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LEGAL AND ETHICAL CONSIDERATIONS IN BIOTECHNOLOGY

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ABSTRACT:

The use of biological processes to solve issues is known as biotechnology, and it has advanced quickly in recent years. With its abundant biodiversity and developing scientific capacity, India has become a major force in the world of biotechnology. But the speed at which innovation is developing has also brought up important moral and legal issues.¹ This article examines the intricate relationship that exists between law and biotechnology. It looks at the laws that control biotechnology, such as those pertaining to intellectual property, oversight, and the environment. Biotechnology is a comprehensive word which apply to a variety of biotechniques & bio methods. It's an area with a lot of different subfields.

KEYWORDS: Biotechnology, Intellectual Property Right, TRIPS agreement, Ethical Implication, Legal Framework, Patent.

INTRODUCTION:

Understanding biotechnology may be done by separating “bio” from “technology”. Use of biological processes is known as “bio”, whereas “technology” refers to solving problems or producing valuable goods. The use of biological processes to solve issues is known as biotechnology, and it has advanced quickly in recent years. With its abundant biodiversity and developing scientific capacity, India has become a major force in the world of biotechnology. But the speed at which innovation is developing has also brought up important moral and legal issues.

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178936/> last seen dated 19/08/2024

MEANING AND HISTORY OF BIOTECHNOLOGY:

Biotechnology describes as "Body of knowledge related to the use of organisms, cells or cell-derived constituents for the purpose of developing products which are technically, scientifically and clinically useful. Alteration of biological function at the molecular level (i. e., genetic engineering) is the central focus; laboratory methods used include transfection and cloning technologies, sequence and structure analysis algorithms, computer databases, and gene and protein structure function analysis and prediction."²

Biotechnology is also defined by the U.S. Office of Technology Assessment as "any technique using organisms and their components to make products, modify plants and animals to carry desired traits, or develop micro-organisms for specific uses". Biotechnology has existed ever since humans began domesticating micro-organisms, plants and animals.

ANCIENT BIOTECHNOLOGY:

Ancient biotechnology can be described under the following subheadings:

- a) MICRO-ORGANISMS: As far back as 8000 years ago, our ancestors knew that certain foods and drink changed during storage, sometimes in tasty ways. Fruit juice would become alcoholic to produce wine; dough would rise and produce pleasing aromas and tasty bread when baked; and milk would sour and curdle to produce cheese. Long before this fermentation process had a name, ancient people learned to control the process by controlling ingredients, temperature and time.
- b) PLANTS: Stone-age farmers began by planting seeds of wild plants. Later they selected the most productive of their domesticated plants to provide the next year's seedstock. Over thousands of years, this process gave rise to most of today's crops.
- c) ANIMALS: Man's symbiotic relationships with animals date to the beginning of recorded history as well. Virtually every society depended to some extent on food-producing animals, beasts and pets. Today, we still rely on animals for much of our food, fibre and pets.

MODERN BIOTECHNOLOGY:

Modern biotechnology was initiated with the development of recombinant DNA technology, or genetic engineering and monoclonal antibody technology. They are described in brief in

² <https://www.iipta.com/role-of-ipr-in-biotechnology-industry/> last seen dated 19/08/2024

the following sections

(a) **GENETIC ENGINEERING:**

Genetic engineering became possible as biologists deepened their understanding of deoxyribonucleic acid, or DNA, the molecule that codes the instructions for growth, maintenance and reproduction of all living things. Each instruction is called a gene.

Many genes (100,000 to 300,000) make up an organism's genome, its entire instruction manual. Each gene is a blueprint for a single protein. Proteins are natural substances that give living things their structure and control their functions. Enzymes, antibodies, some hormones are proteins. Genetic engineering is a process by which biologists combine the gene(s) of one organism (the donor) with the genome of another organism (the recipient). The resulting organism is genetically altered to produce a new gene product, be it human insulin, antisense RNA, or an industrial enzyme. The resulting organism can pass this alteration to its offspring, thus insuring an endless supply of transgenic organisms.

