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BIOTECHNOLOGY PATENTS AND PROBLEM OF NON-OBVIOUSNESS

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INTRODUCTION

The fields of medicine, food, fertilisers are affected by biotechnology. Biotechnology is integral and essential to living and non – living organisms. Recent years have seen an explosion in Biotechnology research. One such significant research has been the research on DNA recombinant engineering. Biotechnology research has benefited the society by bringing advancements in the fields of medicine, agriculture and industry. Hence, it becomes absolutely necessary to ensure protection to biotechnological inventions, which encourages the researchers to pursue research innovation. Hence, the issue of biotechnological inventions and patent law forms an integral part of the law.

To proceed further, it is essential to understand the meaning of biotechnological inventions and biological material. Inventions that consist of biological material or a process by which biological material is produced, processed or used can be termed as biotechnological invention. A material which contains genetic material or genetic information and has the capacity to reproduce itself or can reproduce in a biological system can be termed as biological material. This is the cause of struggle between patents and biotechnological inventions.

The TRIPS Agreement prescribes the basis of granting patents to biological material as well as other kinds of inventions. Patents are to be made available when the inventions are novel and have an industrial application. The main aim of the TRIPS agreement is to grant uniformity and international standards while applying for a patent. Granting patents to a biotechnological product has arisen in many courts. In the case of *Dimminaco AG v. Controller of Patents and Designs*, the Hon'ble Calcutta granted patentability rights to the plaintiff even though the invention contained a living organism. However, in India, there has not been much of an advancement in the issue since then.

NOVELTY AND BIOTECHNOLOGICAL PATENTS

Novelty is a prerequisite for granting patents. If the invention was known to the public before filing the invention for a patent application or before its date of priority, then, the invention cannot be patented. One of the important motives behind granting patents is to prevent the prior invention from being patented again.

A legally enforceable monopoly is created when an inventor is granted a patent. This implies that any third person can be restrained from exploiting the invention. If such an invention is exploited, legal actions can be taken against him. However, patents cannot be claimed on

inventions which the public have been using freely. For example, patents cannot be claimed on wheels.

In Europe, novelty is specified in Article 54 of the EPC, it states that an invention can be considered to be novel if the invention does not form a part of the state of art. To understand this, it is crucial to state what constitutes state of art. State of art has been defined as everything made available to the public by mean of a written or oral description, by use, or in any other way before the date of filing the European patent application.

In the United States, novelty is defined under Section Article 102. It is sufficient to show that the product was not previously known or used by anybody in the United States. The invention which is applied for invention should not be granted patent in the United States nor in any other foreign country.

In addition to these hurdles, biotech applications also face the challenges faced by other patent applications – namely, novelty, non – obviousness, an inventive step should have been involved in the making of the product and lastly, the invention should be useful.

NON-OBVIOUSNESS AND BIOTECHNOLOGY PATENT

The main aim of the principle of non – obviousness is that the invention should be sufficiently inventive. The non-obviousness principle asks whether the invention is an adequate distance beyond or above the state of the art.”

The term “inventive step” is used in Europe, whereas the term “non – obviousness” takes a predominant position in the patent law of the United States. Each country has its own methods of evaluating inventive step and non – obviousness. The basic principle of non – obviousness is to refrain granting of patents to those inventions which are not novel, but have a normal design and development. These inventions must be abstained from granting of patents because granting patents to normal inventions does not foster in encouragement of new inventions.

Under this topic, the author aims at examining the scenarios of different countries before moving on to the scenario in India.

1. European Patent Convention – under the Convention, two important articles, namely Article 52 (1) read with Article 56 states that the patents granted in Europe shall be granted to those inventions which involve an inventive step, the invention should have regard to the state of art and the invention should not be obvious to a person skilled in the art.

Whether the invention involves an inventive step or not is determined by The Examining Divisions, the Opposition Divisions and the Boards of Appeal of the European Patent Convention. These Boards usually use the problem – solution approach to determine whether the invention involves an inventive step or not. The approach involves the following steps –

- a. identifying the *closest prior art*, the most relevant prior art;

- b. determining the *objective technical problem*, that is, determining, in the view of the closest prior art, the technical problem which the claimed invention addresses and successfully solves; and
- c. examining *whether* or not *the claimed solution* to the objective technical problem is obvious for the skilled person in view of the state of the art in general.

