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INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN

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INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY

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ABSTRACT

The main objective of this paper is to highlight the importance of intellectual property in relation with biotechnology. The areas of biotechnology deals with mainly pharmaceuticals, nanotechnology, plant variety, patent protection for the invention etc. The field of biotechnology is blooming in the world of science and medicine with the new inventions & innovation. These new invention and innovations are the sign for rise in patent filing. Hence patent filing are rise in state and many people realize the value of intellectual property protection for their inventions. As the invention is unstoppable and these recent invention, innovations in the field of biotechnology are considered as budding stage of the field. Hence by protecting these inventions, ensures trust among the inventors and motivate others to invent further in this field and other field as well. Intellectual property rights does not solely concern with field of biotechnology they are relatable to other fields. So inventions from all the field in a country can lead to better economy by providing open market to country it gets opportunity to increase GDP and growth of the nation.

Key words: biotechnology, nanotechnology, pharmaceuticals, plant variety, invention, prior art, GDP growth, inventors etc.

INTRODUCTION

Intellectual property is the right which is granted for the inventors of the products. Intellectual Property Rights has covered inventors or say protected their products getting infringed by other individuals. IPR is not given for a mere discovery of the existing product but it is granted for

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inventor for using his intellect to create that product. In short it clearly emphasise that the product created by inventor should possess some inventive or innovative quality in nature and it should not be against any public morality. An intellectual property is at times described as "knowledge goods". An IP is an invisible and intangible right granted to the intellect of the inventor.

By granting this right to inventors it clearly makes a statement that it is exclusive rights to inventors. Due to this exclusive rights many inventors are getting attracted to invent the new products and file the IPR for their work.so technically this boost the countries reputation and economy.

Example; Many inventors from India invents many products in various field and files the IPR protection for the same then other countries want to invest in India thinking that they have various new inventions and they are getting developed and attracting large number of investments increases the economy of the country and keeps the country supreme and reputed.

HYPOTHESIS.

From the title we can say that this paper discuss about the intellectual property rights (i.e.) patentable subject matter in the field of biotechnology and challenges faced in their field. This paper would highlight the major challenges in the field of biotechnology.

Types of Intellectual property

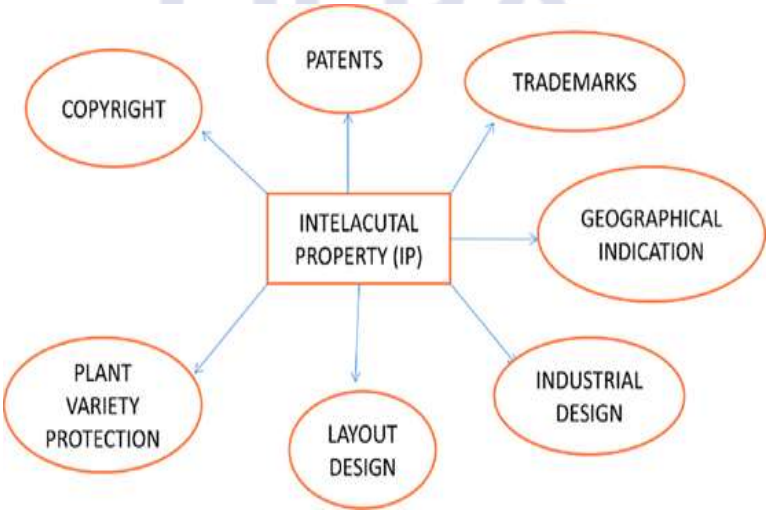

Fig1.1

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Above image represents the types of intellectual property which are used day by day by various researchers, innovators & creators etc.

1. **Patent:** A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.
2. **Trademark:** A trademark can be any word, phrase, symbol, design, or a combination of these things that identifies your goods or services. It's how customers recognize you in the marketplace and distinguish you from your competitors.
3. **Geographical indication:** A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. In order to function as a GI, a sign must identify a product as originating in a given place.
4. **Industrial Design:** An industrial design may consist of three dimensional features, such as the shape of an article, or two dimensional features, such as patterns, lines or colour.
5. **Layout design:** Layout design is the process of arranging visual and textual elements on-screen or on-paper in order to grab a reader's attention and communicate information in a visually appealing way
6. **Plant variety protection:** Plant variety protection provides legal protection of a plant variety to a breeder in the form of Plant Breeder's Rights (PBRs). PBRs are intellectual property rights that provide exclusive rights to a breeder of the registered variety
7. **Copyright:** Copyright law protects creators of original material from unauthorized duplication or use.

