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PATENTING OF MICROORGANISMS IN DEVELOPING COUNTRIES: THE INDIAN PERSPECTIVE

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ABSTRACT

Advances in biotechnology have made the patenting of microorganisms a subject of increased interest and controversy. This article deals with the major challenges faced by developing countries in understanding intellectual property rights (IPR) laws in the context of recent innovations in biotechnology involving microorganisms. The analysis of the data from Patent Facilitating Cell (DST, Govt of India) revealed the trends in various countries on the issue of patenting microorganisms which may help us to frame the system of patenting microbes. Indian machinery of patenting has to be geared up and also tuned to cope up with the new trend of patenting microorganisms. The strategies and policies to be adopted at present are also highlighted.

KEYWORDS: **Biotechnology, Intellectual Property Rights, Patents, Microorganisms, TRIPS, WTO, *sui generis***

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INTRODUCTION

India's patenting system has undergone significant change over the past few years. Intellectual Property (IP) in India can be traced back to the colonial era when the English Trademark Ordinance was introduced. National and international developments have necessitated reforms in the intellectual property system of different countries. The World Trade Organization's TRIPS (Trade Related Aspect of Intellectual Property Right) Agreement of 1994, obliges members to provide intellectual property protection in its laws. The TRIPS Agreement makes it mandatory to provide patent protection to micro-organisms and non-biological and microbiological production of plants and animals. This makes it difficult for the developing countries to exclude inventions within this category altogether.[1]On living organisms, WTO allows countries to patent microorganisms but requires them to use a *sui generis* system to protect new plant and animal varieties or by the application of the two types of protection. As a WTO member, India is under obligation to reform its intellectual property laws in this direction even though Indian Model Law disapproves the patent of any life form. Under Article 27, TRIPS includes patents for both processes and products, to be granted in all fields of technology. Article 27.3 (b), however allows the exclusion of plants and animals and essentially biological processes for their production from patent grant but obliges the protection of microorganisms and microbiological or non-biological processes for their production. In this regard issues like microbes, genes, gene sequences, genetic engineering and bioinformatics become very relevant as they are important processes of biotechnological inventions which are often carried out through genetic modification. A few recommendations have been offered. A study need to be carried out to determine which model of IP office the country should adopt - an umbrella body or a decentralized system of having the different IP registries in different ministries. The strategy should be how to limit the scope of these provisions. As far as the patent protection of micro-organisms is concerned, TRIPS does not provide the definition of micro-organisms. The national rule-makers must define micro-organism in such a way as to include the following: bacteria, virus, and fungi, algae and protozoa. Another important way to limit the scope of patent protection to biological materials is to differentiate between the concept of 'invention' and 'discovery' as microorganisms, as such occur in nature.

MICROORGANISMS

Microorganisms are diverse group comprising of bacteria, fungi, viruses, archeabacteria and protists. Microbes are exploited by Biotechnologists in traditional food beverage preparation, in modern technologies based on genetic engineering and in Intellectual Property Rights in the form of patents. Initially the system of patenting was developed for machines. Most of the problems of life science patenting arise from the fact that it is being forced into living things. Also to consider the living organisms, such as, microbes, plants or animals as objects of invention is still controversial. Differences in interpretation of the same invention by different patent offices are commonly observed in many instances[2]. A patent is granted as an exclusive right by the Government for an invention for a limited period of time in consideration of disclosure of the invention by an applicant. A patentee enjoys exclusive right to prevent a third party from an unauthorized act of making, using, offering for sale, selling or importing the patented product or process within the country during the term of the patent.[3] Patents granted on living matter (microorganisms), genetically modified plant and animal species, genes, cell lines, etc., are commonly referred to as "bio-patents".[4] Microorganisms that are naturally occurring cannot be the subject of patents. Microorganism *per se* and non biological and biological processes are patentable.[5] However excluding microorganisms *per se* from patent protection would be violative of TRIPS Agreement.[6] Hence these days a naturally occurring microorganism that is manipulated or altered by means of genetic engineering can be the subject of a patent.

