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ANALYSIS OF CURRENT INDIAN LEGISLATION ON BIOTECHNOLOGY

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ABSTRACT

The present study evaluates concern prevailing legislative provisions pertaining to biotechnology in India. Legislation related Environment Protection Act of (1986), Biosafety Rules (1989), Biotechnology Safety Guidelines (1990), Regulatory Committees, Patent-laws, and bill of Biotechnology Regulatory Authority of India (BRAI) have been discussed.

Key words: Indian legislation, biotechnology**,** patent-laws, regulatory committees

1. INTRODUCTION

The term biotechnology was first introduced by Hungarian scientist, Earl Carley in 1919 which comprises two words bio and technology; bio means life and technology mean to use scientific research in getting desired result. Biotechnology means using living organisms (plant and/or animal) with technology for getting desired result. Development of the genetic resources of biodiversity is known as biotechnology. By using genetic engineering modifies basic DNA prevailing in plant or animal to enhance its functions to solve desired problem and to make useful products out of it. DNA (Deoxyribo-nucleic Acid) is a molecule which is made up of biological instructions that result in the uniqueness of each species; it is passed from adult organisms to their offspring at the time of reproduction.

Biotechnology may be broadly categorized into two groups *viz*., Gene and Non-gene, the latter being more popular practice. Gene biotechnology deals with genes wherein genes are transferred from one to another organism. Non-gene biotechnology deals with the entire cells, tissues or even individual organisms. Using biotechnology, scientist have developed vaccines for certain infectious diseases and some medicines beneficial to human health; developed good quality of seeds for higher crop productivity. In couple of years, modern biotechnology is revealing many advances in healthcare, food and energy security, and environmental conservation.

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Biotechnology is utilized in four major sectors mostly depending upon its use like medical, agriculture, industry and marine. In medical sector it is used in pharmaceutical (drugs) and in employing stem cells to replace or regenerate tissues. In agriculture sector it is used to evolve pest and disease resistant seeds. In industrial sector it is used in process of developing novel chemicals or vehicle-fuel. In marine aquatic sector it is used to control harmful water borne organism.

In India, biotechnology is at threshold of fantastic growth; around 60, 10 and 30 per cent industry is devoted to human health applications, agri-biotechnology and bioinformatics and genomics, respectively.[1] Recombinant DNA (rDNA) technology is being successfully used in agriculture, health care, process industry and environment management. Currentfocus is on genomics, proteomics, transgenics, stem cell research and product development. In these sectors, adequate balance between benefit, safety, access and consumer interest is required. Scientifically rigorous, transparent, efficient and consistent regulation for biosafety evaluation and product-release are essential to achieve the goal.[2] India has now startedattracting global attention in the field of clinical trials, contract-research and manufacturing and other services of Bio-pharma segment.[3] Biotechnology in its true sense was escorted into India in the year 1997 by the launch of an indigenously developed rDNA technology-based product, hepatitis-B vaccine, by Shantha Biotechnics. Approval for cultivation of the first genetically manipulated (GM) crop in India was given for *Bt* cotton in 2002 and about 135 GM cotton varieties from 16 companies have been approved by now. Presently there are 7- recombinant crop-products indigenously developed and manufactured in India.[4]

2. BIOTECHNOLOGY REGULATIONS

India's journey with biotechnology began in the 1980s with the establishment of the Department of Biotechnology (DBT) under Ministry of Science and Technology. This marked the beginning of institutional support for biotechnology research and development in India. DBT played crucial role in framing policies and creating encouraging environment for biotechnology to flourish in India.

[1] Available at: file:///C:/Users/NAIK/Desktop/Laws%20of%20biotechnology%20in%20India/Biotechnology %20 Laws%20in%20India%20-%20Mondaq%20India%20-%20Blogs%20-%20VLEX%2029357790.html
[2] Wiley-VCH (2009). Biotech regulation in India: problems & promises. Biotechnol. J. 4 Pp. 306–309 www. biotechnology-journal.com (DOI 10.1002/biot.200800328).
[3] Dubey, R. Biotechnology-destination India (2004). JIBL: 1(I), Pp. 205-210.
[4] Ibid 2.

