

The Indian Patenting System in Microbiology

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Abstract

In the present modern scientific world, patenting of the microorganisms and microbiological processes plays an important role in the field of microbiology. The study of microorganisms is known as Microbiology, in which an organism that can be viewed under the objective lens of microscopes which are not visible to our human naked eyes known as microorganisms. Microorganisms can be differentiated such as Algae, Bacteria, Fungi, Archaea, Protista, Diatoms, Protozoa, Planktons etc., The term microorganisms do not include Viruses and Prions, which are generally classified into a class of non-living materials. Microbiological processes which include microbes to perform metabolic activities under certain procedure in order to manufacture a useful product. Microorganisms with some genome level modifications can engage in many microbiological activities, such as for the production of useful fermented products like beer, bread, antibiotics, drugs and biofuels. Thus, patenting such microbes will prevent it from further studies and uses. In the field of microbiology patenting right gives privilege for that invention and provides a monopoly right over the product for a certain period of time, by giving the special title of right to restrict others from using and making profits from the patented microbes and its processes. India allows patenting rights to microorganisms in accordance with **TRIPS** agreement and the **Indian Patents Act, 1970**. Original forms of such microorganisms cannot be patentable. Possibility of patenting microorganisms on a specific strain and microbiological process occur only when it undergoes human intervention with genetical modifications and shows the features of any novelty and industrial application. On considering those scientific developments and commercialization of microbiological work patenting became necessary. Thus, in India approaching microbiology with legal framework regarding patenting is a must. This article explores the statutory protection for microorganisms and emphasizes the awareness about patenting in microbiological studies and its applications.

Keywords: Microbiology, Microorganism, Microbiological Processes, Patenting, Patenting rights.

Introduction

Microbiology is the study of all living organisms which are not visible for human's naked eyes, but it can be seen through the objective lens of the microscope. Microorganisms were categorized as Algae, Bacteria, Archaea, Viruses, Fungi, Prions, Protozoa, Nematodes and Planktons (Phytoplanktons & Zooplanktons). Industrial microbiology is a subfield of Applied microbiology that focuses on the microbial processes with use of certain economically important microorganisms in the manufacturing of critical goods such antibiotics, food items, enzymes, amino acids, vaccines, and fine chemicals. There was more possibility for economic exploitation by using the potential of microorganism and microbial processes advancement in microbiology. This has actually sparked a lot of discussion about the intellectual property of those economically important and beneficial microorganisms. A patent is a form of an intellectual property

A patent is an intellectual property right granted to an inventor for a limited period in exchange for full disclosure of their inventions under the Patent Act, 1970. This right prevents others from using, selling, or importing the patented product or process for the same purpose.ⁱ Many people feel that a patent is granted only for major technological breakthroughs. But patenting paved the way even for scientific discoveries in the field of Microbiology, Biotechnology and Genetic engineering. Before 1980, no patent was given for the living organisms because they were considered as nature's products. After many debated over a period of time, agreements and changes were made in legal structure of patenting. India as member of World Trade Organization (WTO) signed in **TRIPS** (Trade-Related Aspects of Intellectual Property Rights) agreement obliges all signatories to renew patents on microorganisms, non-biological and microbiological processes. Patenting in India is governed by the Patents Act of 1970, and which was further amended in June 2002. In accordance with TRIPS agreement, it grants patent rights to new microorganisms.

