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ISOLATED GENE PATENTING: ETHICAL IMPLICATIONS OR FUTURE PROMISES, LOOKING AHEAD

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ABSTRACT

The issue of gene patenting has taken the centre stage of growing international community concern towards the recent decisions of the Supreme Court of the United States on *Association for Molecular Pathology v. Myriad Genetics* in context to the patentability of isolated genetic material and its analogues. Gene patenting including human gene and the intervened gene products which are biological in nature and is a part of many technologies, treatments, diagnostics, drugs, treatments etc, and the IP protection which provides them exclusive right and the reward for their intense contribution of technology to society, it also make the unavailability and more hindrances to the patients for getting maximum commercial benefits. These all are associated with the policies made by the concerned governing nation which considers the gene mere a chemical substance, a biological tool or a nature product. This paper extensively studies the world scenario on the nation specific IP policy overview and implications in the various spectrum of novelty criteria, biogenetic healthcare services, dissemination of research and innovations, concerns regarding the limitations on access to genetic testing to different economic strata, to address the broad area of gene patenting and their analogues as inclusive of cDNA, recombinant DNA etc.

Keywords: Gene Patenting, IP Protection, Novelty Criteria, Analogues, Isolated Genetic Material, Biogenetic Health Care Services.

1. INTRODUCTION

Gene Patenting is a broader term that does include natural genes as well as their analogue which may be termed as cDNA, recombinant DNA etc. Natural DNA or naturally

occurring, mere extracted and purified DNA, can be considered as a discovery but that also included various steps as well as methods for the extraction, annotate, sequentially analyze DNA. Patent implication on DNA can be understood if DNA is considered as a chemical substance. In that case, it can be stated that process, method, product generated, of the natural DNA, a chemical, can be patentable and the modified version that form by various recombinant techniques, gives novel DNA sequence, can be patentable.[1]

But, DNA is simply not a chemical substance, it also possess physical and moreover biological and hereditary importance. Every person contains a unique DNA and thus universally get the "exclusive right" for its ownership.[7]CDNA or recombinant DNA, which are produced by the human intervention and the biological skills can be a subject matter of patentability as it does contain novelty .

2. WORLD SCENARIO ABOUT GENE PATENTING

2.1 US SCENARIO ABOUT GENE PATENTING

US as far as concern is the most liable IP protection nation with," everything under sun can be patentable". This scenario was well implicated in the US and makes the domestic US industry a profitable economy booster and biotech industry flourish and lived a successful era with milestone achievements including Human Genome Project, RNA related medicines , genetic testing , mapping and the individual molecular level diagnostics. But then the Supreme Court judgment prohibits the natural DNA to be patentable considering it to be the "product of nature" and associated with a human. But does allow the cDNA and recombinant DNA to be patentable and also the products associated with.[2]

Association of Molecular Pathology (AMP) v. *Myriad Genetics*
On 13 June 2013, the United States Supreme Court lays down its much anticipated decision in the *Association of Molecular Pathology (AMP)* v. *Myriad Genetics* (*1*). The case involves the gene patenting of mutated genes of BRCA1 and BRCA2 which are responsible for breast or ovarian cancer. The decision came up with the ruling that natural DNA are not patentable as they have the nature ownership but cDNA which are synthetic DNA which are produced by human skills and intellectuals.[8]

2.2 EU SCENARIO ABOUT GENE PATENTING

EPO and its member states does have the provision of patentability of Human genes clearly which is novel and industrially applicable and in this context, mere discovery of the gene sequences which was not known in public domain and does possess specific function can be patentable. It has also been stated that the product that contain gene is patented means protection against all the products that contained that gene. [3]

CASE STUDY: Neurons with stem cells
The decision of rejecting patent on neurons by stem cells was flourished by European court evaluating that stem cells are a part of life and nature origin. Genes are although patentable and along with it, all the products containing that intervened genes are a part of protection. The case of neurons involves the destruction of embryonic cells at any stage which should be banned [9]

3. IMPACT OF GENE PATENTING

3.1 ECONOMY

Considering economy and the industry policies, it can be well understood to be the beneficial approach of patenting the gene innovated products by the industry which gives the exclusive right for the use and hindered others from their use and if the genetic product is a part of an important process for example diagnostic tests, molecular testing etc, thus gives the monopoly right over the process. This can be well evaluated that US biotech industry increased from $5 billon in 70s to $ 26 billion till date with great shoot up patent grants.[4]

3.2 RESEARCH

Research and IP are both interconnected and it can be considered that the IP protection is an award for the research contribution to the society. With the patent application enhancement, the research has been conducted on important and special areas which consider most importantly, Human Genome Project, which provides the reference to all diagnostics testing and molecular testing. Along with it, RNA interference drugs and associated kits are all a subject mattered patentable researches which techno driven our society and contribute a new direction and young era to biotechnology.[5]

3.3 PATIENTS

Patients get benefited with the highly advanced technology given by researchers but paid heavily for the same to the monopolistic industries.[6] The very concept that a biotech company possibly hold a monopoly on a isolated gene of the human genome or specifically the genetic test is as offensive to the very core, even if the purpose was a noble one: a diagnostic test that could possibly reveal whether a person carrying a mutation in the gene composition that would make her vulnerable to develop most dreaded breast or ovarian cancer.

4. CONCLUSION AND FUTURE PROSPECTS

It can be thus concluded that IP Protection in the biotechnology industry is a necessity for its growth and development so that proper advancement can be continued and biotech industry along with its genetic, molecular basis can be enhanced and approached to all countries and contribute to the economy of nation. Also, it is important to set few parameters for the protection of the gene associated invention so that individual ownership should not be harmed. As the genes are nature product, it should be kept after considering ethical issues and regarding the needs and hindrance to the avail of technology or invention to the patients. It can be taken for consideration to make the process for the same to be patentable prima facia in countries where genes are not patentable but that too cDNA or Recombinant DNA which are generated and invented by human intervention and that has industry application.

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