of basic knowledge by immature knowledge, and reasonably limiting the scope of gene patent objects.

Key words: Gene patent rights; Discovery; Invention; Equal and shared benefits

Wang, X. L. (2024). On the Patentability of Human Genes: Based on the Principle of Equal and Shared Benefits. *Canadian Social Science*, 20(3), 54-60. Available from: <http://www.cscanada.net/index.php/css/article/view/13453>
DOI: <http://dx.doi.org/10.3968/13453>

In recent years, biotechnology has rapidly advanced, particularly in molecular biology and bioinformatics. This has significantly contributed to the analysis of the human genome sequence and the development of tests, treatments, and vaccines tailored to specific diseases. However, the key to developing these commercially valuable tests, vaccines, and drugs often lies in understanding the functions of specific gene sequences. Many biopharmaceutical companies are investing heavily in researching the relationship

between specific genes and diseases, while also vying to patent their discoveries. This has led to the question of whether certain human genes with specific sequences or functions can be validly patented. There has always been a common understanding in the patent field that DNA fragments of specific sequences isolated from nature are valid patent subject matter. Prior to the Myriad case, the US Patent and Trademark Office and courts never questioned this principle. The EU's 1998 Legal Protection Directive on Biotechnology Inventions also confirmed this understanding, as did China's Patent Examination Guidelines. However, why did the U.S. Supreme Court reverse its previous decisions? Were human genes discovered or invented? If they were invented and granted patent rights, how can the interests of all parties be balanced?

1. THE BEGINNING AND END OF THE MYRIAD GENE PATENT CASE IN THE UNITED STATES

Myriad discovered the precise location and nucleotide sequence of the BRAC gene, and developed a reagent that can detect cancer risk based on the nucleotide sequence of the BRAC gene. The company immediately applied for and obtained a large number of patents around these findings. Afterwards, the company quickly gained a market monopoly based on the aforementioned patents and gained huge profits, but at the same time, it also resulted in many patients not being able to enjoy the company's research and development achievements, leading to delays in treatment. Later, several American medical associations and breast cancer patients as co plaintiffs sued the United States Patent and Trademark Office and Myriad Corporation to the District Court of New York State, claiming that the patent application violated Article 101 of the United States Patent Law,

requesting the court to declare the patent invalid. In detail, the plaintiff claims that the BRAC gene has always existed in humans and nature, Myriad just discovered the association between BRAC gene and breast cancer, and did not invent or create BRAC gene. Therefore, the contested patent is a collection of natural products, natural discoveries, natural laws and human basic knowledge, which does not comply with the provisions of Article 101 of the United States Patent Law on qualified objects of patents. The New York State Court also held that, Myriad Company applied for a patent for a gene that belongs to natural products and made a judgment in favor of the plaintiff based on this. The defendant Myriad Company is dissatisfied and has filed an appeal. The second instance judgment determined that the isolated gene sequence has a unique chemical structure and is significantly different from natural gene sequences. Therefore, the DNA isolated by Myriad Company is a qualified object protected by Section 101 of the United States Patent Law. In 2012, the Public Patent Foundation and the Civil Liberties Union of the United States requested an appeal order from the Supreme Court, which held that, Myriad only discovered the specific location and nucleotide sequence of the BRAC gene, which constitutes the discovery of natural products and has not invented or created any new products, and is a non patentable subject under Section 101 of the United States Patent Law; The subject matter for requesting patent protection must be novel and have distinctive features distinct from natural products (new with marketing differences from any found in nature), not a “discovery” of an inappropriate subject matter, but an “invention” of an appropriate subject matter. Nucleic acids such as cDNA that are not naturally present or have a natural sequence change are still patentable, because cDNA is reverse transcribed from mRNA carrying complete information about synthetic proteins by reverse transcriptase, containing only exons and introns that have been removed by experimenters. It is an artificially synthesized single stranded DNA, clearly an artificial product. After three trials, it is not difficult to find that the focus of controversy in this case is whether the BRAC gene applied by Myriad company differs from natural products? Is gene “discovered” or “invented”?