History of Microorganisms Patenting

Louis Pasteur filed the first microorganism - purified yeast for patent on January 28, 1873 for the fermentation method of Production of fermented beer.ⁱⁱ The claim made by him was that the concerned invention furnished better quality of beer from the same quantity and quality of work through the process of fermented beer by yeast. The most significant case involving the patentability of microorganisms was by Dr. Ananda Mohan Chakrabarty in the USA. A landmark case in patent is *Diamond v. Chakrabarty*, 1980. In the case the Supreme court held that the microorganism which he called as a “Multiplasmid hydrocarbon-degrading *Pseudomonas*” is subjected for patentable under [Title 35 U.S.C]. Section 101 and the Plant Patent Act, 1930 in according to the patent examiner, a living organism may not be patented. After many appellate review panels reached clashing decisions as patent protection is available for a micro-organism that is artificially constructed rather than naturally occurring.ⁱⁱⁱ In 1980 patent was granted for bacteria a strain of *Pseudomonas* undergone with genetical modification capable of breaking down multiple components of crude oil which is used to treat oil spills. Later on 1988 first animal Oncomouse which was a genetically engineered animal designed to research about cancer got patented. As like U.S, Europe, Canada follows same manner of patenting system.

Evolution of Indian Patent System

Early from British rule, Patent law was enacted and undergone with several amendments. The history of Patent law specifically for India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact comprehensive patent law owing to substantial changes in political and economic conditions in the country. Accordingly, the Government of India made several amendments. Amendment made on June 2002 in the Indian patent act 1970, inserted the term “microorganism” in **Sec 3 (j)** says about not considering as inventions within the meaning of this Act, for patentability. It clearly says that other than microorganism cannot be consider as invention.^{iv}

The below table briefly explain about patent law and amendments.

YEAR	AMENDMENTS
1856	The Act VI of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
1859	The Act modified as act XV Patent monopolies called exclusive privileges (Making. Selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).
1872	The Patterns and Designs Protection Act is a law that protects patterns and designs.
1883	The Inventions Protection Act.
1888	The Inventions and Designs Act was merged.
1911	The Indian Patents and Design features. Act is a piece of legislation that governs patents and designs in India.
1999	The Patents (Amendment) Act of 1999, which took effect on March 26, 1999, replaced the Patents (Amendment) Act of 1995, which had been in effect since January 1, 1995.
2002	The Patents (Amendment) Act 2002 took effect on May 20, 2003.
2005	The Patents (Reform act) Act of 2005 went into force on January 1, 2005.

Governing Bodies of Patent

The Office of the Controller General of Patents, Designs & Trade Marks (CGPD TM) is located at Mumbai. Under the Department for Promotion of Industry and Internal Trade which administers the Indian law of Patents, Designs and Trade Marks. The Head Office of the Patent office is at Kolkata and its Branch offices are located at Chennai, New Delhi and Mumbai. The Offices of The Patent Information System (PIS) and National Institute of Intellectual Property Management (NIIPM) are at Nagpur. The Controller General supervises the working of the Patents Act, 1970, as amended, the Designs Act, 2000 and the Trade Marks Act, 1999 and

also renders advice to the Government on matters relating to these subjects.^v

Controller General of Patents, Designs & Trade Marks
(CGPDTM) -MUMBAI

Head Quarters of Patents - KOLKATA

Branches - CHENNAI, NEW DELHI & MUMBAI

FIG. 1 - GOVERNING BODIES OF PATENT

Patentability of Microorganisms in India

India allowed patenting for microorganisms under the Indian patent act, 1970. But it does not provide any clear definition for microorganisms. This leads to many confusions and debates and thus the Government of India constituted an Expert Committee under the chairmanship of **Dr. R.A. Mashelkar (2006)** to examine the issue related to patentability of microorganisms. The committee report clearly suggested that microorganisms can be patentable and need for strict guidelines for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.^{vi} In many countries, including Europe, USA, Republic of Korea, Japan and China, patenting of microorganisms is not an issue. In India native form microorganisms which exist in nature is consider as discovery, so it cannot be patentable as per **Sec 3(d)** of the Indian Patent Act 1970^{vii}, but its genome can be sequenced submitted in the DNA Data Banks such as NCBI, DDBJ or EMBL and microbes with genetical modified and which must be novel and having industrial application that can be patentable as per **Sec 3(d)** of the Indian Patent Act 1970.