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In order to understand today's regulatory system of biotechnology in India, one should look back at the prevailing system in 1997. All regulatory requirements were based on the provisions under India's Environment Protection Act (1986) wherein, three provisions formed basis for biosafety regulations; these were formulated and formalized as Biosafety Rules (1989), which applied to research, manufacture, use, import and storage of microorganisms, gene-technology products and products made out of genetically engineered microorganisms. The 'Rules' were supplemented by Biotechnology Safety Guidelines (1990) issued by central governments' Department of Bio-technology (DBT) which subsequently revised in 1998 and 1999. Several committees were then institutionalized in India through the DBT policies.

3. REGULATORY COMMITTEES

Recombinant DNA Advisory Committee (RDAC) reviews biotechnology developments at both national and international level. It recommends suitable and appropriate regulations infor recombinant research, its use and applications. Review Committee on Genetic Manipulation (RCGM) monitors safety-related aspects of ongoing research and activities involving genetically engineered organisms. To navigate this complex policy landscape, India needs to craft a more streamlined regulatory system and take other concrete steps to support growth in its domestic biotech sector.[5]

Apart from pharmaceutical sector, biotechnology innovations and research are instrumental in health care systems, agricultural industry, and polymers and materials sectors.Research and development in these areas is relatively time consuming and involves huge investment with risk involved with outcome. To promote such results much more importance is affixed with respect to patenting the inventions in said field and enabling growing research sector to monetarily sustain itself. In order to help the patent seekers, Biotechnology Patent Facilitation Cell (BPFC) was established by DBT in 1999. Another government authority working for the same cause is Council of Scientific and Industrial Research (CSIR) which formulated Science and Technology Policy (2003).[6]

DBT is parent body of Recombinant DNA Advisory Committee (RDAC). Committee bears

[5] Supra 2.

[6] Rastogi, (2026) Protection of biotechnology under Indian laws. Available at: file:///C:/Users/NAIK/ Desktop/ Laws%20of%20biotechnology%20in%20India/Protection%20Of%20Biotechnology%20Under%20Indian% 20Laws%20-%20Patent%20-%20Intellectual%20Property%20-%20India.html

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the responsibility of studying and reviewing the changes and developments made in the field of biotechnology at the national and international arenas. Consequently, it rendersapposite suggestions to enhance safety regulations in the area of recombinant research and their applied utilities.

DBT is parent body of Review Committee on Genetic Manipulation (RCGM). However,this committee concerns itself with the safety and precautionary aspects of research in genetic engineering. In order to ensure the same, the committee has to stipulate the specific guidelines regarding the activities involving genetic engineering of organisms and theirconsequent use or release. The utmost importance is given to its prime objective which is to ensure environmental safety. It also bears the responsibility of monitoring the products, field experiments, production, sale and shipment involving even a fraction of genetically engineered organisms and cells which are classified as so in the schedule.

DBT is the parent body of Institutional Biosafety Committee (IBSC). Duty lies with institution which is conducting research that includes usage of even the smallest proportionof genetically modified organisms and even microorganisms that are not natural to the local conditions. This committee needs to be comprised of head of the parent institution directly invested in the research, the scientists hired by the institution for the genetic engineering of organisms, at least one medical expert and one nominee of the Department of Biotechnology. The parent institution is required to prepare an up-to-date emergency procedure(s) with the aid of the IBSC which conforms to the guidelines of the RCGM. It is also imbibed with the duty of providing the copies of such a contingency plan and procedure to the District Level Committee and the Genetic Engineering Appraisal Committee.

Genetic Engineering Appraisal Committee (GEAC) is constituted by the Ministry for Environment and Forests and grants requisite approvals for activities or procedures involving large-scale commercial use and discharge of potentially hazardous microorganisms not excluding any such import comprising of GMOS and recombinant DNA. Committee has the authority to prohibit production, sale, shipment, GMOs use if deems it threat to environment.

