

ROLE OF PATENTS IN THE BIOTECHNOLOGY INDUSTRY

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An Intellectual property rights refer to the creating an invention from the mind and then protecting it. Something new which is created needs a protection because the essence of creativity requires the progress and growth without the protection of the invention or any kind of the intellect created would be misused. It is way too important to grant something to the owner of the intellect who worked as per his skills to create something new which society would be getting benefits from.

The term intellectual property law refers to the rules and regulations made for the protection of the skills or the creativity, the law has various branches like copyright, trademark, trade designs and patents as well. The right over the intellectual property is created as soon as it is created why the owner or the inventor however in some cases the registration may not be compulsory but if someone want it plays a vital role.

This research paper includes the role of patents in biotechnology industry, where the term patents define an exclusive right which is given to the inventor over his invention for a limited period of time by a recognised statute. As per section 2 1(m)¹ of the Indian patents act patents on any invention can be granted under this act but the following requirements are need to be fulfilled accordingly.

As per Indian patent act it provides the patents not only to the product or the invention which is created but process as well. Patent is a monopolistic right which helps in creating the monopoly in the market where the exclusive right to given to the individual who invented the invention or product or process. It is basically ensure no duplication of the invention or the process and it always helps in promoting something new which can be granted by the individuals to the society.

An invention requires the following requirements to be fulfilled to get the patent over the invention:

- The exclusive right over an invention can be made when something new is been created whether a product or process involving an inventive step, therefore it is important to understand the term new defined under section 2 (1) of Indian patents act which includes that the invention is not anticipated properly, it is not a part of public domain and is also not analyse by any other source or publication before the grant of patent, thus it is important to have something new in the invention otherwise no patent can be granted.

In the case of *bishvanath radhey sham vs. Hindustan metal*² industries held that defendant created the same machine to keep the utensils for the production and it lead to the suit of infringement where the patent over a same product can't be granted just by adjusting the parts here and there as a result the controller rejected the application for the same as there was no newness in the development of an invention.

- The second most important thing is inventive step defined under section 2 1 (j(a)) of the Indian patent which defines that it should add an economic value to the invention along with the technical advancement of the invention since it will then only ensure the monopolistic right.

¹ This definition is according to Indian patent act 1970

² <https://indiankanoon.org/doc/1905157/>

- Concept of non obviousness states that an invention should not be a part of a prior art and or is already under the public domain otherwise it won't be considered to be patented as per the patent act.
- The another most important aspect is industrial application which states that an invention is capable of being marketed in the market of the society however it is important to understand an invention which is needing a monopoly in the society should has a industrial value itself so to ensure that it would be adding value to the society itself so it is also one of the most important aspect of an invention being patented.
- The last but not the least it will require a written description something which is in writing would add a good evidentiary value for the registration of the invention.

And above all it should not fall under section 3 and 4 of the Indian patent act ³because it won't be granted a patent.

Thus these are the requirements which are needed to keep in mind so that it would be helpful in the fulfilment and grants of patents.

BIOTECHNOLOGY INDUSRTY AND PATENTS: the term biotechnology is refers to the process of creating or modifying the living organisms as well as biological material which are genetically modified which includes the result and use of such process .

Ever since a genetically engineered micro-organism was granted patent, the field of biotechnology gained enormous significance and patents have been granted on genetically engineered plant and human genetic material. Though evolution of patent law on biotechnology dates back to seventh century, the global adoption of the patent system started in Venice as the first patent law was enacted in 1494, which regarded as the foundation for the world's patent system⁴. The requirements enshrined in the Venetian Statute such as utility, novelty and non-obviousness are still the basis of modern patent law around the world. Earlier nobody thought that biotechnology could manipulate either plant or animal or human being and therefore none thought of the need for evolving a comprehensive law on biotechnology for regulation. However, as biotechnology has progressed in various generations at different times and this field mandated a comprehensive legal framework for proper regulation, TRIPS agreement provided protection and regulation of various biotechnology inventions as well. Under the patent regime around the world the significance of biotechnology and its inventions are recognized and protected. The biotech inventions could be patented following the patentability criteria; however there exists complexity of manipulating of living forms hence need special attention. ⁱ

When we consider the role of biotechnology it drives a question of its existence in intellectual property rights where everything works with human intellect and according to the development of an idea and giving that idea a concrete shape plays an vital role, especially in the case of patents where the invention of a product or a process is way more important then what idea took place⁵.

³ Exceptions under Indian patent act 1970.

⁴ <https://www.epo.org/news-events/in-focus/biotechnology-patents.html>

⁵ [BIOTECHNOLOGY PATENTING ISSUES IN - Venture Center](#)

Trade related intellectual property rights known to be TRIPS is an international agreement being signed by various countries it comes under world trade organisation and later replaced it in Uruguay round when the meetings and conferences took place in context with intellectual property laws .

