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Laws Relating to Patenting of Microorganisms in India : Issues and Challenges

ORIGINAL ARTICLE

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Abstract

Microorganism, gene, and viral patenting is a controversial topic having moral, spiritual, and political ramifications. People who think that no one should own living things are on one side of the debate. The opposing viewpoint holds that living things can be patented and owned just like any other innovation. Whether it is morally acceptable to own anything alive is at the centre of the ethical discussion. Apart from that there must be some unified and universal laws to be made for the patenting of microorganism. In this article, we'll look at the patenting of viruses, genes, and microorganisms. Although, the Government of India permitted patenting of microorganisms in India under The Patents (Amendment)Act 2002. But the World Intellectual Property Organisation introduced the new Regulation in 2023 which is based on The Budapest Treaty made some radical changes in the protection of patents relating to microorganisms. This paper also deals with the position of patenting of microorganism in India with relevant international norms and to find out the lacuna in the domestic law regarding patenting of microorganism in India.

Key Words

Patent, Microorganisms, Challenges.

Introduction

Before analysing the relevant laws regarding the patenting of microorganism it is necessary to understand the words which are the core of the whole debate around the patenting of microorganisms. There are two words which have to be examined: firstly Patent and the second one is Microorganism.

Patent

The word Patent originated from the Latin verb *patere (adj. clear, Obvious)* to noun *patent- mean to* 'lying open' (i.e., to make available for public inspection)[1]. This was an open document or instrument issued by a monarch or Government granting exclusive rights to a person relating to doing some specific act in unrestricted and uncontrolled liberty with monopoly in that field.

According to the Oxford Dictionary the word patent means an official right to be the only person to make, use or sell a product or an invention; a document that proves this.[2]

The definition given by World Intellectual Property Organisation (WIPO) is that "A patent is an exclusive

right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application".[3]

According to section 2(m) of The Patent Act, 1970 "patent" means a patent for any invention granted under this Act.[4] This definition does not provide any inference about the meaning of word patent, only provides that there are two types of inventions: firstly those can be patented under this Act and secondly those inventions which can not be patented under this Act.

A "Patent" refers to one of the Intellectual Property Rights associated with a legal document that grants the creator an exclusive right to their innovation for a particular period of time and forbids anyone from using, selling, or importing it without their consent.

It can be summarised that a Patent is the protection granted by the Sovereign State as per the international norms to the person for any new and unique scientific inventions with exclusive rights against the whole world.

Microorganism

The word microorganism is composed of two words Micro and Organism.

The word micro originated from *latin* word *Mikros*, Attic form of Greek *smikros* from *smika* from root *smik* means small[5]. And word Organism also composed of two word organise and ism. The word organise originated from the latin *organum* from *organ* mean to form into a whole consisting of interdependent parts. The word *ism* derived from the Latin word *isma* means the practice or teaching of a thing.[6]

The word microorganism defined as a living thing which on its own is too small to be seen without a microscope.[7]

In the biological sense microorganism defined as A microorganism is a living thing that is too small to be seen with the naked eye. Examples of microorganisms include bacteria, archaea, algae, protozoa, and microscopic animals such as the dust mite.[8]

In a simple way we can understand that microorganisms are those living very small animals that exist in nature having the capacity of all necessary functions of living things including the reproduction of its own without any external interference.

It may be inferred that the microorganisms are those small living animals of any genre that exist in this world with their own. But what if scientists made a new microorganism in the laboratory? People are often against the interference of humans in nature, on the preposition that only God can have the power to generate, and humans are not supposed to interfere in the power of the almighty. On the other hand, some groups of people in favour of scientific invention favour the scientific inventions of new microorganisms that are beneficial to mankind.

International Provisions

The World Intellectual Property Organisation adopts some important international documents which are also associated with the patenting of microorganisms. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977).