DEFINING MICROORGANISMS

Generally, microbes or microorganisms are tiny living things that are invisible to the naked eye. For the purpose of patent protection, the term microorganism often applies to biological material including, for example, viruses, bacteria, actinomycetes, yeasts, filamentous fungi, mushrooms, protozoa, unicellular algae, cell lines of plants or animals, fused cells, transformants and vectors used in genetic engineering, plant cells, DNA and RNA.[7] There is a widespread controversy regarding the consideration of microorganism as an "invention" or discovery".[8] The European Commission (EC)[9] directives on microorganisms define it as any microbiological entity, cellular or non cellular, capable of replication or transferring genetic material. EC directives have also defined biological material as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. Various definitions of microorganisms could be quoted from the following:

- Any of various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses (The Concise Oxford Dictionary).
- Any organism, such as virus, of microscopic size (Collins English Dictionary).
- Microorganisms are microscopic life forms including microscopic fungi, protista, prokaryotes and viruses.[10]
- A microscopic organism consisting of a single cell or cell cluster, including the viruses.[11]

Hence a quotation from an English dictionary would not be sufficient to provide a definition of the term 'microorganism'. Neither the Indian Patent Act nor TRIPS Agreement define 'microorganisms'. Moreover, no single commonly accepted scientific definition exists.[12] Microorganism may be defined as any biological material that is self replicable or replicable via a host organism and includes sub cellular material like genes, gene sequences, plasmids, etc.[13] A microorganism exists as a part of the nature; hence its discovery is not an invention. If it is an invention, logic of treating scientific theories and principles as non-patentable inventions gets defeated. If microorganisms isolated from the nature for the first time are considered patentable, then minerals and ores discovered from the interior of earth and deep seabed would qualify for patenting. Thus, microorganism can be considered as invention only if it has not been described in the literature and there is an element of human intervention with the discovery. A more precise and scientific definition is required for the purposes of providing a clear definition of the scope of exceptions to patentability set out in Article 27.3(b) of TRIPS agreement. Hence TRIPS agreement is ambiguious in defining microorganisms. The more authentic decisions regarding the patentability of microorganisms were made by the US Supreme Court in 1980 (Diamond v. Chakrabarty case), when the genetically modified bacterium was granted a patent.

MICROORGANISMS AS POTENTIAL PATENT SUBJECT MATTER

Whether microorganisms fall under the category of patentable inventions is a challenging issue that is prompting countries across the globe to consider what constitutes a patentable invention in this regard.[14] The first patent based on microorganisms was made by Louis Pasteur, the famous French scientist, on 28 January 1873, for the process of fermenting beer. The claim made by him: .... *invention produces a better quality and greater quantity of beer from the same quantity and quality of wort (the boiled extract of malt or other material)*.... *the yeast or pure ferment is added to provoke or induce fermentation.*[15] Louis Pasteur, received US Pat No 141,072 on 22 July 1873, claiming 'yeast, free from organic germs of disease, as an article of manufacture'.[16] In 1980, the United States Supreme Court held in Diamond v. Chakrabarty that non naturally occurring, man made, living microorganisms plainly qualify as patentable subject matter within the definition of § 101. At issue in Chakrabarty was whether a human-made, genetically engineered bacterium capable of breaking down crude oil constituted a "manufacture" or "composition of matter" within the meaning of the statute. Chakrabarty's Pseudomonas bacterium manipulated to contain four plasmids controlling the breakdown of

hydrocarbons was 'a new bacterium with markedly different characteristics from any found in nature'. The Supreme Court stated that new microorganisms not found in nature were either 'manufactured' or 'composition of matter' within the meaning of US Patent Act § 101 and thus patentable. The 'product of nature' objection therefore failed and the modified organisms were held patentable[17] The chemical methods or extraction from animal or plant sources do not yield sufficient amount of the compounds of commercial significance in meeting the demands for the ever increasing population. So an alternate method of producing the compounds of commercial importance can be accomplished by means of using microorganisms and more specifically genetically engineered microorganisms. Growth in patenting related to microorganisms reflects the importance of microorganisms as a rich and largely untapped source of DNA, amino acids, and proteins such as enzymes for the pharmaceutical, agricultural and chemical industries.[18]

