

PATENTING OF MICRO-ORGANISMS IN INDIA

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A) INTRODUCTION:

Intellectual Property Rights, as a subject matter has evolved multifold with the passage of time. However, it is only in the recent years has it been given due importance. This is due to many reasons, one of them can be regarded as industrialization in individual countries and in turn the world on a whole. Massive industrialization in the entire globe lead to a spread of globalization. The advent of globalization would not have been possible without the help of the innovative ideas and thoughts of the creative individuals all across the world. The very meaning of protection of intellectual property rights implies, in very simple terms, that a creation by a man with the use of his intellect should be protected. Thus, with a view of protecting a man's original creation he is conferred with certain rights that he exclusively holds as against the public at large. It is of sheer importance to note that these creations originating from the minds of human beings can be in various forms and can be of different kinds. Thereby, directly implying that different creations must all mandatorily be protected but the protection thus conferred must be of a different kind. This lead to the evolution of protection of intellectual property rights in the name of copyrights, patents, trademarks, geographical indication, to name a few. These vary from each other in the sense that they mutually provide a protection to the creator of such products of mind however the protection depends on the kind of creation. This paper exclusively deals with the topic of patents and the protection it confers on the people who create products with the help of their minds.

B) BIO-TECHNOLOGICAL INVENTIONS – MICROORGANISMS:

Biotechnology includes living organisms such as plants, animals and micro-organisms as well as non-living biological material such as seeds, cells, enzymes, plasmids and the like. The question of patenting living organisms has been around for a very long time. The subject matter of this paper is that of patenting micro-organisms, which is one of the aspects of living organisms. Microorganisms can be understood as any organisms which by its form is so small in size that a naked human eye is incapable of seeing. Thereby requiring the help of a microscope, thus referred to as a microscopic organism, like a bacterium or a virus. The entire debate revolving around the patenting of a microorganism is mainly due to it not satisfying the criteria of an invention. Most people regard it to be as mere discoveries and not a creation of a mind. However, the author through this paper begs to differ. In the opinion of the author of this paper, microorganisms must be granted a patent if it satisfies a few conditions that will be mentioned later on. It is of great significance to note that the

entire idea of not granting patents to microorganisms due to them being mere discoveries should be completely disregarded for a very simple reason that patents are granted not only to confer rights and protection but also to provide an incentive to the creator to create more of such inventions to enhance the development of the country. Following are the reasons why, patents must be granted for microorganisms:

1. Serves as an incentive to inventors:

In majority of the cases, the people who do create an invention in the form of a microorganism are those who are scientists, individually or a part of a corporation. This is mainly because only such people have the access to the right kind of resources to venture into the world of microorganisms, let on alone invent a new one. Therefore, by granting a patent to such scientists or corporations, it will prove to be an incentive for them to invent more of products and procedure that not only is profitable to them but also serves as an aid in the development of the country and economy on a whole. The corporations dealing with bio technology normally require huge capital resources and skills to invent microorganisms that have within them some inherent benefit that changes the efficiency of the world. Hence, to reward their investment, the patent must be granted.

2. Breakthroughs:

Patentability of microorganism has led to many world changing breakthroughs that have improved the quality of life of human being. The more famous ones are in the field of medicine and plants. However, it is of great significance to note that many such bacteria have been invented that have helped in increasing efficacy of work in various sectors, the more known being the case of *Diamond v Chakravarty*.

3. In consonance with the existing laws:

It must be noted that the law does provide many provisions that ensure that only an invention is granted a patent. It lays down grounds which must be satisfied for product or process to qualify as an invention. This is further dealt with in detail in the next section. It is important to note that, by virtue of TRIPS agreement not only in patenting of microorganisms allowed in the country, but the court, via *Dimminaco AG v. Controller of Patents and Designs and others*¹ held that micro biological processes can also be patented.