In the case, **Dimminaco A.G. v. Controller of Patents & Designs 2001**, held a landmark judgment which was made by Calcutta High court. In this case patent application was for making of “Bursitis vaccine” – a vaccine used to protect Poultry. The Patent Office Examiner rejected the item under Section 12 of the Patent Act, 1970. He rejected on the grounds that the method or process of manufacturing of a vaccine containing a living virus, so the technique for making of Bursitis vaccine was rejected. Further court held that there is no statutory bar to accept a manner of manufacture as patentable if end products contain a living organism. Since the claim for patenting the process contain a valuable product and useful application. Therefore, the process was an invention and thus it is patentable under Section 2(1) read with Section 5 of the Act.^{viii} Current patenting scenario in India is still at infancy stage and need for proper guideline and progression.

Laws Regarding Microorganism Patenting

Trade Related Aspects of Intellectual Property Right (**TRIPS**) is an agreement on international IP rights to be followed by the member countries. TRIPS came into force in 1995, as part of the agreement that established the World Trade Organisation (WTO). Under Section 5 of the TRIPS agreement deals with patents and Article 27 is about patentable subject matter. **Article 27 (3) (b)** allows the Member States to reject patents on “plants and animals, other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological processes and microbiological”.^{ix} Thus the members were under TRIPS agreement obliged to provide patents for microorganism. Neither microorganism is defined in the TRIPS agreement nor does the agreement specify any parameters concerning the scope of its protection. Some of the patentable micro- biological inventions according to the TRIPS agreement are:

- (i) process of producing a new microorganism;
- (ii) new microorganism as produced by the defined process;
- (iii) new microorganism *per se*; and
- (iv) process of cultivation or otherwise using a known or new microorganism to:
 - a) form of multiplied microorganism itself, for example vaccine or edible biomass

- b) by - products of microbial growth, for example an antibiotic, enzyme, toxin or anotherwise useful industrial product.

In order to bring them into Indian law amendments were made on 2002 in the Indian Patent Act, 1970 added the term microorganism in **Section 3 (j)** and allows the patentability for microorganism and microbiological processes. Under **Section 2(c)** of the Biological diversity act 2002, defined biological resources as plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.^x Thus a live organism is also subjected for patenting. The Patent (amendment) Act, 2005 clearly states about the Pharmaceutical Product Patent in India for the 1st time under Section 3(d).

Thus a microbial oriented pharmaceutical product is also subjected to a patent, which was held in the case, *Novartis AG v. Union of India, 2013*^{xi}

Budapest Treaty

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or Budapest Treaty, is an international treaty signed in Budapest, Hungary, on 28 April 1977. It was coming into force on 19 August 1980. And later it was further amended on 26 September 1980. In 2001 India decided to become a part of the Budapest Treaty. **Section 2 (1) (aba)** of the Indian patent act 1970, gives definition for "Budapest Treaty".^{xii} The main feature of the Treaty is that a contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any "international depository authority"(IDA),^{xiii} irrespective of whether such authority is on or outside the territory of the said State. The Budapest Treaty ensures that an applicant, that is a person who applies for a patent, need not deposit the biological material in all countries where he/she wants to obtain a patent. The applicant needs to only deposit the biological material at one recognized institution and this deposit will be recognized in all countries party to the Budapest Treaty. Article 7 of the Budapest Treaty outlines the requirements for a facility to become an IDA. Institution complies with the requirements for IDAs set out in Article 6(2) of the Treaty. Today more than 80 countries are part of this treaty and there are 39 IDAs in almost 22 countries. India has two International Depository Authority located at the National Centre for Cell Science (NCCS)

located in the University of Pune and Institute of Microbial Technology (IMTECH) located in Council of Scientific and Industrial Research (CSIR), Chandigarh. As per a notification issued by WIPO, scheduled to be published by July 28, 2020, India will have its third International Depository Authority (IDA) under Budapest Treaty. National Agriculturally Important Microbial Culture Collection (NAIMCC) located in Uttar Pradesh it will be also recognized as an International Depository Authority.^{xiv} According to the World Data Center for Microorganism (WDCM), India is among top five countries which stores and holds a maximum amount of microbial cultures.