PATENTING MICROORGANISMS

Before 1980, Patents were given for inventions based on microbiological processes. No patent was given for the living entities per se which were considered to be the products of nature. In 1980, the U.S. Supreme Court , during the hearing of the patent law case of Diamond vs Chakrabarty, for the first time ruled that - "A live micro organism is patentable".[19] Since then many microorganisms like Bacteria, Plant and Animal viruses, Filamentous fungi, Protozoa, Unicellular algae are patentable in various countries. In India a similar landmark decision was made on 15th January 2002 by Kolkata High Court which granted patent to Dimminaco A.G. for invention involving microorganism.[20] Dimminaco A.G., a Swiss company applied for patenting the process for preparation of a live vaccine for Bursitis, an infectious poultry disease and the invention involved a live (attenuated) vaccine to combat the disease. The Controller of Patents refused to allow the application on the ground that the vaccine involved processing of certain microbial substances; this was only a natural process devoid of any manufacturing activities and hence not patentable.[21] However, on appeal, the Kolkata High Court deviated from the above position as it rejected the contention of the controller that a patent is given only for a process that results either in an article, substance, or manufacture. Law does not bar processes where the end-product is living. There is no statutory bar in the Act to accept manner of manufacturing as patentable even if the end product contains a living organism.[22]

TRIPS AGREEMENT: PATENTING MICROORGANISMS

India became a member of the World Trade Organisation on January 1, 1995. As a member, it was required to comply with the Trade Related Aspects of the Intellectual Property Systems (TRIPS) agreement.[23] The agreement on TRIPS sets down minimum standards for many forms of IP regulation as applied to each other WTO members. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade in 1994. Apart from setting the basic minimum standard for patentability, TRIPS obliges member states to allow patenting microorganisms.[24]

Article 27.3(b) of the TRIPS Agreement says that:

3. Members may also exclude from patentability:

(b) 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.[25] 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. Therefore an understanding as to what constitutes a microorganism is essential. However, the term lacks a precise scientific definition because of which there are inherent anomalies in patenting these forms. Although the TRIPS agreement is mandatory for patent production of microorganisms, yet it does not define microorganisms; thus there is no yardstick definition for member nations to follow in this regard.[26] There is no clarity

whether the term would include only genetically modified organisms or naturally occurring substances also. However, the term microorganism will be understood in its widest sense to include any biological material that is self-replicable via a host organism. Sub-cellular material like genes, gene sequences, plasmids, replicons and so on will come under the definition of a microorganism. 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) a form of multiplied microorganism itself, for example vaccine or edible biomass, and (b) a by-product of microbial growth, for example an antibiotic, enzyme, toxin or an otherwise useful industrial product. However, it becomes obligatory to provide patents for 'microorganism' and 'microbiological' processes. Neither microorganism is defined in the TRIPS agreement nor does the agreement specify any parameters concerning the scope of its protection.

PATENTING MICROORGANISMS: INDIAN SCENARIO

Patent Act of India, 1970, Section 2(1)(j) defines "invention" means a new product or process involving an inventive step and capable of industrial application.[27] No definitions of manner of manufacture or substances were given in the Act. Hence the Patent Office adopted the practice of interpreting a manner of manufacture as a patentable subject matter only if it results in a tangible nonliving substance. The Section 3(j) of the Act stated that plants and animals in whole, or in part thereof including seeds, varieties and essentially biological process for the production of plants and animals, are excluded. India joined the Budapest Treaty on 17 December 2001, and Microbial Type Culture Collection (MTCC) and Gene Bank of the Institute of Microbial Technology, Chandigarh (IMTEC) acquired the status of an IDA on 04 October 2002 marking the amendment of existing systems in India. The 2002 amendment of Indian Patent Act added explanation to chemical process, which states; chemical processes include biochemical, biotechnological and microbiological process.[28]

THE PATENT AMENDMENT ACT

The Patent Amendment Act 2002 came into force in May 2003, bringing microorganisms within the realm of patentability. Section 3(j) was couched in terms of terms of Article 27(3)(b). It states that: plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.[29] It excluded microorganisms from the exceptions to patent protection and allowed patenting of *processes* pertaining to microorganisms as well as non-biological and microbiological process. Subsequently, The Patents Act, 1970 was once again amended in the year 2005, so as to establish congruence with TRIPS. The amendment deleted Section 5 of the Act, which provided for only process patents. The provision included inventions where only methods or processes of manufacture were patentable. Therefore, the deletion of this section paves way for product patents, which is in stark opposition to US approach that argues patenting of life forms has tremendous advantages.