State Biotechnology Co-ordination Committee (SBCC) is constituted by the respective State and acts as State nodal agency monitoring and assessing damages caused by the release of genetically modified organisms. The Committee yields power to enforce punitive action

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against violations after it has conducted an appropriate investigation. Committee bears the additional responsibility of periodically reviewing the safety and control measures employed by the industries or institutions invested in the occupation of handling genetically modified organisms and hazardous microorganisms.

District Level Committees (DLC) is constituted at the districts where biotechnology projects are to be undertaken. Its authority is subject to that of the SBCC. The head of DLC isthe District Collector and it is him who reviews and assesses the safety regulations employed by the industries or institutions engaged in the use of GMOs or hazardous microorganism.The committee's responsibilities include the checking of the institution's compliance with recombinant DNA guidelines and reporting the violations, if any, to the SBCC or the GEAC. It needs to coordinate activities of concerned institution or industry to effect that it becomes easier to contain emergency situations caused from accidental or even intentional discharges.

Monitoring and Evaluation Committee which has the duty of undertaking regular visits to sites of experiment and recommends procedures in case any remedial measure is requiredto adjust any potential threat from discharges. Committee also aids the RCGM in tabulating and analyzing primary data from the field so as to ascertain the comparative agronomic advantages of genetically engineered crops or plants.

4. KEY LEGISLATIVE FRAMEWORK

I) Environment Protection Act (1986)

This is one of the key legislations that regulate biotechnology in genetically modified organisms (GMOs). Act provides framework for addressing environmental issues and its provisions are applied to regulate the use, release and containment of GMOs. Under this Act, the Genetic Engineering Appraisal Committee (GEAC) was established to oversee the use of GMOs and ensure that they do not pose threat to the environment or human health.

Regulations pertaining to biosafety constitutes primarily of rules and guidelines that are based on this Act. Sections-6, -8 and -25 jointly form preamble of currently existing biosafety regulations. Section-6 gives authority to central Govt. to form essential rules on standard procedures, implement safeguards and place necessary restrictions for handling of hazardous substances and outright prohibit the others. Section-8 imposes prohibition on person from handling any substances considered to be hazardous except when procedures and safeguards

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have been complied to. Section-25 places responsibility of stipulating the rules regarding procedures and safeguards for handling hazardous substances. As general consensus in our judicial system is that biosafety rules are of statutory nature as their genesis lies in this Act.

A) Biosafety Rules (1989)

Aforesaid provisions have also leaded to announcement of the Biosafety Rules (1989). These rules apply to the products made from genetically engineered micro-organisms and other gene-technology produce and regulate their manufacture, storage and import. These rules also cover the pre-release facet of genetically modified organisms, *viz*., their research and development besides the large scale applications and trials. Hazardous organisms which are not genetically modified are also regulated by these rules. Rule no. -8 of this statute mandates requirement of an approval by the regulatory bodies prior to the discharge or even production of genetically modified organisms and cells. Rules nos. -10 and -11 necessitates requirement of approval for any such substances that contain genetically engineered organisms or even cells. Rule-9 of this statute is foremost in significance as it expressly prohibits deliberate and/or unintentional discharge of genetically modified organisms (for experimental purposes) covered under its schedule, barring situation where it has been approved as 'special case' by the appropriate authority. The said schedule is feature of these 'Rules' which classifies human and animal pathogens in terms of their risk profiles.

B) Biotechnology Safety Guidelines (1998)

Biosafety rules have been augmented appropriately by Biotechnology Safety Guidelineswhich have been put into effect by DBT. These guidelines are the consequence of Rule 4(2) of the 'Biosafety Rules', which mandates the requirement of guidelines manuals which are to be stipulated by 'Review Committee on Genetic Manipulation', which is serviced by DBT. These guidelines are concerned with the assessment of biosafety levels of which it carries a detailed analysis. Detailed reproach on recombinant DNA or rDNA related activities, experiments, shipments and quality control produced by genetic engineering is also provided by DBT. The safety guidelines, before reaching its current form and after being issued by DBT in 1990 were revised and amended two times and finally amended in 1998 in accordance with progressive strides made in the field of rDNA research.