The Budapest Treaty came into force in 1980 after being signed in 1977.The treaty was amended several times, the most recent amendment to the pact was made in 2000. Regulation was also adopted for the better enforcement of this treaty. The first Regulation Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure adopted on April 28, 1977, and amended on January 20, 1981, then in October 1, 2002 and recently in July 22, 2022.

The deposit of microorganisms for patenting purposes is governed by an international agreement. A recognised international depositary authority (IDA) must receive a depositor's microorganism in accordance

with the treaties in order to issue a certificate of deposit. The agreement specifies how the deposited microbe should be handled and preserved and mandates that the IDA make the microorganism available to the public upon request.

The main characteristic of the Treaty is that any contracting State that permits or mandates the deposit of microorganisms for the purpose of patent procedure must recognise the deposit of a microorganism with any "international depositary authority" for such purposes, regardless of whether such authority is on or outside the territory of the said State.

Section 2(ii) of the Budapest Treaty define "deposit of a microorganism" means, according to the context in which these words appear, the following acts affected in accordance with this Treaty and the Regulations: the transmittal of a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;

And Section 2(ix) "depositor" means the natural person or legal entity transmitting a microorganism to an international depositary authority, which receives and accepts it, and any successor in title of the said natural person or legal entity;[9]

Article 3 which deals with Recognition and Effect of the Deposit of Microorganisms (1) (a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.[10]

Article 4 New Deposit (1) (a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular, (i)where such microorganism is no longer viable, or (ii)where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:[11]

The main drawback of this Treaty is that it does not define the word microorganism, therefore it provides whole discretionary power to the concerned state parties to the Treaty to make their own definition of microorganism and allowed or rejected the patenting of microorganisms at the state level.

The second drawback of this Treaty is that only inventions involving genetic modification of microorganisms that add new, beneficial traits that weren't present in natural form are eligible for patent protection. The ability of a person proficient in the art to conduct the same experiment and arrive at the same conclusion is another prerequisite that must be met in order to patent microorganisms. However, in their natural habitat, microbes alter their personalities, making it challenging for others to successfully experiment or invent.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS agreement incorporates some specific provisions regarding patenting of scientific innovations including microorganisms. The Article 27 deals with *Patentable Subject Matter that* 1. Patents shall be accessible for all inventions, whether methods or products, in all branches of technology, subject to the criteria of paragraphs 2 and 3, provided that they are novel, involve an innovative step, and are suitable for industrial

application. Without regard to the location of the invention, the field of technology, or whether a product is imported or made locally, patents shall be issued and patent rights enjoyed, subject to paragraphs 4 of Article 65, 8 of Article 70, and paragraph 3 of this Article. 2. Members may exclude from patentability inventions whose commercial exploitation must be prevented within their borders in order to uphold public morality or ordre public, including to safeguard human, animal, or plant life or health or to prevent serious environmental harm, provided that such an exclusion is not made merely because the exploitation is prohibited by their law. 3. Members may also choose to exclude certain items from patentability, including (a) procedures for diagnosing, treating, or operating on people or animals, (b) organisms other than microorganisms, and essentially biological processes for growing organisms other than those that are non-biological and microbiological. Members must, however, make provisions for the preservation of plant varieties, whether through the use of patents, a strong sui generis system, or any combination of the two. Four years following the WTO Agreement's entry into force, the clauses of this subparagraph must be reviewed.[12]

Also Article 29 relating to Conditions on Patent Applicants, that 1. Members may require a patent applicant to specify the best method for implementing the invention that was known to the inventor at the time of filing the application or, in cases where priority is claimed, at the priority date of the application in order for the invention to be carried out by a person skilled in the art. 2. Members have the right to request information about a patent applicant's related international applications and grants.[13]

Again Article 30 relating to Exceptions to Rights Conferred, that Members may grant limited exceptions to the exclusive rights granted by a patent, provided that these exceptions do not unreasonable conflict with a patent's normal exploitation and do not unreasonable prejudice the patent owner's legitimate interests, taking into account the legitimate interests of third parties..[14]

Again Article 31 provides obligation on the state parties for granting compulsory license and protection of rights of license holders.[15]

From the perusal of these articles of TRIPS it may be submitted that the international organisations are agreed and committed for the protection of the scientific innovations with regards to the microorganisms globally.

