Naveen Shodh Sansar (An International Refereed / Peer Review Multidisciplinary Research Journal)
RNI No.- MPHIN/2013/60638, ISSN 2320-8767, E- ISSN 2394-3793, Scientific Journal Impact Factor (SJIF)- 8.054,
April to June 2025, E-Journal, Vol. I, Issue L (50), ISO 9001:2015 - E2024049304 (QMS)

Biotechnology Patenting : An Indian Perspective

Shivani Chaurasia*

***Ass. Prof., Pt. Motilal Nehru PG Law College & Research Center, Chhatarpur (M.P.) INDIA**

Abstract - "This paper explores In the context of the TRIPS Agreement, the changing ethical and legal environment surrounding biotechnology patents, with a particular emphasis on India. It draws attention to the difficulties in obtaining patents for genetically modified organisms, biological materials, and living things under Section 3 of Indian patent law. Along with these important topics, the paper looks at important cases like Monsanto Technology LLC v. Controller of Patents, the role of creative step and originality in biotech technologies, and patenting human genomes. In order to provide a balanced approach that safeguards both innovation and the public interest, it ends with recommendations for harmonizing worldwide patent rules."
Keywords: Biotechnology, Biotechnology Patenting, Invention, Innovation.

Introduction - In the biotechnology invention, materials, compositions and methods will also be included. Biotechnological products will usually involve a category of recombinant DNA, antigens, monoclonal antibodies, hybridomas, and artificial organs, as well as novel microorganisms, such as bacteria and fungi, microorganisms, plasmids and allied products. Biotechnology has a major impact and potential in the agricultural, plant varied, pharmaceutical, health and environmental fields, and has seen a new expansion in this field of technology that focuses on intellectual property rights claims globally. The new technology has also been widelyrecognised as a frontier technology. Biotechnology, particularly in relation to genetically modified organisms, is a new sector that has become the subject of worldwide attention. It involves techniques for growing, modifying and improving plants or animals, or cultivating microorganisms for particular use using organisms or parts of organisms. The most recent advances in biotechnology research have led to a major transformation in many-functional human activities, in order to make them sustainable for human development and growth, and to reassess legal structures, and particularly the intellectual property rights regime.

Indian Patent Act, 1856[1]

Patent Act in India was enacted in 1856. It has been modified several times since then; one major amendment being in 1970 which satisfied the international norms of patentability covering novelty, inventive step and industrial application. But this version had nothing specific concerning Biotechnology invention and protection. At the same time, since the patent offices and courts in US and EU were seeing increasing number of biotech inventions and patent application, the demand for amendment of Indian Patent Act to introduce biotech patentability gained voice in India. The amendment came in 2002 to explicitly include biochemical, biotechnological and microbiological processes within the definition of potentially patentable process.

Biotechnology Patents

"Biotechnology can transform humanity provided humanity wishes to be transformed" - Geoffrey Carr

Biotechnology inventions are important for human development. It is the broad area of biology involving living systems and organisms to develop or make products, or any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses. Thomas Jefferson the man behind the first Patent Act.

TRIPS scenario for the patenting of biotech products:

The TRIPS Agreement contains the various aspects of existing international patent rights systems that define minimum requirements for the protection of patents and their use that require all the Member States to comply with them. In the form of the 'Indian Patent Act 1970' Indian patent law, like many other WTO Member States, have modified current legislation in order to make it substantially comparable in compliance with the TRIPS Agreement.

Under Article 27 of the TRIPS Agreement, the subject matter of patentability in biotechnology, which is applicable to the field of innovation, is defined in detail. It requires products or processes, which are modern, innovative and able to be industrial in all areas of technology. Under Article 27(3) of the TRIPS Agreement, members are obliged to provide for the patenting of plant and animal plant and non-

biological microorganisms, microbiology and non-biology processes. This provision initiates the patenting of life forms because microorganisms in different agricultural, health and environment sectors are very useful.

However, the TRIPS Agreement also provides, provided that such exclusions are not made simply because the exploitation is forbidden by national law, the exclusion of innovations that are required in order to safeguard the public order, morality or the protection of human, animal or plant life and health or to prevent any serious harm to the environment. Accordingly, as provided for in the TRIPS Agreement, safety for microorganisms as such is important for the Member Countries.

TRIPS Legal System: The TRIPS require patents to be issued to all modern, inspiring and industrially relevant products and processes. Governments may however exempt plants, animals and mainly biological processes for their development from patentability. However, governments are obligated to preserve them for plant varieties through the patenting or combination of an effective sui generis scheme. Explicitly exempt from patentability are the microorganisms and microbiological processes. The absence of definitions, however, leaves national law with the meaning of the words used in this Article.

TRIPS Patent Regime Regulation of Member countries TRIPS legalises the domestic laws of its participating Member Countries substantially. It underlines that countries should establish an efficient patent system for virtually every field of technology subject to two exceptions provided for in the second and third requirement clauses.

