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IS BIOTECHNOLOGY A THREAT?

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ABSTRACT

This research paper primarily focuses on the scopes of development in various fields; biotechnology has created and then will address the various legal issues raised by biotechnology. Being not very exhaustive, this paper will catalogue and describe certain statutes, cases and theories that will be a support to my selected topic.

It is a general allegation that biotechnological research violates certain rules and regulation related to environment, and also sometimes becomes very inhuman and can cause severe harm to the humankind. Most of the experiments are done on animals. The first part of paper deals with the various federal statutes that are governing the genetic engineering. It also surveys the theories and causes related to the same. It is asserted that we need some regulations to set an ethical standard, to regulate the extent of activity by humans that may help but on the other side might harm the living organisms as well.

In the second part, the paper deals with the provision of intellectual property protection of inventions through biotechnological experiments. The inventions and discoveries can be protected by patent (bio-patent), trade secrets or even copyright laws. If we are ignorant and we do not straightaway counter these patent applications, other countries or individuals may take advantage of our rich legacy and we won't be able to bring any action against such loss, as in case of turmeric and neem like herbal medicine of India. However, these patents and copyrights are all attributes to the personal property and thus their owner can transfer their rights therein.

There are certain liabilities associated with these biotechnological companies; those are further dealt in the paper.

"Our world is built on biology and once we begin to understand it, it then becomes a technology"[1]

Introduction

Biotechnology, or we can say biotech, is that area of biology that uses living processes, organisms and systems for manufacturing product or technology that intend to improve the quality of human life. Very often, it overlaps with bioengineering, bionics, molecular biology, nanotechnology and genetic engineering.

Organization of Economic Co-operation and Development defines Biotechnology as "The application of principles of science and engineering to the processing of material by biological agent"[2]

From the very term it is clear that "Biotechnology is the combination of living systems- microorganisms, plants and animals with basic engineering and scientific for providing different solutions for the

[1] Quoted by Ryan Bethencourt

[2] Encyclopedia Britannica. 2021. *Biotechnology | Definition, Examples, & Applications*. [online] Available at: <https://www.britannica.com/technology/biotechnology> [Accessed 25 January 2019].

improvement of our lives. Biotechnology is a mixture of different disciplines of study- biology, microbiology, biochemistry, chemistry and even physics.

With the use and cultivation of cellular and bio molecular-processes, the advancement and acceptance to technology in various fields can be made by the scientists. The natural use of living organism, breeding new living organisms and modification of their general makeup is considered as traditional processes. When these processes are successfully applied, it has a very good outcome which resulted in treatment of disease, reduction of environment impact and efficient use of natural resources. Biotechnology as a practice has implemented by many major biotech companies for bringing medical devices and product to the mainstream market.

Federal Statutes to govern the process

As every coin has two faces, the biotechnology, is same as other advanced technologies, which has the position to be misused. Some government or groups has put on efforts for enacting legislation that restricts or banns certain programs and processes, such as human cloning and embryonic stem-cell research. If groups use biotechnological processes with criminal or malicious intent, the end result could be biological conflict.

There are many committees and organization looking after the proper regulation of biotechnological process. The most important of them are:

- The Institutional Bio-safety Committees (IBSC), they are responsible for the local implementation of guidelines provided.
- Review Committee on Genetic Manipulations (RCGM), they are responsible for issuing permit.
- Genetic Engineering and Approval Committee (GEAC), responsible for monitoring the large scale and business use of transgenic materials.

The industry of Biotechnology in India is being governed by the following legislations upon their applicability and relevance on case-to-case basis. They are:

1. Environment Protection Act, 1986[3]- the Act focuses upon implementation of decision of United Nation Conference that works upon safeguarding and improving human environment.
2. Laws related to Intellectual Property Rights- Regarding Bio-patent and Bio-piracy.
3. Recombinant DNA Safety Guidelines- Being formulated to carry on the task in ethical manner.
4. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[4] - This Act governs the registration and experimental use of pesticides, and regulates their transportation, importation, monitoring, and disposal. Protects trade secrets and other commercial information pertaining to pesticides that are disclosed in the course of such registration and regulation.
5. Federal plant pest Act[5]- Regulates the importation and movement in interstate commerce of all plant pests.