2. United Kingdom – in the case of *Windsurfing International Inc. v Tabur Marine (GB) Ltd.*, the Court of Appeal laid down rules to determine the requirements for the inventive steps

- a. The inventive concept embodied in the patent must be identified.
- b. Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;
- c. Identifying the differences if any between the matter cited and the alleged invention; and
- d. Deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps which would have been obvious to the skilled man or whether they required any degree of invention.

3. United States – the requirements for granting patentability is codified under Section 103 in the United States Code. Non – obviousness is one of the requirements the invention should meet in order to get the label of a patent. Non – obviousness in this instance refers to a person who has the ordinary skill in the art would not have the knowledge to find a solution to the problem, the way the invention is required to do.

Teaching – suggestion – motivation test

The combination of elements which were previously known can also be considered as obvious. In the case of *Winner Int'l Royalty Corp. v. Wang* it was held that prior art should explicitly consist of teaching or suggestions to combine elements in order to find the patent obvious. This prerequisite is generally referred to as the teaching – suggestion – motivation test. The main aim or the idea behind this approach is prevention against hindsight bias. The combination of known elements usually gives rise to inventions. Hence, a patent examiner is required by the TSM test. The patent examiner will display that the known elements have combined to form the invention. One of the main criticisms of the TSM test is that the test requires evidence of explicit teaching or suggestion, however, the Federal Circuit has also declared that the implicit motivation may also be provided. The question of TSM test has also been considered in *KSR v Teleflex* by the U.S Supreme Court. The U.S Supreme Court held that while determining the true test of Non – Obviousness Graham analysis should be utilised as opposed to the TSM Test. However, the TSM Test still remains an integral part of the Federal Circuit.

In CANADA – the test for non – obviousness was laid out in the case of *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*; the basic principles that was laid down are as follows –

- a. Identify the notional “person skilled in the art” and identify the relevant common general knowledge of that person;

- b. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- c. Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;
- d. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

In INDIA, biotechnology inventions have grown massively in the recent past and patent protection plays a crucial role. Processing of gene engineering technologies, methods of isolation of micro – organisms, methods of mutation, cultures form foremost part in biotechnological inventions. The patenting of biotechnological inventions is a controversial issue due to the validity of patenting plants, animals, the genes and morality issues that are related with it. However, the majority of the issues related to patentability of biotechnological inventions relate to novelty of the invention, steps which have been taken to make the invention new, industrial application of the invention, sufficiency of disclosure and support of the description of the claims. During a patent infringement suit or a patent prosecution the claim can be rejected on the basis of obviousness.

PROVISION IN THE INDIAN PATENTS ACT

Further, to understand the concept of patentability in India it should be noted that in India, it is possible to grant patents only to inventions and not discoveries. Invention refers to something that is designed newly and which is created by the inventor. Discovery is a term that is used to describe the act of finding something that was unknown before. The TRIPS agreement however, does not define the term invention. International Conventions such as the Paris Convention or Patent Cooperation Treaty do not define the term invention. However, the US Patent law does not differentiate between invention and discovery. However, the philosophy of patent law states that living things can also constitute inventions. It does not imply that discoveries cannot be living things. Biotechnological inventions are often based on the products that are available in nature.

Section 2(1)(ja) Inventive step constitutes the feature of an invention which comprises technical advance as opposed to existing knowledge or which has an economic significance or both, the invention should not be obvious to a person who is skilled and has knowledge in the state of art. The step that makes the invention new and unique is a defined inventive step. However, what exactly constitutes an inventive step is an ongoing debate.

The Patent Law in India explicitly states that certain subjects that are not patentable. The list has been made in accordance with the TRIPS agreement. The following subject matter, according to the Act, is not patentable.

1. Inventions against natural laws
2. Inventions contrary to public order and morality.
3. Discovery of a living thing occurring in nature
4. A claim for a duplication of an earlier work.
5. Methods of treatment for human beings or animals.
6. Plants and animals in whole or in part, and essentially biological processes for the production of plants and animals.

From the above-mentioned subject list, it can be deduced that microorganisms and living organisms which produce biotechnological processes are patentable subject matters. The Indian Patent Law was amended in 2002 to include biotechnological inventions as patentable subject matter. Prior to the amendment it was stated that chemical processes form part of patentable matter. After the amendment, the definition of chemical processes implies that biotechnological matters are unambiguously patentable. However, judicial pronouncements on the subject matter are not present in India.

Consider the case of an isolated purified form of a protein which is not obvious if it is otherwise identical to the naturally occurring protein that is already known. The courts resorted to the traditional approach of comparing what is claimed with the prior art. In another example, if a protein is already known, but what is claimed in an invention is a gene and the gene has been isolated and purified. Such a gene clears novelty but it is difficult to assess the obviousness/inventive step owing to the fact that a particular gene having a particular nucleotide sequence exists in principle but whether it would be obvious to one skilled in the art to identify and isolate the aforesaid gene is another hurdle.