The above mentioned are the types if intellectual property and their general meanings to it. In this paper we are going to discuss only about patent and its usage of patent in biotechnology. As biotechnology part concern cells, micro-organism, bacteria etc using this the inventors invent or create the medicine or using same they test. So in order to protect this the patent is used as protection in them.

TRIPS AGREEMENT CONCEPT

The intellectual property rights are developing in recent days particularly in the field of commerce demanded the level of protection and enforcement of these rights and they varied

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greatly throughout the world.

So these variations which prevailed across the world made conflicts and created tensions between nations hence resulting in international conflicts. New globally agreed upon trade standards for intellectual property were considered as the systematic approach to resolve the dispute. These standard enhanced the protection of intellectual property before the nation.

Hence General Agreement of Tariff and Trade [GATT] was the only multilateral mechanism then established to oversee commercial aspect until the World Trade Organisation [WTO] overtook the same in 1995.GATT started from round one to eight contributed to the ease the trade related problems mainly tariff oriented and helped the other countries to enhance their relations with other countries. First five rounds of GATT focused mainly on tariff aspect problems and dispute then sixth round included discussions on anti-dumping measures which control the dumping of goods into their territory by other nations that could harm their economies.

The **eighth** round of GATT was game changing round were members of GATT felt that GATT lacked coherent institutional structure and it only dealt with trade in goods alone and it did not have any dispute resolution board to resolve the dispute quickly. So in eighth round which is also called as the Uruguay round where members decided to replace the GATT with WTO. The main purpose for which WTO created to look of intellectual property issues, trading of goods including services, agriculture, and textile as well by not making any favoritism to any developed nations and suppressing under developed nations. All 123 members took part in Uruguay round. WTO is made much stronger than GATT where WTO has adopted various principle to develop the under developed nations and certain tariff reliefs to them. Right now WTO has 164 members in its organizations' which is of 90% of world population.

PATENT

As per Halsbury's laws of England the word patent is used denoting a monopoly right in respect of an invention. In **Telemecanique & controls limited Vs Schneider Electric industries, 2002 (37) PTC 632 Delhi high court** observed that patent created a statutory monopoly protecting the patentee against any unlicensed user of the patented device. **'A monopoly of the patent is the reward of the inventor.'**

Patent is an exclusive right granted practically a monopoly right conferred by the patent office

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on an inventor to exploit his invention subject to the provision of the patents act, 1970 for a limited period of time. During this period, the inventor is entitled to exclude anyone else from commercially exploiting his invention. According to section 2(1) m patent means a patent for any invention granted under this act.

The object of the patent is laid down by the court in this case **Bishwananth Prasad Radhey shyam Vs Hindustan Metal Industries (1979) 2 SCC 511** in this case radheyshyam finds new invention meanwhile Hindustan does the same with new step induced. In this case the object of patent was laid that it encourage scientific research new technology and industrial process. It has another object that it grant an exclusive right and monopoly to disclosure the invention at patent office.

According to 2(j) **Invention** defines the term invention. **It means that new product or process inventive step and capable of application**. The invention should be of absolute novelty as neither it has been published nor used in any part of the world.

IMPORTANT PROVISONS OF THE INDIAN PATENT ACT.

The patent act is the highly debatable and deals with the list of exclusions that are non-patentable that do not satisfy the conditions. In **F.Hoffmann-la Roche ltd Vs Cipla ltd** the court stated that they may otherwise meet the test of invention and 'inventive step' but may still not be granted patents as a matter of policy. According to section 3 the below mentioned things are not considered as inventions within the meaning of the act-

1. An invention which is frivolous or which claims anything obviously contrary to the well established natural law;

   E.g. pre natural laws

2. An invention primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

   E.g. bioterrorism

3. The mere discovery of scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature;

   E.g. Newton's Theory

4. The mere discovery of new form of a known substance which does not result in the enhancement of the know efficiency of that substance or the mere discovery of any new

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use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant like the salts, esters, ethers, polymorphs, metabolites, pure form etc.

E.g. Novartis Vs UOI

Imatinibmesylate (salt) by Novartis invent something inducing salt and when it goes for patent the same gets rejected by patent board saying the things which are already in existence are not patentable.

5. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

E.g. soft drink

6. The mere arrangement or re arrangement or duplication of known devices each functioning independently of one another in a known way;

E.g. improvement of anything or combined things

7. A method of agriculture or horticulture;

E.g. improvement of soil, but agriculture apparatus can get patent

8. Any process for the medicinal, surgical, curative, prophylactic (diagnostic, therapeutic) or other treatment of human beings or any process for a similar treatment of animal to render them free of disease or to increase their economic value or that of their products;

E.g surgical process

Mayo collaborative Vs Promotheus

In this case Mayo collaborative finds an instrument and using same they perform surgery and they wants to get patent for the process of the surgery but patent board denied same by citing this provision

9. Plants and animals in whole or any part thereof other than micro-organism but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals
10. A mathematical or business method or a computer program per se or algorithm;
11. A literary, artistic, musical, artistic work, dramatic or any other aesthetic creation whatsoever including cinematographic works and television productions;
12. A mere scheme or rule or method of performing mental act or method of playing game;

E.g. chess and Sudoku

13. A presentation of information;

E.g. timetable and calendar

14. Topography of integrated circuits;

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15. An invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

In addition to the aforesaid, no patent is to be granted in respect of an invention relating to atomic energy **(section 4 of Indian Patent Act).** From the above list we can derive invention which are non-patentable and same will be rejected by the patent board.

BIOTECHNOLOGY

Biotechnology is the use of biology to develop new products, methods and organisms intended to improve human health and society. Biotechnology is also called as biotech and it had existed since the beginning of the civilisation. In olden day fermentation process, ageing to produce foods, isolates etc. were prevalent and in recent days these methods are utilized in present days like process of ageing to produce food like wine, and fermentation process of milk into curd, isolates are nothing but communicable diseases where the disease gets transferred from infectious person to sound person. So from then to now the biotechnology process evolved and is playing vital role in curing diseases and helping mankind to recover. It's not only helping mankind but it also developed pharmaceutical industry which serves for the country during hard times like COVID19 and it had even expanded the marked to the global range and it does contribute to the economy. The generi-based industry has made strides in reverse engineering, quality, production in accordance with regulations, market development and above all meeting in IPR challenges.

However early applications of biotech let to the development of products such as bread to vaccines. The discipline has evolved significantly over last century in ways that manipulate the genetic structure and biomolecular process of living organisms. With the development of genetic engineering in the 1970s, research in biotechnology with other related areas such as medicine, biology etc. developed instantly because it brought out changes in the organisms' genetic material i.e. DNA. The term biotechnology is vast and its dynamic growth is reached to the extent that it almost covers all the aspect or areas of fields like;

- Agricultural biotechnology
- Transgenic animals
- Health care
- Bio fuels
- Biotechnology

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- Environmental biotechnology
- Genetic Engineering
- Forensic science
- Gene therapy
- Food preservation
- Bioremediation
- Molecular diagnostics
- Pharmaceuticals
- Bioinformatics
- Law

From the above we can clearly observe that biotechnology is the most important field which is currently evolving and will evolve further and for this sake this has to be protected by the law. Law for biotechnology may sound awkward but both are different subject meet at points when an invention happens and when the same gets breached or used for illegal purpose. So the importance of biotech is as important as its protection.

CHALLENGING ASPECT OF BIOTECHNOLOGY

In each and every field there are many challenges which that field has to face in order to shine. So in the field of biotechnology there are many challenges or the risk it has to undergo before any discovery is made and patent grant is also curtail. The risk are as below;

1. High level of Risk
2. Affordability
3. Privacy
4. Societal concerns
5. Laboratory safety
6. Bioterrorism
7. IP Issue
8. High R&D costs
9. Low research productivity.

Each and every things which are listed above is actually concern to the biotechnology. For example Privacy is major as the lab involves many people and invention founds inside the laboratories have to be private in order for its productivity and for the fruitfulness of the research. The IP concern in biotechnology is major as not all the inventions are patentable in

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nature. Only certain products are patentable in nature.

PATENTABLE PRODUCTS IN BIOTECHNOLOGY.

In above stated concern there is IP issues which refers to patent grant some biological material, or some genetically modified biological invention alone. As the one has to state his invention in an elaborate manner which is one of the primary requirement in the patent grant process. So when a biotech company tries to invent eventually they make investment in setting up of research and development (herein after referred as R&D). The R&D team does the research and take time and money to do certain invention but when the same is ready and sent to patent office they in turn refuse citing section 3 provisions, then the resource spent on R&D would be waste.

So for this, certain biological products are patentable but only they have been;

- Distanced from their natural environment
- Have been synthetically or made recombinant and produced
- Even method and process that use or test biological material can be patented.

