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Biotechnology and Intellectual Property Rights: Challenges and Problems facing by the Developing Nations

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Abstract –

Modern Biotechnology is a biological based technology. In which living organisms (or parts of organisms) are use for making or modifying products, for improving plant or animals or for developing microorganisms for specific industrial purposes. Modern biotechnology is considered as a new global technology because of the growth and development in modern biotechnology has been so rapid. These rapid advancements in modern biotechnology create lot of confusion and challenges or issues before patent offices of the developing contraries as well as developed nations to granting IP protection for this naval technological based inventions. The main purpose of this research article is to find out and in depth analysis of these challenges and problems facing by the developing nations as well as devolved nations.

Key words – Biotechnology, Recombinant DNA Technology, Patent, TRIPS etc.

1. Introduction

1.1 Biotechnology

The term 'Biotechnology' may sound futuristic, but it is nearly as old as civilization itself [1]. We have been using the biological processes of microorganisms for 6,000 years to make useful food products such as bread, cheese and to preserve dairy products [2]. The word "biotechnology" was used by a Hungarian engineer named Karl Ereky in his book entitled *"Biotechnologie der Fleisch-, Fett- und Milcherzeugung im landwirtschaftlichen Grossbetriebe"*, "Biotechnology of Meat, Fat and Milk Production in an Agricultural Large-Scale Farm" in 1917 [3]. According to US Office of Technology Assessment, "the term *Biotechnology* includes any technique that uses living organisms or parts of organisms to make or modify products, to improve plant or animals or to develop microorganisms for specific use" [4]. The Convention on Biological Diversity (CBD), 1992 defines the word "biotechnology as any technological application that uses biological

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systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" [5]. Food and Agricultural Organisation (FAO) defines "biotechnology as follows [6]-

1. The use of biological processes or organisms for the production of materials and services of benefit to humankind. Biotechnology includes the use of techniques for the improvement of the characteristics of economically important plants and animals and for the development of micro-organisms to act on the environment.
2. The scientific manipulation of living organisms, especially at the molecular genetic level, to produce new products, such as hormones, vaccines or monoclonal antibodies".

Today, biotechnology has found applications in many sectors like human health care, agriculture, animal husbandry, and environment protection and in industries such as food, paper, and textiles etc.

1.2 Intellectual Property Rights (IPRs)

Intellectual property rights (IPRs) are legal and institutional devices to protect creations of the mind e.g. inventions or innovations [7]. Any artistic works (music, art, video and literature), discoveries or inventions of symbols, designs, monogragraph, words, axioms, and expression are protected by IPRs [8]. Patent, copyrights, trade mark, trade dress and trade secret are main forms of IPRs. "Non-material objective e.g. ideas, inventions and procedures are protected by patent law whereas material objects e.g. publications, literature, music, arts, film are protected by copyrights. The words, names or symbols are protected by trademark law and business information e.g. customer lists is protected by trade secret law"[9]. IPRs are territorial in nature mean they are confined to the nation in which granted. These are monopoly rights which mean that the without prior permission they can not be used [10].

2. Biotechnology and Intellectual Property Rights (IPRs)

The most appropriate form to Intellectual property rights (IPRs) for today's biological based technology like biotechnology is patent [11]. According to WIPO, "a patent is a form of rights to an inventor granted by the government to gain material benefits from an invention for a limited period of time [12]. It provide protection to owner of invention not to exploit by other to copied, sale, use, offer for sale, or import without authorization of the owner of the patent for 20 years of time" [13]. Biotechnological Patent can be classified into three categories: utility patents, design patents and plant patents [14].

3. Biotechnology and Intellectual Property Rights: Challenges and Problems

Modern biotechnology is still considered as a new global technology and the advancement in these areas have been so rapid. So it creates lot of confusion and challenges before patent offices of the developing contraries as well as developed nations. Challenges and problems facing by the patent offices of the developing nations like India are followings.

3.1 Controversy over Patenting of Living Organisms

In biotechnology, the fundamental perspective is biological material or biological process with industrial applicability. However, whether or not living organisms, for example, microorganisms, plants or animals or naturally occurring stuff, for example, CELL, DNA, RNA, GENE and proteins, biotechniques like

bioinformatics, nanotechnology and cloning may comprise the subject matter of a patentable innovation is yet very questionable [16].