¹ 2002, IPLR 255 (Cal)

C) INDIAN LAW ON PATENTS:

The law that governs patenting in India is dealt with in the Patents Act of 1970. Under section 2(1)(m) of the aforesaid Act deals with the term patent and defines it as a patent granted for any invention under this act. Upon a further of the Act, a patent can be defined as a protection or a right given to a creator to exclude others from making, using or selling an invention. Below, a broad category is made, of the factors² that are taken into consideration before a patent is granted:

1. Invention

This next term to be defined is that, what is included under the ambit of invention. The act under section 2(1)(j) defines an invention as a new product or process involving an inventive step and capable of industrial application.

2. New Invention

The act under section 2(1)(l)³ defines a new invention as anything that has previously not been in the public domain and has not been anticipated or used. Thus, it is very clear that the invention can be in any form.

3. Novelty

For an invention to be patentable, it has to be novel, in the sense that it cannot be found in any of the present products or processes that is in the public domain. In the famous case of Novartis AG & Ors. v. Union of India⁴, the court stated that a new product need not necessarily mean something entirely new but can be different from the previous or recent one.

4. Inventive Step

For an invention to qualify as one, it must have either of the two things or both, namely, technical advance to existing knowledge and efficacy and secondly, having economic significance that is not obvious to a person skilled in art, this was added by the 2002 and 2005 amendments.

5. Non-obviousness

This clause imbibes within itself two of the above-mentioned factors as its core in proving that the inventions are not obvious i.e., the inventor has to prove that the invention is a new invention and it is that of a novel nature and must involve and inventive step.

6. Industrial application

Mere usefulness as a factor is not sufficient but its utility has to be proved in order to grant a patent.

² V.K. Ahuja, Intellectual Property Rights in India, 2009, LexisNexis.

³ Patents Act, 1970.

⁴ 2013, (54) PTC 1 (SC) at page 80.

Thus, it can be said that if a patentee (a person applying for the grant of a patent) successfully satisfies all of the above criteria the patent office on its own discretion may grant a patent. Once a patent is granted it can be used by the inventor exclusively for which he can charge royalties for the next twenty years. Upon the expiry of such a period, the invention falls in the public domain and the knowledge behind it is made public. Hereafter, the patentee can no longer charge royalties and earn a profit out of the same.

- Technology v bio technology

In the act, section 2(1)(l) states that:

“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

A perusal of this definition can lead to an implied meaning that the invention could be in the form of a technology that hasn't been in public domain.⁵ In the present case, the meaning could be taken as a one which could include both information technology as well as that of bio-technology. However, an inherent problem with this is that patent offices of certain countries like India, require for a detailed explanation and disclosure of the invention for which the patent to be granted is applied for.⁶ The problem arises when the inventor has to disclose the process through which he derived the new microorganism or the useful utility of the microorganism. It is so, because once these details are mentioned in the patent application and if the application were to get rejected then such sensitive information could be exploited by any person or corporation to their benefit. Therefore, the author believes that there is a twofold solution to this, firstly, the detailed reporting of the invention in the application must be slightly relieved for the inventor applying for a patent in the field of biotechnology. This can be done, by conducting a live demonstration and theoretically explaining the functions of the microorganisms, this could be done to properly and correctly explain all the functions, thereby explaining the practical utility of the microorganism, so it can be said that the patent application must contain the details of all the practical utility functions of the product or the process. However, the steps to create such an invention must be demonstrated in the lab, to fulfill the requirement of a safe surrounding and in presence of three duly appointed persons having authority and the right expertise to grant patents.

⁵ <http://www.wipo.int/patents/en/topics/biotechnology.html>, last accessed on 25.08.18.

⁶ http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html, last accessed on 25.08.18.

However, there are exceptions to the law so as to avoid any kind of duplication and to make sure that the public is not cheated in any way and the inventor does not take any unfair advantage of the available resources, to maintain a standard for products and processes to qualify as invention. Inventions that contravene the following⁷, cannot be regarded as inventions under the law, and thus are not granted patents (in case of microorganisms)

1. Frivolous inventions
2. Contrary to public morality
3. 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
4. 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.
5. 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
6. the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.
7. 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.
8. 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;
9. a presentation of information
10. an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

(for the sake of this paper, the author has mentioned those exception that are deemed relevant to the subject matter)it is not to say that Indian law does not deal with patentability of microorganism, the current law does provide exceptions, as mentioned above that invalidated grant of patents if it falls under any of the above.

