



INTERNATIONAL LAW
JOURNAL

**WHITE BLACK
LEGAL LAW
JOURNAL
ISSN: 2581-
8503**

Peer - Reviewed & Refereed Journal

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

WWW.WHITEBLACKLEGAL.CO.IN

DISCLAIMER

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Editor-in-chief of White Black Legal – The Law Journal. The Editorial Team of White Black Legal holds the copyright to all articles contributed to this publication. The views expressed in this publication are purely personal opinions of the authors and do not reflect the views of the Editorial Team of White Black Legal. Though all efforts are made to ensure the accuracy and correctness of the information published, White Black Legal shall not be responsible for any errors caused due to oversight or otherwise.

WHITE BLACK
LEGAL

EDITORIAL TEAM

Raju Narayana Swamy (IAS) Indian Administrative Service officer



Dr. Raju Narayana Swamy popularly known as Kerala's Anti-Corruption Crusader is the All India Topper of the 1991 batch of the IAS and is currently posted as Principal Secretary to the Government of Kerala. He has earned many accolades as he hit against the political-bureaucrat corruption nexus in India. Dr Swamy holds a B.Tech in Computer Science and Engineering from the IIT Madras and a Ph. D. in Cyber Law from Gujarat National Law University. He also has an LLM (Pro) (with specialization in IPR) as well as three PG Diplomas from the National Law University, Delhi- one in Urban Environmental Management and Law, another in Environmental Law and Policy and a third one in Tourism and Environmental Law. He also holds a post-graduate diploma in IPR from the National Law School, Bengaluru and

a professional diploma in Public Procurement from the World Bank.

Dr. R. K. Upadhyay

Dr. R. K. Upadhyay is Registrar, University of Kota (Raj.), Dr Upadhyay obtained LLB, LLM degrees from Banaras Hindu University & PHD from university of Kota. He has successfully completed UGC sponsored M.R.P for the work in the Ares of the various prisoners reforms in the state of the Rajasthan.



Senior Editor

Dr. Neha Mishra



Dr. Neha Mishra is Associate Professor & Associate Dean (Scholarships) in Jindal Global Law School, OP Jindal Global University. She was awarded both her PhD degree and Associate Professor & Associate Dean M.A.; LL.B. (University of Delhi); LL.M.; PH.D. (NLSIU, Bangalore) LLM from National Law School of India University, Bengaluru; she did her LL.B. from Faculty of Law, Delhi University as well as M.A. and B.A. from Hindu College and DCAC from DU respectively. Neha has been a Visiting Fellow, School of Social Work, Michigan State University, 2016 and invited speaker Panelist at Global Conference, Whitney R. Harris World Law Institute, Washington University in St. Louis, 2015.

Ms. Sumiti Ahuja

Ms. Sumiti Ahuja, Assistant Professor, Faculty of Law, University of Delhi,

Ms. Sumiti Ahuja completed her LL.M. from the Indian Law Institute with specialization in Criminal Law and Corporate Law, and has over nine years of teaching experience. She has done her LL.B. from the Faculty of Law, University of Delhi. She is currently pursuing PH.D. in the area of Forensics and Law. Prior to joining the teaching profession, she has worked as Research Assistant for projects funded by different agencies of Govt. of India. She has developed various audio-video teaching modules under UGC e-PG Pathshala programme in the area of Criminology, under the aegis of an MHRD Project. Her areas of interest are Criminal Law, Law of Evidence, Interpretation of Statutes, and Clinical Legal Education.



Dr. Navtika Singh Nautiyal

Dr. Navtika Singh Nautiyal presently working as an Assistant Professor in School of law, Forensic Justice and Policy studies at National Forensic Sciences University, Gandhinagar, Gujarat. She has 9 years of Teaching and Research Experience. She has completed her Philosophy of Doctorate in 'Inter-country adoption laws from Uttarakhand University, Dehradun' and LLM from Indian Law Institute, New Delhi.

Dr. Rinu Saraswat



Associate Professor at School of Law, Apex University, Jaipur, M.A, LL.M, PH.D,

Dr. Rinu have 5 yrs of teaching experience in renowned institutions like Jagannath University and Apex University. Participated in more than 20 national and international seminars and conferences and 5 workshops and training programmes.