(b) **THE DNA REVOLUTION:**

Rapid advances in the field of molecular biology have brought revolutionary change in human and veterinary medicine, agronomy, animal science, environmental science, and even patent law. Recombinant DNA technology, also known as genecloning, revolutionized the study of molecular biology. Genes can be isolated, amplified, sequenced, and expressed in a different host cell. This process yields large quantities of a gene product. Specific DNA fragments are routinely cut from the chromosome, inserted into a vehicle called a vector DNA, and placed in a host cell. When the host cell divides, this recombinant DNA molecule replicates, producing a clone (a genetically identical copy).

COMMERCIAL BIOTECHNOLOGY:

Biotechnology is a technology comprised of many scientific disciplines (e.g., microbiology, biochemistry, genetics, molecular biology, chemical engineering) that are applied to the production of commercial products by living organisms. Biotechnology is utilized by a diverse group of companies with the shared mission of using biological processes to develop products to meet human needs.

a) **PLANT BIOTECHNOLOGY:**

Biotechnological developments and genetic engineering are revolutionizing agriculture. Some major benefits of this revolution will be crops that are resistant to pests and disease, livestock

that are resistant to viruses, and microbes to increase resistance to frost damage. These benefits will increase food production. Transgenic plants are created by integrating new DNA into a plant's DNA to become a permanent part of the plant's genome. Seeds, tissues or cells are transformed and then regenerated into a whole plant. Transgenic plants can be used to study how a plant controls the transcription and translation of its genes. Many plants are being genetically manipulated.

b) ANIMAL BIOTECHNOLOGY:

Biotechnology has affected animals in many significant ways. Genetic engineering has enabled scientists to transfer genes across species, families, and even kingdoms.

These evolutionary boundaries, which were obstacles in the past, are now readily crossed with modern gene transfer methods that allow the transfer of DNA into living cells and fertilized eggs of animals. Transgenic animals not only provide invaluable research tools for studying gene regulation and disease, but they may be genetically modified for the production of pharmaceuticals, vaccines, and rare chemicals.

Major goals include the generation of livestock that are more economically produced and products that are more nutritious to the consumer. Genetically engineered livestock will yield important products in milk or blood for treating a variety of human diseases and health needs.³

LEGAL FRAMEWORK:

Biotech bodies in India, including the Department of Biotechnology (DBT), the Indian Council of Medical Research (ICMR), and the Council for Scientific and Industrial Research (CSIR), are among the largest bodies. The Biotechnology Regulatory Authority of India (BRAI) is a planned regulatory organisation to control the use of genetically modified organisms (GMOs). The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM), generally known as the Indian Patent Office, is an agency under the Department for Promotion of Industry and Internal Trade that administers the Indian Law of Patents, Designs and Trademarks.

IMPACT OF IPR ON BIOTECHNOLOGY:

Intellectual Property Rights has a very important role in this sector. IPR protects the rights of the inventor from any company that no one other than the inventor/founder can use the name

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178936/> Last seen dated 19/08/2024.

of the substance or the company without the permission of the company. In the case of biotechnology, the IPR can help the inventor/founder to keep his name associated with that product forever. And if some other person tries to take credit for that work, then the rules of IPR will restrict him from doing so. It helps the companies in retaining their patents, trademarks, and their trade secrets. It helps in pharma companies that if a certain company holds IPR related to a drug then that company only can sell the drugs by a specific name, no other companies have the right to sell that drug by that name.

Such as only the company Reckitt and Colman can use the name Disprin in selling their tablets for headache, no other companies have the right to sell any medicine in that name. But other companies can use the name of the compound found in that medicine because the compound of the medicine is the same for everybody. So, IPR has a very important impact in this sector and without it, no companies will be able to establish their ownership. It restricts the chances of conflict between the companies and provides an equal platform for everybody to perform.⁴

IPR AND BIOTECHNOLOGY:

Trademark, copyright, patent, GI, industrial designs are some of the forms of IPR. But the most popular form of IPR corresponding to biotechnology is patent. Section 3 of patent act 1999 gives a list of the things that are not inventions. In this section, subsection (d) of Section 3 says that mere discovery of a scientific principle or the formulation of or discovery of any living thing or non-living substance occurring in nature cannot be termed as inventions and therefore are not liable to get patented.