WORLD DATA CENTER FOR MICROORGANISM (WDCM)

Sample Deposition

- ❖ General Deposit – 5 Years
- ❖ **Safe Deposit – 5 Years**
- ❖ Patent Deposit – 30 Years

For Patent Deposit alone WDCM provides a maximum duration of about 30 years of confidential manner.

Criteria for Patenting Microbial Works

For the patenting of the microorganisms and the microbiological works. It must fulfil the following:

- **Human intervention:** Microbes which undergone with genetical or any artificial modification. Not being found in nature.
- **Novelty:** Microbe or microbiological processes must be new and not previously found.
- **Non-obviousness:** Microbe must not be an obvious variation of a previously knownmicrobe.
- **Utility:** Microbe or microbiological processes must have a specific function and usedfor manufacturing particular products.

Claim for patenting must satisfy the above-mentioned characters, after all examination the

genetically modified microorganisms or processes of manufacturing particular microbial products can be considered as invention and eligible for patenting. Before patenting the microorganisms are further determined via phenotypical characterized, 16S rRNA analyzed, MALDI TOF analysis etc for emphasis on storage of those valuable microorganisms before patenting. After examination of the microorganisms then it is further subjected to the Patent Officer where the officer on satisfaction allows our microorganism or their process for patenting process. A minimum patent ability is for about minimum of 20 years from the date of registration. The patent is charged per annum. The microorganisms which are ready and allowed for patent is set to be in the lyophilized form, where it can be stored for a long period of time preservation without causing any damage to the organism by causing any degradation.

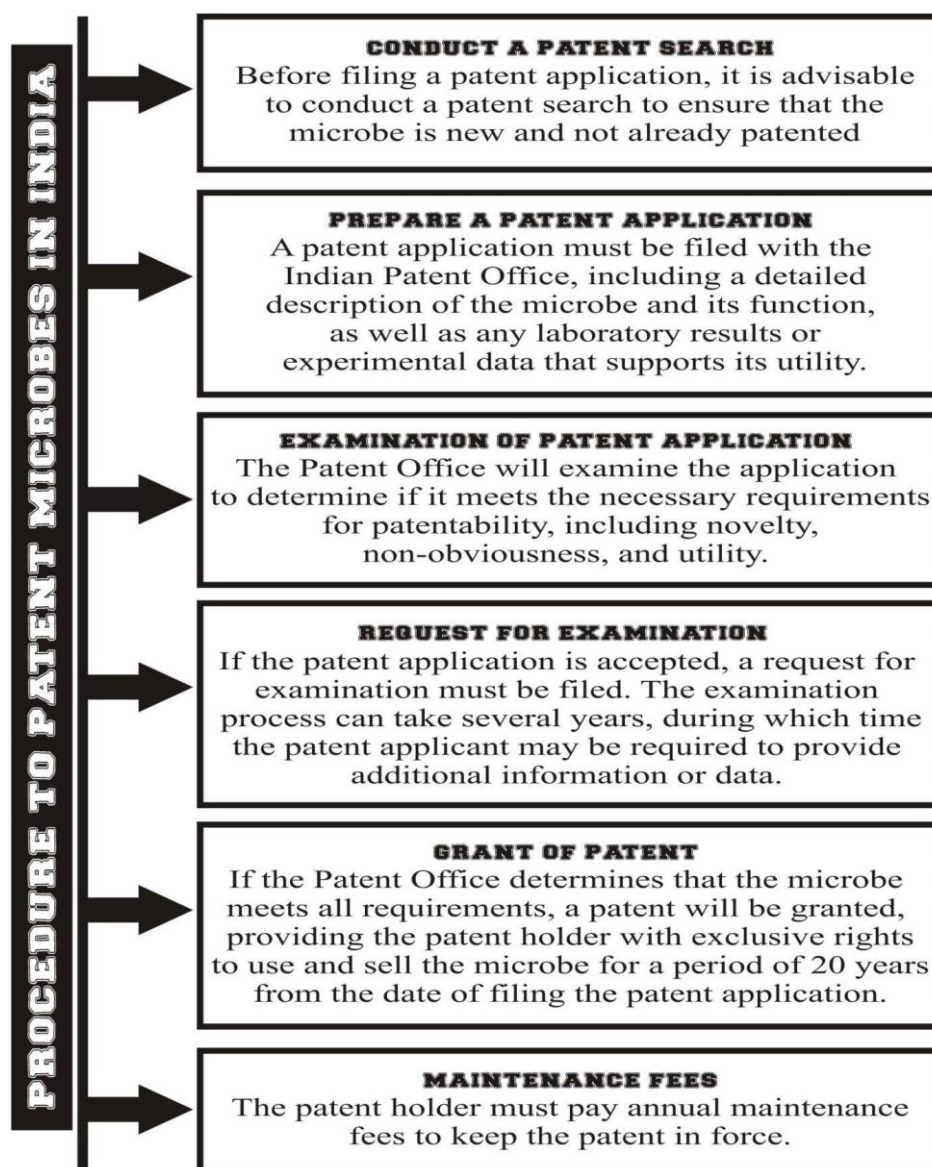
Significance of Patenting Microorganisms