Dr. Nitesh Saraswat

E.MBA, LL.M, PH.D, PGDSAPM

Currently working as Assistant Professor at Law Centre II, Faculty of Law, University of Delhi. Dr. Nitesh have 14 years of Teaching, Administrative and research experience in Renowned Institutions like Amity University, Tata Institute of Social Sciences, Jai Narain Vyas University Jodhpur, Jagannath University and Nirma University. More than 25 Publications in renowned National and International Journals and has authored a Text book on CR.P.C and Juvenile Delinquency law.



Subhrajit Chanda



BBA. LL.B. (Hons.) (Amity University, Rajasthan); LL. M. (UPES, Dehradun) (Nottingham Trent University, UK); PH.D. Candidate (G.D. Goenka University)

Subhrajit did his LL.M. in Sports Law, from Nottingham Trent University of United Kingdoms, with international scholarship provided by university; he has also completed another LL.M. in Energy Law from University of Petroleum and Energy Studies, India. He did his B.B.A.LL.B. (Hons.) focussing on International Trade Law.

ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provide dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

BIOTECHNOLOGY INTERFACE WITH LAW¹

AUTHORED BY - DR. MUHAMMAD AAMIR KHAN

Abstract:

Biotechnology refers to the process of using biological systems, living organisms, or their components to create or produce various goods. In its most basic form, biotechnology refers to technology that is grounded in biology - it utilizes cellular and bimolecular processes to create technologies and products aimed at enhancing our lives and the well-being of our planet. For over years, we have leveraged the biological processes of microorganisms to produce beneficial food items, including bread and cheese, as well as to extend the shelf life of dairy products. When twentieth century is viewed in retrospect, it is likely that the assessment of its most significant development will concern science-the discovery of atom, nuclear fission, advent of Information Technology and elucidation of DNA, Inescapably genetics and technology has grown to respond to scientific advances far beyond human comprehension. Yet the outcomes of genetics are vital in our society.

Keywords – Biotechnology, Human Rights, Farmers Rights, Pharmaceuticals, Genetics

There has been enormous development in Biotechnology and modern biotechnology offers potential benefit to mankind including health-care and longer life with plenty of water and food. The biotechnology deals general with molecular biology and specifically with genetic engineering. The specific legal issues that arise in connection with genetics in context to the developing world specially with especial reference to India are–

- (i) How regulation can match the speed of fast moving genetic revolution;
- (ii) What effect it creates on human dignity and human rights;
- (iii) Should law condone intervention in human genome which alter genetics of future generations;
- (iv) What are the implications of these development for family law;
- (v) How will loss regarding IPR apply to genetic discoveries;

¹ By Dr.Mohammed Aamir Khan, Assistant Professor, MNLU,Mumbai

- (vi) Impact on insurance: In view of predictive doubts about insured's likely health prognosis:
- (vii) If human behavior is depended on their genes, will those circumstances be exculpatory or at least mitigate in criminal law;
- (viii) Combating serious illnesses and everyday threats confronting the developing world.

Different techniques are employed for the purpose of commercial exploitation, such as –

- (a) The selection of natural strains of organisms that possess desirable traits;
- (b) The creation of hybrids through the fusion of cells from diverse parental sources;
- (c) The application of chemicals and radiation to develop mutant strains or genetically modified plants, animals, and microorganisms aimed at producing specific phenotypic characteristics.

Biotechnology law in India is primarily governed by the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (1989), under the Environment (Protection) Act, 1986, which mandates safety in handling GE organisms. Key bodies like the Department of Biotechnology (DBT) and the Genetic Engineering Approval Committee (GEAC) regulate research and commercial applications, supported by other agencies like the Food Safety and Standards Authority of India (FSSAI) for food products and the Drugs Controller General of India (DCGI) for biopharmaceuticals. Policies like the BioE3 Policy (2024) also aim to promote the sector's economic and environmental growth.

