BAFFLING BIOTECHNOLOGICAL ADVANCEMENT AND THE BIZARRE LAWS OF INDIA

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Abstract: The State needs to ensure the enactment of proper Legislation in order to curb administrative and delinquent developmental activities. The role of government and slow pace in the field of development of proper Biotechnological Statues has resulted in the collateral damages caused to mob in direct and indirect means. The approach of the Indian Parliamentarian in the Biotechnological Research and Development has changed from positive to negative in the standard scale of global developments in the field and the countries resources unevenly are being used as a testing ground by the world which needs an uninterrupted attention of the authorities as soon as possible. The current strategy of government is Probability and Dilemma. The paper will examine the **Research and Development Policy** for futuristic sustainable developmental goals.

Keywords: Biotechnological Laws, Genetic Material, Intellectual Property Rights, Licensing.

Introduction: This India is a state of intellectuals and advancements in the realm cannot only be determined by technological advancements. The present India is a battle ground for such biotechnological advancements in the field of genetic engineering. Biotechnology was first defined in the Article 2 of the United Nations Convention on biological diversity and thereby referred to as
"Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use and "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity"[1]

Apart from the 1992 Rio de Janeiro convention India also ratified the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* and thus is bound to accept the terms of international agreement which "ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health".[2]

It is well evident that the nineteenth and twentieth century has seen a lot of diversification in the genetic modifications and molecular structural DNA engineering after the 1953 research works of noble laureate Francis Crick and James Watson like "Transgenic"[3] plants and animals new traits of sheep, cow, Vegetables, Narcotic Plants and industry beneficial cotton were the major products.[4]

The rapid growth in the arena bifurcated the biotechnology into four distinctive categories
- Red biotechnology for the medical field
- Blue biotechnology for the aquatic field
- Green biotechnology for agricultural field
- White biotechnology for industrial field

Making it a commercial giant and a major catalyst in many technological genetic engineered products market value ranging from $5 billion U.S. dollar to $11.5 billion U.S. dollar industry in 2017 capturing 12% of the world trade from India.[5]

The drastic shift in the market in the past few years created a room for the intensive research and development in the field of biotechnology and many commercial giants came forward to keep in pace the futuristic aspect of the filed. Governments funding and grants in the advancement of the new generations genetic products created a need to develop the stringent policies and regulations for the industry and keep it in pace with the international agreements and conventions. With the support of

government, India is going to become the major determinant in acquiring more advanced research and production techniques with more patents indigenously. Few of the government future initiatives are:

- The Telangana state government's flagship pharma and biotech event - BioAsia 2017 attracted investments to the tune of Rs 3,382 crore (US$ 507.3 million).[6]
- During the Vibrant Gujarat Global Summit-2017, 54 MoUs worth Rs 5,022 crore (US$ 736.1 million) in the biotechnology sector were signed by 37 companies.[7]
- Syngene International Ltd, the contract research services arm of Biocon Ltd, is setting up a drug discovery and development center in Bengaluru for Amgen Inc., a biotechnology company based in the US[8]

Such initiatives of the government and public private partnership shall certainly increase in the calibration of the joint aspects related to the industry. Some of the aspects which will connote to the positive deliberations of the investments shall bring about with it a great boom in the marketization of the furnished products and will ultimately provide low cost efficient high yielding varieties for the general public uses. The age of genetic engineering and DNA modifications and restructuring indigenously will create immense opportunity in the areas of Job, Production, and Infrastructure that too at a rapid rate.

Although India being a signatory to the 1992 convention and Cartagena Protocol apart from such a vibrant futuristic aspects of the biotechnology, India is likely to lose the competition with the world as India still lacks a stringent statue to regulate the activities of the area.

The non-compliance of the commercial entities with the existing law and unregulated arbitrary licensing is significantly acting as a major determinant in the disputes of patents and thus the discovery becomes a distinctively a subject matter justiciable under the Intellectual Property Rights Law creating a delay in use of such advancement in the commercial market for the benefit of the public. India is stringent about the parallel goals of this advancement and currently accounts with the 921 companies actively working in field and 109 of which are concerned with the advanced biotechnology.

Classified areas of Research and Market Share[9] are

- Health and Medicines 48%
- Agricultural Developments 17%
- Industry & Applied Works 35%

The Indian competitive market of genetic restructuring is soon going to dominate the potential outburst of the advanced biotechnology ultimately affecting the economic growth of the country is the South East Asia and Asia Pacific major due to the suitable business and climatic condition of the land.
Biosafety is an essential measure as per the Cartagena Protocol[10] which acts as an equalizer for such advancement and mass production of genetically modified products. Environmental concerns related to the development of these types of products thus becomes an important part of the whole technological advancement.