3.2 Problems Associated with Transgenic Animals

An additional objection is one concerning experimentation with animals. "A host of questions come to mind. Are animal experiments necessary? Is it permissible to conduct animal experiments for purposes other than the health and well-being of the animals themselves? Should the use of animals as bioreactors be prohibited in all cases, or should it be permitted in certain circumstances, such as the production of pharmaceuticals? Whatever the merits, or demerits, of these arguments, the relevant question is whether or not the harm to animals is outweighed by the benefit to humans. The philosophical issue is whether or not genetic manipulation violates animal integrity. In addition, the possibility of negative impacts of transgenic animals on their own species cannot be ruled out. The concern is based upon the assertion that transferring genes inter-species transgresses natural barriers between them, thus violating the integrity of the species" [17].

3.3 Problems Related to Alteration of Human Genes

The most complex issues happen when allowing for genetic alteration of human beings. Viewed from the public perspective the risk posed by contemporary biotechnology is the possibility that it will alter human nature in an irrevocable manner. "Some of the more important questions arising are:

a) Do we, as humans, own our genetic material, or does it belong to society as a whole? Does the "common heritage" argument, i.e., anything possessed profusely by huge number of people cannot be brought under private monopoly, apply.
b) Is intervention into the human genome an attack on human dignity?
c) Is gene therapy, i.e., the provision of healthy copies of flawed genes, acceptable? Proponents of genetic engineering argue that intervention into the human genome is necessary, ultimately leading to an increase in human biodiversity; while opponents claim such a step is turning the sacred into the profane".

3.4 Problems Related to Patentability of Gene as Information

With the coming of human genomics and accomplishment of the renowned Human Genome Project [18], the gene has picked popularity which could be attributed more to the informational content it possesses than its material characteristics (physical properties). It's pertinent to see here as to whether or not a sequence of genetic material is a patent appropriate matter. According to a few reviewer, if it is itself information instead then patenting it would run contrary to the conventional patent doctrine, "which is based on an agreement to disclose information in exchange of giving the inventor rights over material invention" [19].

3.5 Problems Related to the Tragedy of "Anticommons"

"Human genes have turned out to be a standout amongst the most questionable topics of patent law as a result of its differing nature. Since a gene involves a number of elements, as a result, it is conceivable that a number of patents could be conceded in connection to one gene. For example, in connection to a specific gene, patents could be well sought not only on the full sequence of a gene, but also on an expressed sequence tag

(EST), or a single nucleotide polymorphism (SNP) or other variants of the gene. Multiple numbers of patents on a single gene often lead to issues of anticommons, patent thickets and royalty stacking. In the USA, Heller and Eisenberg portrayed the issue of anticommons in the biomedical field as *the tragedy of anticommons* [20], where genes and gene fragments can be used as research tools; however, multiple patents on them often discourage genetic innovation [21]. The obvious reason is that access to these tools requests arrangements with all the patent holders, thereby raising the transaction costs [22]. The tragedy of the anticommons has become a more pressing concern because of the shift from the commons model to a privatized scheme marked by private investment rather than governmental sponsorship. A patent thicket involves an overlapping set of patent rights necessitating those who seek to commercialize new technology to get licenses from multiple patentees [23]. The problem caused by patent thickets is that it may be too costly to obtain licenses from each firm that owns individual patents. Innovative products are delayed due to licensing issues. Not only does the tragedy of the anticommons have an effect on the commercialization of revolutionary medicines; it also has an effect on applied research. Researchers may be less willing to conduct research in areas that are covered by patents" [24].

3.6 Problems Connected with Patents on Genetic Research Tools (GRT)

The rise in commercialization to basic or upstream genetic research has prompted patents on gene fragments, for example, "Expressed Sequence Tags (ESTs)" and "Single Nucleotide Polymers (SNPs)", that are fundamentally research techniques. Though these techniques are not direct valuable for therapeutic or diagnostic purpose yet are immensely valuable in the pursuit of research. The genetic innovation may very well get smothered in case these tools are patented [25].

3.7 Issue Related to Propriety over Human Genetic Material

Another controversial issue is who owns human genetic material. Since such material has potential promising use, so, hereditary material is gathered from individual populaces and stored in nationwide bio-banks, wherever it is claimed as a national property. Additionally, such substance is gathered at the time of research studies and medical treatment, where individual research subjects and patients defend their own assets rights in their body parts. Now the inquiry emerges: "Is there any acknowledgeable input from research subjects or patients who have given their genetic material"? Moreover, whether is it justified for researchers to obtain property rights through study, segregation and alteration of such material, without giving credits to the research subject, without whose contribution it would not have been possible at the very first place? Additionally, it is also a matter of great concern that rising nations as a seller of hereditary material may finish up shelling out exorbitant price for the very goods that ultimately originated from their self hereditary material [26].