[3] Came into force on 19-11-1986, vide G.S.R 1198(E), dated 12th November, 1986

[4] U.S.C. §§ 136-136y (1982 & Supp. II 1984)

[5] U.S.C. §§ 150aa-150jj (1982)

6. The Biological Diversity Act, 2002- This Act for preservation of biological diversity in India, provides mechanism for equal sharing of benefits with the help of traditional biological resources and knowledge.
7. Drugs & Cosmetic Act 1940[6]- This Act deals with adulteration and misbranding of products.

Biotechnology and Intellectual Property Rights

Section-2(m) of Patent Act[7] provides the knowledge about patent. The right of Patent is given by the government authority. It is a licence that gives the right for a specified period so that others are excluded from making or using or selling any invention.

There are commonly three words used under the protection of Intellectual property. They are Copyright, Patent, and Trademarks.
Copyright is provided to protect any work or art, which is authored.

Patent is provided temporary to a particular idea or invention. The patent of bacterium can also be done.[8] Patent is not granted for just ideas, it is granted when the invention comes into existence.[9] Later on, it was felt that the patent needed to be disallowed which are not actually invented and not necessary to be invented.[10] And also, some inventions are such which didn't require to be protected with a patent.[11]
Trademark is there to protect language or symbol which is unique for a particular person or company.

Bio-piracy, splitting the word, 'bio' and 'piracy' literally means 'the patenting of life'. With the help of Patent, the identified and developed genetic material from plants, animals and other biological resources, are being owned by companies and manufacturers.

Let us for more understanding take one example of bio-piracy and to understand how it is a threat for the development of a particular nation too, the distribution of rice in India is one of the richest in world. The unique aroma of Basmati Rice makes it distinctive from any other rice in India. There are 27 registered varieties of Basmati that is produced in India. Reference of basmati is made in ancient texts, folklore, scriptures and poetry too, as it has been produced for centuries. In the year 1997, US Patent and office of Trademark gave Patent rights of Basmati rice to a company of America due to which the company was allowed to sell an exclusive variety of Basmati in US and abroad. This 'exclusive' kind of Basmati had been derived from farmers of India. The patent extends to useful equivalents, stating that other people shall be restricted by patent, for selling the Basmati Rice. If we are ignorant and we do not straightaway counter these patent applications, other countries or individuals may take advantage of our rich legacy and no action can be taken against such loss.
Taking one more instance, the case of Enola Bean Patent or Mexican Bean Bio-piracy, these beans are commonly grown by Mexican farmers. Later, US Company Pod-Ners patented it in 1999 under Patent No:

[6] U.S.C. §§ 301-392 (1982 & Supp. II 1984)
[7] The Patent Act,1970 (39 of 1970)
[8] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[9] O'Reilly v. Morse (1853), 56 U.S. 62 (1854)
[10] KSR v. Teleflex, 550 U.S. 398 (2007)
[11] Alice Corporation v. CLS Bank International 573 U.S. 208 (2347)

584079 and filed a case against Mexican farmers selling yellow bean in US. The patent was challenged at USPTO[12], on 29 April, 2008 board of patent appeals declares rejection of the case and Federal court in October, 2009 affirms BPA's rejection. Due to the patent rights of biological substances, the localities of the countries which are affected would have either negligible or no access to those new developments which primarily is their original discovery. The person who are granted patents would have absolute right to their inventions and can therefore manipulate the prices if they want to.

Application of Biotechnology

In the field of application of biotechnological principles and processes, the major concern is related with or the industry is mainly devoted to human health applications, and then comes the agricultural biotechnology and industrial applications, genomics and bioinformatics.

With the trained manpower and proper knowledge and as the government is co-operating in the development of this industry, so it is day by day achieving a new height.
For instance, Alcohol production comes on the part of industrial biotechnology. For instance, beer is made from water, and the starch in the barley must be transformed to sugar by enzymes which happen when the starch is activated and it happens with the malting process. The two equipments used in industrial biotechnology are Enzymes and microbes.

