

PATENT REGIME OF INDIA RELATED TO MICROORGANISMS: A CRITICAL ANALYSIS

Kumar Salva Raghuvanshi

National Law School of India University, Bengaluru

A patent for a new invention in the field of patent law, grants the inventor an exclusive right to exclude others from using the invention within a specified jurisdiction for a limited period of time (20 years). In sum, an invention is patentable if it is novel, non-obvious, and useful, involves inventive step, is having industrial applicability and is not excluded subject matter. A patent for any invention comes into existence only when it has been registered. In some countries including India there is a requirement of examination as to whether the patented invention satisfies the statutory conditions of patentability or not. The application must also disclose and describe the invention sufficiently for it to be put into effect by a person skilled in the art. Since, the late 1970 scientist in India have been applying their engineering to cause living organisms to express genetic material from outside their own species, with an extraordinary result. A new strain of plants produces higher yields, resists viruses and pests, and is productive in formerly unwelcome climates and promotes the agricultural sector which is considered to be backbone of Indian economy. These scientists with these latest inventions thought for their protection under Patent Law regime and hence the prospect of patents on “living inventions” ultimately provoked a dreadful clamour, with intense public concern overly a field of law often considered obscure. However, the legislators, considering the holistic impact of the “patentability of microorganisms” in India, made a departure from the discovery of microorganisms to invention of microorganisms so as to reward only the genuine invention. In this paper the researchers will try to answer as to how and why patenting of living organisms in India is a need of hour towards promoting scientific development. For the aforesaid purpose the research will be largely doctrinal, analytical and comparative in nature depending on primary and secondary source material.

Keywords: Microorganisms, Patent, TRIPS, Biotechnology and Scientific Developments.

AIMS AND OBJECTIVE OF RESEARCH

The research topic seeks to understand the Indian patent law regime with respect to microorganisms and its impact on development of biotechnology industry. This project aims to draw a detailed picture of microorganisms patenting in compliance with TRIPS agreement with relevant case laws. The aims and objective are explicated in the three categories. Namely,

- To illuminate the various provisions of Indian Patent Act and TRIPS with reference to relevant precedents of the court.
- To analyse the facts in the context of statutory provisions and case laws and relate it with the fundamental principles of patent law.
- To critically evaluate the grey areas prevalent and to make suggestions.

INTRODUCTION

It is often said that, “Patenting of microorganisms and their related processes and products involves some unresolved questions and seems to be in a state of flux. Considering that the patenting of microorganism started in 1981, it is natural that the laws and practices in this regard will need some time to stabilise. This condition is further complicated by the rapid scientific and technological developments in biotechnology”.

The most vital distinction between legal practices of India and developed countries is that India does not allow patenting of microorganisms that already exist in the nature but genetically modified versions of the same microorganisms that result in enhancement of its efficacies are patentable.

The first patent to living organisms was issued to Finland in 1843, and in the U.S. in 1873 a patent was granted for isolated yeast¹. There was a belief that living organisms and cells were non-patentable products of nature due to which patent protection for biological materials for many years was restricted.

The dictionary definition of microorganisms is “*microscopic organisms*”. These are such tiny living things which cannot be visible from the naked eye. It includes vires, bacteria, yeasts, fungi, algae etc. microorganisms have been used as tools for the production of antibiotics and vaccines, food products etc., and are also used for industrial purposes. The use of modern biotechnology makes the potential application of microorganisms is vast.

The classical view was that patent law does not, to a great extent concern itself with living organisms no longer accords with reality. Under the assumption that naturally occurring organisms were not new, the assumption was that patents could not be granted. The TRIPs agreement makes it obligatory for all WTO members, after the end of any applicable transition period, to grant patents for microorganisms. If the microorganisms are one which occurs in nature, it will be necessarily to claim it in form of isolated type, in order to avoid possible novelty objections. In USA, inspite of the precedent of the Pasteur patent mentioned above, it had become practice of the Patent Office to refuse claims to living systems as being not patentable subject matter, in 1980, however, the supreme court decided (by five to four majority) in the famous *Chakrabarty*² case that a new strain of bacteria produced artificially was patentable invention.

¹ It was granted to Louis Pasteur, United States Patent No. 141,072 (claiming pure yeast culture).

² *Diamond v. Chakrabarty* 206 USPQ 193 (Sup. Ct. 1980)

INDIAN PATENT SYSTEM.