3.8 Problems Related to Disclosure, Best Mode and Utility Requirements

Having regard to utility and capability of disclosure, the grant of monopoly rights should be permitted merely where a patent application discloses a proper point of practical and real exploitation of the biotechnological innovations. The important point to ensure here is that claims are not extensive than is

defended by the innovation revealed in the patent claim, more specifically, where it is an untimely and elementary phase of development or a new gene with its prospective application still under consideration [27]. This requirement is contained in Art. 112 of the US patents law and Sec. 10 of the Indian patent law. The "*Best Mode Requirement*", that is found gigantic discussion in the United States recently and do not locate leave in the EPC, implies "the best method of carrying out the invention known to the inventor at the time of filling for the patent should be disclosed in the patent application, for each aspect of the invention" [28]. While "*Disclosure*" is regularly alluded to as an important prerequisite, it is crystal clear that the "Best Mode Requirement" is a prejudiced one, while what is essentially required is the disclosure of the most excellent way mulled over by the creator. Practically speaking, it is extremely hard to ascertain the "Best Mode Requirement" while collapse of fulfillment must be demonstrated by comprehensible and decisive proof [29]. The "Best Mode Requirement" has earned heavy criticism because under it; the disclosure requirement is too onerous upon the innovator [30]. In *Young Dental Manufacturing Inc. v. Q3 Special Products Inc* [31] court conclued that "two factual inquiries are required to be made to ascertain compliance with Best Mode first, the subjective one, that tests whether at the time of filing the patent application, any better method of making the invention was known to the inventor and second, the objective one, to determine whether what was disclosed as the Best Mode can be put to practice by those having ordinary skill in the art". But, in *Evans Medical Inc. v. American Cynamide* [32], "the opponents contended that a better method was known by the plaintiffs and that the best antibody was not disclosed for the patented process. This contention was rejected on the ground that though there might have existed better methods, the plaintiff chose that particular antibody for the purification process. As regards the objective part of the Best Mode disclosure, the plaintiffs asserted that their disclosure was sufficient for a person skilled in the art to perform the patented process. The Court said that though the descriptions were vague, and suspiciously so, there was insufficient evidence to uphold that there had been a Best Mode violation". Further, the utility requirement has always received strict interpretation by the US courts as could be seen in *Brenner v. Manson* [33] wherein the Supreme Court refused the patent because though the alleged steroid compound carried a possible tumour inhibiting effect in mice but was silent as to any use in humans. Is it that the invention must be of some utility only to humans and not just beneficial to nature or other flora/fauna in order to get patented?

3.9 Problems Related to First Inventor to File System

In the sector of biotechnology, laboratory notebooks, which assume a noteworthy job in establishing the prior conception, seems to lose its noteworthiness under the "Leahy-Smith America Invents Act, 2011", wherein first to invent system has been replaced by first inventor to file system. Since this field is a plethora of uncertainties, first inventor to file system may prompt inventors to seek patent protection as early as possible, even at premature stage [34].

3.10 Problems Related to Inventive Step and Utility Issues in Gene Patents

In gene patenting the pertinent novelty issue is whether something new has been turned into from the pre-existing natural matter or whether only flaws have been rectified in the original. Though earlier considered

as arduous manual tasks, gene sequencing and its isolation have now become profoundly mechanized and routine components of the laboratory exercise. Consequently, it has become very tough for patent claims concerning these tasks to satisfy the non-obviousness/ inventive step criterion. Here, the utility criterion is too problematic because patents are often conceded on genetic material parts of unidentified functions and genetic material sequences of questionable or limited usefulness. At times, only a correlation between a disease and its corresponding gene is disclosed without describing how it was used to envisage the disease [35].

3.11 Legal Protection of Biotechnological Inventions: A Complex Issue

Because of ethical and technical issues involved in the biotechnology in universal and crop biotechnology in specific, grant of legal protection to it remains extremely delicate and complex issue. Indian biotech industry at present is confronting extraordinary difficulties on account of the rising "Trade Related Aspects of Intellectual Property Rights (TRIPS)" in India w.e.f. January 1, 2005. As per Article 27.3 (b) of TRIPS, "though biological processes for the production of plants or animals have been kept outside from patentable subject matter, but microorganisms, non-biological, and microbiological processes used in the production of plants and animals have been retained within the scope of patentable subject matter". With the rise in transgenomic research both in public and private sector, the issues of royalty payments, material transfer agreements (MTA), and legal obligations and bindings are to be thoroughly comprehended [36].