BUDAPEST TREATY: DEPOSITION OF MICROORGANISMS

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 enforced on 9 August 1980, and was later amended on 26 September 1980. The treaty is administered by the World Intellectual Property Organisation. As of December 2008, 72 countries were party to the Budapest Treaty. The accession to the Treaty is open to States party to the Paris Convention for the Protection of Industrial Property of 1883. Article 1 of the Budapest Treaty says that "The States party to this Treaty(herein after called "the Contracting States") constitute a Union for the international recognition of the deposit of microorganisms for the purposes of patent procedure."[30] The

treaty allows 'deposit of microorganisms at an international depositary authority to be recognised for the purposes of patent procedure'. The Patent law requires disclosure of the full details of an invention. Descriptions and drawings are inadequate and insufficient if the invention involves the use of microorganisms or microbial components. Therefore, it has been agreed internationally that microbial samples must be deposited in a culture collection that is recognised as an 'international depository authority'(IDA) within the framework of the Budapest Treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure.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 in order to obtain a patent. The applicant needs to only deposit the biological material at once recognised institution and this deposit will be recognised in all countries party to the Budapest Treaty.

INTERNATIONAL DEPOSITORY AUTHORITY(IDA)

Patent law requires disclosure of the full details of an invention. Descriptions and drawings are inadequate and insufficient if the invention involves the use of microorganisms or microbial components. The deposition of patents of microorganisms in a culture collection recognised as an IDA might be necessary in the realm of IP rights. It is likely that IDAs will transform into 'biological resource centres' and further into 'global common genetic resources', with an internationally agreed legal basis for benefit sharing. The deposits are made at an IDA in accordance with the rules of the Treaty on or before the filing date of the complete patent application. Article 7 of the Budapest Treaty outlines the requirements for a facility to become an IDA. In order to obviate complications in seeking patent protection for inventions involving microbes in more than one country and to have a uniform system and guidelines, the British Government proposed in 1973 that the World Intellectual Property Organization (WIPO), Geneva, Switzerland should take initiative to study the feasibility of a "single deposit" fulfilling the need of depositing cultures in other countries where patent applications are filed.[31] On the recommendation of an expert committee, a conference was held in Budapest, Hungary during April, 1977 and a treaty was adopted called the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure." The Budapest Treaty came into effect in 1980. Under the Budapest Treaty, certain culture collections were recognized as "International Depository Authorities (IDA's)". As on July 15, 2002, there are 55 contracting states and 33 International Depository Authorities (IDA). Deposit made in any one IDA is recognized by all the contracting states for patent procedures.

MICROBIAL TYPE CULTURE COLLECTION(MTCC)

MTCC - a national facility, sponsored jointly by the Department of Biotechnology (DBT) and Council of Scientific and Industrial Research (CSIR), located in the Institute of Microbial Technology, Chandigarh has excellent infrastructural facilities for long term preservation of microorganisms. It maintains a database on its collections and transactions are computerized. The MTCC has a website of its own (http://mtcc.imtech.res.in) which provides users with access to the catalogue of cultures and related information through internet. On October 4, 2002 MTCC was recognized as an IDA and now microorganisms can be deposited here under the Budapest Treaty and patent protection may be sought in contracting states. The MTCC, like other IDA's, follows the guidelines prescribed in the rules and regulations of the 'Budapest Treaty' on the international recognition of the deposit of microorganisms for the purposes of patent procedures.

HARMONISATION OF INTERNATIONAL PATENT SYSTEM

The harmonization of international patent system is a trend, a process and a result in internationalizing the patent system. A trend means the intrinsic direction that the patent system possesses in the process of unification. A process means the whole courses that the patent system in different countries tends to unification. A result means the final conclusion that the patent system in

different countries tends to unification. The patent systems in different countries developed at different times. The provisions in such systems were according to the social and economic conditions of the country. So a lot of dissimilarities exists among the patent systems of different countries. Due to intense globalization of trade with the help of communication and transport technology, there is a need for internalization of patent system. The inventor needs to protect the invention in the countries of his interest. But often the inventor is frustrated with the complexities and dissimilarities in the provisions of the different patent systems. The patent offices are also bearing huge loads of backlogs of patent applications and there is continuous increase in the number of applications. The application for one invention is filed in many countries individually for protection.[32] This leads to duplication of work in the patent offices. So to reduce the work load of the patent offices duplicated work should be stopped. As long as there will be dissimilarities in the basic provisions of patentability, there will be such duplication problems. The solution to above problems is harmonization of patent systems. What are the obstacles? why it is not achieved yet? In the global forum for discussion on patent, the world is divided into two blocks, the developed and the developing nations. The interests of both the blocks are different and so is their priority. Though the objective of the patent system is to provide incentive for innovation and dissemination of technology, it has a social impact due to the monopolistic nature of it. There should be right balance between the private right and the interest of the public at large. This social impact will depend upon the social condition and economic situation of the country. A patent system that is effective in developed country may not be effective for developing country. So the effort to harmonize the patent system may be futile. On this back drop the chosen hypothesis is that: "Regarding harmonization what is advantageous to the developed countries may be disadvantageous to the developing/least developed countries."

