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THE LEGAL LANDSCAPE OF BIOTECHNOLOGY: BETWEEN INNOVATION AND PROTECTION

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ABSTRACT

Biotechnology is rapidly moving forward from the laboratory to encompass every domain of human life-healthcare, agriculture, pharmaceuticals, environmental management and genetic research. But these innovations are not without various legal and ethical issues, which our conventional regulatory framework is yet to answer. In India, instead of a single statutory body, biotechnology is regulated by a framework including environmental legislation, patent law, biodiversity regulation, data-ownership law, pharmaceutical regulation and many other constitutional principles. This article explores the primary legal tensions arising from Biotechnology in India, with main focus on genetically modified organisms, intellectual property, biodiversity, targeted gene editing, informed consent and protection of human rights. It critically reviews the patent eligibility issues or the Patents Act, 1970 and the friction between the Patents Act and the Biological Diversity Act, 2002. There is a need for a comprehensive statutory framework which should be coherent, risk-based and rights oriented and will be capable of safeguarding constitution, sustainable environment and a fair distributive justice.

INTRODUCTION

The field of biotechnology is growing at a rapid pace and will prove to be a critical facet in national economy. Unlike conventional innovations, biotechnological advancement encompasses cellular and biochemical processes to manipulate life, living organisms and altering genetic blueprint. However, this rapid progress continuously faces the challenges of existing legal structure.

The legal challenge rests mainly on answering the questions related to: who should control it, who should benefit from it, who should hold the liabilities and the extent of limitations the constitution places upon us.

Consequently, Indian legal system must create a balance between capital-intensive research & strong intellectual property protections, and upholding public policy, biosafety standards, environmental preservation, and constitutional mandates like the Right to Health under **Article 21** of the Constitution of India.

The contemporary Indian legal ecosystem on biotechnology includes overlapping statutory regimes, judicial interpretation of statutory exclusions, and evolving specific guidelines.

PATENTIBILITY HURDLES UNDER THE PATENTS ACT, 1970

The innovations in biotechnology faces a crucial challenge relating to rules governing Patent eligibility.

The core challenge confronting biotechnological innovation in India lies within patent eligibility thresholds under the Patents Act, 1970 (as amended in 2002 and 2005). The international enforcements like TRIPS agreement endorses for a broader protection of biological inventions, but the Indian patent law provides stringent safeguard rules to prevent evergreen patents and domination over the essential biological processes. The Patents Act, 1970, particularly Section 3, establish matters excluded from patent protection.

Section 3(b) excludes inventions whose primary purpose or commercial exploitation would be contrary to public order, morality, or cause serious prejudice to human, animal or plant life or health.

Section 3 (c) prohibits patenting of ‘the mere discovery of a scientific principle or discovery of any living thing or non-living substance occurring in nature’.

Section 3(j) excludes ‘plants and animals in whole or any part thereof, including seeds, varieties, species, and essential biological processes for production or propagation of plants and animals’.

THE LIFE FORM DOCTRINE

The Indian Patent Office (IPO), prior to 2002, routinely denied patency claims to biological materials on the ground that life forms could not be considered as manufactured products. The landmark case of *Dimminaco A.G. v. Controller of Patents and Designs* (2002) marked the turning point, where the Calcutta High Court held that a process for preparing a live vaccine containing a live virus was patentable. It confirmed that the mere presence of an end-stage life form in the output process could not disqualify an invention from being a 'manner of manufacture', provided the product is commercially useful.

The 2002 amendment considered the microorganisms patentable under Section 3(j). However, Section 3(c) still acts as a barrier for patents on discoveries of living or non-living things found in nature. A natural bacterium or gene alone cannot be patented, but if it demonstrates any substantial human intervention, such as genetic modification, then the organism is patented as new properties not found in nature.

THE CONFLICT OVER AGRICULTURAL BIOTECHNOLOGY

The statutory limit under 3(j) of the Indian Patents Act was tested in *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* (2019). Monsanto held a patent on a nucleic acid sequence encoding the Cry2Ab toxin in Bollgard II cotton. After Indian seed companies stopped making payments, citing price controls, Monsanto sued for infringement. The Delhi High Court Division Bench held the patent void, reasoning that once the DNA is bred into hybrid seeds, it merges into the seed or plant part. The Supreme Court recognised the highly technical nature of the dispute and ensured that the matter to have proper adjudication, rather than resolution only through the preliminary proceedings.

In India, the Protection of Plant Varieties and Farmers' Rights Act, 2001 recognises farmers as breeders and protects the traditional rights to save, utilise, exchange and market farm-saved seeds. This system tries to balance breeder incentives with wider agricultural access and food security, making it a significant model in a country with small farmers in the agricultural sector.