A patent can protect wide range of biological inventions like;

- Plasmids
- Isolated bacteria
- Protozoa
- Plasmids
- Viruses
- Prions
- Cell lines
- Hybridomas
- Proteins which are distanced
- Polypeptides
- Process of enzymology
- Apparatus
- Composition of enzymes
- Genetic engineering
- Fermentation process

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- Testing process
- Diagnosis process
- Use of organisms to produce foods and beverages
- Mutagenesis
- Genetic vectors
- Any genetically modified organisms (GMO) like proteins, bacteria, cells etc.

By seeing above, interested person may ask can DNA be patented. The answer is no. Patents are not available for DNA till date as gene are not made by other person nor invented it is just present in human body in nature. Only RDNA (i.e.) Recombinant DNA is patented.

The Recombinant DNA US 4,237,224 – COHEN AND BOYER BY UNIVERSITY OF CALIFORNIA

Stanley Cohen's and Herbert Boyer's invention were patented and became an anchor in Stanford's highly successful technology licensing programme which indeed bought in total of about $200 million in licensing revenue. The invention was on how to split the pieces of DNA from different sources derived in molecular genetics. This patent was prosecuted by legendary Bert Rowland of Townsend. But patent was issued for the Recombinant DNA.

INVENTIONS IN ACCORDANCE WITH TRIPS

In biotechnology not all the products invented and submitted before patent board is patented and accepted. Meanwhile many patents applications were rejected due to non-technical aspect in invention. So before patent board submitting the patent application for the biotech invention is highly complex, it should be elaborated in detail format and the invention has to prove its non-obviousness and technical advancement then the patent may considered. So it completely depends upon the facts of the cases and invention. Due to these issues the legal protection in case of biotechnology is highly complex and challenging.

Article 27 of the TRIPS Agreement states which invention that government should make eligible for patenting, and some exclusions from patenting. So broadly speaking of article 27(3) (b) exclude some kinds of inventions from patenting i.e. plants, animals and mainly biological process but some micro- organisms and microbiological process have to be made eligible for patent. So with the advancement in biomedical research the patent granters have granted patent

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to certain research or inventions, which indeed encourage research and development like GMO, genetic engineering, and even certain technology like genome editing and CRISPR-Cas9. Genome editing is also called gene editing which is group of technologies that gives scientist the ability to change an organisms DNA. These technology allow genetic material to be added, removed, induced or altered at particular locations in the genome. In this process the CRISPR-CAS9 is the well-known process which is made for clustered regularly interspaced short palindromic repeats and it is associated with protein 9.

So with fine and modern techniques of genetic engineering by biotechnologists the microorganisms like bacteria, fungi, and viruses which were used as raw materials then but now converted into products.

NOVELTY

All bio patents are granted for its invention and not for discoveries it is highly difficult to say whether new invention is innovation in biotechnology or a scientific discovery. So based on this we can say patent for biotechnology is utility patent. So basically the utility patent functions as prohibition to other companies, third parties, or any other individual from making use of patent without proper authorization. So most people preferring patent is mostly utility patent. This utility patent allows the inventors to give exclusive commercial rights to produce and utilize the latest technology covered by patent. So obtaining the utility patent is highly difficult as it's loaded with monetary benefit to inventor. Thus Indian patent law considers the microorganism as patentable, there is so much fuss in the patentability of microorganisms claiming to be lacking novelty element in it.

OVERCOMING THESE OBSTACLE

An IPR invention to a company is considered as a goodwill to the company which creates the brand name. As modern India demands new technology, strong focus on science and growth so the biotech companies knowing these things will concentrate on the patent grant at any cost. Many btech companies obviously relies on IPR. So to overcome these issues the government need to develop clear and strict IPR polices. Spreading awareness to the inventors regarding their rights, duties and their infringement issues. So that inventors will never miss an opportunity to protect their rights.

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There should be facilitation cells to be installed for ensuring the rights of the inventor by the government. However this is enabled in TRIPs agreement where Biotechnology patent facilitation cell is provided by the TRIPs agreement for protecting the new plant variety by means of patent or sui generis.

CONCLUSION.

When an invention is made it comes with lots of issues like whether the invention gets patented, whether the invention remains as private, whether invention goes for moral cause or for immoral cause. So in order to avoid this government has to formulate the clear cut policy and clarify certain things which are necessary for patent grant. And there should be strict rules when the same invention is used for bio terrorism and bio piracy. And many scientist and inventors to be made aware of their rights for user friendly smooth business. These technology, inventions are necessary to lead better tomorrow.

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