II) Patent (Amendment) Act (2005)

Intellectual property rights (IPR) play crucial role in biotechnology sector. This Act aligned

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India's patent laws with trade-related aspects of Intellectual Property Rights (TRIPS) agreement. Amendments were made earlier in 1999, 2002 and 2004. Amendment allows patenting of biotechnological inventions, including microorganisms and provided protection for biotechnological processes and products. Under current patent law, provisions made areas under.[7]

A. Compulsory licensing: Necessary u/s 92(1) for public, non-commercial and governmental use or in situations of national emergency or extreme urgency or for local production of generics under many conditions. It concerns about public health and access to medicines significantly restricts pharmaceutical patent rights in the new Indian law. It is important because in India more than 70 per cent of medicines are sold through the private retailers. There are no restrictions on the kinds of diseases for which this provision can be applied. Thecompulsory licensing provisions can be used for all classes of drugs. Article 31 (f) of TRIPS restricts the export of compulsorily licensed medicines in member countries to an amount inferior than that destined for the domestic market; however, as the domestic market in India is relatively large, the country could still supply most export markets.

B. Restrictions and opposition to the concession of patents: Major concern associated withthe patenting of drugs and food products refers to granting extension of term of the patent (20years old) or patenting of molecules that are similar to pre-existing ones and that represent relatively little innovation. Section 3 (d) says that the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy is not patentable; further says that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. The Section is most controversial and powerful instrument to prevent patents, banning patenting activity in absence of an innovative or inventive step. Indian law allows opposition to patents before and after their concession. Section 25 (1) requires that the Controller publish the patent application and enables any entity or individual to challenge such patent before it is granted. Section 25 (2) allows any entity or individual to submit an opposition to the patent after it is granted, but before the expiration of the one year deadline from the date of its publication. One of the main grounds for patent

[7] Available at: André de Mello Souza. https://repositorio.ipea.gov.br/bitstream/11058/4551/1/BEPI_n10_indian Last seen on 3-8-2024

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pre or post-grantopposition is the lack of an inventive or innovative step. The object of the patent can't be commercially exploited by any entity other than its holder or third party licensed by it. TRIPSallows for exceptions in cases wherein this object is used for non-commercial purposes; thisis known as 'Bolar exception' and allows for use of patented innovations without permission from the patent holder and is embodied in Section 107 (a) of the Indian patent law. It is an important provision, because it allows generic drug companies to conduct research on patented drugs and biological resources in order to obtain the approval of and to market equivalent or similar drugs or biological resources immediately after the patent expires.

C. Patenting of biological resources: Within the constraints imposed by TRIPS, Indian law seeks to limit patent protection of living beings and biological materials. Amendment (2002)of patent law restricts patenting of genetically modified organisms (GMOs) to their processesor preparation methods. Living entities of artificial origin *e.g.* microorganisms or vaccinesmay be proprietary as well as biological material that has been subjected to substantial humanintervention such as recombinant DNA and plasmids. Other manufacturing processes ofbiological materials that are also produced by substantive human intervention, relating tomicroorganisms or chemicals using microorganisms, may also be protected by patent rights. However, the technology of genetic seed sterilization, procedures for cloning or modifyinggerm line or genetic identity of either humans or animals, because they are contrary to public order or morality, can't be patented in India. Similarly, the use of human embryos or animalsfor any purpose is also excluded from the patent protection. Since it does not meet theinvention requirement, mere discovery of a scientific principle, the formulation of an abstracttheory or the discovery of any living matter or nonliving substances occurring in nature are also disqualified for patents in the country. Biological materials, such as organs, tissues, cells,viruses, or substances obtained merely by mixture, resulting only in the aggregation of the properties of its components or in a process for producing such substances, where there is noincrease in efficacy, also do not meet the invention requirement and can't be patented. In addition, agriculture and horticulture methods and any procedures for medical, surgical dressings, prophylactic, diagnostic, therapeutic or other treatments of humans or any process for similar treatment of animals to prevent them from acquiring diseases or to increase their economic value or that of their products including prophylactic treatments *e.g.* vaccination and inoculation are not patentable. Whole or part of plants

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and animals other than microorganisms, including seeds, variety, species and clones or essentially biological processes for the production of plants and animals as well as any source of artificial living entities, *e.g*. entirety or part of transgenic plants or animals, cannot be patented. The matter which has no determined function nor industrial application or inventive activity *e.g*. sequences or inventions which in effect are traditional knowledge or which are an aggregation or duplication of known properties of traditionally known components are likewise not eligible for patenting.