Firstly, Article 27(2) specifies that Members can exclude inventions from the patentability where it is appropriate to protect the public order or morals, including the protection of human, animal, plant life or health, or serious environmental harm, by preventing the commercial exploitation of the invention.

Secondly, Article 27(3) allows for members to exempt the care of human, animal, animal and plant and non-microorganisms and, in particular, biologic processing of plants and animals other than non-biological and microbiological methods from their diagnoses and therapies and from their operating procedures. However, members have to ensure that plant varieties are covered either by patent or sui generis. It is important to note that the implementation of Article thirty of the TRIPS does not hinder the usual use of the patent and the valid interest of the patent owner in implementing these exceptions.

Indian Perspective for Grant of Patents: In the history of patent regimes, the Indian Patent Act of 1970 defined a clear description of the term "invention," as the basis of which the steps for grant of patents can have been decided. The following is described under Section 2(1) (j) of the Act as:

"Invention means an innovative phase that is ideal for industry" New product or process An over-definition approach can be taken which shows that innovation, non-obviousness, and industrial application or usefulness are the requirements for patentableness of an invention. Novelty or Newness is that the innovation must be newer and distinct from "prior art" as the primary critical criterion. 'Prior art' states that before the date of filing of the patent application it may have not been written elsewhere in the world or in the public domain. An imaginative move or a non-obviousness requires a person skilled in the art not making an idea obvious. An artist who knows the common general knowledge in the arts before the date of filing shall be assumed to be aware. Such an individual does not require imaginative move and will never contradict the scientific principles developed and try not to enter an unpredictable field or risk himself unpredictably. If similar problems arise in such areas, the skilled person would perform a transfer of technology from a nearby field into his particular field of interest if this transfer involves routine experimental work. The skilled individual could be expected to search for suggestions in the nearby field.

Therefore, in order to make an invention patentable, India's patent law demands that the invention be novel, innovative (non-obvious) and industrial (utility). The innovation must also be reproducible. It is to be determined by applying the above-mentioned criteria if the substances such as microalgae or other organic materials, which are present in nature, can be considered as new. One of the most challenging problems in the field of biotechnology is the criteria for inventive phase. Detailed information on the invention to be covered is mandatory under patent law. The word 'sufficiency of disclosure' is widely used. The need for properly disclosed data presents particular problems in the field of biotechnology because innovations in this field include live individuals (biological material). Such materials cannot be clarified in words easily. It should be noted that the practice of the inventor to apply his living entity in the invention to the approved depository authority is now established with a view to fulfilling the test of 'sufficiency of disclosure' with regard to biological inventions. However, while the requirement to be adequately specified stipulates in Article 10(4), it remains silent on how to comply with the requirement for inventions involving the biological materials' Such biotechnological inventions, such as life and non-living substances, are not permitting patents under the Indian Patent Act. This encompasses any usable or in-kind microorganism but does not include a single, altered or insulated microorganism. However, where such modified micro-organisms and the resulting substance or process are contrary to public law or morality which is a severe prejudice to the life or health or the environment of humans, animals or plants.

In addition, the Act also states that no process is authorised to be patented for the treatment of human beings or any process for medical, surgical, curative, prophylactic or diagnostic treatment of animals that would free them

from any disease, boost their economic value or increase their value or that of their product. The Act forbids the patenting of seeds, varieties and organisms and primarily biological processes of plants and animals in whole or in part thereof, including plants and animals. It must be noted that, despite these restrictions on patentable innovations, biotechnology inventions are rising in particular from conventional biotechnology such as fermentation, east, and other sources.

However, innovations relating to processes or methods for the processing, through bioconversion or through the use of the above-noted biologically active substances, of tangible and non-living substances were considered and held to be patentable. While no special reference was made in the 1970 Act concerning the patentability of live types such as micro-organisms, gene cell lines, etc. they were to be exempt from patentability by the spirit of patent law.

The Famous Indian Landmark Judgment – Monsanto Technology LLC v Controller of Patents and Design[2]

In the context of Section 3(j), the recent decision of the Intellectual Property Appellate Board (IPAB) in Monsanto Technology LLC v Controller of Patents and Designs is interesting. Monsanto Technology LLC applied for a patent in respect of a method of producing a transgenic plant that was capable of withstanding harsh environmental conditions. It argued that the production of the transgenic variety involved substantial human intervention in inserting the rDNA molecule into the plant cell and transforming the cell into a climate-resistant plant. However, the IPO was not persuaded and held that the invention claimed related to an essentially biological process of regeneration and selection which was excluded from patentability under Section 3(j) of the patent statute. Further grounds for rejection included lack of inventive step and ineligible subject matter under Section 3(d). On appeal, the IPAB upheld the findings on inventive step and Section 3(d), but disagreed with the IPO on the applicability of Section 3(j). The IPAB unequivocally clarified that the claimed method "includes an act of human intervention on a plant cell and producing in that plant cell some change", and consequently fell outside the scope of Section 3(j).