And subsection (j) of Section 3 says that plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals are not patentable inventions. Thus, the Patent Act 1999 protects the usage of microorganisms in inventions. But those need to be an invention rather than mere discovery. Thus, the use of microorganisms to process subject matter to prepare utilized products with the help of the human brain and technological support is protected under the biotechnological patent, under the Patent Act 1999. Biotechnology includes scientific and industrial strictness to utilize living and biologically active material in the final product.

⁴ https://biotechnology-trade-laws/#Impact_of_IPR_for_biotechnology last seen dated 21/08/2024.

HISTORY OF PATENT LAW:

- 1856** The Act VI of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
- 1859** The Act modified as act XV Patent monopolies called exclusive privileges (making, Selling and using inventions in india and authorizing others to do so for 14 years from date of filing specifications).
- 1872** The Patterns & Designs Protection Act.
- 1883** The Protection of Inventions Act.
- 1888** Consolidated as the Inventions & Designs Act.
- 1911** The Indian Patents & Designs Act.
- This Act was further amended in 1920 to enter into reciprocal arrangements with UK and other countries for securing priority. In 1930, further amendments were made to incorporate, inter-alia, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase of term of the patent from 14 years to 16 years. In 1945, an amendment was made to provide for filing of provisional specification and submission of complete specification within nine months.
- After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact comprehensive patent law owing to substantial changes in political and economic conditions in the country. Accordingly, the Government of India constituted a committee under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India in order to ensure that the patent system is conducive to the national interest.
- 1999** On march 26, 1999 Patents (Amendment) Act, (1999) came into force from 01-01-1995.
- 2002** ↓ The Patents (Amendment) Act 2002 came into force from 20th may 2003
- 2005** The Patents (Amendment) Act 2005 effective from 1st January 2005⁵

⁵ <https://ipindia.gov.in/history-of-indian-patent-system.htm#:~:text=The%20first%20legislation%20in%20India,disclose%20secret%20of%20their%20inventions.> Last seen dated

Patenting of biotechnology invention in India:

Biotechnology has a vital role in covering and touching lives in various aspects. Biotechnology in recent years has created unprecedented opportunities not only for humankind but also for industrial development. It has become the world's fastest growing technology. The pharmaceutical and agricultural sectors in India, a developing nation, are built in part on advanced biotechnology.

General rules for patent:

The Indian Patent Act of 1970 established the following criteria for a technique or product to qualify for a patent:

1. **Inventive step-** For a product or technique to qualify for a patent in India, it must be novel and involve an inventive step.
2. **Capable of industrial application-** It is possible to patent an innovation in India that relates to a good or a method that is applicable to the industry.
3. **Novelty-** This means that prior to the date of the application, the invention must not have been disclosed to the public, not even by the inventor.
4. The patent must not, however, come under the definition of an invention that is not patentable, as stated in Chapter 2 (Inventions Not Patentable) of the Indian Patents Act, 1970.

Landmark cases in biotechnology Patent Law:

1. Diamond vs. Chakrabarty

Diamond vs. Chakrabarty is a landmark case in biotechnology patent law that established that genetically engineered microorganisms are patentable subject matter. This decision, issued by the Supreme Court of the United States in 1980, had a profound impact on the biotechnology industry and paved the way for the patenting of other living organisms.

Facts: The case involved Ananda Chakrabarty; a microbiologist who developed a genetically engineered bacterium capable of breaking down crude oil. Chakrabarty filed for a patent on his invention, but the Patent Office rejected his application, arguing that living organisms were not patentable. Chakrabarty appealed the decision to the Supreme Court.

Decision: The Supreme Court held that genetically engineered microorganisms are patentable subject matter because they are "new and useful" inventions under the Patent Act. The Court

reasoned that the bacterium was not a product of nature, but rather a “human-made invention” that was the result of Chakrabarty’s “ingenuity and hardwork.” *The Diamond v. Chakrabarty* decision had a number of important implications for the biotechnology industry.