First bio fuel, Ethanol was produced by fermented sugars which is derived from the plant, the process is similar to that of which is used for making beer and wine, or the process similar to which the plant-oils are converted to biodiesel. This requires crops such as corn, wheat, oil seed sugar cane, corn, wheat, oil seed rape or sugar beet. Bio fuels such as bio ethanol and biodiesel are blended with petrol and diesel to meet legislation on greenhouse gas emissions.

Bacillus Thuringiensis or Bt are the two naturally occurring toxin. It is a soil-borne bacteria used since 1950's for controlling natural insects. There is the spore in it which consists of protein crystal i.e. toxin, when certain insects consume this bacteria, it releases the toxic crystal insect's highly alkaline gut. This bacterial reaction penetrates the pest's stomach of its own digestive juices and the insect dies by poisoning from the content of the stomach and the spores. This mechanism is not harmful to birds, fishes and mammals in which the bacterial effects are neglected by their acidic guts condition. The protein that Bt gene produce, in the plant is toxic to few groups of insects- For example: European Corn Pores or corn Rootworms.

In the mid of 1990's first GM crops were established in US. Mostly they are grown in US. Corn, Soya-bean and cotton are largest cultivated GM crops.

Taking the example of some of the GM crops, the first one that is, in 2005, first agreement was signed to develop the Bt Brinjal between India's leading seed company, Maharashtra Hybrid seeds company, also known as Mahyco and other two agricultural universities i.e. University of Agricultural

[12] United States Patent and Trademarks Office

sciences, Dharwad[13] and Tamil Nadu Agricultural University, Coimbatore.[14]

In 2006, an expert committee was set up for examining the bio safety data presented by Maharashtra hybrid Seeds Company. It was concluded from the current state that Bt Brinjal was not harmful and it is not different from it's not Bt counterpart.

It was required to state strongly the findings and further trials were required to discover the benefits from Bt Brinjal depending upon the management of pest and reduction of pesticide. In 2009, a second expert committee was developed and it concluded the benefits of event EE-1 of Bt Brinjal, which was developed by Maharashtra hybrid seed company (Mahyco) far outweighs the risks that are projected and recognized. An advice was given to Genetic Engineering Appraisal Committee (GEAC) for the recommendation of Bt Brinjal commercialization.

On 9th Feb 2010 an announcement was made by the Central Government officially that the releasing of Bt Brinjal requires more time. With the statement of Minister Jairam Ramesh[15] who said that it is not urgency for the origination of Bt Brinjal in India.[16] On 17th February 2010, Jairam Ramesh recapitulated that the centre had not made a permanent ban on transgenic brinjal but has only imposed a prohibition and stated that until they arrive at any political, scientific and societal agreement, the prohibition will remain. Companies with any seeds of Bt Brinjal need to be registered with the government. The testing labs are being set up. National bureau of plant Genetic Resources were responsible for the storage of all Bt Brinjal seeds in India.

A notice of irregularity was brought to the Karnataka Biodiversity Board by Environment Support Group that found that at least 10 varieties of Brinjal were accessed from two states (Karnataka and Tamil Nadu) without taking any consent from the National biodiversity Authority.[17] Mahyco was the first company which was accused for bio-piracy or misappropriation of local germplasm. Criminal proceedings were persuaded against senior officers of Mahyco-Monsanto. India's National Biodiversity is searching for the crops scientists who developed Bt Brinjal for the violation of India's Biological Diversity Act, 2002[18] for the usage of local cultivators and foreign technology without taking their permission.
On 9th August, 2012, the Agriculture's Parliamentary Committee has directed the government to ban the genetically modified Bt Brinjal. A search was to be made that how the permission was granted to commercialize Bt Brinjal seeds when no proper evaluation tests were carried out. The licence of Mahyco's was cancelled by Maharashtra Government to sell its Bt Brinjal seeds.