Human Genome Patenting: Human genome patenting needs a high degree of concern. The most common objection to this form of patent is that human genes are naturally found and not invented. The patenting of genes poses two competing questions:

1. Is the patentability of segments of the human genome acceptable ethically when the segments are part of human 'natural' or universal patrimony?
2. Given the massive economic and human capital expanded to detect the patenting of human genomes, is it unethical?

It should be remembered that, as a result of morality and social justice, the least developed countries are rich in genetic wealth and have many objections to legislation on intellectual property and suspected 'bio piracy.'

The agreement on TRIPS does not include specific microbiological processes or microorganisms. This leads to questions as to whether the current micro-organisms are patentable, or whether their pure isolation is patentable or human interference is required to determine the degree of innovation in the discovered micro-organism in the patenting phase. It also leads to the question whether a product made by a known microorganism can be patentable or the process can be patented. The country should draw a distinctive line between the result of human activity that leads to novelties and those freely present in nature if micro-organisms and micro-biological processes are not described clearly in the TRIPS agreement.

There are further debates and issues related to the right to patent living organisms in the neighborhood of biotechnology, especially property and seed, which have been established or accepted as traditional and community knowledge.

This public knowledge situation often clashes with indigenous knowledge and the interests of indigenous people, local ecosystem protection and even the ability to protect the global environment. Biotechnology innovations may not be adequately covered by the present patent system. For these reasons the invention of genetically engineering is too complicated to explain precisely, which makes it impossible to decide whether it is patentable or infringing and that the complex of species prevents disclosure of innovations that would make it possible for the general public to manufacture and make use of the invention after expiry of the patent. With biotechnological patents, an unreserveable patentee will gain greatly, as the involved parties in this technology sometime allow genetic fragments, genetic tests and proteins to be patented while the true function is not fully understood. The concerns of biotechnology products are linked not so much to the product, but to the new IPR regime and to MNC regulation of intellectual property.

Some Suggestion Regarding the Patent: Laws In order to improve and better understand the consequences of biotechnological patents, it needs comprehensive study and collective studies in the context of biotechnological progress. The driving spirit and key to enabling creative biotechnology patent granting initiatives should be the harmonisation of the divergent views of various countries. In order to preserve sovereignty over resources while simultaneously undertaking international cooperation in biotechnological science, the International Patent System should be harmonised.

The countries should follow a number of measures to ensure that the new patent scheme does not hamper their human rights to health in order to preserve the equal and sufficient provision of biotech based medicines and other health products. And they must ensure that their IP security

regimes are not contrary to their public health policies and comply with the protection of human rights.In the field of utility requirements, the issuance of a patent requires strict implementation of high standards and only inventions of clear significant, trustworthy and present utility should be permitted. Such a strategy would prohibit several patents that could hinder research and also allow scientific progress in the public domain.

Conclusion: In developing countries the international legal framework explicitly linked to the patent regime must be redefined with the combination of continuous biotechnological growth. Biotechnology is actually capable of serving the general public in different ways by offering significant advantages to health, food, medicine and the environment. The method should be realistic and effective in the context of biotechnology.

Patent is still the most viable patent protection instrument. By enabling inventors to focus on commercial applications too, the patent scheme offers maximum security. Intellectual property rights approaches still have a contentious problem between inventor rights, artistic rights, and the needs of society and the public. Thus, a balanced approach towards IP regimes in order to facilitate and increase the growth of scientific attitude is also imperative. Therefore. Broadly speaking, the effect on a person, community level and the advantages of the source are also immediately beneficial at both levels.

References:-

1. Indian Patent office (www.ipoindia.in)
2. TRIPS Agreement and Amendment of Patents Act in India, Economic and Political Weekly, 2005, Vol.37, No.32, P.3354-3360
3. Gupta, S. (2002), The Problems Raised by Biotechno -logical Inventions for Patent Scope Interpretation.
4. Occoferri, Patents – Patentability of Biotech Inventions, European Intellectual Property Review, Italy, EIPR 2000, 22(10), N142-144
5. Intellectual Property Reading Material, (World Intellectual Property Organization (WIPO)), Publication 476E, Sections 4.60 and 4.61, p .59.
6. Dahl, Pending resolution: the question of who owns DNA. Environmental Health Perspectives, 109 (1), 2007, A31-A33
7. Correa Carlos M., (2000) 'Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options', Zed Books Ltd, London and Third World Network, Malaysia.
8. World Intellectual Property Organisation (www.wipo.int)
9. K.K. Tripathi, Biotechnology and IPR Regime: In the Context of India and Developing Countries

Footnotes:-

1. Indian Patent Act, 1856
2. Monsanto Technology LLC versus Controller of Patents and Design (2407/DELNP/2006)

****