2. IS GENE “DISCOVERED” OR “INVENTED”

As mentioned above, the District Court of New York in the United States holds a negative view, stating that genes are only discoveries, not inventions, and should not be granted patents. However, what is the fundamental difference between discovery and invention? No one seems to be able to explain it clearly. For example, did Edison invent the light bulb or simply discovered materials suitable for heating and emitting light with electric

current? Essentially, it is not easy to distinguish. The reason behind this is that the boundary between invention and discovery lacks its own character and is deeply driven by commercial interests. We firmly believe that industrial policies have a profound impact on intellectual property, especially the patent system, but industrial policy is not a law after all, and we still need to focus on distinguishing the principles of invention and discovery to examine the eligibility of the object of patent rights. The concepts of “discovery” and “invention” are easily distinguishable in intuitive experience, but extremely difficult to operate in legal rules. On the one hand, before separation and extraction, genes had never existed independently from the natural environment, which seems to be an invention; On the other hand, even if genes are detached from the natural environment, the genetic information contained within them remains unchanged, making it seem like a discovery. Every year, China receives a large number of patent applications for natural products that involve separation or purification, such as microorganisms, proteins, traditional Chinese medicine extracts, genes, etc, entering the United States. However, based on the considerations and examples provided in the new USPTO guidelines, if only microorganisms, proteins, genes, and even compounds are isolated from nature, they are likely to be considered as not significantly different from natural products and therefore unsuitable. In 1959, the Australian Supreme Court also lamented in the NDRC case that there was not a clear enough distinction between “discovery” and “invention”, which was always full of misunderstandings. [See National Research Development Corporation (NRDC) v. Commissioner of Patents (1959) 102 CLR 252.] It can be seen how elusive the concepts of “discovery” and “invention” are.

Moderators believe that in order to avoid unnecessary disputes, the law should downplay the difference between “discovery” and “invention”. However, the author believes that this kind of compromise not only does not resolve disputes but also widens differences: first of all, to what extent does it “dilute”? Unable to provide patent applicants and the general public with a clear legal expectation; Secondly, how can administrative and judicial agencies achieve synchronization in “dilution”? Therefore, attempting to dilute the compromise between “discovery” and “invention” is not advisable. However, there are still many scholars who need to draw a clear line between “discovery” and “invention” of genes. Some people believe that researchers need to invest a lot of time, manpower, and funds to discover gene sequences. However, genes are still just the discovery of natural materials, not man-made creations. Therefore, their contributions should be recognized academically, and patents should not be granted. In the past, technological means were low and technological costs were high. However, under modern science and technology, the cost

of “discovery” has become very low, and “discovery” is no longer an accidental event, especially in the field of biotechnology, continuing to adopt extreme measures to make “discovery” the object of patent rights will only lead to the proliferation of patents, thereby seriously hindering subsequent technological innovation. Scholars who hold opposing views believe that the separated DNA is separated from the surrounding histones, and the covalent bonds between the two have been broken. At the same time, the separated and purified DNA does not exist in its natural state and is a non-natural product, representing a new and different chemical molecular entity, which is the result of human intelligent labor. Some scholars in Taiwan argue that rather than debating the distinction between discovery and invention, it is more prudent to return to the essence of patents and consider that patents are a property rights system centered on technology, aimed at fostering technological innovation and allowing the public to reap the benefits of new technologies. Therefore, adjustments to the application of patent laws should be made in line with societal conditions and technological advancements whenever they contribute to the goal of encouraging technological innovation. The author concurs with this view that there should not be excessive distinctions between “discovery” and “invention” when it comes to genes. From the historical development of genetic technology, research on genes entails substantial costs and involves a high degree of uncertainty. However, once groundbreaking achievements are made, they yield qualitative leaps for both the biological community and the biotechnology industry, and provide significant benefits to human welfare in terms of life, health, and well-being. From this perspective, it is inadvisable to deny genes as patentable subject matter solely on moralistic grounds such as “life should not be patented”.

3. GRANTING GENETIC PATENTS SHOULD FOLLOW THE PRINCIPLE OF EQUAL AND SHARED BENEFITS

3.1 Application of the principle of equal and shared benefits

Unlike most parties involved in patent invalidation cases, The plaintiff in the Myriad case includes scientists and scientific groups, patients and groups, involving multiple interests. Scientists advocate freedom of scientific research, while patients advocate the right to enjoy technological progress, which are the core contents of the Universal Declaration of Human Rights, which emphasizes the sharing of benefits from scientific progress and its applications. In 2007, In the article “Intellectual Property and bioethics”, WIPO establishes “equal sharing of interests” as one of the four basic principles for coordinating intellectual property and bioethics, along

with informed consent, information disclosure, and the coordination of diverse value systems.

However, the ethical principle of equal sharing of interests seems to be at odds with the monopolistic nature of patented technology, particularly in the field of biotechnology closely related to human life and health. Although the judges in the Myriad case were all arguing about whether genes are natural products, the case goes beyond the legal scope and fully demonstrates the intense interest game triggered by gene patents.