On June 1, 2000 the World Intellectual Property Organisation (WIPO) adopted The Patent Law Treaty for the smooth and easy protection of patent by the signatory parties of this treaty

Position in United State of America

In USA the patent of microorganism is governed by U.S. Patent Act (Title 35 of the United States Code) as amended by the Leahy-Smith America Invents Act. This Act provides for the proceedings for the filing of patent of microorganism and granting of patent to the inventor. This Act is further amended according to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

PART II of U.S.C. 35 deals with the patentability of inventions and grant of patents. The Chapter 10 deals with Patentability of Inventions. Section 101 of the code provides about the Inventions patentable. Subject to the limitations and requirements of this section, which places a restriction on the issue of patents, whomever creates or discovers a new and useful process, machine, manufacturing, or composition of matter, or any new and useful improvement thereof, may receive a patent therefore.

Section 102 relating to the Conditions for patentability; A person is eligible for a patent unless — (a) the invention was known or used by others in this country, or was patentable or described in a printed publication in this country or another country, before it was created by the applicant for a patent; or (b) the invention was patentable or described in a printed publication in this country or another country, or was in use or available for sale in this country more than a year before the date of the application for a patent in the United States. or (d) the applicant or his legal representatives or assigns first caused the invention to be patented, or was the

subject of an inventor's certificate, in a foreign country before the date of the application for patent in this country on a patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or (e) the invention was described in — (1) an application for a patent made in the United States prior to the invention by the applicant for a patent and published under section 122(b). or (2) a patent granted on an application for a patent made by someone else and filed in the United States prior to the invention made by the applicant for a patent, with the exception that an international application filed under the treaty defined in section 351(a) will only have the same effects as an application filed in the United States for the purposes of this subsection if it designates the United States and is published in the English language under Article 21(2) of such treaty; or (f) he did not independently create the invention that is the subject of the patent application, or (g) (1) If another inventor involved in the interference proves, to the extent authorised by Section 104, that the invention was made by that other inventor and was not abandoned, repressed, or disguised during the course of an interference under Section 135 or Section 291 performed there under, or (2) The invention was created in this nation prior to such person's invention by a different creator who hadn't abandoned, suppressed, or hidden it. Priority of invention under this subsection shall be established by taking into account not only the dates on which the invention was first conceived and last put into use, but also the reasonable diligence of the party that did so from the time of the other's conception forward.

Under Section 103 of the said code provided for the Conditions for patentability; non-obvious subject matter - A patent for a claimed invention may not be obtained if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention relates, regardless of whether the claimed invention is not identically disclosed as set forth in section 102. The way the invention was created shall not affect its patentability.