Like in other disciplines, for biotechnology, protection of intellectual property provides encouragement for innovations involving genetic engineering, in addition to according incentives for investments, which may lead to new products and processes. The general prerequisites for patentability, namely, novelty, inventiveness and industrial applicability (or utility) apply to biotechnology inventions as well. As a rule, though this may appear paradoxical, new biological material is patentable, if obtained through non-biological processes. Non-biological processes are defined as those where the *hand of man* had a part to play.

It actually the foundation for the biotechnology patenting concept to state the following where article 27 clause 3 states that there will be no discrimination based in the field of technology and all laws will be equally applies in the field of biotechnology and will be applicable to the countries who signed the agreement. Whereas Article 27.3 (b) of TRIPs⁶ gives members the freedom to exclude plants, animals and “essentially biological processes” from patentability. However, it also states that micro-organisms and non-biological and micro-biological processes have to be patentable, clause 3 (c) deals with the discovery of the genetically modified organisms and 3 (j) dealing with the Patentability criteria for the plants and other animals. where every country has its own norms to play and work according to the guidelines given on the biotechnology where united states of America tends to deals with the patent over the living organisms where as India doesn't follow the same context in respect of living organisms where it deals with something which is created genetically being modified with the help of those living organisms since section 3 of the Indian patent act⁷ it deals with exceptions where the patent over a plant or animal is not possible as per Indian patent act where for India everything is based on the moral values , ethical grounds and most importantly the humanitarian laws which doesn't allow the patents over something which we pray or respect for . Biotechnology, particularly modern biotechnology, which is primarily based on the exploitation of the genetic engineering techniques, is in a relatively infant stage. Like in any other R&D activity, investment requirements are high and returns are never assured in terms of bankable products and processes of commercial utility. The time frame involved also could be long. Consequently, rewards for such risky investments have to be assured, and protection of intellectual property of the inventor or his sponsor is one system which will ensure returns on investments. The uncertainties inherent in biotechnological product development are common to both healthcare and agriculture-related biotechnology products and processes. There have been some successes, but the majority of companies survives of R&D funds, venture capital and sponsored projects from large corporations. Due to various concerns and ambiguities, including moral, ethical, theological and political factors, there has been no consensus on uniform standards for inventions in this area.

As per clergy he tends to state that biodiversity is a soul arena of god where his concern was based on the depletion of biodiversity and along with destruction created by human beings for their own benefit that's where the law came into the existence for GMO⁸ stating the creation the l microorganisms can be made nut not directly the patents over them.

The trips agreement doesn't gave an adequate definition which comes in the ambit of article 27 clause 3 b it simply gave an opportunity to choose whether to grant the patent or not it lies in the soul desecration of the country itself however India only opted for genetically modified organisms not the plants and animals since this article doesn't define what to patent or not , countries do have their own thinking process and cultures to

⁶ Trips is trade related intellectual property rights, is an international treaty signed by various authority.

⁷ Indian patent act 1970.

⁸ Abbreviation for GMO is genetically modified organisms.

make the laws over the same on the other hand united states deals with the fact patent over the plants and animals can be possible but not on gmo because they aren't naturally occurring and European countries have their own context of patenting plants , gmo but not their varieties however this article comes with the concept of reviewing the laws made like after 5 years still the ambiguity of defining what to be patent by the countries or not with aspect to the biotechnology is still vague hence the ambiguity has its existences till date

Since its every country has its own way of making the rules and regulations following the guidelines one of the most important case related to biotechnology, where united stated of America tends to play an important role in providing the patents over the microorganisms and bacteria unlike other countries especially India which tends to follow the concept of something which genetically modified and where patents over plants and animals is restricted.

Case: Diamond v. Chakrabarty - 447 U.S. 303, 100 S. Ct. 2204 (1980)

The U.S. Supreme Court reads the term "manufacture" in 35 U.S.C.S. § 101 in accordance with its dictionary definition to mean the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery. Similarly, composition of matter is construed consistent with its common usage to include all compositions of two or more substances and all composite articles, whether they are the results of chemical union, or of mechanical mixture, or whether they are gases, fluids, powders or solids, Respondent microbiologist filed patent claims for human-made, genetically engineered bacterium that was capable of breaking down multiple components of crude oil. The US Court of Customs and Patent Appeals allowed the claim. Petitioner, Commissioner of Patents and Trademarks, appealed the judgment. The court affirmed the judgment that allowed respondent microbiologist's patent claims. The language of the patent statute covered respondent's invention of a living, genetically engineered micro-organism. The court affirmed the judgment that allowed respondent's claims. The court rejected the argument of the patent office board of appeals that 35 U.S.C.S. § 101 was not intended to cover living things such as laboratory created micro-organisms. The court held that respondent's micro-organism constituted a "manufacture" or a "composition of matter" within the meaning of and thus qualified as patentable subject matter. The court found that respondent had produced a new bacterium with markedly different characteristics from any found in nature and which had the potential for significant utility. The court held that the language of 35 U.S.C.S. § 101 embraced respondent's invention.