The Supreme Court of India in *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries*³, reiterating the patent law held that “fundamental object of patent is to promote scientific research, new technology and industrial progress”. The court also stated that prior condition of patentability is novelty. In the words of Cotton L.J. put in *Blackey v. Latham*⁴, “to be new in the patent sense, the novelty must be shown in the invention”. Determining of this test which is important principle of patentability, is most difficult aspect of Patent Law, which has held in astronomical conflict of judicial opinion.

2.1 History of Patent Law in India

The seeds of Indian Patent system were sown 160 years back when the first Patent Act was enacted in 1856 under the British colony. India has inherited “The Patent and Design Act, 1911” from the British colony which provided protection to all inventions except inventions related to atomic energy⁵. After the independence the Act was revised so as to facilitate the needs of industrial community and to promote the stage of development of country. The Patent Act, 1970 is largely based on the recommendation made by *Justice Rajagopal Ayyangar Committee (1958)*. Initially this Act provided for process patent only but in 1994 when India became member of WTO it became obligation of India to respect the provisions of TRIPS. India being a developing country was given a grace period of 10 years to fully comply with the provisions of TRIPS. In this grace period India made three amendments in year 1999, 2002 and 2005 to fully comply with the requirement under TRIPS. These amendments made a journey from old process patent to new TRIPS compliant product patent system. Under the agreement there was also *mailbox system* for the countries which does not provide product patent. It was a mechanism for accepting applications till the product patent system was put in place. Thus, this system was created to receive and store the product patent applications.

2.2 Patent regimes in India.

In the province of IPR, patent is considered as most important intellectual property because it deals with those inventions which have a direct industrial applicability and thus scope for getting big money. The aim of patent law is to protect innovative ideas by granting exclusive monopoly to the inventor for limited period of time. The procedure followed for such grant, conditions of patentability, extent of right conferred and exceptions allowed differ in various jurisdictions according to the law of country and international agreements.

As discussed earlier Indian Patents Act, 1970 is based on the model of British Patent Act, 1949 as amended. However, they differ with each other in the sense that Indian Act

³ Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries AIR 1982 SC 1444.

⁴ Blackey v Latham (1888) 6 Pat. Ca. 184

⁵ This exception is still recognized under Section 4 of the Patent Act, 1970 which says , “No patent shall be granted in respect of an invention relating to atomic energy falling within sub section (1) of Section 20 of the Atomic Energy Act, 1962”

provided product patent only after 2005 but British Act continued to provide product patent since its inception.

Broadly speaking, after the Patent (Amendment) Act, 2005 India broadly recognizes two categories of Patent:

1. Product Patent, and
2. Process Patent.

When one refers to a patent as product patent it means that he has developed a new product. Similarly, when one refers a patent as process patent, it implies that he has developed a new and improved process for producing a known product. In the case of a product patent, one will have claims (defining the area of the legal protection) for the new product and if he desires can also have claims for the process for preparing the said product. Of course if he does not claim the process is mandatory that the process for the preparation of the new product should be disclosed in the text of the document (specification). Whereas, in the case of a process patent, one can have only claims for the process and not for the product, as the product prepared by the said process is already known and therefore there is no novelty in such a product.

3. PROTECTION OF LIVING ORGANISMS.

As regards to microorganisms, US is the first country to bring the phenomenal change to biotech industry by granting the patent to a living organisms, which was a biotech invention, which was infact a discovery rather than an invention, in modern terms. But in the case of *Funk Bros. Seed Co. v Kalo Inoculant Co*⁶ court categorically rejected the patent application for bacteria. The landmark case of *Diamond* had changed the whole scenario of biotechnological inventions.

When the patent system was evolved many years ago, it was the presumption that technology can be developed only using the tools of physics, chemistry and engineering. The possibility of using the tools of biology was not recognized at that time. Further all matters connected with life were presumed to be the property of Almighty. Therefore, human intervention for the development of inventions employing living matters was not given recognition or importance. Consequently, no patent protection was granted for such inventions.

But, on the passage of time, due to the dramatic developments in the ability of the scientist to select and manipulate genetic materials, interests in the development of commercially useful inventions involving living materials and their protection gained momentum. Further, as a result of the success of the development of technologies based on tools of biological sciences, such as microorganisms, producing commercially valuable industrial products such as alcohol, enzymes, and antibiotics also resulted in the recognition of such

⁶ Funk Bros. Seed Co. v Kalo Inoculant co, 333 U.S 127 (1948)

tools. Slowly and steadily patents covering invention in the field of biotechnology started issuing. For this purpose, either the interpretation of the existing provision was modified or specific provisions allowing patents for such inventions were incorporated in the patent legislations.

