PATENTABILITY OF MICRO-ORGANISMS: COMPARATIVE ANALYSIS

Anandita Arora

INTRODUCTION

PATENTS

“A patent is an intellectual property right relating to inventions and is the grant of exclusive rights, for limited period, provided by the Government to the patentee, in exchange of full disclosure of his invention, for excluding others, from making, using, selling, importing the patented product or process producing that product for those purpose.”

A patent is a bunch of exclusive rights granted by the state or the patent officer to an inventor for his inventions. The essentials of patentability are innovation, utility and non-obviousness. The inventor is given a monopoly right over the invention for a fixed period in exchange for the public disclosure of certain details of a machine, method or the product. The aim of patent law is to encourage inventions, promotion of technological innovation, and transfer of information for further inventions. It stimulates that the new inventions should have a commercial utility. The patent is granted for a limited period i.e. 20years to the inventor and after the period of expiry of the patent, the invention goes into public domain. Patent right is territorial in nature and patent obtained in one country cannot be enforced in other country.

BIOTECHNOLOGY

Biotechnology is a science of developing techniques for the application of biological processes and organisms to the production of materials of use in industry. The term signifies to the use of generic engineering to modify the bacterial cells to formulate a completely new substances or to introduce a novel trait in plants and animals. As biotechnology inventions are formulated through recombinant DNA technology so usually involve a large investments in research and development(R&D) and therefore there is a need to protect the inventions by the way of granting patents and protecting the interest of the inventor.

1 4th year B.A.LLB(H),Amity Law School, Noida
MICRO-ORGANISMS

Microorganism is an organism that is microscopic (too small to be seen by the naked human eye) and which can be seen only under a microscope, usually, an ordinary light microscope. Microorganisms are incredibly diverse and include bacteria, fungi, archaea and protists as well as some microscopic plants such as planktons and organisms such as amoeba. Thus, it may consist of a single cell or a cell cluster.  

Various definitions of microorganisms could be quoted as follows:

- Any of various microscopic organisms, including algae, bacteria, fungi, protozoa and viruses (The Concise Oxford Dictionary).
- Any organism, such as a virus, of microscopic size (Collins English Dictionary).

CAN MICRO-ORGANISMS BE PATENTED?

Living organisms are present in nature and cannot be considered to be manufacturers or composition of matter are viewed non-patentable. Prior to 1980, Microorganisms were "products of nature" and as such were not considered patentable. However, the era of bio-technology has changed that. Living organisms such as micro-organisms, fungi etc are now patentable. Whereas mere discovery of any living organisms is not patentable. “The patenting of inventions per se seems to be interwoven with the doctrine of product of nature. The doctrine specifies that potentially patentable subject matter must be created through human intervention. Thus a newly discovered mineral or plant found in the wild is not patentable subject matter under 35 U.S.C S.101.” There should be fulfillment of threefold requirements of patentability i.e. “that the invention must be new; that it must involve an inventive step; and that it must be capable of industrial application.” A micro-organism exists as a part of the nature, its discovery is NOT an invention. Micro-organisms can be considered as an invention only when the micro-organism have an element of human intervention with its discovery.

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USA

A new avenue for patenting system had opened up after 1980, a case Diamond V. Chakrabarty was filed in US Supreme Court. Anand Chakrabarty, a genetic engineer and a researcher of the

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3 Journal of Commercial Biotechnology (2010)
4 35 USC 100-section of the U.S. Patent Act (found in Title 35 of the United States Code [35 USC § §1 et seq.]
General Electric Company, filed a patent application in relation to a bacteria that was intended to consume the crude petroleum (oil) spills ruled that genetically altered microorganisms were indeed patentable based on the following criteria:

- They were man-made
- They were products of human manipulation and therefore considered similar to any other invention
- They had a specified industrial application or commercial utility.  

The Patent Office had initially rejected the application on the ground that in being a living organism had no novelty, therefore cannot be patented.

The Board of Patent Appeals and Interferences agreed with the Patent Office decision; however, the United States Court of Customs and Patent Appeals overturned the case in Chakrabarty’s favour, writing that ‘the fact that microorganisms are alive is without legal significance for purposes of the patent law’. Sidney A. Diamond, Commissioner of Patents and Trademarks, appealed to the Supreme Court. The court ruled in favour of Chakrabarty, and upheld the patent, holding that: A live, human-made microorganism is patentable subject matter.  

Chief Justice Warren E. Burger wrote the decision, and was joined by Potter Stewart, Harry Blackmun, William Rehnquist and John Paul Stevens. Burger wrote the interpretation of 35 U.S.C. 101, which says:

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*

We can that in USA after the case of Diamond v/s Chakrabarty a new venture was opened patenting system. The basic criteria for micro-organisms patenting in USA was that it should a novel idea which is non-obvious in the field and has commercial utility.

**EUROPE**

In 1969, the first case relating to patenting of living beings was filed in Europe which made Europe ahead of the United States. 11 years before USA, in Germany, a patent case was filed on a method for breeding doves with red plumage which was rejected by both German patent office and Su-

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6 Patentability of Microorganisms by Shradha Diwan. http://www.iitrade.ac.in/
8 *ibid*
The Supreme Court on the ground that the living organisms cannot be patented and the method used was not repeatable. This was the very first case which opened the door for patenting biotechnology inventions. Further, in the early 1970s, the German Federal Supreme Court upheld patent protection for new micro-organisms if the inventor were to demonstrate a reproducible way for its generation.9

The European Union adopted the European Patent Convention (EPC) laying down the structural framework on the law of patents. The convention does not include patents for essential biological processes but it does include patenting of products of non-essential biological processes.

In 1993, in the same it was held that micro-organisms are patentable and were defined as single-celled organisms with dimensions beneath the breaking points of vision, which can only be engendered and controlled in research facility.

