

**DPIIT, MCI Chair on Intellectual Property Rights &
Centre for Intellectual Property Rights Research and Advocacy
National Law School of India University, Bangalore**



Biotechnology Patenting

Difference between US and Indian Perspective

Under the Guidance of
Prof. (Dr) T. Ramakrishna,
MCI Chair Professor on IPR

Submitted By
Mrityunjay Joshi
Intern, CIPRA
Student, Symbiosis Law School, NOIDA

Certificate

This is to certify that Mr. Mrityunjay Joshi, Student of Symbiosis Law School, NOIDA, Uttarpradesh has successfully completed and submitted his report, **Biotechnology Patenting : Difference between US and Indian Perspective**. This has been submitted in fulfilment of his internship at the Centre for Intellectual Property Research and Advocacy (CIPRA) during the month of 1st January to 31st January 2021.

Indore, 31 January 2021

Prof. (Dr.) T. Ramakrishna
DPIIT, MCI Chair Professor of IPR

Research Associate

DECLARATION

Certified that this research work is my original work and I have not borrowed any material from other's work nor have I presented this partly or fully to any other institution/college/university.

I have completed with all the formalities prescribed in this regard.

A photograph of a handwritten signature in blue ink on a light-colored surface. The signature is stylized and appears to read 'Mrityunjay Joshi'.

Date: 31 January 2021

Signature

Place: Indore

NAME - MRITYUNJAY JOSHI

Biotechnology Patenting

Difference between United States and Indian Perspective

By – Mrityunjay Joshi (Intern, Symbiosis Law School, NOIDA)

Abstract

The aim of this paper is to explore the impact of patents on innovation with a view to biotechnology, usage and associated efficiency of the existing patent system in promoting biotechnological inventions and related issues and challenges. This article discusses the biotechnology patent-related field. It addresses the different problems in patenting of biotechnology.

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 widely recognised 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, 1856¹

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

¹ Indian Patent Act, 1856

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 practise 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 Judgement –

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

² Monsanto Technology LLC versus Controller of Patents and Design (2407/DELNP/2006)

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).

US Perspective for Grant of Patents

In the US, the patent act contains no exclusive provisions and has proven to be the country with the most liberal approach to the patent of inventions in the field of biotechnology. It is allowed for patented animals and plant species in the US.

An invention must comply with the following conditions in order to secure a patent in the United States:

- Patentable subject matter
- Utility
- Novelty
- Non-obviousness

Patentable subject matter: Patentability first of all, and most significantly, must fall within the scope of the patentable subject matter as specified by the law of the patent. Patentable subject matter is very wide-ranging and open in the United States. The limit of the patentable subject matter lies beyond only the jurisdictions of the natural world, major phenomena, philosophical and abstract concepts.

Utility: Section 101 of the United states Patent Act stipulates that a patent grant is valid for an invention or discovery. Usability is a highly subjective inquiry and is not strictly considered by the USPTO when dealing with biotech inventions to satisfy this demand. In the form of immediate benefit to the public, the invention should have some practical utility. If any were eligible for patent protection, a biotech innovation could be shown to have significant and reliable usefulness judged by a person with the ordinary ability of the art.

Novelty: Novelty means creativity or originality. In the light of prior art searches (existing data and knowledge when the invention is concreted in the public domain), the categories of invention must be patentable and new. The novelty provided under paragraph 102 does not differ from the novelty mandatory according to section 101. In the field of biotechnology innovations, the criterion for novelty is very low compared with other inventions.

Non-obviousness: An invention should not be evident in view of the state of the art, in order to be patentable. It would not be possible for the invention to be patented if the variations between the subject-matter to be patented and the prior art had been such that, in the entire subject-matter, an individual having ordinary artistic talent had become apparent when the invention was made.

According to US patent law, DNA sequences are considered by the US Patent Office to be chemical compounds and are patentable as matter compositions. The United States therefore grants patents for all plants of a genus to which a new gene is added by means of biotechnology. This makes the patents of a gene and of legal claims over the isolated gene and DNA sequences, the engineering methods used in genetic engineering sequences and the derived plants.

The Famous US landmark Case -

Diamond vs Anand Chakrabarty³

The most famous case of Diamond v Anand Chakrabarty where a biochemist at GE developed a genetically modified organism that had the ability to decompose crude oil. At first his patent application was rejected which on further appeal was granted by the court with order stating “His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter-a product of human ingenuity”. Biological Materials Patenting Issues .

The exclusive characteristics of new technologies can lead to complicated questions of patent law explanation. The feature between invention and discovery is becoming indistinguishable in modern biotechnology. GMOs are also distinct as inventions. GMOs are a genetically modified organism. Not only are some of them alive, they can replicate themselves and are not well consistent, well defined etc. If they are unbounded, they intermingle unpredictably with the climate.

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 expended to detect the patenting of human genomes, is it unethical?

³ Diamond Versus Anand Chakrabarty, 447 U.S. 303 (1980)

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 neighbourhood 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.ipointdia.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 Biotechnological 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