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IPR ISSUES IN BIOTECHNOLOGY IN INDIA

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INTRODUCTION

Karl Ereky, a Hungarian agricultural engineer, really came up with the term "biotechnology" at the beginning of the 20th century. He defined it as a field of technology that encompasses all activities used to generate goods from raw materials using living organisms. Due to different interpretations, the definition of biotechnology subsequently became more and more ambiguous throughout time. It is also now believed that the first official broad definition provided by the US Office of Technology Assessment, which states that "biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses," is no longer valid. The phrase "biotechnology" broadly refers to methods used on living things and its components to create, discover, or develop substances or to alter living things for particular purposes. Since biotechnology is highly interdisciplinary and encompasses almost all branches of science, there are likely many different definitions of it. To put it another way, biotechnology combines fields like genetics, molecular biology, biochemistry, embryology, and cell biology, which are connected to more practical fields like chemical engineering, information technology, and robotics. 1

India has the 12th place in the world for biotechnology. The biotechnology sector demands a sizable intellectual investment in the form of research and development. Knowing the IPR rights associated in it is crucial. Research into stem cells, embryology, and cell biology, bioremediation (an engineering method used by humans to clean the environment), and biodegradation (a natural process that happens in the environment), among other recent fields, all benefit greatly from modern biotechnology. The use of biology, and particularly the genetic engineering of microbes, to the creation of antibiotics, hormones, and other valuable chemicals is known as biotechnology. Animals and plants are not the same as microorganisms. They are extremely small living creatures that are employed in biotechnology as a medium and are invisible to the human eye. such as fungus, protists, archaea, and bacteria.

The question now is whether anything created or discovered utilising microbes qualifies as an innovation. Can it be safeguarded by applicable IPR laws? Or can you patent any creation that involves a live thing? How are biotechnological inventions handled under IPR law?

BIOTECHNOLOGY UNITS

Biotechnology is the combination of bio (living cells) and technology (the use of scientific knowledge). Since the dawn of civilization, mankind has utilised a range of biotechnology-related technologies. Examples include ageing processes (wine, bread, and yoghurt), fermentation (fermented foods), and preservation, which is a way of increasing the shelf life of food by employing natural or controlled bacteria. Examples include salting, drying, freezing, etc., and the breeding of particular plants, which show various appealing features. It is the intentional crossing of distantly related or closely related breeds to create new crop types.

There are several stages in the history of biotechnology.

The traditional expertise of different tribes, such as how to make fermented foods and medicinal distillates, can serve as the foundation for first-generation biotechnology.

The use of microorganisms on an industrial scale during the Pasteur era, which involved the mass production of alcohol, the fermentation of antibiotics, and the creation of traditional vaccines for diseases like cholera, typhoid, yellow fever, etc., may be considered the second generation of biotechnology. Since mass manufacturing of vitamins, amino acids, organic acids, plant tissue culture, and animal breeding techniques were also created, this generation can be regarded as the longest.

When rDNA techniques, hybridoma technology, polymerase chain reaction (PCR), and cloning procedures appeared during post-secondary developments in molecular biology, the third generation of biotechnology might be referred to as "modern biotechnology."

The fourth generation of biotechnology would see additional advancements where interdisciplinary techniques like information technology and nanotechnology would get involved in further advancement of this discipline, especially using the bioinformatics, which is the basis of contemporary biotechnology. Breakthrough uses of modern biotechnology in medical and agriculture have been made possible by quick advancements in information technology, notably in the field of bioinformatics. The "genomic age" has been made feasible by bioinformatics, which is widely defined as the use of computers to process biological information.

India has excelled in science over the past 1.5 years, as evidenced by the volume and calibre of publications in international journals with research leads on cover pages and numerous citations of Indian authors, but its performance in technology and business is subpar, as measured by the number of patents issued per unit of R&D investment. Since India joined the PCT, there has been a lot of discussion on IPR issues, but there is still more to be done to raise awareness of these issues. The product patent would be enforced in light of India's recent approval of the Patent Amendment Bill of 2005. Additionally, the present and upcoming GATS discussions, particularly for the R&D service sectors in general and the R&D in biotechnology in particular, will have a significant influence on the biotech industry in India and other developing nations.