In 2001, India became member of the Budapest Treaty on International Recognition of Deposit of Microorganisms for purposes of patent procedure. Treaty allows that the depositof micro-organisms in an international depositary authority be recognized for the purposes of patent applications. Its relevance stems from the fact that the reproduction of micro- organisms based solely on their description in patent applications is not feasible in practice,making it necessary to deposit their lines to allow for their testing and examination by others.The authorized depositary is Institute of Microbial Technology, Chandigarh.

III) Protection of plant-varieties and Farmer's rights (PPVFR) Act (2001)

Article 27.3 (b) of TRIPS states that members shall provide protection of plant varieties either by patents or by an effective *sui generis* system or by combination of both. Indian *suigeneris* law was created to comply with TRIPS is the PPVFR Act (2001). India was the firstcountry to include farmer's rights in its legislation in order to counter balance breeders rights.Farmers' rights in Indian law are protected by provisions that determine the following:

A. Farmers have right to keep and sell seeds, even those of protected varieties, provided they have not been imported and branded with the breeder's registered name so as to indicate that they are seeds protected by law.
B. Farmers who breed or develop new plant varieties also have privilege to register them andto benefit from other forms of protection. The law recognize farmer not only as cultivator butalso as conserver of agricultural gene pool and an informal breeder.
C. Creation of National Gene Fund through which breeders have to pay for use of farmers' plant varieties in the generation of essentially derived varieties. Any individual is entitled to register claim for protection of plant variety at a notified center that, if deemed genuine, will lead to initiation of a procedure for benefit sharing and the deposit of share of the resulting profits in the Fund. This procedure allows for the registration of plant varieties on behalf of farmers even when farmers themselves are handicapped by illiteracy or

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ignorance.

D. Full disclosure of the sources and origins of plant varieties and of passport data on the partof breeders. Failure to meet this prior requirement is punishable with heavy fines and imprisonment. The law adopts the principles of prior informed consent and benefit-sharing endorsed by the Convention on Biological Diversity (CBD).
E. Use of reproductive technology for genetic seed sterilization *i.e.* terminator, is prohibited.
F. Farmers can't be prosecuted for violating rights of breeders if they can prove that they were not aware of the rights.
G. Farmers who wish to examine documents and papers or receive copies of the rules or decisions taken by the various authorities may do so with exemption of all fees.

The law effectively exploits flexibilities of TRIPS, meets requirements of CBD and protects farmers' rights. The law also allows use of registered and protected varieties for research purposes, even when creating new varieties, provided that they are not essentially derived varieties so as to include natural selection, mutant selection, soma-clonal variants, backcrosses and transformation by genetic engineering. The law aimed at preserving public interest allowing exclusion of certain varieties from protection when the ban on commercial exploitation of these varieties is necessary to protect the order or public morality or human, animal and plant life and health or to avoid serious prejudice to environment. Compulsory licenses shall be issued if the protected varieties are not available at reasonable prices without justification from the breeders.

Breeders' rights include not only marketing exclusivity for registered plant varieties, but also exclusivity for the production, sale, distribution, import or export of such varieties or for appointing another party to do so. Moreover, such rights are not applied only to the varieties, but also to their packaging and trademarks and when there are suspicions ofviolation or infringement of these rights the burden of proof of innocence is placed on the accused. Use of trademarks or packages similar to those registered by breeders without their permission constitutes violation of those rights. In cases of conviction, the punishment includes heavy fines and imprisonment for up to two years.