3.12 TRIPS Agreement: Uncertainty and Patentability Issues

Article 27(1) of the TRIPS Agreement provided that subject to certain clauses, patents ought to be allowed for inventions in any field of technology without prejudice. No definition for the term "invention" has been appended with this article and has been left to the interpretation by individual nations. Moreover, Art. 27(2) of the convention permit member countries to keep innovations out from patenting for putting into effect "*ordre public* or *morality"*; though, the quintessence of such provision has not been suggested. Art. 27.3 (b) of the instruments connected with biotechnological innovations, in particular, and rule out flora and fauna from patentability, saves for mandatory IP protection for microbes and there processes. But, the treaty is quiet on defining the words "microorganisms" or "microbiological processes" and setting no restriction for circumventing the extent of these words. Whether multi-cellular organism, fungi, virus are included in the definition of micro-organism? Whether cell lines should be excluded from patentability? Further, whether mere isolation or purification of a microorganism would render it patentable or that only man-made/biotechnologically altered microorganisms would be granted patent protection? As such, huge uncertainty is left as regards the degree of patent protection to be provided to biotechnological inventions. Moreover, Article 27.3 (b) of the convention states that states can rule out from patenting "essentially biological processes for the production of plants or animals"; but, no parameter has been provided to determine the arena of essentially biological processes.

3.13 Bioethical Issues in Patenting Life Forms

Since invention and not discovery qualifies for patent protection, in the field of biotechnological inventions, there are hard to declare whether the novel living variety in the form of genetic material, cell etc. is

a technological invention or a mere scientific discovery. The requirement of industrial application is another impediment for securing patents for innovations in biotechnology. Still, in India there are man bioethical issues as well, the most critical being the degree of personal rights that might be stretched out to living forms [37].

3.14 Discovery Eligible for Patenting in USA

Article 35 USC Sec 101 of the US patent law states: "whoever invents or discovers any new and useful process, machine, manufactures, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof". The use of word "discovers" needs correction/ explanation for it is a general notion of patent law that only invention and not discovery qualifies for patent protection.

3.15 Ethical Propriety and Sharing Bio-Resources

The patent regimes across the globe that permit biotechnological patenting have been under heavy criticism with reference to the ethical and moral ground. It is irrefutable matter of fact that the potency of the pharmaceutical and agricultural sectors has been appreciably upgraded by biotechnological advances. These developments go parallel with ingenuity and human creativity. Accordingly the contradictory issues of sharing biological resources and the granting IP shield to the creator of biotechnological innovations demand great attention.

3.16 Plight of Marginal Farmers under PPVFR Act

For protecting a new plant variety, member states have been provided by TRIPs three options to exercise: either to use patent or to employ sui generis system or an arrangement of both. In pursuance thereof, India chose "*Sui Generis Protection System"* and consequently enacted "***The Protection of Plant Varieties and Farmers Right Act,*** 2000" (PPVFR Act) under which "a farmer is enabled to save, use, sow, re-sow, exchange, or share the seeds of protected variety, in addition to protection offered on farmers' variety, essentially derived variety and extant variety". Though as a matter of fact, research in the area of plant biotechnology might get boosted by public and private sector in consequence of plant variety protection, there is great possibility of rising prices for seeds, which would ultimately take away new technologies from the access of small and marginal farmers. On account of royalty payments, restrictive contracts and rise in commercialization seeds would be pricier for the small farmers; therefore it can be said that patents will bring barrier between seeds and genetic resources on one hand, and their access to farmers and breeders on the other hand [38].

3.17 Scope of Stealing Traditional Knowledge under PPVFR Act

The "PPVFR" Act has been criticized for being anti-farmers for it is alleged to give opportunity to thieves of Traditional Knowledge (TK) to acquire patent protection [39]. Sec. 18 of the Act includes "a disclosure requirement, with description of its novelty, utility, geographical origin and a declaration that the plant variety has been acquired by lawful means". Once this requirement is fulfilled, it is feared that the farmers and traditional people are left with much less leverage power to negotiate their TK and plant varieties [40].

3.18 Issues Arising from Self-Reproducing Capability of Biological Material

Since biological matter is capable of reproducing itself, there arises multiple numbers of complex questions of law to be settled in relation to biotechnological inventions; such as "(i) the extent of legal protection of future generations; (ii) exhaustion regimes; (iii) special rules, if any, for animal and plant breeders" [41].