"Ranging from 1989 rules on manufacture and use of genetically engineered organisms till the 2013 biotechnology supervisory authority of India bill, all the rules, regulations, guidelines, protocols, bills on biotechnology regulation in India have been discussed and analyzed. The institutional mechanism for regulation of biotechnology in India comprising of various technical, review, advisory and approval committees have been presented and appraised. Government of India approach towards biotechnology promotion, Parliaments concerns on biotechnology in agriculture, supreme court technical appraisal of biotechnology promotion and regulation have been debated and highlighted. The objective of the chapter was to present, analyze and highlight the existing and prospective regulatory mechanisms in India on biotechnology with its policy underpinnings from different organs of the government of India. The various piecemeal mechanism that India currently is having on the matters of

biotechnology regulation is analyzed in detail in this chapter. The infamous Biotechnology Regulatory Authority of India Bill, its concerns and the failures have been analyzed, and at the same time, certain other Bills such as DNA Profiling Bill have also been analyzed. At the outset, the author says regulatory spear on biotechnology in India, which is still at the nascent stage."²

There have been certain definitions like what is set out by the Organisation for Economic Cooperation and Development to be - "the application of scientific and Engineering principles to processing of materials by biological agents to produce food and services" and convention on biological diversity give its own definition. In the year 1989, India framed hazardous microorganisms rules to define biotechnology as to mean "the application of scientific and Engineering principle to the processing of materials by biological agents to produce goods and services".

The Biodiversity Act of 2002 establishes provisions for the conservation of biological diversity, the sustainable utilization of its components, and the equitable sharing of benefits derived from biological resources, along with other related matters. Also, the Act mandates the Central Government to implement measures aimed at regulating, managing, or controlling the risks linked to the use and release of living modified organisms resulting from biotechnology, which may adversely affect the conservation and sustainable use of biological diversity as well as human health.

The Plant Variety Protection and Farmers Right Act, 2001 grants plant breeders rights on new varieties of seeds for the very first time. It has provided farmers right to sell seeds. Breeders can create derived varieties only with express permission of the farmer involved in the conservation of such variety. Breeders are also required to declare that they are variety does not contain gene-use restricting technology or terminator technology.

There is a great need for regulating biotechnology either by licensing or by other regulation. In US millions of acres of soya, cotton and corn are planted with genetically modified plants.

Apart from agriculture biotechnology, in environmental sector too, the subject has been helpful

^{2 2} "Law relating to Biotechnology" (Book Review) Sreenivasulu N. S. Professor of the National University of Juridical Sciences, Kolkata, India

in providing products which are biodegradable or by the use of biopesticides which are environmental friendly. The advancement of commercial biotechnology, while offering solutions to global issues across various sectors, also presents certain challenges that carry both actual and potential risks to human health, plant life, and the environment. Concerns have been raised regarding the presence of unknown toxins, the emergence of antibiotic resistance, and the risk of genetic pollution. Additionally, there are apprehensions related to bio-colonialism and bio-piracy. Beyond the scientific and political implications of biotechnology, ethical and religious concerns are also prevalent. When unbridled development could cause chaos in the society, law should be responsive to the technology or changes that take place in the society or community.

India's biotechnology sector presents a multitude of opportunities for both domestic and international players, driven by its cost-effective infrastructure, skilled workforce, and significant market needs.

Opportunities in India's Biotechnology Sector

1. Drug Discovery and Development Partnerships: Foreign pharmaceutical companies are increasingly looking to partner with Indian counterparts, particularly in the early stages of drug discovery. This trend is fueled by the challenges large pharmaceutical companies face in conducting the entire drug discovery process in-house. India offers a more economical infrastructure for research and development, leading to the emergence of specialized Contract Research Organizations (CROs) focused on drug discovery services. These services primarily encompass:

Molecular biology

Bioinformatics

Genomics

Stem cell research

Furthermore, the clinical research and trials segment is projected to experience substantial growth in India over the next five years.³

2. Data and Software Development India offers significant opportunities in areas requiring extensive computing power, such as:

Data-mining

³ (Solanki et al., 2024; Sunil & Sameer, 2011, pp. 13–19).

Gene annotation

Development of software interfaces India's established supremacy in computing capabilities makes it an attractive hub for these activities.

3. Collaborative Models Foreign companies can engage with the Indian biotechnology landscape through various collaborative models, including:

Forming joint ventures with Indian companies.

Entering into technology transfer agreements.