The legal concern still remains unresolved – when biological innovation is commercialised, who should receive its benefits? Biotechnology cannot be guided exclusively through private

intellectual- property rights, legal recognition should also be furnished to farmers and other traditional communities.

BIODIVERSITY AND ACCESS TO GENETIC RESOURCES

In this biodiversity rich country like India, the corporate sectors freely take the genetic resources, develop commercial products and patent them without sharing benefits thus exploiting the local communities and source countries- this is known as Bio-piracy. Parallel to the patent regime operates the Biological Diversity Act, 2002 (BDA), which implement the principles under the UN Convention on Biological Diversity (CBD), 1992 and the Nagoya Protocol on Access and Benefit Sharing (2010). This aims to conserve biodiversity, ensure sustainable use and conferred fair benefit-sharing from biological resources and associated knowledge.

The key legal issues under the BDA:

- Any person or corporate establishment applying for IP rights within or outside India for a discovery related to a life form or traditional knowledge in India, must obtain prior approval from the National Biodiversity Authority (NBA)
- The framework guards against the unauthorised exploitation of indigenous biological materials without compensating the source communities and conservation efforts.
- The 2023 Amendment Act: the BDA (amendment), 2023 creates important compliance obligations for domestic AYUSH practitioners and streamlining the benefit-sharing mechanism.

BIOSAFETY AND ENVIRONMENTAL REGULATION

Biosafety, a sensitive area in biotechnology, includes the potential adverse effects of biological products related to plant, animal, human health and environment. The Genetically Modified organisms (GMOs) often cross-pollinate with wild relatives, affecting non-target species and result in herbicide resistant weeds, or irreversible alteration of the eco-system.

The legal landscape thus requires risk assessment, field trials, environmental clearance, monitoring, labelling and regular post- market surveillance. The precautionary regulations

become quite relevant when there is a risk of serious harm in the context of no certainty in the scientific theory.

Biosafety and GMOs in India are regulated by Rules for the Manufacture, Use, Import, Export, and Storage of hazardous Micro-organisms/Genetically Engineered Organisms or Cells, 1989, enacted under the Environment (protection) Act, 1986.

The 1989 Rules led to an elaborate, multi-layered statutory matrix:

1. Recombinant DNA Advisory Committee (RDAC) – Reviews national policy and scientific developments under the Department of Biotechnology (DBT).
2. Institutional Biosafety Committees (IBSC) – on-site monitoring of recombinant research and safety
3. Review Committee on Genetic Manipulation (RCGM) – Evaluates safety parameters for contained laboratory and small-scale field trials.
4. Genetic Engineering Appraisal Committee (GEAC) –apex regulatory body within the Ministry of Environment, Forest and Climate Change (MoEFCC), approve large-scale environmental releases and commercial cultivation
5. State and District level Biotechnology Coordination Committees (SBCC) for State and ground level enforcement monitors.

PRECAUTIONARY PRINCIPLE AND THE GM DEBATE

India has struggled to commercialize genetically modified crops. Even after the GEAC cleared Bt Brinjal in 2009 and transgenic mustard (DMH-11) more recently, government moratoria and long Supreme Court cases have blocked their farming.

Courts often depend on the Precautionary Principle and the Public Trust Doctrine, linked to Article 21's right to a healthy environment. Critics argue that safety tests must prove there are no long-term ecological harms, allergy risks, or accidental cross-pollination. In contrary, this approach is so cautious that it freezes regulation and slows farming progress.

In cases like *Gene Campaign v. Union of India*, the petitioners highlighted the urgent need for a dedicated, autonomous framework which will focus on transparency, independent

toxicological assessment, enough public opinions, as well as encourage commercialisation efforts.

In 2022, the Environment Ministry exempted certain genome-edited plants (SDN-1 and SDN-2) from the 1989 Rules, only if they carry no foreign DNA. The idea is that small, targeted genetic edits resemble natural mutations, separating precision gene editing from traditional transgenics.

BIOETHICS, CLINICAL TRIALS, AND HUMAN GENETIC TECHNOLOGIES

Beyond agriculture and patents, the field of biotechnology poses raises various questions on fundamental ethics and human-rights within the Indian legal landscape.

1. CLINICAL TRIALS AND THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019

The development of biologics, monoclonal antibodies, and advanced therapy medicinal products (ATMPs) requires intense scrutiny in human trials before approval, since they will be directly used in human beings. Historically, regulatory doctrines surrounding informed consent, adverse event compensation, trial approvals, manufacturing quality and post marketing risks suffered from significant compliance deficits, leading to Supreme Court interventions in cases like *Swasthya Adhikar Manch v. Union of India* (2013).