Thus from the above case it is seen that every country has its own definition of patents in biotechnology industry and in Indian patents laws section 3 clause j states that plants animals even whole or a part of it including the varieties of species except micro organisms cannot be patented in India as plants and animals itself have their protections and laws pertaining in other acts codified under Indian laws as a result artificial plants can be patents but not the real one as India is a religious country and secular as well they tends to believe it that monopoly over something cannot be created which already a part of traditional knowledge the term is not defined anywhere in the act however it states that something which is already existed and the real

owner is not known is a part of traditional knowledge thus the right of monopoly over the living organisms be it human being plants or animals is not granted with respect to our country but something which is created modified and is new to the phase can be patents but should not include all these elements mentioned as a part of expectations under Indian patent act .

INDIAN CASE LAW: DIMMINACO A.G. v. CONTROLLER⁹

The Assistant Controller of patent observed that “in India till date, no patent had been granted for any process of preparing a living organism. In the Controller’s view, if such a process became patentable, “there will be further problems as foreign sophisticated technologies will have to be patented in India. The Assistant Controller also contended that the framers of India’s Patents Act, 1970, had relied on the 1959 recommendation of the government commissioned Iyengar Committee that “invention” should be defined narrowly. Appellant Dimminaco countered that the Patent Office had not cited any anticipatory prior art against the claimed process, nor had it questioned the utility of the end-product vaccine. Therefore, the process should be held a patentable “manner of manufacture” coming within the Patent Act’s enumerated categories of inventions. After summarizing the parties’ respective arguments, the Calcutta High Court considered the scope of “manner of manufacture” under section 2(I) (j) of the Patents Act, 1970, and noted that the word “manufacture” was not defined in the Patents Act. In such cases, the court explained, the dictionary meaning of “manufacture” or its usage “in the particular trade or business must be accepted. Further, in order to decide whether a particular process of manufacture “ought to be patented or not, “one of the most common tests is the vendibility test. This test is satisfied “if the invention results in the production of some vendible item something which can be passed on from one man to another upon the transactions of purchase and sale claimed method was a patentable invention because the dictionary meaning of the word manufacture does not exclude the process of preparing a vendible commodity which contains a living substance. Where, as in this case, the Patents Act, 1970, provided no definition of “manufacture,” then “the dictionary must be accepted. The Assistant Controller had legally erred “by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention. In overturning the Assistant Controller’s decision, the court held that there was evidence that the Indian Patent Office had already granted a few biotechnology process patents producing a living end product. The Assistant Controller had “not acted on correct principles” by rejecting Dimminaco’s application on the ground that it could not be called a “manner of manufacture” because it involved a living virus in the end-product. The Indian Patent Office appears to have adopted Dimminaco’s teaching that the fact that an invention is living (or produces a living product) does not automatically exclude it from patentability. The MPPP states that a “living entity of artificial origin such as micro-organism, or vaccines are considered patentable, although higher life forms such as plants or multi-cellular animals, whether of natural or artificial origin, are not. Moreover, biological material such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention. In addition, the processes relating to micro-organisms or producing chemical substances using such micro-organisms are patentable.

⁹ <http://notesforfree.com/2018/01/18/patent-case-brief-dimminaco-g-v-controller-patents-designs/#:~:text=%C2%A7%20The%20Appellant%2C%20Dimminaco%20A.G,preparation%20of%20the%20bursitis%20vaccine.&text=%C2%A7%20Acting%20under%20delegated%20authority,Application%20and%20Upheld%20the%20objection.>

Conclusion:

The concept of biotechnology in India is new and however it deals with certain exceptions being provided under the patent law acts as India's post-trips patent laws include several provisions that make biotechnology patenting more attractive as a basis for competitive advantage. The dimminaco decision likewise signifies greater judicial and administrative appreciation of the importance of biotechnology patenting. It is apparent from the allowable claims disclosed hereinbefore, that the biotech patents can be obtained in diverse areas provided the description/enablement requirements be complied with and prosecuted articulately. Furthermore, India being one of the bio-diversity rich countries, it would, thus, be prudent to protect biotechnological inventions as that would help Indian biotechnology research to compete globally. India needs to reap the due benefits from its rich bio-resources with an enabling provision for patent protection in biotechnological innovations and inventions.

Whereas other countries have their own rules and regulations however the role of patents helps

in creating a stepping edge in the development of state ,nation and individual as a whole it helps in enduring the royalty and incentives benefits of an individual over the idea being made in terms of inventions and process in contest with the novelty in nature so that it becomes easy for an individual to enjoy the perks without any manipulation and it also help in abridging the gap between the inventions and resources which are taken into the countries and some have restrict rules , some have no rules and some work with the guidelines itself depends upon the development rate and along with the intellectual ability to built and design the inventions and processes so to ensure grant of patents and later on can be used by other people also. therefore patents ensure the role of biotechnology along with the certain exceptions.