THE USE OF BIOTECHNOLOGY

• Healthcare: Biotechnology may be utilised to provide fresh and creative solutions to address societal demands through improving immunogens, diagnostics, and other tools, as well as managing healthcare for ageing populations and developing nations.

• Crop production: Through agronomically and nutritionally enhanced crops, biotechnology may increase food quality and have a positive impact on the environment. It can be used to create foods with improved properties, such as desired nutritional advantages.

• Crops with non-food purposes: Biotechnology may also enhance the utilisation of crops with non-food applications as sources of industrial feedstock or brand-new materials like biodegradable plastics. For instance, high-quality industrial oil is currently made from canola. Biomass may contribute to alternative energy by producing liquid and solid biofuels (like biodiesel and bioethanol) as well as by using processes like bio-desulfurization under the right economic and fiscal circumstances. It can offer resources for the mass reproduction of tree and woody species in poor nations for use as fuel, fodder, afforestation, and shelter.

• Environmental applications: Biotechnology opens up new avenues for environmental protection and enhancement, including the bioremediation of contaminated waste, soil, water, and air, as well as the creation of more environmentally friendly industrial products and procedures like biocatalysts. Additionally, GMOs can be utilised in biomining, which is the low-cost use of microorganisms to extract precious metals from low-grade ores. Additionally, plants are increasingly being created to mine valuable metals (e.g., Brassica, which is being developed to concentrate gold from the soil in their leaves).

IMPLICATIONS OF BIOTECHNOLOGY IPR

Some examples of IPR are industrial designs, patents, GI, and trademarks. However, patents are the most widely used IPR kind in relation to biotechnology. A list of what is not an invention is provided in Section 3 of the Patent Act of 1999. This section's paragraph (d) of Section 3 states that the simple formulation or finding of any living organism or non-living material present in nature cannot be considered an invention and is consequently not eligible for patent protection.

Additionally, plants and animals in whole or in any part—aside from microorganisms—as well as seeds, variations, and species—as well as fundamentally biological processes for the production or propagation of plants and animals—are not patentable inventions, according to Section 3's paragraph (j). Thus, the use of microorganisms in innovations is protected by the Patent Act of 1999. But those must be inventions, not just discoveries. Thus, under the Patent Act of 1999, the use of microorganisms to process raw materials to create finished goods with the aid of human intelligence and technological assistance is covered by the biotechnology patent. Utilizing live and biologically active material in the finished product is subject to severe scientific and industrial regulations in the field of biotechnology.

Although biotechnology is crucial for preserving, enhancing, and extending human life, the process of patenting these scientific developments is incredibly difficult.

According to Indian Patent Act Section 3(e), "a substance obtained by a mere admixture develops only in the aggregation of the properties of the components thereof or a process for producing such substance." For instance, apple juice is a combination of apples and sugar, which is the only aggregation of the original taste of apples and sugar. Therefore, this is not an innovation.

the significant financial, infrastructural, and human resources invested in R&D to produce outcomes using biotechnology. Patenting the ideas in the aforementioned field is crucial to promoting such outcomes, providing financial security to the expanding research industry, and providing compensation for their intellectual labour. You might not be able to submit an application for a patent if your idea doesn't fall inside the aforementioned four parameters of patentability. Traditional approaches often make use of living organisms, whereas current biotechnology typically involves sophisticated alterations to biological systems.

• Inventions and TRIPS compliance: As is common knowledge, the law does not allow for the patenting of mere discoveries of items that already exist. It should incorporate technical innovations to get benefits that are not evident. But proving the invention is the key issue. The law does not provide a rigid methodology for describing discoveries and inventions. The case-specific facts will determine this. Legal protection in the context of biotechnology continues to be extremely delicate and complex because of the technological and ethical considerations involved. The lack of a Trade-Related Aspects of Intellectual Property Rights (TRIPS) compatible patent system in India now presents significant difficulties for the Indian biotech industry. The biological processes used to create plants or animals are not considered patentable under Article 27.3(b) of TRIPS, however microorganisms and microbiological processes used to create plants and animals are eligible for patent protection.