A patent gives the owner the sole authority to use and market the microorganism for a predetermined amount of time, often 20 years from the date the patent application was submitted. Patents can serve as an incentive for businesses and people to devote time and money on creating novel, practical microorganisms. Louis Pasteur was the awardee of the first patent for the microorganisms during 1873. A patent holder gets legal immunity from infringement, enabling them to sue anybody found using, manufacturing, or selling the patented microorganism without authorization. New microorganisms can be commercialized with the use of patents, allowing businesses and individuals to make money off of their efforts and advancements in this area. Patents can encourage businesses and individuals to produce novel microorganisms with specified functions, which can boost innovation in the field of microbiology. The microorganisms genetic material was used as a key tool for the patent as a raw material by the microbiologist and biotechnologists.

Government of India permits patenting of microorganism in India under the Patents (Second Amendment) Bill of 2002, which came into force on May 2003.

Procedure to Patent Microbes in India

The patenting procedure for microorganisms in India involves a systematic and comprehensive process regulated by the Patents Act, 1970, and subsequent amendments. Initially, the applicant must file a patent application with the Indian Patent Office, providing detailed information about the microorganism's characteristics, isolation methods, and potential industrial applications. Subsequently, the application undergoes a thorough examination by the patent office to assess its novelty, inventive step, and industrial applicability. In cases where the microorganism is a part of a biotechnological invention, the applicant may need to comply with additional guidelines set forth by the Indian government. Throughout the examination process, the patent office ensures adherence to legal requirements while considering ethical and environmental implications. Once granted, the patent provides exclusive rights to the applicant for the specified duration, enabling them to prevent others from exploiting the patented microorganism without authorization. This procedure not only encourages innovation but also safeguards the interests of inventors and promotes the development of biotechnological advancements in India.