IV) Drugs and Cosmetics Act (Amended in 2008)

Act governs manufacture, distribution and sale of drugs. With growth of biotechnology particularly in the field of biopharmaceuticals, the Act of 1940 was amended twice in 1998

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and 2008 to include provisions for the regulation of biotechnological drugs, including recombinant DNA products, bio-similars and other biologics. The Central Drugs Standard Control Organization (CDSCO) is the regulatory body responsible for overseeing the approval and monitoring of biotechnological drugs in India.

V) Biological Diversity Act (2002)

Act was enacted to provide for conservation of biological diversity, sustainable use ofits components and fair-equitable sharing of benefits from use of biological resources. It addresses issue of biopiracy and ensures that indigenous communities receive their due share of benefits from use of their traditional knowledge in biotechnological inventions.

VI) Establishment of Biotechnology Regulatory Authority of India (BRAI)

The bill was introduced in parliament on 22-4-2013 by the Ministry of Science and Technology which was referred to the Standing Committee on 17-5-2013 and the Committee was supposed to submit its report in June 2014. Its current status however is still not clear. It will provide single-window platform for scientific risk assessment of all biotechnological products *viz*., agriculture, health, environment and industrial sectors. It will help to keep pace in regulatory measures with rapid technology advancement in biotechnology and to ensure safety to human and animal health and the environment. It will supervise and regulate field trials of genetically modified crops and research, transport, import, manufacture, use of organisms and products of biotechnology. It will provide necessary certification and approvalwhether it is safe for use. It will only grant regulatory approval after a multi-level process of assessments is undertaken by scientific experts in the field. It will impose penalties for conducting field trials without its approval. Regulatory Appellate Tribunal will be formed to hear civil cases that involve substantial question relating to biotechnology and hear appeals on the decisions and orders of BRAI. Certain criticisms expressed on this bill are the proposed new institute doesn't clearly defining boundaries of responsibilities and powers; the bill was introduced without consulting stakeholders; bill is considered to be unconstitutional as agriculture comes under the domain of State; term 'confidential commercial information' has been kept out of the Right to Information (RTI) Act; the uses vague wordings which would criminalize sequencing or isolation of DNA and PCR techniques, requiring approval for each usage which may hinder the field of education and research; there is no provision formandatory labeling of Genetically Modified (GM) foods; Regulatory Appellate Tribunal will consist of just one judicial member

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and five technical members that is against the directivesof Supreme Court that bench of tribunal can't have more technical members than judicial members; Tribunal has jurisdiction over substantial question relating to modern biotechnology however, Bill does not define this term, leaving term undefined increasesambiguity; it does not specify any liability for damage caused by biotech-product etc.[8]

5. CASE LAWS IN INDIA

1) Indian subsidiary of Swiss pharmaceutical multinational Novartis has filed lawsuit against the rejection of its patent application for the leukemia drug Gleevec. This drug was originally patented abroad in 1993 and TRIPS allows countries such as India that did not recognize patents on pharmaceutical products before complying with the Agreement to render drugs patented before 1995 forever ineligible for patenting. However, Novartis applied for patent inIndia for the beta crystalline form of Gleevec arguing that such drug represented improvement over its previous form, because it is less hygroscopic and therefore more stable.Nevertheless, Indian patent office rejected such application arguing that in its new version, Gleevec did not meet the requirements of inventive step and non-obviousness. This version did not constitute a new molecule; moreover researchers versed in chemistry of the molecule could see that its patented beta crystalline form would already have useful properties indicated by Novartis. In other words, the new version of Gleevec would represent structurally distinct form of previously known substance, the patenting of which would be specifically vetoed by Section 3 (d) of the Indian patent law. Novartis filed the lawsuit in 2006 in Chennai High Court, which upheld the patent office's denial to grant a patent for Gleevec.
2) Novartis has filed lawsuit challenging the constitutional validity of Section 3 (d) and claiming that it violates TRIPS. Chennai High Court considered itself without jurisdictionand unfits to judge the conformity of national legislation with TRIPS, something which canbe done by WTO in response to member country complaint and denied unconstitutionality of Section 3 (d). For these reasons, lawsuit was dismissed in 2007. Subsequently, Switzerland informed it would not take complaint to Dispute Settlement Body of WTO. Novartis has however decided to continue to pursue the case in the ambit of Intellectual Property AppellateBoard and Supreme Court of India. Patent applications filed by other multinationals such as Roche were also denied. Novartis

[8] Available at: https://byjus.com/free-ias-prep/biotechnology-regulatory-authority-india/ Last seen on 3-8-2024.