⁷ Patent Act, 1970.

The question of it being a mere discovery is also addressed by the current law by stating clearly what can be patented in the name of a microorganism. However, the law is still at the stage of infancy and for it to evolve further, a change is required which elevates the law further by defining purpose for which the microorganism is invented, its application and use along with the micro biological process. This change, indeed, can be brought about by way of an amendment after gaining some insight about the same which is already in use by the other countries, like the U.S and Europe.

D) INTERNATIONAL AUTHORITIES

(i) Budapest treaty:

As previously mentioned, there can arise a problem with complete disclosure of the invention. However, there is another problem that can arise which is related to the problem of disclosure. At certain times, due to such stringent disclosure norms, when a detailed description of a microorganism is practically impossible to describe, the microorganism itself is considered to be a part of the disclosure. In such an instance, the patent office requires the inventor to not only submit a written disclosure but also deposit the biological material in question with a specialized culture collection.⁸ This idea seems rational on the face of it, however in practical implementation, it is a tedious task to store all the samples of microorganisms that come in through way of patent application. Not only is storage an issue, but also a mechanism for preservation of such samples has to be devised. Moreover, it is practically impossible to deposit multiple such samples with each patent application. This method is not only time consuming but also is not cost efficient as the inventions in question are numerous in number and range differently.

Hence, to come up with a solution to this, the policy makers decide to adopt the Budapest treaty which is administered by WIPO (World Intellectual Property Organization). The treaty was adopted to streamline this entire process and make it more cost effective. The treaty was aimed to be directed at the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. With this treaty, the aim was to eliminate the need for multiple deposit centers by centralizing it completely. Thus, there would exist no more a need to deposit multiple samples of the same biological material with biological resource centers in different countries. Adherence to the Budapest treaty requires the countries to make no changes in their respective national legislation as nor does it define a microorganism neither does it regulate the patentability of the same. The treaty recognizes certain centers around the world as International Depository Authorities (IDA's) where such samples that are collected are stored.

⁸ http://www.wipo.int/wipo_magazine/en/2015/04/article_0001.html, last accessed on 25.08.18.

The storage is possible only if the laid down requirements are satisfied. Only if the biological material deposited with any one of the depositories is recognized by all members of the Treaty as valid for patent purposes by all countries in which protection for the relevant invention is sought which is presently 79 countries. Such IDA's store the sample for 30 years or five years after the most recent request for a sample, whichever is later. The related costs are relatively lower, thus making it cost efficient.⁹

(ii) TRIPS Agreement:

In the landmark case of *Diamond v Chakravarty*¹⁰, a patent was sought for a genetically engineered bacterium capable of breaking down multiple components of crude oil and applied for a patent on the ground that it a trait possessed by the bacterium is not found in the naturally occurring bacteria and sought patent protection. Initially, the US patent office reject the application stating it is a product of nature and hence cannot be granted the protection of a patent. However, when the case went to the supreme court of the United States, the court held that the microorganisms per se were patentable in the united states. The bench in that case held that "anything under the sun made by man" including life forms could be patented.¹¹ This provides another perspective as if the decision of the court in the present cases is carefully perused, it can be gathered that the supreme court has stated the ingenuity of the human mind. To simply state this, according this to decision, anything under the sun even if it is man-made can be patented if there exists enough evidence to prove that it could not have been achieved naturally but requires the application of mind in a complex way, therefore hinting at the requirement of skill to manipulate the already existing material whether or not microscopic, to come up with an invention that satisfies the other criterion of patentability. This case is a landmark case not only in the US but it affects all the countries in the like manner who are a party the agreement on Trade Related Intellectual Property Rights, famously referred to as the TRIPS agreement. The first major step taken towards the protection of creations of mind or intellectual property was through the way of Paris Convention in the year of 1883.¹² TRIPS can be said to have originated from General Agreement on Tariffs and Trade (GATT)¹³ and the General Agreement on Trade in Services (GATS). TRIPS agreement calls for protection of inventions in all field of technology that involve an inventive step and can be industrially applied. TRIPS¹⁴ is a detailed agreement that outlines the rights of the patents owner and under what circumstances can exceptions be granted.