3.1 Discovery versus Invention.

In the realm of Patent system protection is accorded to invention and not the discovery. Discovery is a step prior to the invention of any product or process. The concept of discovery and invention is similar to the notion of '*idea expresso dichotomy*' in the copyright law which says that idea per se is not entitled to copyright protection only the expression of those ideas into some tangible form applied through some labour, skill and knowledge is entitled to copyright protection.

There is a close resemblance between the discovery and invention. Merely saying that some known article is found with some unknown properties will simply amount to discovery and not an invention. However, based on the same discovery a conclusion can be drawn that article can be used for the purpose of making a particular material or in particular process, then the said article will lead to invention and hence it will be subject matter of Patent⁷.

In the line of above propositions it can be said that when any microorganism is discovered, it is not an invention but a microorganism is called invention only when it is genetically modified and reason for that is human intervention. Generally, patent is not provided on genetic microorganisms also. Genetic microorganisms perform number of activities. If a researcher makes his research upon some specific activities, then he is granted patent of such genetically modified microorganisms. Further, as we have discussed that only inventions are qualified for patenting, thus naturally occurring microorganisms in form of blood cells, DNA structure, genes etc. are excluded from patent protection.

On the above propositions it is important to know the provision of TRIPS Agreement⁸ under Article 27.2 which permits member states to exclude those inventions which are injurious to health and environment of both humans and animals. Thus, on these grounds member states are at liberty to exclude certain inventions in the field of microorganisms from patent protection.

INTERNATIONAL INSTRUMENT RELATED TO MICROORGANISMS:

4.1 TRIPS Provision relating to Microorganisms

⁷ Elizabeth Verkey, "Law of Patents", 1st ed. 2005, p. 165

⁸ "There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality (Article 27.2)."

According to Article-27(3)(b) of TRIPS Agreement of the WTO, “Members state may exclude from patentability 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”. Thus, it is essential for the member countries to provide protection for microorganisms *per se*. India being signatory to the WTO agreement, has to honor the commitments of the Agreement by providing protection for microorganisms *per se* provided they satisfy all the essential criteria of patentability.

Accordingly, Section 3 of the Indian Patent Act, 1970 was modified. The modifications effected it is now possible to protect microorganisms *per se* if it satisfies all the patentability criteria. Thus, now microorganisms have been excluded from the scope of Sub Section (j) of Section 3. In other words, making such inventions patentable.

The TRIPS Agreement also stated that WTO (World Trade Organization) council for TRIPS would monitor compliance with TRIPS provisions and overseas disputes between member countries. The WTO Council has resolved patent enforcement problems that existed before trade sanctions were imposed. However, it tends to pass resolution in favour of developed countries⁹.

The foundation regarding patentability of microorganisms was laid down in the landmark judgement of United States Supreme Court in the case of *Diamond v. Chakrabarty*¹⁰. In this case Chief Justice Warren E Burger made a very comprehensive statement under the realm of Patent Law as “anything under the sun that is man-made is patentable *per se*”. This case has led to series of legislation from U.S to Europe to India and also in other jurisdictions for granting patent protection to life forms. In addition to this TRIPS agreement of WTO also mooted for protection of microorganisms. In fact TRIPS was the first international instrument which legalized the patenting of life forms by requiring the WTO member states to make their laws in consonance with the agreement to provide protection in all fields of technology.

Clause (b) of paragraph 3 of Article 27 of the TRIPS Agreement states as under: “Member may also exclude from patentability (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the production of plants varieties either by patents or by an effective *sui generis* system or by any combination thereof.” However, this provision is subject to review four years after the entry into force of the agreement.

In the field of microorganisms, TRIPS does not advocate the heightened standard of Budapest Treaty system for patent protection of microorganism; however, through bilateral treaties, countries have still entered into this administrative standard. Under bilateral agreements, member countries must implement their own substantive provisions. These

⁹ Leanne M. Fecteau, “The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy”, 21 B.C. THIRD WORLD L.J. (2001), p.78

¹⁰ *Diamond v. Chakrabarty* 447 U.S. (1980), p.303, 309.

obligations go beyond TRIPS standards because the Budapest Treaty obliges parties to recognize the physical deposit of microorganisms' samples with an international depository authority instead of full written disclosure of invention.