According to Article 53 EPC 2000, the following inventions are not eligible for European patents: inventions the commercial exploitation of which would be contrary to “ordre-public” or morality; plant or animal varieties; essentially biological processes for the production of plants or animals; methods for the treatment of the human or animal body by surgery or therapy; and diagnostic methods practiced on the human or animal body.10

European patent law includes an ‘ordre-public and morality clause’11 in its legislation that allows the European Patent Office (EPO) to exclude biotechnology patents for inventions which violates fundamental moral norms in Europe. There four types of such inventions that are exemplified, namely: processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; use of human embryos for industrial or commercial purposes;12 and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.13

Although varieties plant or animal present in nature are not patentable, however, if the technical feasibility of an invention concerning a plant or animal is not confined to a particular plant or animal variety, such an invention shall be patentable. Therefore, a claim wherein specific plant varieties are not excluded from patentability even though it may embrace plant varieties.

CHINA

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9 Wagner (1976), p. 335
11 Ibid.
12 G 2/06 Use of embryos/WARF; C-34/10 Oliver Brüstle v Greenpeace eV
13 Article 6.2, Biotech Directive; Rule 28 EPC.
In China, patent claims for micro-organisms are allowed. Article 25 of the Chinese Patent Law provides a list of subject matter that are excluded from patent protection. The list found in Articles 52 and 53 of the European Patent Convention is similar to that of Chinese Patent Law. The standard for applying Article 25(1) of the Chinese Patent Law is that a mere discovery of material from the nature is not patentable but it may be patented if it has been isolated or purified from its natural environment and has been absolutely described.

China has a product of nature rule that implied that naturally occurring DNA sequences cannot be patented. However, it has been interpreted that patentability claims covers purified and isolated DNA sequences as new composition if matter.

Therefore, we say that purified and isolated micro-organisms and DNA sequences can be patented in China. 14

INDIA

Patent Act of India, 1970, Section 2(1)(j) defines an invention as a new and useful manner of manufacture or a substance produced by manufacture.15

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.

In 2002, The Patent (Amendment) Act brought microorganisms within the realm of patentability. Section 3(j) was couched in terms of Article 27(3) (b) of TRIPS agreement.16 It stated 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 are not inventions within the meaning of this Act. It excluded microorganisms from the exceptions to patent protection and allowed patenting of processes pertaining to microorganisms as well as non-biological and microbiological processes.

The act was once again amended in 2005 to establish congruence with TRIPS. The main provision of the Act is now to allow the grant of product patents in the field of chemical, pharmaceutical, food and biotechnology. Patentable biotechnological inventions can be broadly categorized as: ‘Products in the form of chemicals, microorganisms, plant extracts, fermented material; processes/methods for using useful products and compositions/ formulations of product such as vaccines, proteins, hormones’.17

17 Patenting of microorganisms in India: a point to ponder by Suja Senan, M. G. Haridas and J. B. Prajapati
It 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. Earlier patenting of Microorganisms was considered to be a product patent and the protection provided was for five years from the date of grant or seven years from the date of filing of application for the respective patent. Now microbiological inventions patenting grant is for a period of 20 years from the date of filing. The most vital distinction between the legal practices of India and developed countries is that India (or developing countries) does not allow patenting of microorganisms that already exist in nature as the same is considered to be a discovery according to the provisions of the section 3(d).\textsuperscript{18} Section 3 of the Act, deals with non-patentable inventions: (d) 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 mere discovery of any new property, or new use of a known substance, or mere use of known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant.\textsuperscript{19}

**DIFFERENCE BETWEEN DISCOVERY AND INVENTION**

A discovery is disclosing or recognizing a new form or a new use of an already known or existing substance. A mere discovery of an already existing product is not considered to be patentable. An invention is creating of a new product or processes which involves a technical knowledge as compared to the prior art. Inventions are novel and unique but if they increase the efficacy and have commercial utility then they fall in the category for patentable inventions.

The first case filed in India was Dimminaco A G v. Controller of Patents (2002). It was in this case that The Calcutta High Court decision held that patentability of biotechnological process with living end product.

This decision on the Calcutta High Court was synchronous with the position in the United States, most of the European countries, as most processes in the biotechnology field will be patentable: irrespective of whether resultant product is living or non-living. After the Dimminaco decision, the Indian law kept pace with the needs of thriving biotechnology industry.\textsuperscript{20} In India, a patent protection was granted to only those genetically modified versions of the microorganisms which enhance its known efficacies.

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\textsuperscript{18} ibid
\textsuperscript{19} The Patent Act,1970 and amendment 2005
\textsuperscript{20} Journal of Commercial Biotechnology Vol. 16, 4, 337–347
CONCLUSION

Patenting of life forms may have many dimensions related to the use of intellectual property rights concept in the industrialized world. Varieties of plants and animals are not patentable but microorganisms have been excluded from the category. Microorganisms are defined as single-celled organisms with dimensions beneath the breaking points of vision.

In the worldwide situation, the TRIPS agreement makes it compulsory to provide patent protection to microorganisms and non-biological and microbiological production of plants and animals.

The main patentability criteria is that
• Should be an invention i.e. new or novel and not be a part of prior art.
• Should include an inventive step i.e. non-obviousness and technical advancement
• Should have industrial application i.e. utility and commercial value.

These provisions laid above do not establish any discrimination to the patentability of the invention in any field of technology including biotechnological inventions. However, there are certain exceptions and conditions to patentability are provided under patent act of different countries. These provisions are however more or less similar to the provisions laid down in the patent laws of various developed countries.

Microorganisms are present nature and a mere discovery of an already present organism cannot be called as an invention. When microorganisms when are genetically modified by human input, intercession and isolation from pure form they became an invention and thusly are patentable.