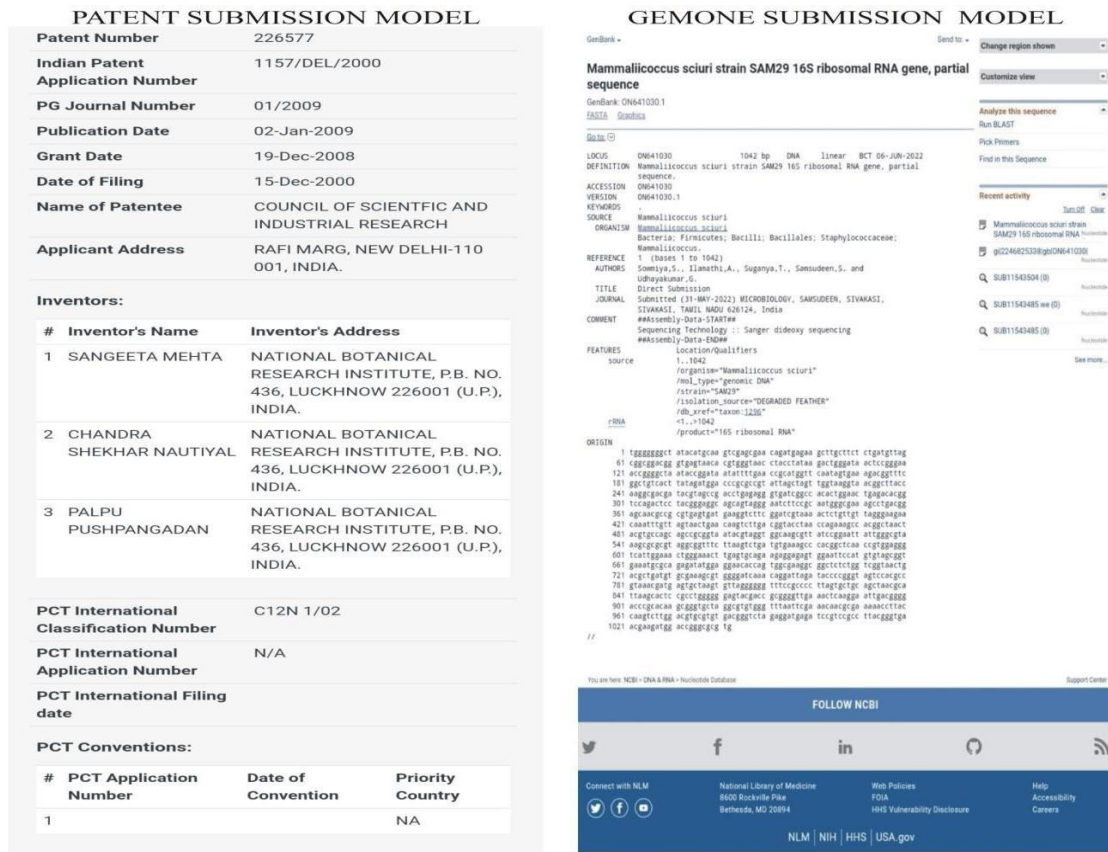
FIG. 2 – PROCEDURE TO PATENT MICROORGANISMS**Patenting Virus in India**

In the scope of definition of microorganism, viruses are considered as non living organism. The viruses can't develop or reproduce on their own, they are seen as existing somewhere in between the term living and non living, because they are dormant in nature. But once a virus reaches a live cell, it draws energy from the host cell and begins to replicate. Given that reproduction is a crucial aspect of living things, this renders them to be alive things.

According to Section 3(j) of the patent Act, 1970 says that living microorganisms with modifications can be patented but it does not cover non living microorganism (virus). The current pandemic brought on by COVID-19 has raised a lot of questions for us, one of which calls for a solution to the uncertainty surrounding the patentability of viruses under the Indian Patent System. Since viruses are form special classes, they must be defined separately in the manual and need a guideline to examine patent applications on viruses must be issued as soon as possible by Indian patent system.^{xv}

Microbial Strain Patent Vs. Microbial Genome Sequencing

The difference between a microbial strain patent and a microbial genome sequence patent is that a microbial strain patent covers the physical microorganism, while a microbial genome sequence patent covers the genetic information of the microorganism. Microbial strain patent provides legal protection for the physical microorganism itself, including its culture, derivatives, and parts. The patent holder has exclusive rights to use, sell and license the microorganism and others cannot make use of it or sell the patented strain without any permission. This type of patent is usually granted based on the unique properties or characteristics of the strain, such as its ability to produce a useful compound or its resistance to environmental stress. In contrast, a microbial genome sequence patent covers the genetic information of the microorganism, including its DNA sequence, gene expression data, and other genetic information. This type of patent is typically granted based on the discovery of a novel genetic sequence that has potential applications in research, biotechnology, or industry. The patent holder has exclusive rights to use the genetic information for specific purposes, and others cannot use or commercialize the patented sequence without permission. In summary, a microbial strain patent covers the physical microorganism, while a microbial genome sequence patent covers the genetic information of the microorganism. While both types of patents are related to microorganisms, they have different legal and commercial implications and are typically granted based on different criteria.