4.2 Budapest Treaty: International Depository Authority & MTCC

It is well known principle of Patent law that invention is not new, if it has been disclosed to the public either in writing, orally, by public use or otherwise, before the date of priority of the application. As in other technological fields, the requirement of inventive step (non-obvious) also constitutes one of the complex questions in the field of biotechnology. The consideration of industrial application is yet another obstacle for securing patents for invention in the field of biotechnology. A question, therefore, arises as to whether the substance such as microorganisms or other biological materials which are present in the nature can be considered as new, one of the main criteria for securing patents?

It is mandatory requirement of the patent law to provide detailed information of the invention to be protected. This is commonly referred as "sufficiency of disclosure".in the field of biotechnology, satisfying the requirements of the condition of sufficient disclosure poses specific problems, due to the fact that the inventions in this field involve living entities. Such materials are difficult to describe in words.

To satisfy the condition of novelty and sufficient disclosure requirement of the patent law in the field of biotechnology, a Treaty called "The Budapest Treaty¹¹" has been established.

The Treaty provides for the deposit of microorganisms in an "International Depository Authority" (IDA) where a deposit is necessary to satisfy the requirement of "sufficiency of description" of patent law for inventions involving microorganisms or the use of the microorganisms. When the biological materials are deposited with such an authority in the manner prescribed, the authority provides an accession number. This accession number when quoted in the patent document serves as the equivalent description of the invention satisfying the condition of "sufficient disclosure" of the patent law. The reference made to the accession number, provided by the Depository Institution for the biological material, in the specification is considered as part of the description of the invention.

In India for the purpose of depositing the sample of microorganisms "The Microbial Type-Culture Collection (MTCC) and Gene Bank" which is a national facility was jointly established by Government of India, Department of Biotechnology and Council of Scientific Research (CSIR), which is established in Institute of Microbial Technology, Chandigarh. The MTCC is recognized as International Depository Authority by the World Intellectual Property Organization (WIPO), Geneva, Switzerland. Thus, it has become the microorganism's depository authority of India under Budapest Treaty.

¹¹ Budapest Treaty on the International recognition of the Deposit of Microorganism for the Purposes of Patent Protection was signed on 28th April 1977.

Unlike other International Depository Authority (IDA), MTCC also follows the guidelines set out by the treaty on the international recognition of the deposit of microorganisms for the purpose of fulfilling the disclosure requirement under the patent procedure. MTCC has cultivated an excellent facility for the preservation and protection of samples of microorganisms. It also had reserved the right to reject the samples which can be hazardous to MTCC or not possible for processing under it. Deposit from other countries will be accepted only if it is cleared by the authority of India. The depositor from outside India should communicate with the MTCC regarding deposits before dispatching the samples.

INDIA: A CRITICAL ANALYSIS

After becoming member of TRIPS Agreement, India has to make its Intellectual property right in line with TRIPS and thus it is required to meet minimum IPR standards. Thus, Indian Patent Act, 1970 was amended in June, 2002 to provide patent protection to new microorganisms. Thus, Section 3(k) of the Act excludes from patent protection “plant and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals.” It is pertinent to note that the Patent (Amendment) Act, 2002 also added explanation to chemical process. It states “chemical processes include biochemical, biotechnological and microbiological process”.

In the case of *Dimminaco AG v Controller of Patent Design*¹², Calcutta High Court of India has raised the issue that whether a process involving microorganisms that are living as an end product can be patented or not. The material facts of the case are that the said patent applicant Dimminaco AG which is a Swiss company made an invention relating to process for preparation of ‘Bursitis vaccine’ which was helpful to prevent infectious poultry disease, and applies for process patent of its preparation. The said patent application was examined by the examiner of patent office under Section-12. On examination of such process patent the examiner refuted the contention of applicant on the ground that the vaccine involves processing of certain micro organic substances came to the conclusion that the said process is not an invention within the meaning of the term invention mentioned under Section-2(1)(j) of the Patent Act.

The applicant filed an appeal before the Calcutta High Court against the order of examiner. After hearing the facts of the case the court rejected the contention of examiner that process patent is given only in respect of article, substance or manufacture. Thus, vaccine with a living organisms is neither of these and hence not patentable. The examiner claims that the meaning of article according to *Webster Dictionary* means “material thing item, a thing of particular class or kind as distinguished from a thing of any class of kind” and he claimed that living things does not fall under this definition.