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court cases should create jurisprudence with significant effects for our patent regime and production-pricing of medicines in country and abroad.

3) Indian companies asked Monsanto, the licensor to reduce their license fees as new price control policies were pursued by the State government. Indian companies the licensees stooped payment of royalties when Monsanto denied their request. In 2015 Monsanto filed an application for an injunction for trademark infringement and violation of registered patentwith a view of the termination of the agreement. Monsanto started the arbitrary procedure ofrecovering 400 corers from the licensees. Defendants alleged that the patent is in violation ofsection 3(j) of Indian Patent Act (1970) and claimed revocation of a patent u/s 64 of the sameAct. Section 3(j) states that plant and animal in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes forproduction or propagation of plant and animal; the said Section points out that biologicalprocesses for production or breeding by natural process unless it is microorganisms. Processis considered to be essentially biological if it is entirely natural phenomenon. However,Indian Patent Act (1970) doesn't define essentially biological process; Section-64 of the Actstates grounds for revocation of the patent. High Court stated that license terminated by Monsanto was reinstated; Indian companies were allowed to use the patented technology; the patent protection can't be enforced until the suit was disposed of and rejected all the claims.
4) Appeal in Supreme Court of India, the interpretation of the judgment was as under.
   a) Defendants (Naziveedu Seeds & Ors) claimed that there is no inventive step in plaintiff's (Monsanto) patent until artificial NAS is inserted into plant so that plant starts producing the delta-endotoxin which is toxic to the Bollworms.
   b) Defendants claim that there is no capability of industrial application of NAS except to become part of plant and to develop transgenic plant.
   c) Supreme Court states that will not define essentially biological product for now, we do not consider it necessary to deal with the same at this stage and leave open all questions of facts and law to be urged for consideration in appropriate proceedings.
   d) Section 64 of Indian Patent Act 1970 provides for revocation of the patent based on the counter-claim in suit. It presumes valid consideration of claims in the suit and counterclaimin accordance with the law and not summary adjudication. This section is available as a defense against an infringement action.
   e) Civil Procedure Code provides detailed procedure with regard to manner in which a

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suit instituted under Section-9, including counterclaim has to be considered and adjudicated.

f) Supreme Court was satisfied in facts and circumstances of the case that nature of the injunctive relief granted by the Single Judge of Delhi High Court was in order and merits, no interference during the pendency of the suit.

g) Supreme Court expresses that Division Bench should have confined itself to examination of the validity of the order of injunction granted by the learned Single Judge.

h) The order of Division Bench was set aside and the order of single Judge was restored and the suit was remanded to the Single Judge for disposal in accordance with the law.

6. CHALLENGES IN BIOTECHNOLOGY LEGISLATION

Despite the comprehensive legislative framework, several challenges remain in the regulation of biotechnology in India are given below.[9]

a) Coordination among regulatory bodies: Regulation of biotechnology involves multiple regulatory bodies, which can lead to overlap, confusion and delays in decision-making.

b) Public perception and acceptance: GMOs often faces public opposition due to concerns about safety and environmental impact which requires clear and transparent communication from the government and regulatory bodies.

c) Capacity building: There is need for continuous capacity building among regulatory bodies, researchers and industry stakeholders to keep up with rapid advancements.

d) Ethical and safety concerns: Use of biotechnology in human health and genetic modification raises ethical questions; there is need for robust ethical framework to guide research and application in these areas.

7. CONCLUSION

Indian legislation on biotechnology has evolved significantly over the past few decades, providing widespread framework to regulate this sector. Since this sector will continues to advance, it is essential for legislation to adapt and address new challenges. Ensuring coordination among regulatory bodies, addressing public concerns, building capacity and establishing strong ethical framework to be key to continued growth and safe application.

[9] Supra 7