Technology comes with a positive and negative extensions depending on the use of such technology for human mankind explorations or for human mass destruction. Failing to regulate such advanced technology shall result in the adverse effect of biotechnical developments resulting in Bio- Terrorism. On the other hand if used effectively with environment control and regulations can account for food security in India and effective industrial growth ensuring better healthy conditions for the mass.
The crucial advancement which have been accounted so far in the sector includes:

- Genetically Modified Seeds
- Disease resistant vaccinations
- Pesticide control and tolerance to the herbicides
- Arid condition high cultivated lands efficiency with higher rates of production.
- More advanced organism development as an alternative to chemically created medicines.[11]

Legal violations of the existing laws and manipulation in the use of high productive biotechnological technology has also created a problem for others which are dependent on the use of ethical and natural ways of creating a product or for cultivating a crop.[12]

One such disadvantage of and uncontrolled growth of advanced was brought before the court in the case of B.T. Cotton production and Monsanto an Unites States based company dealing in Genetically Modified Seeds production using Indian land as a testing ground from 1998 for its B.T. cotton production units developments which ultimately affected the Indian famers as the pollens blown away by the air from theses genetically modified seeds attracted the corn crops insects growing nearby which hampered the ethnically grown species of cotton by the Indian Famers yet no pesticides or insecticides vaccination available in the market worked to restrict the new variety of insects generated by the pollen of the genetically modified seeds produced by Monsanto and therefore the famers sued the U.S. based company for damages. Taking into consideration the quantum of damages suffered by the Indian Farmers the suit is still pending in the Supreme Court of India as Monsanto claims the IPR of such genetically modified seeds in joint development with a Maharashtra based seeds manufacturing company (Mahyco) and it's licensing thereto.[13]

Bio-terrorism is another such problem which is directly on the face of state to be though upon as a unregulated licensing granted to a foreign company indirectly paved paths for the quantum damages to Indian Farmers yet in the absence of the precedent and legislation such advanced biotechnology can be utilized as a tool for mass destruction. In a country like India any such activity which directly hits the grass roots of the population can amount for a greater damage directly affecting the national security of the country. Thus is becomes a matter of primary importance that a stringent legislation to be drafted for a millenniums developmental goals sustainably. The present legislation which amount to restrict and regulate such activities of genetic modification are primary based on the conduct of the company in health impacts and its share in polluting the environment. Such major to conduct the companies are a part of vital branch of law that deals with mostly with Environmental protection and Health related issues. Legislations controlling such activities are:

- Food Safety and Standards Act, 2006[14]
- Drugs and Cosmetics Rules 1945[15]
- Environment (Protection) Act, 1986[16]
- Seeds Bill 2003 introduced in the parliament 09 December 2004[17]
- Protection of plant varieties and farmers' rights act, 2001[18]
- Biotechnology Regulatory Authority of India bill 2013[19]

The aforesaid Statues and Bills are only a hand full of laws that India has at present for the purpose for control and advanced developmental activities in the field of Biotechnology, Genetic Engineering and Restructuring.

Conclusion: Some of the key arears government needs to ensure its mechanism's proper working in order to enhance and control the drastic changing technological field are:

- Creation of a ***Bio-edu-Grid*** among Universities and companies for better practical and theoretical approach and Facilitation of industries and Universities for such activities through aid and support ensuring minimal brain drain.
- Infrastructural Development through creation on ***Biotechnology Parks of India (BPI)*** and incubation centers following the same paths of Software Technology Parks of India (STPI) and Special Biotechnology Zones depending upon the climate, surroundings and resources rich are as it was in the case of special economic zones ensuring better opportunities for each sector of society.
- Rigid Contract and agreements made only the light of Stringent National Legislations.

Waste disposal and its effects to environment has always been a bigger issue to any advanced technology creation of minimal waste and initially developing and controlling the release of any such pollutant or organism in the environment which harms the environment will eventually lead to a pure biotechnological word with greater efficiency yet the role of government to any such activity is of primary importance.

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17. An act to replace and control the quality of seeds sold in the market as per the Seeds Act, 1966 forwarded to Rajya Sabha on 28 November 2006.
18. "Essentially derived variety", in respect of a variety (the initial variety), shall be said to be essentially derived from such initial variety when it –
    a) is predominantly derived from such initial variety, or from a variety that itself is predominantly derived from such initial variety, while retaining the expression of the essential characteristics that results from the genotype or combination of genotypes of such initial variety;
    b) is clearly distinguishable from such initial variety; and
    c) conforms (except for the differences which result from the act of derivation) to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety;
19. Introduced in the parliament on 22 April 2013 still in discussion.

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