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Gene patent: can genes be patentable?

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Abstract

Biotechnology research results in new inventions, new methods and innovative tools for sustainable development of food, agriculture and healthcare. These new inventions can be protected through patent rights. However, field of biotechnology throws up newer challenges for the repertoire of patent law, as the clear difference between the patentable inventions and the not patent eligible subject matter is difficult to identify. Recently, an important court case in US, involving human gene patent wherein the court ruled that 'synthetic DNA' sequences are different from their natural counterpart and can be patentable but the natural DNA is not patentable, can have a significant impact on future of gene based research.

Key words: Gene patent, gDNA & cDNA, Myriad Genetics Case, invention, patentability

Introduction

Biotechnology 'is the integration of natural sciences and engineering in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services'(1). Modern biotechnology has envisioned newer horizons of development and applications. It has pervaded into nearly all the major fields of human endeavour and has significant effect on medicine, food, agriculture, energy and protection of the environment (2).

A patent is an exclusive right provided to an inventor, to create a monopoly by excluding all others from creating, producing, selling or importing the invention for a limited period of time. Patents are generally granted for invention that is either a product or process and that should be new involving an inventive step, and capable of industrial application.

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Patent system and biotechnological inventions

The scope of patent system has been expanded to accommodate fast evolving arena of biotechnology. However, modern biotechnology poses greatest challenge for patent regime where a clear distinction between patentable inventions and unpatentable discoveries is difficult to identify. The core substance for biotechnological invention is living material which is the 'product of nature'. According to patent law of most countries, 'products of nature' are not patent eligible subject matter.

In US, a gene patent can be granted for a claim on an isolated nucleic acid that is a fragment of DNA or RNA sequence, or gene chips and microarrays, or diagnostic kit tests or for a method of diagnosing a genetic condition, or a method of identifying the existence of a specific DNA or RNA sequence in an individual. Isolated nucleic acid includes both coding and non-coding DNA (2). Human gene takes the shape of "DNA double helix." Each strand in the helix composed of chains of nucleotides. These nucleotide sequences contain the information necessary to synthesize

amino acid chains – the protein molecule. Now, the nucleotides that code for proteins are known as "exons," and those that do not are known as "introns." Specific DNA segments from mammalian cell can be isolated, that is the genomic DNA (gDNA) containing both exon and intron. gDNA is the product of nature, not patent-eligible subject matter under section 101 of the US Patent Act. On the other hand, we can synthetically create exons-only strands known as composite DNA (cDNA). Patents have been granted for a part or complete gene sequence responsible for a predisposition to a genetic disorder.

According to a 2007 study, nearly 20% of human genes are explicitly claimed in some way in US patents (3). This represents 4,382 of the 23,688 of genes in the NCBI's gene database have been patented. Similarly a large proportion of the human genome is the subject of patent claims at EPO.

Serious debate on human gene patenting has been raised in legal, political, health, and philosophical circles. Patents on human genes will result in a lack of respect for human life and a devaluation of human dignity. It would restrict free flow of scientific information (4).

Arguments for gene ownership are that, patent protection is critical for investment in biotech sector. These investments in turn translate into more research and health care benefits.

However, an important case started in 2009 has questioned the practice of gene patents that has serious practical, clinical and ethical consequences for the future of gene-patents. Let's understand the gene patent issue in the light of Myriad Genetics and BRCA gene case.

The Myriad Genetics Case

Myriad Genetics, a US company was granted patents for two human genes: *BRCA1* (5) on chromosome number 17 and *BRCA2* (6) on chromosome number 13, two genes predisposing to breast and ovarian cancers, were isolated in 1994 and 1995, respectively. Mutations, in particular those arising at a young age in these two genes cause serious disruption to the open reading frame of the transcriptional unit and are linked to an increased risk of breast and ovarian cancer. Women with specific genetic mutations in these two genes are estimated to have up to an 85 percent risk for breast cancer and 50 percent risk for ovarian cancer. The patent legally entitled Myriad Genetics for the life of the patent to exclude all others from using these genes in breast & ovarian cancer research, diagnostics, and further treatment (2, 7).

In May 2009, the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) filed a lawsuit in the Federal District Court for seeking to overturn the Myriad Genetics patents on *BRCA1* and *BRCA2*. The suit charges that the patents stifle diagnostic testing and research that could lead to cures and that they limit women's options regarding their medical care.

The lawsuit was filed on behalf of researchers, genetic counsellors' women patients, cancer survivors, breast cancer and women's health groups, and scientists (the plaintiffs). The lawsuit was filed against the U.S. Patent and Trademark Office, as well as Myriad Genetics and the University of Utah Research Foundation, which hold the patents on the genes, *BRCA1* and *BRCA2* (8). The lawsuit charges that patents on human genes violate the First Amendment and patent law because genes are "products of nature" and therefore can't be patented.

The historic court case of *Association for Molecular Pathology v. Myriad Genetics* has finally come to an end on 13th June 2013. The United States Supreme Court has unanimously ruled that naturally occurring isolated human genes cannot be patented, but that a synthetic DNA sequence, known as complimentary DNAs (cDNA)—are eligible for protection. The court ruled that cDNA or 'synthetic DNA' sequences are different from their natural counterpart, and can be patentable.

The court ruling is a huge relief for scientist and also having an open access to the genome could result in increased competition, development of newer technologies and more cost effective of kits.

Myriad Genetics and future of personalized medicine

Many gene patents have been granted world over and many of these patents claim gene sequences. Those investigating genetic testing should thoroughly analyse the patent landscape of that particular chromosomal unit to understand the scope of freedom to operate. Gene patents, unlike patents in most other technical areas, are difficult to invent around (4). Even if it is possible to invent around a gene patent, it may be very costly and time consuming to do so.

Also, for a complex genetic disorder many have different mutations in many different genes that are required to be tested. The transaction costs of investigating the patent landscape, including identifying relevant patents, determining whether the investigation in question falls within the claims, and then negotiating necessary licences, or defending infringement proceedings, becomes too expensive (2).

In Myriad genetics case, Chris Hansen, staff attorney of

of the ACLU said, “It’s wrong to think that something as naturally occurring as DNA can be patented by a single company that limits scientific research and the free exchange of ideas”. It creates a difficult situation, if a single laboratory could use its patents to control most of the data about a gene especially when that gene affects life of many.

The discovery and development of pioneering diagnostics and therapeutics require a huge investment and patents provide access to commercial funding in the absence of institutional, charitable or government support. But broad claims on gene patents could have a damaging effect on the conversion of basic biomedical research into clinical application.

David Koepsell, author of ‘Who Owns You: The Corporate Gold Rush to Patent Your Genes’, discusses practice of gene patenting and develops arguments regarding moral realism. He states biotech companies and corporations should compete with the actual values of their products (9).

Conclusion

Biotechnology companies, universities, and laboratories, could develop and patent new tests, therapies, diagnostic methods, methods of isolating genes, drugs, and other inventions based on genetic information and sequencing but broad claims on gene pose serious concerns (2).

Myriad genetics case could have broad practical, medical and ethical consequences for the future of personalized gene-based medicine for millions of people worldwide. This decision can have a telling impact on biotech research. The court ruling draws a delicate balance between incentives to develop new technologies for companies and guarding the interest of scientists with open access to the genome. This decision favoured those eagerly waiting for personalized, gene-based approaches to medical care.

Finally, there are several unanswered questions, such as how the ‘product of nature’ doctrine would be applicable to substance like, purified gDNA that has been altered in some other way, other isolated natural substance like proteins, cell lines etc. (2). It appears gene patents in biotechnology arena will be decided on a case by case basis.

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