- A. First, it opened the door to the patenting of other living organisms, such as genetically engineered plants and animals.
- B. Second, it provided a framework for determining which living organisms are eligible for patent protection.
- C. Third, it helped to establish the United States as a leader in the field of biotechnology.

Despite these concerns, the *Diamond v. Chakrabarty* decision remains a landmark case in biotechnology patent law and has played a major role in the development of the biotechnology industry.⁶

2. Monsanto Technology Pvt. Ltd. v. Nuziveedu Seeds⁷

Facts: Monsanto Biotech Pvt Ltd (India), is the Indian joint venture of Monsanto. This company has been licensing its biotechnological products to various seed companies in India. Monsanto licensed its patent IN214436 to Nuziveedu Seeds and its subsidiaries Prabhat Agri Biotech and PravardhanSeeds on 21/2/2004 which was relating to BT cotton in which there was recombination of DNA due to which the plants became resistant to bollworms. Due to the refusal by Monsanto to reduce the special compensation which was payable by the Indian companies under the license, the Indian Companies stopped paying royalties. Thus, Monsanto filed the petition for violation of registered patent before the High Court of Delhi.

The plaintiff claimed that their patent is the man-made NAS(Nucleotide Acid Sequence, Bt gene), which is useful for killing bollworms when it is inserted in cottonseed. And the respondent claim was that NAS was just a chemical composition that is not capable of reproduction and not a man-made inventive microorganism, which can be useful for industrial application.

Decision : The Division Bench of the Delhi High Court rejected the application on the ground that the said invention was not patentable subject matter under section 3(j) of patents act, 1970. The Supreme Court in this case set aside the order of the division bench and held that the

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁷ *Monsanto Technology LLC v. Nuziveedu and Ors.* is Civil Appeal No. 6472 of 2004

validity of the patent cannot be on the basis of prima facie examination. The Hon'ble Apex court then reverted back the matter back to the single bench of the Delhi High Court to be decided on the basis of expert advice and evidence. Though the decision of the Delhi HC may not have any significance for the immediate parties, since the patent period already expired in 2019, it would definitely establish the law for future applications for similar inventions.

The decision has also been criticised by some, who argue that it could lead to the patenting of human beings or other higher life forms. Others have raised concerns about the potential impact of gene patents on biodiversity and the environment.⁸

INDIA IN RELATION WITH TRIPS:

In reference to the patentability of biotechnological inventions, the Patents (Amendment) Act, 2002, provided substantial changes to Indian patent law. The law met the requirement of article 27.3(b) of the TRIPS AGREEMENT by specifically providing for the patentability of microorganisms.

India joined the World Trade Organisation (WTO) in 1995. Under the WTO, member countries had to comply with the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement. It is a multilateral agreement of the World Trade Organisation in relation to intellectual property rights (IPR). Under the TRIPS Agreement, every member country had to shift from process patents to product patents. India formally became a signatory member of the TRIPS Agreement in 1995 when it joined the World Trade Organisation (WTO) (Trade-Related Aspects of International Property Rights). India needed to change its current patent system to comply with TRIPS, subject to a few transitory provisions allowed for developing nations in Article 65 of TRIPS.

The TRIPS Agreement, to which India is a party as a member of the World Trade Organisation (WTO), mandates that biotechnological inventions, including plant varieties, receive some level of protection. For different member countries, different time periods were given in order to comply with this agreement. The developed countries had to comply within a period of one year. For developing countries like India, the time period was 5 years. Within 5 years, they had to comply with this agreement. In case of any emergency, the developing countries can extend the time period to another 5 years along with the existing 5 years, making it 10 years. For least

⁸ https://what-are-the-different-issues-regarding-ipr-in-biotechnology/#IPR_involved_in_biotechnology last seen dated 22/08/24

developed countries (LDC), the time period given was 11 years.⁹

According to the TRIPS Agreement, every member country has to shift from process patents to product patents. The TRIPS-mandated process of extending the term of Indian chemical (including biotechnological) patents from seven to twenty years from filing, along with a shifted burden of proof for alleged infringement of process patents, will cooperate with the country's biotechnology industry's goal of setting the global standard for the production of generic biologics.¹⁰