In the matter of *Diamond v. Chakrabarty*[16] Scientist Chakrabarty applied for patent protection for his approach of creating a microbe that could break down various components of crude oil. He made claims about the bacterium's development, the bacterium itself, and an inoculum that contained the bacterium and a carrier substance. Chakrabarty was refused a patent for the bacteria itself on the grounds that it did not fit the criteria for a patent, even though the examiner determined that a patent was eligible for the procedure and the inoculum. The patent examiner states that a live organism cannot be patented in accordance with 35 U.S.C. Section 101 and the 1930 Plant Patent Act. The Acting Commissioner of Patents and Trademarks requested certiorari review from the Supreme Court after conflicting decisions were made by various appellate review bodies on the issue.The majority opinion of Warren Earl Burger Lord Chief Justice Potter Stewart, Harry Andrew Blackmun, William Hubbs Rehnquist, and John Paul Stevens justice held that 'Acknowledging that patents cannot protect laws of nature or physical phenomena, Burger still felt that a broad interpretation of 35 U.S.C. Section 101 and particularly the term "manufacture" was appropriate. He discovered that the word "manufacture" ought to mean just as broadly as it does in a regular dictionary. Burger further asserted that the 1930 Plant Patent Act, which was designed to distinguish between natural and artificial creations, did not call for the examiner's interpretation. Since the bacterium did not exist in nature, Chakrabarty created it himself. Burger further disagreed with the idea that Congress would need to expressly approve the patenting of microorganisms because Congress could not have anticipated this scientific advancement when writing the original patent statutes. Burger claims that since patents are intended to reward innovation and cleverness, denying protection to unanticipated inventions would be against the law.Held: Respondent's microorganism qualifies as a "manufacture" or "composition of matter" under section 101 of the Patent Act, which defines a live, artificially created microorganism as patentable subject matter.[17]

Position in INDIA

In India the laws relating to protection and regulation of rights relating to patents deal with The Patent Act 1970, which was amended in 2005. The relevant provisions of this Act are -

Section 2(j)"invention" means a new product or process involving an inventive step and capable of industrial application;

Section 2(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

Section 2(l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art;

Section 2(m) "patent" means a patent for any invention granted under this Act;

Chapter 2 deals with the inventions not patentable - The following are not inventions within the meaning of this Act,— (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws; (b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment; (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature; (d) the mere 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. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy; (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; (f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way; (g) Omitted by the Patents (Amendment) Act, 2002 (h) a method of agriculture or horticulture; (i) 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. (j) plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals; (k) a mathematical or business method or a computer programme per se or algorithms; (l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions; (m) a mere scheme or rule or method of performing mental act or method of playing game; (n) a presentation of information; (o) topography of integrated circuits; (p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.[18]

In matter of Dimminaco A.G. v. Controller of Patents and Designs,[19] The appellant had applied for a patent for the process that he had invented for the creation of a "Bursitis vaccine" to protect poultry from Bursitis infection. The procedure involves developing a Bursitis vaccine and used a live virus both in the development of the vaccine and in the finished product. The Patent Act of 1970's Section 12 had been used to analyse the application by the Patent Office Examiner, and upon his findings, rejected said application on the grounds that the claim did not meet the requirements of an "invention" under Section 2 (j)(i) of the Act and that the application fell under Section 5 (a) or 5(b) of the Act because a meal or medication was the end result of the process. The appellant then appealed to the Controller of Patents and Designs, who, in accordance with Section 73(3) of the Act, further delegated power to the Assistant Controller of Patents and Designs (hereinafter referred to as Assistant Controller). The application was denied because the Assistant Controller

upheld the Examiner's judgement. As a result, the appellant filed a case with the Calcutta High Court in accordance with Section 116 of the Act.

The Assistant Controller's main argument, according to the court, was that the finished product contained a live virus, invalidating the claim as a method or process of manufacture. The Assistant Controller maintained that maintaining the patentability of such a procedure would make the Indian patent system more complex and had not before been authorised in India. The Assistant Controller cited the Patent Enquiry Committee report, which contained Justice Iyengar's advice, to support their position of not accepting the broader definition of "manufacture". The Assistant Controller further emphasised that a live entity cannot be changed into another product through physical or chemical processes, hence a product containing a living organism is not a substance.