The following are a few examples of microbiological innovations that are patentable under the TRIPS Agreement:

i. the process of creating a new microbe,
ii. the new microbe itself,
iii. the process of cultivating or using a novel or known microorganism to,
    a. the actual creation of multiplied microorganisms, such as vaccinations;
    b. a microbial growth byproduct, such as an antibiotic or another beneficial industrial product.

Microorganisms and microbiological processes are subject to patent protection under the TRIPS Agreement, however neither the definition of the microbe nor the requirements for the scope of its protection are provided.

• The necessity of novelty and disclosure: Biotechnology patents are under the purview of utility patents. A utility patent is accessible for the creation of a brand-new, useful machine, manufacturing method, etc., and is particularly available for process enhancements that are intended to be treated as brand-new, useful processes.

In the case of biotechnology advancements, it is difficult to determine if the new life form is a scientific discovery or a technological invention because patent protection is only awarded for inventions, not for discoveries. When it comes to genetically modified organisms, tissues, and cells, he can simply say that it is an apparent variant of what organically occurs in nature, making it ineligible for a patent. This is how biotechnological patent applications may be rejected on the grounds that they are only a creation of nature.

Making available what is already there in nature and is not patentable is all that is meant by discovery. However, if a method is created or produced to get the material by removing it from its natural surroundings, such method is regarded as an invention and is therefore patentable. However, by applying this standard, it is possible to classify as innovations the minerals and ores found in the ocean and deep earth. Therefore, despite the fact that the Indian patent regime regards microorganisms as patentable, there is significant debate over the patentability of germs that contend they lack a novelty component.

As a result, a unique criterion of depositing biological material at a recognised institution must be met for inventions involving microorganisms. i.e. International Depositary Authority as recognised in the Budapest Treaty, an international agreement signed on April 28, 1977, in Budapest, Hungary, and overseen by the World Trade Organization. This treaty states that the biological material only has to be deposited at one approved institution in order for it to be accepted in all of the Budapest Treaty's signatory nations. As a result, the multistep and intricate patenting process for biotechnological ideas grows.

• ***Commercial application and monetization:*** Obtaining patents for biotechnology inventions still faces challenges due to the consideration of the commercial application. However, there are significant moral concerns about the patenting of living things in India. The most crucial question is whether or not living things can have private property rights. There are many uncertainties and conflicts surrounding the IPR protection of living forms because there is no established practise to do so under the applicable IPR legislation. It isn't the case when it comes to owning items having a definite market value. It is vital to determine how to assign a monetary value to something that is not material or physical yet nonetheless has market worth. Therefore, it is vital for emerging nations like India to set out specific IPR regulations that only apply to scientific and technical breakthroughs.

Even in this day and age, naturally existing creatures are seen as a gift from God that cannot be taken by anybody by simply altering or fiddling with it. Therefore, there are several issues surrounding biotechnology's eligibility for IPR protection.

• ***Corporate dominance:*** Plant biotechnology is another milestone that humans may reach through R&D activities that could generate profitable rewards. However, it might also lead to increased seed prices, prohibiting naturally small and local farmers from obtaining such cutting-edge technologies. This would go along with encouraging research in the field of plant biotechnology.

Furthermore, there is a severe issue with private corporations claiming the only right to produce and market a variety of "modified" plants and animals by exploiting farmers' traditional knowledge of plants or animals. The fact that these people's knowledge, creativity, and efforts are not recognised today is a serious topic of worry since the current legal "intellectual property rights systems" provide patents on genetic and biological elements as well as on living things to private enterprises. Local communities don't benefit from this process while companies profit greatly from it. Furthermore, it is possible that in the future, consumers would be forced to pay excessive costs for these corporations' goods. Therefore, such an IPR system mainly serves the interests of large businesses or multinational corporations in wealthy nations at the expense of poorer nations.

POSITIVE RESULTS

The most valuable resource in the country is frequently biotechnology patents. Science and technology are given a lot of attention in modern India since the country recognises its importance for economic development. As a result, despite these challenges, biotechnology businesses nonetheless manage to patent their ideas. In actuality, intellectual property rights are clearly essential to the operations of the majority of biotechnology enterprises. Investor risk is reduced by robust IPR protection.