ETHICAL IMPLICATION IN BIOTECHNOLOGY:

The field of ethics tells us to give explanations for our actions and describe our intention. The intention to do good does not matter, what matters is that, a reason should be given on why that particular action is being done and what is being done. The field of biotechnology needs to address three main areas:

- A. Incentives- the way scientists are promoted to research.
- B. Intentions- end results of that research.
- C. Actions- prospective applicability of the research.

The benefits of biotechnology are advertised largely but its risks are not covered properly. We cannot remain ignorant about the social, legal and ethical concerns of biotechnology. The ethical concerns related to gene patenting are:

Human cloning- for the sake of utility one should not alter the genetic structure. Humans cannot be used as a commodity. Genetic material is a common heritage and one cannot have a monopoly over it. Crossing biological borders and exchanging genetic material is not ethically correct. An example is the "Dolly" sheep where the human genes were inserted into the animal genes. Genetically modified living things will be considered not less than a commodity, so all the intrinsic value will be lost. The exploitation of women is brought about when biotechnology is used in reproductive biology. Many embryos are taken for doing various researches such as stem cell research. There are debates concerning that due to human cloning there can be the creation of slaves. Humans are used as a subject in many research institutions,

⁹ Amie Barcombe; Jordan M. Gringauz; Maeve O'Flynn; Amanda K. Murphy, Ph.D.; Craig Slater, Ph.D., Patentability in US and Europe, May 15, 2024, <https://www.finnegan.com/en/insights/articles/how-clinical-trials-affect-patentability-in-us-and-europe.html> last seen on 20/08/24.

¹⁰ <https://biotechnology-patenting-in-india-and-a-comparison-with-the-us-perspective/#:~:text=inventions'%20commercial%20potential.-,India%20in%20relation%20with%20TRIPS,for%20the%20patentability%20of%20microorganisms> last seen dated 22/08/24

the concern should be taken before conducting the research and all the procedures should be explained before any experimentation¹¹.

1. Bioethics:

Bioethics considers the ethical issues raised in biology and medicine, and especially those raised by human activity in society and the environment using biotechnology.

Bioethics considers issues affecting all living organisms and the environment, from individual creature to the level of the biosphere in complexity. All living organisms are biological beings, and share a common and intertwined biological heritage. The term bioethics reminds us of the combination of biology and ethics, topics that are intertwined. Bioethics especially includes medical and environmental ethics. The word was mainly applied for issues of medical ethics in the 1970s and 1980s, but the 1960s and 1990s saw much more attention on environmental ethics. Agricultural systems include economic, environmental and human interactions. To resolve the issues, and develop ideals or principles to help us do so, we must involve anthropology, sociology, biology, religion, psychology, philosophy, and economics; we must combine the scientific rigor of biological data, with the values of religion and philosophy to develop a world-view. Bioethics is therefore challenged to be a multi-sided and thoughtful approach to decision-making so that it may be relevant to all aspects of human life.¹²

2. Beneficence :

One of the underlying philosophical ideas of society is to pursue progress. The most cited justification for this is the pursuit of improved medicines and health. It has often been assumed that it is better to attempt to do good than to try not to do harm. A failure to attempt to do good, working for people's best interest, is taken to be a sin of omission. Beneficence is the impetus for further research into ways of improving health and agriculture, and for protecting the environment. Beneficence supports the concept of experimentation, if it is performed to lead to possible benefits.

The term beneficence suggests more than actions of mercy, for which charity would be a better term. The principle of beneficence asserts an obligation to help others further their important and legitimate interests. It means that if you see someone drowning, providing you can swim, you have to try to help them by jumping in the water with them. It also includes the weighing

¹¹ https://legal-social-and-ethical-implications-of-gene-patenting-2/#Ethical_implication_of_gene_patenting
Last seen dated 23/08/2024.