The purpose of the patent system is to balance public and private interests. Overly and widely recognizing gene sequences and detection technologies as patent subjects will hinder other research institutions that wish to engage in related gene testing or treatment methods, slow down the overall development of gene related technologies in society, and go against the purpose of patent law to promote technological innovation. However, it is worth noting that with EST The maturity of technology seems to have made gene sequencing an effortless task. Researchers sometimes submit hundreds of EST patent applications, and applicants are not sure about the role of these ESTs. They usually search for protein and DNA data to guess the biological functions of these gene fragments. The reason for patent applications for these unknown DNA sequences is that they can be used as research tools, but it is also this reason that leads to the proliferation of gene patents, The owner of the EST sequence can demand that researchers who use this tool pay patent fees, and even any gene sequence containing the EST sequence becomes part of their patent scope, forcing more people to pay patent fees. Many genetic testing technologies are granted patents, which rapidly increases the research costs for researchers, this greatly hinders the progress of genetic technology and infringes upon the rights of patients who rely on relevant genetic testing and treatment technologies to survive. From the perspective of public property, human genes have a public nature and do not belong exclusively to anyone. They are similar to resources shared by other humans, such as the ocean and atmosphere. If human genes are patented, it will limit the public’s right to free medical treatment, thereby making it impossible for the public to receive sufficient medical treatment. Professor Dominic Frey of the Federal Institute of Technology in Lausanne calls this situation a “tragedy of anti-communist property”. He believes that anti communist property is a block of private property that the law carves out from indivisible property. In this way, the owners of each piece or block of property can exclude others from accessing their own piece or block of property, so no one can use it in its entirety. Due to the fragmentation of knowledge, patent rights cannot be applied in industry, causing endless obstacles. In other words, when countries begin to tolerate immature knowledge as the object of patent applications, it will lead to all researchers competing

to apply for patents with immature knowledge in order to quickly separate their own fragments or blocks from the property. In this way, the patent system is used to encourage technological innovation, and the essence of enjoying the benefits brought by new technologies in society is no longer present. The United States Supreme Court in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, it was also pointed out that because natural laws are the foundation of all scientific research and technological progress, the granting of patents should not limit anyone's future application of natural laws, otherwise it will have a negative impact on the overall technological innovation of society. If *Prometheus Laboratories* is allowed to obtain patents in this case, it will improperly limit the progress of future diagnostic methods and scientific research. The two precedents of the *Myriad* and *Mayo* cases in the United States in the same year were like a combination punch in boxing, breaking down a monopoly restriction in genome research and commercial development. This is a rare reshuffle for the global biotechnology field, undoubtedly bringing them opportunities to rise later.

Scholars from other regions advocate that human genes are the "common heritage of humanity" and that no individual should have the exclusive or exclusive right to claim them. This viewpoint is obviously not conducive to the development of genetic technology. Genes are indeed the "common heritage of mankind", but denying the right to genes based on this may be very far-fetched, because no organization or institution can exercise such a right on behalf of humanity. If the benefits generated by genetic research can be appropriately distributed, granting genetic patent rights to applicants does not violate the principle of "common heritage of mankind". If the right to genes is denied based on this principle, it is suspected of choking on food. As for the patents involved in the *Myriad* case, some scholars are concerned that denying their patent eligibility may reduce the incentive for the biotechnology industry to invest in related technologies. However, due to the strong market monopoly power granted to patent holders, if the scope of rights is too broad, it will also have a negative impact on the subsequent innovation of related technologies. After careful study of the scope of the *Myriad* patent application, it is not difficult to find that it includes many types of subsequent innovations. Although the patent only lists a few application methods, the patent application essentially excludes any possible use of the gene and its sequence by others. In other words, the scope of the disputed patent claim has exceeded the original invention (or discovery) scope of *Myriad Company*, which will inevitably hinder subsequent related genetic research and limit the possibility of subsequent related inventions.