Criticism about Indian Patenting System in Microbiology

The Indian microbiological patenting system has faced criticism for its inconsistent standards for patentability and protection of traditional knowledge. Some experts argue that the requirements for patentability are too low, leading to weak and poorly enforced patents. The system also lacks adequate safeguards for traditional knowledge and biodiversity, which is essential for India's diverse range of microorganism-related knowledge in medicine, agriculture, and food production. This knowledge can be exploited without proper compensation or recognition. The lack of openness and uniformity in the patent examination process and the backlog of patent applications in India also raise concerns. Experts argue that the patent office needs more funding, including hiring additional examiners and creating more effective processes for patent examination and issuance. Despite the system's progress, there are still issues that need to be resolved to encourage innovation, safeguard traditional

knowledge, and ensure fair competition in international markets.

Conclusion

In the modern world all developing countries are moving towards knowledge-based economy. Thus, intellectual property rights like patenting are the necessary instrument. One of the objectives for sustainable development outlined by the Indian government is to promote innovation. Patenting of microbes is a complex and controversial issue with unclarified terminologies in patent system. Patenting rights gives the sole authority to use and market the microbe, by the patent holder which might encourage investment and advancement in the microbiology industry. But due to lack of awareness on patenting microbes current patenting scenario in India is still at infancy stage and need for proper guideline and progression. It is important to note that various definitions of microorganisms are available only from other reliable sources not from the statutory provisions. And another issue regarding patenting virus is still on debate. Unlike bacteria, viruses have no cells of their own. This means that they're not, strictly speaking, living organisms.^{xvi} Accordingly, there is a huge requirement for an amendment in the provision. Additionally need for a proper manual and a guideline to examine patent application. This will promote the advancement of microbiology field and structure the legal framework on patenting of microbial system in India.

Endnotes

ⁱ AS Nair, “Intellectual Property Rights (IPR): Indian scenario”, Everyman’s Science, 1999

ⁱⁱ P Debre, Louis Pasteur, John Hopkins University Press, 2000

ⁱⁱⁱ Environmental Sustainability (2020) 3:333-335. <http://doi.org/10.1007/s42398-020-00117-x>.

^{iv} <http://ipindia.gov.in/history-of-indian-patent-system.htm> (Last modified 20/12/2019)

^v <https://ipindia.gov.in/about-us.htm>. (Last modified 27/12/2020)

^{vi} Government of India, Report of the Technical Expert Group on Patent Law Issues (*Ministry of Commerce*)

^{vii} “discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant”

^{viii} *Dimminaco AG v. Controller of Patents and Designs* (Kolkata HC, 2001)

^{ix} plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

^x “biological resources” means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material

^{xi} <https://www.lexology.com/library/details.aspx?> (Last visited 21/02/2023)

^{xii} “Budapest Treaty” means the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure done at Budapest on 28th day of April, 1977, as amended and modified from time to time.

^{xiii} <https://www.wipo.int/portal/en/> (last visited on 16/02/2023)

^{xiv} PCT NEWSLETTER NO.07/08/2020(JULY-AUGUST 2020)

^{xv} <https://articles.manupatra.com/article-details/Virus-Patents-in-India-A-Techno-Legal-Analysis> (Last visited 16/02/2023)

^{xvi} <https://www.ncbi.nlm.nih.gov/books/NBK279387/%3C/u%3E/> (Last visited 16/02/2023)