INDIAN SCENARIO - MICROORGANISMS

Scientific issues affecting patentability, competent legal counsel, and inconsistencies in the way courts apply and interpret biotechnology patent law can all affect a company's ability to obtain, and retain, market exclusivity. Therefore, judicial developments will continue to define the scope of patent protection and guide the future.[33] Growth in patenting related to microorganisms reflects the importance of microorganisms as a rich and largely untapped source of DNA, amino acids, and proteins such as enzymes for the pharmaceutical, agricultural and chemical industries.[34] Concerns in connection with the rise of intellectual property protection over microorganisms can be briefly summarised as follows:

- The ethics of patenting life-forms;
- The eligibility of such organisms for patent protection on the grounds of whether they are new (or novel), involve an inventive step(are non-obvious) and susceptible to industrial application(utility);
- The terms and conditions of bioprospecting arrangement between companies and developing country institutions, and indigenous peoples and local communities, and;
- The longer term implications of the temporary enclosure of the world`s microorganisms through patent grants for the promotion of research and innovation.[35]

STRATEGIES AND POLICIES

- A separate system of legislation for microorganisms should be adopted. Framing a 'sui generis' and implementation on patenting microorganisms. It is essential to prepare draft proposals and discuss their biological and legal implications and consequences with a forum consisting of expert representatives from all segments.
- Need to define 'microorganisms'. The broad categorization as 'biological materials' as used in European Union is preferable. However microorganisms under the umbrella of 'biological materials' should be treated individually. This is because microorganisms are distinct from other life-forms and the intricacies in

treating them along with other life-forms or their molecules (like DNA) cannot be predicted now.

- It is better to group viruses, prions (for probable applications in future), archaebacteria,eubacteria, actinomycetes, photosynthetic microbes, yeasts,filamentous fungi and mushrooms,protozoans, Micronematodes(forprobable applications in future) into microorganism with a clear definition of each category.
- It is essential to develop a system of classification of microbial processes and products. This will enable to identify the items suitable for patenting with a view to safeguard the interest of the nation. This will also be helpful for the patent examiners to identify whether the patent filed is eligible for patenting or not.
- Patent professionals with life sciences background should be employed in dealingthelitigationsinvolving biotechnological inventions for a better understanding and proper delivery of the judgement.

CONCLUSION

Harmonization process that has been started with the Paris convention has reached a long way, from where it can go ahead only. There are advantages and disadvantages of the harmonization of the patent system. The developed countries are in an advantageous level in economy and technology. Most of the developing countries are certainly economically and technologically at lower levels. So the provisions of formal and substantive laws have to be harmonized to some extent to suit the interest of both developing and developed countries. The main concerns regarding the dissimilarities in the substantive patent law are the inventive step determination and exceptions to patentability. The developed countries are obviously pressing for higher standards of inventive step. The outcome of Research and Development from the developing countries may not meet that standard and cannot get patent protection. This will discourage the innovation. For both the developed and developing countries the advantages of harmonization will be in reduction in workload and duplication of work in patent offices and improve the IP environment.Theharmonizationof biotechnologicalpatentsinvolving microorganisms has both advantagous and disadvantagous effect. It all depends upon up to which level the laws are harmonized. As pointed out in the preceding chapters adopting a strong patent system may not be beneficial to the developing countries. India being a developing country may have the same concern. India has a fully TRIPS compliant patent law since 1st January 2005. The impact of TRIPS on the economy is not yet studied or understood. But due to increasing number of applications and demand from the user harmonization have become inevitable. So India should gear up for harmonization of the patent laws. India has included microorganisms as patentable inventions in the Patents (Amendment) Act, 2002, but has not defined it. So India must take that advantage to define the term ‘microorganism’ as early as possible in future amendment of the Patent Act to avoid the confusion in patenting microorganisms especially. The harmonization of patent system is not a goal by itself. However it is a long journey. In the first few steps by harmonizing the provisions related to Prior art, grace period, novelty and inventive step, India can get the benefit of mutual exploitation of search and examination results of other countries, thereby reduce the backlog duplication of work and thereby reducingthecostofpatenting microorganisms.

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