In the *In Re Bell* case, it was held that "it may be true that knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one has the potential for obtaining that gene" Therefore, only when there is something in the prior art which would recommend the researcher about a particular gene, the nucleotide sequences purification and isolation are considered to be not obvious and they can be patented. It is to be noted that the process for looking for the right nucleotide sequence may be known; however, it is not obvious that from the entire human genome the right sequence will be chosen. The Indian Patent Office provides the draft guidelines according to which the examiner ought to design a comprehensive search strategy. The comprehensive search strategy is designed by coalescing various key words.

NON-OBVIOUSNESS – THE ULTIMATE CONDITION OF PATENTABILITY

All the subject matters which are new cannot be considered as patentability. An inventive step must be involved in granting patents to inventions. According to the TRIPS agreement, patents will be available for inventions if they are new, involve an inventive step and they are capable of industrial application. Non – obviousness and inventive steps are considered as equal. The demand for inventive steps has great potential to act as a hurdle for patentability. The most challenging aspect of patentability is non – obviousness. Biotechnological inventions such as genes, gene sequences, DNA and DNA sequences involve biological components that occur in nature. However, the identification of a biological matter is a discovery and not patentable. However, if an isolated and pure gene from any human, animal or plant is invented, then such an invention is patentable. However, it should be noted that such an invention should be proved that it is beyond mere discovery. DNA and genes are not easily discoverable.

Hence, it is believed that the efforts of ingenuity in isolating and purifying genes or DNA signifies a leap forward from the prior art comprising of naturally existing un isolated and unpurified genes.

As mentioned above, the first time the question of granting patents to biotechnology had come before the Calcutta High Court in the case of *Dimminaco A.G V. Controller of Patents Designs & others* The main issue in this case was whether the preparation of infectious Bursitis Vaccine

constitutes an inventive step? The inventors of the vaccine claimed that making of the vaccine involved certain chemical steps and hence the invention is patentable. The application was initially rejected by the Patent Office. However, the Hon'ble Calcutta directed the patent office to grant a patent to the invention. The reasoning given by the Hon'ble High Court was that there exists no statutory bar on granting patents to living organisms. If the biotechnology invention involves an inventive step, then, a patent can be granted.

Further as per the patent law if the invention is anticipated in the prior art or is published, used, patented it does not involve an inventive step. In case of biotechnology inventions also the claimed invention does not constitute an inventive step if is anticipated or published or used or patented earlier or in any way forms part of the prior art.

In addition to being non – obvious, an invention must be useful and capable of industrial application for the invention to be patentable. The public must be benefitted from the invention. At the time of granting the patent, the requirement of industrial application must be satisfied. It is to be noted that the requirement of industrial application need not be satisfied at the time of filing for the patent. If the inventor can prove that the invention has industrial application at the time of granting the patent, the inventor can continue with the process of filing for the patent.

CONCLUSION

Indian Patent Law states that the application for patent law shall be conveyed with the specifications of the invention. The invention should be innovative and non – obvious. In addition, the invention must be useful to the public. In the year 2002, the Patent law was amended, keeping in mind the biotechnology inventions and the need to patent such inventions. The amendment identifies the Budapest Treaty for facilitating the deposit of biotechnology inventions for the sake of patent procedure. When the application is filed for a patent of a biotechnological invention, it has to be accompanied by a deposit of the invention in any recognised depository institution. The depository institution should be recognised by the Government of India. In India, the biotechnology industry is the nascent stage. In the subject matter of granting patents to biotechnological inventions, there has not been much development. As opposed to laws in the US and European Union, Indian laws require the disclosure of source and geographical origin of biological material which is utilised in creating the biotechnological invention.

The biological diversity Act read with the patents Act states that the use of biological resources in producing the claimed biotechnology invention shall be disclosed and mentioned in the patent application in order to share the benefits of the patents to the geographical regions, which conserved the source.

However, the TRIPS agreement does not mention any requirement of stating the source. However, in every case, it is not possible to describe a biotechnological invention in a clear and comprehensive manner. Due to the fact biotechnological inventions are living beings it may not be possible to describe the invention as required under the patent laws. Therefore a biotechnology invention satisfying the requirements of novelty, non-obviousness, industrial application and written description or deposit of the invention is patentable throughout the world.