3.19 Lack of Prior Informed Consent for TK: A Major Flaw under Indian Patent Law

Traditional Knowledge (TK) has now become a frequently seen component of many Biotechnological patent applications. TK refers to the knowledge gained during a long time back, by indigenous people, as to the genetic resources or biological components as to their utilization for a number of purposes [42]. A plethora of issues of law relates to the patenting of biotechnology with a TK component. According to Article 8 (j) of the Convention on Biological Diversity (CBD), "prior informed consent (PIC) of the community is mandatorily required to be taken before utilization of TK in any manner whatsoever" [43]. The concealing of TK component in a patent application would violate the enablement prerequisite. Though, sec. 10(4)(d)(B) and (D) of the Indian Patents Act, 1970 offer relative protection as to the description of the resource, geological origin and technological information concerning the patent; yet, there is absence of provision which mandates insisting upon of PIC prior to patenting of a product using TK. This is a key fault in the law which demands immediate correction [44].

3.20 Bio-Piracy and Food Security

Recently, numerous instances of bio-piracy of traditional knowledge from India have been reported. The theft of biological resources coupled with the indigenous knowledge concerning them would impinge on food security, livelihood of indigenous people, and consumer's choice. As over 70% of our nourishment is subject to few palatable plant items, fundamental to food security, mainly wheat, rice, maize and potato; patents on these items will certainly pose threat to the consumers [45].

3.21 Patentability of *In Vitro* Diagnostic Methods in India: Uncertain

A number of recurrent objections during the examination of biotechnological inventions have their basis in Section 3(i) [46], which excludes from patentability "any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products". Notably, though, in a number of cases, in vitro diagnostic methods performed on tissues or fluids removed permanently from the body, have been granted patents by Indian Patent Office. However till date, the judiciary has not yet decided on keeping the *In Vitro Diagnostic Methods* outside the reach of Section 3(i) [47].

3.22 Diversity in Law of Patenting of Biotechnological Inventions under Major Regimes of World

Ingenuity should receive liberal encouragement [48]. Due to territorial nature of the patent, each states have own patent laws. If we compare the patent-eligible subject matter as between the USA, Europe and India,

wide variations could be seen in patent practice, legislative framework and interpretation by courts. A common point among every one the three nations is that they allow IP protection on biotechnological innovations including genetic materials and there parts, though through varied level of shield. Similarly, the each of the three jurisdictions has embraced relatively comparable methodology with respect to the patenting of microorganisms except for macro-organisms. For instance, in the USA, genetically tailored animals are patentable; in the European Union, patentable only when the agony caused to the animal is less as compared to the advantage to the mankind. In India, genetically tailored macro-organisms and the parts thereof are not patentable. Under US patent law, legislature has not carved out any list of exclusions, and it is the judicially tailored exclusions, for example, laws of nature, abstract ideas, and physical phenomenon which have been construed copiously to enlarge the arena of patentable subject matter. In USA, much inconsistency could be seen in the patent approach in respect of human gene and genetic information. Likewise, human gene and gene fragments enjoy patent protection in Europe and India. In Europe, the complete or partial sequence of an isolated gene might qualify for patent, although its structure is the same as that of natural one. In India, genome sequencing with disclosed utility are deemed patentable. The "*ordre public* and *morality"* provision is absent under USA patent law. Whereas, "*ordre public* and *morality"* exclusion has been recognized under European and Indian patent law. Similar concern is echoed in Indian Patent Manual, 2011 wherein it declares, "An invention, the primary or intended use of which is likely to violate the well accepted and settled social, cultural, legal norms of morality, e.g. a method for cloning of humans."

3.23 Trends in IPR Policy of US and India: In Relation to Genetic Resources

"The IPR policy of the United States is leading India to adopt a more commercial and private property view of information. The change is occurring not only in relation to high technology fields but also with regard to traditional knowledge and genetic resources. India is gradually beginning to redefine its approach towards patents and has rejected the common heritage view of genetic resources due to US patent policy [49]. US policy of acquiring patents derived from genetic resources and traditional knowledge has been labeled as "bio-piracy" by India. However, India has not yet evolved a clear-cut policy on the issue" [50].

4. Conclusion

Biotechnology is a modern discipline of life science. Biotechnology works on molecular (DNA/GENE) levels. Using modern biotechnological tools and techniques the genetic makeup of the living organisms may be changed. Modern biotechnology is most useful technology in human health care, agriculture, environment protection etc. Insulin, human growth hormone, GMOs like Bt cotton are some example of the modern biotechnology. The recent and rapid advancement in the biotechnology pose complex challenges and problems before the patent offices of the developing nations. The patent offices of the developing nations have no experte in the biotechnological inventions and pre colonial patent laws of the developing nations are main region for these challenges and problems.

5. Recommendations

Authors' suggestions from research that have been done are as follows:

1. Appoint statutory "Biotechnology Expert Committee" in patent offices of the developing nations.
2. Mention and clear all these issue in TRIPS agreement.
3. As far as possible Harmonize the patent laws of the all developed and developing nations.

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