⁹ http://www.wipo.int/wipo_magazine/en/2015/04/article_0001.html, last accessed on 25.08.18.

¹⁰ 447 US 303 1980

¹¹ V.K. Ahuja, *Intellectual Property Rights in India*, 2009, LexisNexis.

¹² <http://www.wipo.int/treaties/en/ip/paris/>, last accessed on 25.08.18.

¹³ Suman Sahai, *GATT And Patenting Of Microorganisms*, *Economic and Political Weekly*, Vol. 29, No. 15 (Apr. 9, 1994), JSTOR

¹⁴ P.K. Vasudeva, *Patenting Biotech Products: Complex Issues*, *Economic and Political Weekly*, Vol. 35, No. 42 (Oct. 14-20, 2000), JSTOR.

Herein, the concept of compulsory licenses is also highlighted wherein the government is permitted to issue the license which allows a competitor to produce the product or use the process under license without the owner's consent. But this can only be done under specific conditions set out in the TRIPS Agreement aimed at safeguarding the interests of the patent-holder.¹⁵ TRIPS provides a basic framework with the help of which the countries can streamline their domestic laws with that of the international laws. In India, the agreement became binding in the year of 2005, after a ten-year transition. Due to the same reasons, an amendment was made to the Indian Patents Act in the year of 2002, that made micro-organisms patentable.¹⁶

(iii)European Patent Office:

The importance of Intellectual Property in the European economy is often highlighted by the European patent office(EPO) and rightly so as this industry is so vast and currently growing at a fast pace increase the current employment level in the country. Hence, the country is extremely careful with their IPR policy, especially with the topic of patenting of living organisms. EPO has stringent guidelines that address patenting of living organisms that include animals, plants and microorganisms.¹⁷

➤ Patenting of animals

Such patents are granted by the office only if testing that is carried out on the animals results in production of a drug that enhances the life expectancy and quality of life of a human being. Many breakthroughs that have been achieved in the form insulin a drug for diabetes, anti-cancer drugs, auto immune disease drugs have been granted patents. Similarly, medical inventions that have led to breakthroughs like DNA fingerprinting, paternity testing and blood transfusions were also granted patents. Such patents are granted with twofold objective, and that is to enhance human life and secondly, to provide incentive to these pharmaceuticals to keep inventing such medical breakthroughs. If such exclusive rights are not granted then their high cost, research and investments may go in vain also, it simultaneously prevents illicit copying of medicines that may prove to be harmful to health.

➤ Patenting of plants

Similarly, even in the case of plants, such patents are allowed if by any such alteration and cross breeding the resultant variety yield more, is drought resistant or any other such characteristic that help the plant life indirectly also benefitting the human beings as well. However, there are certain heavy restrictions upon breeding processes which involve classical breeding steps such as crossing and selection.

¹⁵ https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm, last accessed on 25.08.18.

¹⁶ V.K. Ahuja, Intellectual Property Rights in India, 2009, LexisNexis.

¹⁷ <https://www.epo.org/news-issues/issues/biotechnology-patents.html>, last accessed on 25.08.18.

The principle of Breeders Exemption¹⁸ is given under the law wherein, breeders may use protected varieties for further breeding, and commercialize the resulting new varieties without a license from the owner of the earlier variety. However, the patent system does not provide for such an exemption.