The New Drugs and Clinical Trials Rules, 2019 posed strict institutional ethics committee (IEC) registration, defined statutory compensation frameworks for trial-related injuries or deaths, and came up with distinct pathways for accelerated approvals of biologics and biosimilars.

2. REPRODUCTIVE TECHNOLOGIES AND SOMATIC VS. GERMLINE EDITING

Gene therapy and genome editing further add to the ongoing controversy. The Assisted Reproductive Technology (Regulation) Act, 2021 and the Surrogacy (Regulation) Act, 2021 set clear limits on the use of assisted reproductive technologies in India. At the same time, the

2019 National Guidelines for Gene Therapy Product Development and Clinical Trials, issued by ICMR and DBT, prohibit germline gene editing (alters genes which can be inherited by future generations) and reproductive cloning.

Somatic gene therapy, which changes cells in an individual, can be allowed with proper clinical approval in some jurisdictions. However, editing human embryos or zygotes for reproductive purposes is not allowed, to regulate the unsafe or unregulated use of CRISPR technology in human reproduction.

GENOMIC PRIVACY AND DATA PROTECTION

With rapid advancement in clinical research, genetic testing, large scale projects like Genome India Project are creating serious legal concerns related to genetic data security.

In 1951, John Hopkins Hospital harvested cervical cancer cells from Henrietta Lacks without her knowledge during her cancer therapy, which was legal at that time, but violates modern bio-ethical standards. The Lacks family filed a lawsuit against Thermo fisher Scientific in 2021, arguing that the company made huge profits in an unjust way selling a biological material taken without informed consent. This disclosure of the genetic data of Lack's descendants without consent sparked National Institute of Health to reform policies keeping a balance between research access and family privacy.

The **Digital Personal Data Protection Act (DPDP Act), 2023** makes it mandatory to get an explicit, informed, and revocable consent to process sensitive health and genetic data. Genetic data is especially risky as it discloses information not just about the individual, but also a detail about the blood line. Because genetic data is inherently non-anonymous—revealing immutable details not only about an individual but also about their biological relatives—it poses unique privacy risks. Insurers, employers or researchers could misuse them, thus violating the Right to Privacy under **Article 21** (K.S. Puttaswamy v. Union of India).

COMPARATIVE ASSESSMENT

The patent structure in the field of biotechnology is significantly stricter in India as compared to global standard. Section 3 excludes plants, animals and mere discoveries, whereas US and EU allow broader patents under utility and industrial applicability tests. Section 3(d) requires ‘significant therapeutic efficacy’ for pharmaceutical derivatives- a problem stricter than US law, as seen in the landmark Novartis case. India actively uses compulsory licensing (Natco, Bayer, etc), while US rarely exercises this statute. Both countries restrict human gene patents following Myriad and the EU Biotech Directive. Uniquely, India focuses on protecting its traditional knowledge through its Digital Library, while genetic data privacy regulations under the DPDP Act still remains less consolidated compared to GDPR.

STRUCTURAL REFORMS AND POLICY PATHWAYS

To establish a resilient, balanced legal architecture, India should focus on certain strategic reforms:

1. The IPO must set up more explicit, law binding guidelines to define that constitutes sufficient human intervention to overcome Section 3(c), avoiding inconsistent examiner-level rejections of advanced synthetic biologics.
2. A digitized, synchronized clearance system between the Controller General of Patents, Designs and Trade Marks (CGPDTM) and the National Biodiversity Authority should be implemented to prevent patentability delays while preserving access and benefit- sharing compliances.
3. A balanced mandatory licensing regime which can ensure affordable access to essential biological products without interfering on patent incentives.
4. The fragmented structure among MoEFCC, DBT, ICMR and MoA&FW should be revived with the help of unified Biotechnology Regulatory Authority of India (BRAI) into an independent, scientifically competent statutory authority.

CONCLUSION

Biotechnology has the potential to alter the way we live, but it is not without a range of social, legal and ethical concerns that need to be focussed upon. A collaborative link between biotech companies, regulatory bodies, governments and the public is required to address these issues, while developing new products and technologies. Encouraging innovations with strict supervision by regulatory bodies on biotechnology will promote equity, economic growth and

a sustainable environment. The public should always be informed and engaged in the process to ensure that their voices are heard and their issues are looked into seriously.

The key legal task is not to choose between science and regulation, but to design a resilient structure in which biotechnology can develop for the societal benefit and revolutionise the world soon.