Another GM crop, that is the first genetically engineered food that was granted the licence for human consumption is flavr-savr Tomato

[13] Established in 1986 by the government of Karnataka which provides education and research in the field of agriculture, forestry, food science, and home science
[14] Established in 1906
[15] An Indian economist and politician belonging to INC who represents Andhra Pradesh in Rajya sabha as a member of parliament.
[16] The first GM crop was put on hold on safety ground by India.
[17] Formed on 1st October 2003 under the ministry of environment, climate change, forest and government of India.
[18] The Act of parliament of India to preserve the biological diversity in India (Act No. 18 of 2003).

that was produced by Calgene[19], a Californian company and was submitted to US Food and Drug Administration (FDA)[20] in 1992. After the evaluation of Flavr-savr Tomatoes by FDA, it concluded that the new variety of tomatoes were safe and the use of amino glycoside 3'-phosphotransferase II is safe for the use in the evolution of new varieties of tomatoes as a processing aid. The first sale of this new variety of tomato took place in the year 1994 and in 1997, its production was ceased.

The normal tomatoes which were intended to be shipped are picked which they are not ripen and are made to be ripen before the delivery with the aid of ethylene gas[21]. Whereas Calgene, with the aid of genetic engineering tried to slow down the ripening process of tomato so that it does not get soften so that the tomatoes retain its natural colour and flavour. The flavr savr tomato became hostile to rotting by the addition of antisense gene due to which the enzyme polygalacturonase was not able to produce. This resulted in the softening of the fruit which became more suspectible to the damage by fungal infection. FDA stated that it was not necessary to give any specific labelling to these modified tomatoes as they had a characteristic of non-modified tomatoes especially there was no evidence of risks to health and no nutritional content was changed.

This growth and further sale of genetically modified tomatoes (Flavr-savr tomatoes) were failed due to inexperience of Calgene in the business of shipping and growing tomatoes.

The next crop to be in instance is Bt cotton which was first introduced in 2002 and is supplied in Maharashtra, India by the agri-biotechnology company Mahyco. India has varieties of Bt cotton such as Bikaneri Nerma (Bred) and NHH-44 (Hybrids). India is considered as the cotton's largest exporter and has become second largest producer of cotton globally. The cotton absorbs the cry1Ac gene from Bacillus Thuringiensis which makes the cotton toxic to Bollworms. In 2012 the trading and spread of Bt cotton was banned by the Maharashtra Government and promoted local Indian seeds as it demanded reduced quantity of water and pesticide input but the ban was lifted in 2013. Country's first cotton varieties were successfully developed by Punjab Agricultural University (PAU). Three varieties of cotton was identified by ICAR[22], namely PAU BT 1, F1861 and RS 2013.

As the BT cotton has reduced the need for pesticides due to which it was enveloped in controversies. The introduction of Bt cotton in India and the farmer's suicide are not related to each other, however the former has decreased the farmer's suicide.

Conclusive Remarks

The industry of biotechnology in India is a growing industry with a significant promise for development and growth. At both National and State levels, there is strong government support which has led to acquire

[19] Monsanto Co. existing from 1901 until 2018, headquartered in Creve Coeur, Missouri.

[20] FDA formed on June 30, 1906, headquartered at white Dak campus, Maryland and its jurisdiction lies with Federal government of US.

[21] Colourless, flammable gas having a faint "sweet and musky odour when pure".

[22] Indian council of Agricultural research, established on 16th July, 1929 located in Pusa, New Delhi.

great opportunities of investment in the biotechnology sector. The main challenge is management that is about deriving maximum satisfaction from limited resource and also to carry on the works in ethical manner and in accordance with the federal statutes governing the biotechnological research and development.

It is my keen belief that the newly accounted fungus, Candida Auris's[23] disease can be cured with the assistance of vaccines or medicines which will be developed by this industry. With the development of this industry the days are not far when we the people of India proudly says that we are Indian, citizens of that nation where the main concern is on the advancements and that too in account of tradition that is maintaining the ethics.

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[23] Candida Auris is a species of fungus first described in 2009, which grows as yeast.