The author also believes that whether genes themselves can be granted patents should not be examined solely from the perspective of whether the subject matter of the patent

application is suitable, but should be examined from the perspective of the purpose of the patent system and balancing the interests of all parties, in order to reasonably limit the scope of patent rights and avoid immature knowledge excessively cutting basic knowledge, causing obstacles to anti common property. At the same time, patent applicants should also re-examine the value of the patent itself, not only exclusive value, but also from the perspective of cooperative value, in order to jointly create social wealth. Firstly, in terms of whether a disputed invention is a natural product, the court must have a clear understanding of the scientific nature of the disputed invention and the structure and function of generally naturally generated substances or organizations before determining whether it is a natural product; Secondly, the eligibility of the patent object must be closely linked to the institutional purpose of promoting technological innovation in patent law; Finally, balance the interests of gene providers, researchers, and the general public. We cannot simply focus on the public interest and deny the discovery or invention of genes, because in the absence of patent protection, biotechnology companies lack innovation motivation, and the interests of scientists and patients cannot be harmed. The conflict of interests in the field of patents cannot be eliminated. Finding a balance of interests among all parties is necessary to better implement the principle of "equal sharing of interests". The reason why *Myriad Company* has become a target of criticism from all parties is because it still starts from the perspective of exclusive value thinking, does not consider cooperative value, and disregards the public interest. The handling of this case by the United States Supreme Court also demonstrated the art of balance. From the ruling results, it is evident that the judges believe that the interests of scientists and patients have been more severely damaged, so they made a ruling against *Myriad*. However, it completely negates the patentability of human DNA and would cause a devastating blow to the biotechnology industry, posing a threat to the national economy and even security. Therefore, the court affirmed the patentability of cDNA. Patent applicants should take this as a lesson and construct new thinking on patent rights from the perspective of cooperative value. Patent authorities and legislation should also intervene appropriately to avoid the abuse of patent rights, establish a system that is in line with the public interest and can moderately protect patent holders.

3.2 Restriction of the Object Scope of Gene Patents

The purpose of the patent system is to balance public and private interests. Overly and widely recognizing gene sequences and detection technologies as patent subjects will hinder other research institutions that wish to engage in related gene testing or treatment methods, slow down

the overall development of gene related technologies in society, and go against the purpose of patent law to promote technological innovation. However, it is worth noting that with the maturity of EST technology, which involves extracting mRNA from cells, using random primers for reverse transcription polymerase chain reaction, and cutting with appropriate restriction enzymes, cDNA reproduction is carried out. Then, automatic sequencing technology is used to sequence the 3' or 5' end of the propagated plants to obtain EST sequences and quickly find complete genes on chromosomes. Gene sequencing seems to have become an effortless task. Researchers sometimes submit hundreds of EST patent applications, and applicants are not sure about the role of these ESTs. They usually search for protein and DNA data to guess the biological functions of these gene fragments. The reason for patent applications for these unknown DNA sequences is that they can be used as research tools, but it is also this reason that leads to the proliferation of gene patents. The owner of the EST sequence can demand that researchers who use this tool pay patent fees, and even that gene sequences containing the EST sequence become part of their patent scope, forcing more people to pay patent fees. Many genetic testing technologies are granted patents, which rapidly increases the research costs of researchers, greatly hindering the progress of genetic technology and infringing on the rights of patients who rely on related genetic testing and treatment technologies to survive. From the perspective of public property, human genes have a public nature and do not belong exclusively to anyone. They are similar to resources shared by other humans, such as the ocean and atmosphere. If human genes are patented, it will limit the public's right to free medical treatment, thereby making it impossible for the public to receive sufficient medical treatment. Professor Dominic Frey of the Federal Institute of Technology in Lausanne calls this situation a "tragedy of anti-communist property". He believes that anti-communist property is a block of private property that the law carves out from indivisible property. In this way, the owners of each piece or block of property can exclude others from accessing their own piece or block of property, so no one can use it in its entirety. Due to the fragmentation of knowledge, patent rights cannot be applied in industry, causing endless obstacles. In other words, when countries begin to tolerate immature knowledge as the object of patent applications, it will lead to all researchers competing to apply for patents with immature knowledge in order to quickly separate their own fragments or blocks from the property. In this way, the patent system is used to encourage technological innovation, and the essence of enjoying the benefits brought by new technologies in society is no longer present. The United States Supreme Court in *Prometheus Laboratories, Inc. v.*

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As for the patents involved in the *Myriad* case, some scholars are concerned that denying their patent eligibility may reduce the incentive for the biotechnology industry to invest in related technologies. However, due to the strong market monopoly power granted to patent holders, if the scope of rights is too broad, it will also have a negative impact on the subsequent innovation of related technologies. After careful study of the scope of the *Myriad* patent application, it is not difficult to find that it can almost encompass many types of subsequent innovations. Although the patent only lists a few application methods, the patent application essentially excludes any possible use of the gene and its sequence by others. In other words, the scope of the disputed patent claim has exceeded the original invention (or discovery) scope of *Myriad Company*, which will inevitably hinder subsequent related genetic research and limit the possibility of subsequent related inventions.