➤ Provisions in the law

(i) Article 53 and Rules 26-29

The exceptions to the European patent law state the cases in which a patent may not be granted. The provisions for the same may be found in Article 53 of the European Patent Convention (EPC). To broadly sum it up, firstly, an invention cannot be patented if it goes against public morality or “ordre public”, secondly, inventions relating to production of plants or animals excluding microorganisms. Lastly, inventions relating to methods of treatment of human beings and animals, specifically through surgery or therapy and diagnostic methods, however, not applicable to products or composition related to carry out such a treatment.¹⁹ These rules not only lay down the procedure but also take care of the factors that are dearer to the general public like that of traditional knowledge²⁰ and ethics. The EPO ensures through powerful tools and comprehensive databases the novelty of an innovation. It not only encompasses the databases within its own country but also takes a look at that of the other countries ex, China and Korea. Similarly, EPO also ensures that ethical boundaries are not crossed and for this purpose, article 53 serves as a backing. The article lays down the exceptions in the EPC, stating all the inventions that cannot be patented.

On a careful perusal of the rules stated in the EPC, the provisions stated are with respect to the inventions that can be patented. The rules, to put it broadly, state that any isolated biological material can be patented if it is invented through a technical process. Therefore, upon an understanding of the rule it can be said that microorganisms can be patented even if it already exists in the nature. The rules also exclusively state that any micro biological process can be patented provided that that process results in the creation of a microorganism.

¹⁸ Suman Sahai, *Patenting Of Life Forms: What It Implies*, Vol. 27, No. 17 (Apr. 25, 1992), *Economic and Political Weekly*, JSTOR.

¹⁹ <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html>, last accessed on 25.08.18

²⁰ Wangari Maathai, *The Link between Patenting of Life Forms, Genetic Engineering & Food Insecurity*, *Review of African Political Economy*, Vol. 25, No. 77, JSTOR.

E) CONCLUSION: NEED TO PATENT MICRO ORGANISMS

India has been a party to the TRIPS agreement for some time now. As a result of the same, India is obligated to amend its domestic or national laws in consonance with the international framework provided by TRIPS. To comply the regulations that India is under an obligation to adhere to, it made certain amendments to its generic patent law in the year of 2002 by virtue of which, patentability of microorganisms became legal. However, when this was legalized a lot of questions arose in the minds of many regarding the many aspects of patents being granted for microorganisms. Some questioned the patentability of the same on the grounds that it does not qualify as an invention as it is a mere discovery. Others raised eyebrows at the fact that it is unethical, it amounts to bio piracy and that granting patents on microorganisms is an extreme step that may further pave wave for patenting of human DNA and genes. The questions raised were many, however as a means of this paper, the author has addressed the first issue of it not just being a mere discovery but a valid invention.

Granting patents for microorganisms is a step forward for the country as well as the economy. In the opinion of the author, the amendment in the act that allowed microorganisms to fall under the ambit of patent law was the first step. To be completely successful in this aspect, the country needs a foolproof system that ensure such grants lead to major breakthroughs that benefit the country as a whole. The author with the help of the European Patent Convention, wherein guidelines regarding the same are provided in greater detail believes it could help India frame its laws to seek further definition in its approach. These guidelines specifically state in which case a microorganism can be patented and enlists various factors that must be satisfied to qualify as an invention in the first place. For this purpose, the guidelines also mention the situation where the patenting of a micro biological process is also possible. Taking the help of the same, along with the landmark case in the US, the author has provided areas which needs more development and how they could possibly be developed. Thus, to conclude, there exists various lacunae in the Indian Patent Law when it comes to the subject matter of microorganisms. Not to say that the law is inefficacious, it provides guidelines at the base level. But, it is at its stage of infancy. An efficient method of filling up this area is seeking to help of those mechanisms or systems that are more wholesome, and in the present case they are American and European Patent Laws. With the guidance of these two laws, it is a possibility to bring up the standards of Indian Patent Law and ensure it does not go against the concept of public morality, bio piracy and other ethical issues. Hence, as a conclusion to the paper, India should implement the guidelines followed in Europe and America to further provide a defined system of patenting of microorganisms in the country.