• It is without a doubt necessary to establish explicit and stringent national IPR regulations in order to resolve all the concerns relating to IPR and biotechnology.

• The patentability of the subject matter should also be made clear with reference to biotechnology and novel life forms.

• Educating farmers about the country's legal system, which takes the shape of living cells and protects farmers' rights to protect their interests and make provisions for incidents of infringing behaviour, is the most effective approach to do this.

• In addition, given their primary and direct contribution to the development of novel plant varieties or the preservation of biodiversity, farmers must get a fair portion of the profits through proper benefit-sharing agreements.

• In conclusion, the most useful tool for encouraging investment in biotechnology will be an effective IPR system.

DISCLOSURES OF THE WTO

If we compare the WTO requirements to the Indian Patents Act of 1970, we can observe that they have changed in a number of respects, including the following:

(a) The Indian Patents System exclusively grants process patents and, as of this writing, does not provide product patents for medications, foods, or chemicals. The WTO grants product patents in all disciplines of technology.

(b) The WTO would award patents for any novel ideas with innovative step (non-obvious), valuable for industrial applications (products or processes), and applicable to all sectors of technology, but would allow for flexibility in areas that are not patentable, such as:

i. creatures;

ii. techniques for diagnosing, treating, and operating on both people and animals;

iii. biological processes that result in the development of plants or animals.

On the other hand, the WTO offers patents on microbes and microbiological processes. Contrarily, Indian patent rules prohibit the patenting of any form of life; as of this writing, however, patents based on microbiological processes are allowed.

(c) While the Indian system has just lately brought it on line with the WTO, for processes only, the WTO guarantees coverage of patent-life for all patents for a standard length of 20 years duration (including drugs, food and chemicals, which was only 7 years).

(d) The Plant Variety Protection (PVP) Act is in place, but the WTO mandates that plant varieties be protected by patents, an effective "sui generis" system, or any combination of the two. Biotechnology and IPR Regime 12 Asian Biotechnology and Development Review Currently, India lacks a system for protecting plant varieties.

(e) In the WTO, the burden of proof in a patent infringement action mostly rests with the alleged infringer, but in the Indian system, the duty rests with the plaintiff.

(f) The WTO forbids discrimination between imported and native products, however importation is not considered working a patent under Indian law.

(g) The WTO mandates giving citizens of "any other Member country" the same advantage, favour, privilege, or immunity offered by "a member country."

The intellectual property rights (IPR) issues before India and developing countries include the position that needs to be taken on the distinctions between biological discoveries and inventions, the definitions and scope of patentable microorganisms, the scope of patentability or protection of other living materials like the plants and animals, the conditions

of depositions connected with the patentable inventions involving living entities including viruses, bacteria, fungi, plasmids, and more. The WTO's position on many of these topics is likewise unclear; the WTO hasn't issued any firm recommendations on most of these concerns, leaving the member nations to speculate and make assumptions about the situation.

Nevertheless, aside from the following, IPR concerns with contemporary biotechnology have been brought up in a number of WTO-affiliated international forums:

- Biological Diversity Convention (CBD)
- Organization for Food and Agriculture (FAO)
- Economic Cooperation and Development Organization (OECD)
- Worldwide Organization for Health (WHO)
- Organization for World Intellectual Property (WIPO)
- Economic Cooperation in the Asia-Pacific (APEC)
- International Office of Epizootics (OIE)
- Convention on International Plant Protection (IPPC)
- Commission for Codex Alimentarius (CAC)

World Bank

A number of international agreements that deal with IPR concerns in relation to contemporary biotechnology are also in existence. Apart from the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) rank as the most significant among these.

A CASE STUDY

A novel product or technique incorporating an innovative step and suitable for industrial application is what the Indian Patent Act of 1970 defines as a patentable invention. Previously, living things could not be patented. The Supreme Court of the United States' famous Diamond v. Chakraborty ruling from 1980, in which the genetically altered bacteria was given a patent, altered this situation.

• ***Controller of Patents & Designs v. Dimminaco A. G.***

In India, the Calcutta High Court's ruling in the matter of Dimminaco A. G. v. The Controller of Patents & Designs, rendered on January 15, 2002, set the bar for subsequent decisions on the patentability of biotechnological techniques involving live organisms. This ruling cleared the path for the patenting of innovations in which live microbes are the end result of the claimed procedure.