In order to respond to the appellant's challenge to the findings based on the lack of any explicit justification for the Examiner's rejection, the Court examined the procedural framework of the examination of the patent office. The bench emphasised the procedural nuances of such an examination conducted in accordance with Section 12 of the Act, emphasising Section 12(c)'s reference to the inquiry report under Section 13 and thereby underscoring the relationship between the two sections. The court noted that in addition to their being no such inquiry in the record, the main conclusion that the claim does not qualify as an invention has not been supported by any logic. The bench cited "Terrell on the Law of Patents" in order to stress the essential of the adjudicatory nature of the Examiner's role and the quasi-judicial nature of their conduct, which requires that their objections be supported by explanations. The Court's interpretation, which leaned towards the justification offered by the appeal counsel, stated that just because a product contained a live organism did not automatically make the process by which it was made unpatentable. Instead, the novelty and utility criteria would need to be used to evaluate patentability. The court determined that the application satisfied both requirements since it used a unique procedure under particular circumstances and was helpful in preventing the contagious Bursitis disease in chicken. A patent could be issued for the claim in this situation in accordance with Section 2(1) of the Act read with Section 5. The bench went on to describe the "vendibility test"'s complexities for determining whether a method of manufacture is patentable. According to the Court, a product that can be the object of commercial sale or purchase transactions is defined as being vendible. The test determines if the procedure results in an improvement, restoration, production, or preservation of the commodity in question. The test for vendability would have been satisfied if the innovation, which has the nature of a manufacturing method, accomplishes any of the aforementioned goals. The court determined that the Controller's arguments that the presence of a living creature in the finished product would render the invention ineligible for patent protection and that the creation of such a product did not meet the definition of manufacture were unfounded. In the cases cited by the appellant where patents had previously been granted despite the process containing living organisms, the Controller argued that the end product did not contain such living organisms but rather involved lyophilizing such cells, which in their interpretation killed such organisms. In its ruling, the Court rejected this claim, stating that lyophilization is a technique of preservation rather than the eradication of such organisms. The Controller's apparent last-ditch effort to support their position by promising that previously granted patents incorporating living beings will be withdrawn was rejected by the Court on the grounds that doing so would violate Section 64's legal requirements. Thereby, the bench ordered fro the reconsideration of the application wit in the period of two months.[20]

In *Monsanto Company v. Nuziveedu Seeds Ltd.*[21] Nuziveedu Seeds Ltd., The maker of GM cotton seeds, Monsanto, granted a technical licence to a big seed company in India. Despite being forbidden from using the technology, Nuziveedu Seeds Ltd. stopped paying Monsanto royalties and continued to use it. Nuziveedu Seeds Ltd. had violated Monsanto's patents, according to the company's claim, by utilising the company's genetically modified cotton seeds without permission. Monsanto's patent was deemed invalid by Nuziveedu Seeds Ltd. because it made reference to a natural product, which is not eligible for a patent. The Court determined that Monsanto's invention was ineligible because it made a claim about a natural chemical,

disqualifying it from receiving a patent. The court ruled that the patent must be sufficiently inventive and meet the non-obviousness requirements in order to be patentable in India.

Conclusion

The legality of patenting viruses, genes, and microbes is a difficult and debatable subject in the law of patents. If these biotechnological inventions meet the requirements for novelty, non-obviousness, and usefulness and are fully and precisely disclosed in the patent application, they may be eligible for patent protection. By allowing biotechnology businesses and researchers to commercialise their discoveries and recover their investments, patenting these biotechnology ideas can offer important protection. In addition, the possibility of monopolies in the biotech sector and access to necessary medications and technologies can both be raised by the patenting of microbes, genes, and viruses.

Since the public needs access to vital innovations, it is crucial for patent offices and Governments to strike a balance between protecting inventors' rights and doing so. To ensure that patent applications are examined consistently and fairly and that only truly unique and beneficial inventions are granted patents, guidelines for reviewing biotechnology applications in patents might be created. The moral and ethical ramifications of patenting genetic information and living things are still being debated. These conversations emphasise the necessity of continuing to examine and discuss the patent system to make sure it is just, equitable, and benefits the general welfare.

In India there is sufficient legislation for the patenting of microorganism and protection of rights of patent holder, but with the gradual changes in the laws relating to protection of patent worldwide the Indian Legislature have to make changes in there laws for the protection of patent relating to microorganisms.

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