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3570997/> last seen dated 23/08/2024.

of risks, to avoid doing harm. Governments have a duty to offer their citizens the opportunity to use new technology, providing it does not violate other fundamental ethical principles. Just what the definition of fundamental ethical principles is may be culturally and religiously dependent, especially in the way that they are balanced when opposing principles conflict. Beneficence also asserts an obligation upon those who possess life-saving technology, in medicine or agriculture, to share their technology with others who need it.

3. Confidentiality:

The emphasis on confidentiality is very important. Personal information should be private. There may be some exceptions when criminal activity is involved or when third parties are at direct risk of avoidable harm. It is very difficult to develop good criteria for exceptions, and they will remain rare. A feature of the ethical use of new genetics is the privacy of genetic information. This is one of the residual features of the existing medical tradition that needs to be reinforced. It is not only because of respect for people's autonomy, but it is also needed to retain trust with people. If we break a person's confidences, then we cannot be trusted. If medical insurance companies try to take only low risk clients by pre-screening the applicants, there should be the right to refuse such questions (Holtzman, 1989). The only way to ensure proper and just health care is to enforce this on employers and insurance companies, or what is a better solution, a national health care system allowing all access to free and equal medical treatment.

4. Environmental Ethics:

Humans also have interactions with the environment, and in fact depend upon the health of the environment for life. The easiest way to argue for the protection of the environment is to appeal to the human dependence upon it. There are also human benefits that come from products we find in nature, from a variety of species we obtain food, clothing, housing, fuel and medicine. The variety of uses also supports the preservation of the diversity of living organisms, biodiversity. As we have learnt, the ecosystem is delicately balanced, and the danger of introducing new organisms into the environment if that may upset this balance is another key issue raised by genetic engineering. However, we have been using agricultural selection for 10,000 years, so the introduction and selection of improved and useful microorganisms, plants and animals is nothing new, and we should learn from mistakes of the past.

Nature has life; thus it has some value, looking at the world is a religious view, that God made the world so the world has value, and we are stewards of the planet, not owners. This

paradigm can make people live in a better way than if they look at the world only with the paradigm of human benefit.¹³

Suggestion:

- 1. Privacy and Data Protection:** Examine the implications of biotechnology for data privacy and protection, especially in the context of genetic information.
- 2. Equity and Access:** Investigate the potential for biotechnology to exacerbate social inequalities and explore strategies for ensuring equitable access to its benefits.
- 3. Public Trust:** A lack of public trust in regulatory agencies or biotechnology can hinder the effective implementation of ethical guidelines.
- 4. Global Inequalities:** The benefits and risks of biotechnology may not be distributed equitably, leading to ethical concerns about social justice.
- 5. Dual-Use Technology:** Biotechnology can have both beneficial and harmful applications. Ensuring that safeguards are in place to prevent the misuse of biotechnology is a significant challenge.

Conclusion:

In order to maintain a check and balance on the advancement of biotechnological material (e.g. gene patenting) legal, ethical and moral criteria must to be taken into consideration. Through the employment of bacteria and viruses, the biotechnological innovation has the potential to create a biological weapon with global devastation. The development of such an invention will have detrimental impacts on both the environment and people. The biosafety principle is in danger due to the possibility of transgenic animals being released into the wild and causing ecological disruption. The government should ensure that a discussion about what inventions should be protected by patents, which inventions should be permitted to reach the market, and whether cooperation is necessary takes place in order to effectively regulate what is being invented.¹⁴ Clear guidelines and institutional safeguards should be put in place, and effective means of control should be guaranteed, coupled with transparent information aimed at the public. Patent applicants, on their side, should develop a sort of ethical sensibility and weigh the possible socio-political impacts of their inventions.

¹³ Modern Biotechnology: Legal, Economic and Social Dimensions, Biotechnology, Volume 12, ed. D. Brauer (Weinheim, Germany: VCH, 1995). Author: Darryl R. J. Macer

¹⁴ <https://www.legaleech.com/blogs/patents-on-biotechnology-and-related-laws-in-india> last seen dated 24/08/2024.