¹²Dimminaco AG v Controller of Patent Design , AID No. 1 of 2002, Cal. H. C.

The Calcutta High Court through judicial explanations mentioned that India law on patent does not put any fetters on patentability of microorganisms developed in a controlled environment in laboratories. The court concluded to accept the process of manufacturing bursitis vaccine as patentable subject matter under Section 5 read with Section 2(1)(j) of the Act, even though the end product contained is a living organisms. This historic decision open the way for numerous such inventions related to microorganisms. In the context of India, this decision has helped in expansion of biotech industries.

Another significant thing to note here is Patent (Amendment) Act, 2005 which was established in harmony with TRIPS Agreement amended Section 5 which earlier provided inventions where only methods or process of manufacture were patentable. This amendment deleted Section 5 which now opens the way for product patent also. To assess whether after this amendment India had indeed become TRIPS compliant and the measures taken to ensure TRIPS compliance were in national interest, the Mashelkar committee was set up in April 2005. One of the issues the committee dealt with was whether it would be consistent with TRIPS to exclude microorganisms from patenting. This committee submitted a report in December 2006 which it later withdrew citing technical inaccuracy and plagiarism as reasons¹³. The revised version of the report was submitted which restates to a large extent the committee's previous findings, which had been criticized for not taking into account public health goals. The committee concluded that it shall be in total violation of TRIPS to exclude microorganisms from patentability and that microorganisms involving human intervention and utility are patentable subject matter under the TRIPS Agreement, provided that they meet the prescribed patentability criteria.¹⁴ After the passage of Patent (Amendment) Act, 2002, Government of India allowed the first ever patent in respect of microorganism was granted for a strain of yeast to Dabur Research Foundation which is part of Dabur Pharma limited. The company was granted both product patent (strain of yeast) as well as process patent to grant exclusive protection on procedure of manufacture¹⁵.

CONCLUSION

From the above highlighted points and after extracting the nuts and bolts on the research topic with the help of various provisions of law and precedents it can be said that Indian Patent Act, 1970 with regard to microorganisms has made a departure from discovery of microorganisms to invention of microorganisms. The most decisive and integral categorization betwixt the legal provisions of India and other developed countries is that India does not allow patenting of microorganisms that are naturally found as it merely amounts to discovery under Section-3(d) and therefore non-patentable subject matter.

¹³ Dr. Raju K D, "the debacle of Novartis patent case in India: strict interpretations of patentability criteria under Article 27 of the TRIPS Agreement", *IJPL* 1 (1) (2008)

¹⁴ Sharma Ravi and Hiddleston Sara, "Mashelkar committee on Patent Law withdraws report, seeks more time", *The Hindu*, 22 February 2007

¹⁵ Nithya Subramanian, *Dabur Gets First Patent*, *THE HINDU, BUSINESS LINE*, December 8, 2005, at New Delhi

However, genetically developed microorganisms involving human intervention which enhance its efficacy as compared the one already existing in the nature are made patentable. One of the important criteria of patentability is “sufficient disclosure”. During the initial days of micro-organisms patent procedure there was lots of difficulty faced by the state with respect to disclosure of microorganisms as it was not sufficient in written description. Thus, Budapest treaty was convened to remove this difficulty which provided for establishment of International Depository Authority to remove this problem. Many stakeholders have raised the issue of granting monopoly on microorganisms on the ground that it is a product of nature and thus it should be available to all. To counter this, it was said that Patent Act only provides protection on transgenic microorganisms which took birth due to human intervention and which has enhanced efficacy. Another argument raised was in reference to Article-I, Section 8 of the U.S Constitution which says that “congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventor’s exclusive rights to their respective writings and discoveries”. Thus, the promotion of the progress of science and useful arts is socially useful purpose, morally justifiable on utilitarian grounds. Moreover, this also promotes general welfare by encouraging the commercial introduction of products which are also beneficial to the general public.

The most important issue with respect to microorganisms patenting is about the definition of microorganism. As we know that neither in the domestic laws of country nor in any international instrument the definitions of microorganisms is not provided. In such a case reference may be given to Vienna Convention on Law of Treaties, 1969. It states that in the absence of any definition of any term in the treaty, the basic rule of interpretation may be applied in order to give the term its ordinary meaning in the context of its object and purpose. In this respect, the dictionary meaning of microorganisms would suffice in distinguishing plants and animals from microorganism by the WTO members to TRIPS agreements.