According to the case's circumstances, a Swiss company named Dimminaco A.G. submitted a patent application for the method of creating an infective chicken disease vaccine against bursitis. The live virus that was employed to produce the vaccination claim did not fulfil the requirements of a "invention" under Section 2(j)(i) of the Act, and as a result, it cannot be considered to have been "made," making it non-patentable, according to the Assistant Controller of Patents & Designs.

The Honorable Calcutta High Court decided that the preparation of a vendible item that contains a living material is not beyond the scope of the term "manufacturing," thus overturning the assistant controller's verdict and admitting the appeal. Therefore, the use of the live virus in vaccinations does not invalidate the patent protection. The procedure was an innovation since the final result was unique, suitable for industrial usage, and helpful for preventing infectious Bursitis infection in chicken. The court upheld the petitioner's appeal and ordered that the patent application be reassessed within two months of the judgment's publication or delivery.

• ***Nuziveedu Seeds v. Monsanto Technology Pvt. Ltd.***

The joint venture between Monsanto and Mahyco in India is called Mahyco Monsanto Biotech Pvt Ltd. Various seed firms in India have been granted licences to use this company's biotechnology goods. On 21/2/2004, Monsanto leased its patent IN214436 to Nuziveedu Seeds and its affiliates Prabhat Agri Biotech and Pravardhan Seeds. This patent related to BT

cotton, in which DNA recombination resulted in the plants developing bollworm resistance. The Indian firms stopped paying royalties because Monsanto refused to lower the special compensation that was required to be paid by them under the licence. As a result, Monsanto petitioned the Delhi High Court for infringement of a registered patent.

The Nucleotide Acid Sequence, Bt gene, which may be used to kill bollworms when placed in cottonseed, is claimed by the plaintiff to be their invention. And the allegation made by the respondent Nuziveedu was that NAS was only a chemical composition with no capacity for reproduction and not a synthetically created innovative microorganism with potential for industrial use. The application was denied by the Division Bench of the Delhi High Court on the grounds that the claimed invention did not qualify as a patentable invention under Section 3(j) of the Patents Act, 1970.

So, the main question was: following its implantation, is NAS a component of the plant or the seed?

In this case, the Supreme Court overturned the division bench's decision and ruled that the validity of the patent could not be determined by a prima facie investigation. The issue was subsequently returned to the single bench of the Delhi High Court for decision-making based on professional advice and supporting documentation by the Hon'ble Apex Court. Since the patent term ended in 2019, the Delhi High Court's ruling may not be significant for the parties involved immediately, but it will undoubtedly set the standard for applications for comparable innovations in the future.

CONCLUSION

Indian patent law provides excluded lists and not included lists for patents. Due to the ambiguity of these exclusions and the complexity of biotechnology, this is particularly true for innovations involving the field. In order to ensure that individuals like farmers and scientists are both recognised for their efforts and contributions to stop bio-piracy, it is necessary for there to be clear rules and laws for the application of Intellectual Property Rights (IPR) in India.

Granting Intellectual Property Rights (IPR) is a useful instrument to safeguard biotechnology inventions since it takes time and money to do research and development. The government has designated the biotechnology industry as one of the 25 industries that will be covered under the Make in India programme, which was just unveiled by our prime minister. However, there are no standards that are widely acknowledged for the administration of IPR. In order to accomplish the general expansion of the country, it is urgently necessary to establish user-friendly, seamless commercial procedures and precise legal frameworks for intellectual property rights.

Patents are a crucial instrument to make sure that these life-saving inventions are appropriately safeguarded in order to better the world, given the difficulties and limits of biotechnology. Otherwise, the time will come when we will have to import copyrighted goods or methods from elsewhere even if we have had them for decades.

References

1. *https://ris.org.in/sites/default/files/article1_v7n2.pdf*
2. *ADB. 2001. Agricultural Biotechnology, Poverty Reduction and Food Security. Manila: Asian Development Bank. Commission on Intellectual Property Rights. 2002.*
3. *Integrating intellectual property rights and development policy, London, September. Available at http://www.iprcommission.org*