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researchers, and the general public. We cannot simply focus on the public interest and deny the discovery or invention of genes, because in the absence of patent protection, biotechnology companies lack innovation motivation, and the interests of scientists and patients cannot be harmed. The conflict of interests in the field of patents cannot be eliminated. Finding a balance of interests among all parties is necessary to better implement the principle of “equal sharing of interests”. The reason why Myriad Company has become a target of criticism from all parties is because it still starts from the perspective of exclusive value thinking, does not consider cooperative value, and disregards the public interest. The handling of this case by the United States Supreme Court also demonstrated the art of balance. From the verdict, it is evident that the judges believe that the interests of scientists and patients have been more severely damaged, so they have made a ruling against Myriad. However, it completely denies the patentability of human DNA and will cause a devastating blow to the biotechnology industry, posing a threat to the national economy and even security, so the court affirmed the patentability of cDNA.

4. CHINA'S EXPECTED POSITION ON HUMAN GENE PATENTS

Regarding the patent right for human genes, China has responded in Section 2.1 of Chapter 10 of Part 2 of the Patent Examination Guidelines: Genes or DNA fragments found in natural form by humans belong to the “scientific discovery” stipulated in Article 25 (1) (1) of the Patent Law and cannot be the object of the patent right. However, if a gene is first isolated or extracted from nature and its base sequence is not recorded and has industrial value, the gene or DNA fragment can be granted a patent right. It can be seen that China, like most developed countries, holds an open attitude towards gene patent rights. But the question is, China's overall level of genetic technology lags behind developed countries. Is it inappropriate to adopt more aggressive legislation just because biotechnology is developing rapidly? For example, The EST sequence, as an instrumental gene sequence in the upstream of biotechnology, is widely used in cloning, gene recognition, sequencing, and expression analysis, fully complying with the standards of gene patent eligibility objects in the Chinese Patent Examination Guidelines. However, with the maturity of EST technology, researchers have sometimes filed hundreds of EST patent applications because they can serve as research tools. However, this reason can also easily lead to the proliferation of gene patents. As long as other researchers use gene sequences containing EST sequences, they will have to pay high patent usage fees to the former, greatly increasing the cost of downstream

genetic technology innovation. Therefore, granting EST gene sequences monopolizes the downstream biotechnology industry and seriously hinders the long-term development of biotechnology. However, the scope of gene patent objects stipulated in China's Patent Examination Guidelines is relatively general and broad, and there is no clear exclusion of instrumental genes such as EST sequences, which is very detrimental to the long-term development of China's biotechnology industry. Such instrumental genes should be responded to and excluded from the scope of patent eligibility.

Given that the scope of gene patent objects stipulated in China's Patent Examination Guidelines is too general and broad, this more radical legislation can easily lead to a large influx of foreign biotechnology companies to apply for gene patents in China, thereby monopolizing the downstream biotechnology industry, which is not conducive to the long-term development of China's biotechnology. Therefore, in the early stage of the flourishing development of biotechnology in China, with the legislative purpose of encouraging innovation, the first consideration should be whether the patent object is qualified and closely combined with the institutional purpose of promoting technological innovation in patent law; Secondly, attention should be paid to comprehensively considering the interests of patent developers and the general public, and finding a balance of interests among all parties. Based on the above two points, China should not currently choose the legislative model of Article 101 of the United States Patent Law, as the generalization of gene patents damages public interests, nor should it choose the legislative model of Article 611-17 of the French Intellectual Property Code, which completely negates gene patents. Instead, it should choose the legislative model of the Swiss Patent Law, which limits the scope of the object of gene patents and further limits the scope of the object of gene patents in the Patent Examination Guidelines, excluding instrumental genes such as EST sequences from the object of gene patents. Secondly, the system of granting back licenses should be added in the form of mandatory provisions in the Patent Law. The so-called backlicensing refers to allowing gene providers to use a gene patent free of charge after the developer obtains it. At the same time, the licensor cannot re license it, and gene providers can conduct subsequent research and development and apply for a patent based on the patent. Finally, in patent examination, attention should be paid to avoiding the distinction between “invention” and “discovery”, focusing on the three requirements of the patent, namely novelty, creativity, and practicality. At the same time, to avoid a large influx of foreign biotechnology companies applying for gene patents in China, the examination standards for practicality should be moderately strict.

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