Establishing strategic research partnerships with key research institutions.⁴

4. Addressing Public Health Needs: The Indian market provides a crucial opportunity for the production and sale of vaccines and therapeutics tailored to meet the healthcare needs of its large, economically diverse population.

5. Agricultural Biotechnology: Following the commercial release of the first genetically modified product, Bt Cotton, India is poised to approve other genetically modified crops in the near future, such as mustard, soybeans, corn, and potatoes. This indicates a growing market and regulatory acceptance for agricultural biotechnology innovations.⁵

These opportunities highlight India's potential as a global hub for biotechnology innovation, research, and manufacturing, particularly in pharmaceuticals and agriculture.⁶

India's biotechnology sector possesses a unique blend of strengths and weaknesses, supported by proactive government initiatives and a structured regulatory framework. Foreign entities looking to engage with this market have several established methods for doing business.

Strengths of India's Biotechnology Sector

India's biotechnology industry benefits from several inherent advantages:

Skilled Workforce and Knowledge Base: The country boasts a substantial pool of trained professionals and a strong academic foundation in scientific research.

Robust Research Infrastructure: A well-established network of research laboratories supports innovation and development.

Rich Biodiversity and Genetic Resources: India's diverse human gene pools offer significant opportunities for genomics research.

Developed Ancillary Industries: Strong foundational industries, such as pharmaceuticals and seeds, provide a supportive ecosystem for biotechnology.

⁴ (Farley & Rouse, 2000, pp. 133–141).

⁵ (Prakash, 1990, pp. 789–794; Shikha et al., 2024)

⁶ (Kumar & Srivastava, 2012; Parmar, 2005, pp. 61–66).

Access to Global Intellectual Resources: The intellectual contributions of Non-Resident Indians (NRIs) in this field further enhance the sector's capabilities.

Extensive Clinical Research Opportunities: India offers a vast and diverse patient population, making it an attractive location for clinical trials and research.

Weaknesses of India's Biotechnology Sector

Despite its strengths, the sector faces certain challenges:

Limited Venture Capital: A notable lack of venture capital funding can hinder the growth of new biotechnology ventures.

Low R&D Expenditure by Industry: The industry's relatively low investment in research and development compared to global standards can impede innovation.

Steps Taken by the Indian Government

The Indian government has actively promoted the biotechnology sector through various initiatives:

International Cooperation: The central government has forged numerous biotechnology cooperation agreements with other countries to stimulate growth.

State-Specific Policies: Several state governments, including Karnataka, Tamil Nadu, Andhra Pradesh, and Maharashtra, have introduced their own biotechnology policies. These policies often involve:

Announcing dedicated Biotechnology Policies for their states.

Establishing expert Task Forces to provide guidance on policy matters.

Setting up exclusive Biotechnology Parks, with a focus on agricultural and health biotechnology.

Emergence of Hubs: Cities like Bangalore in Karnataka, already known as India's IT capital, are rapidly becoming major hubs for the biotechnology industry.

Key Methods for Doing Business in India

Foreign companies considering entry into the Indian market have several options, depending on their business volume, nature of products (e.g., active pharmaceutical ingredients, generic bulk drugs, or finished pharma products), market potential, and long-term strategy:

Appointing a Distributor: This is often the most straightforward entry option, requiring minimal resource commitment. The success of this approach heavily relies on selecting the right exclusive indenting agent or distributor, which is a common arrangement for industrial

products.

Opening a Liaison Office: A liaison office can undertake market development activities but is not permitted to conduct any business transactions. Its expenses must be covered by inward remittances from the foreign Head Office. Approval from the Reserve Bank of India (RBI) is required.

Opening a Branch Office: Foreign companies involved in manufacturing and trading abroad can establish a branch office in India to engage in buying and selling activities. These offices can also provide technical support and professional consultancy services but are prohibited from manufacturing. RBI permission is necessary.

Joint Venture/Wholly Owned Subsidiary: Foreign companies can establish operations by incorporating a company under the Indian Companies Act (1956), either as a joint venture with an Indian partner or as a wholly-owned subsidiary.

Regulatory Framework in India

The biotechnology sector in India is governed by a structured regulatory framework:

Department of Biotechnology (DBT): Under the Ministry of Science and Technology, the DBT serves as the nodal agency responsible for policy formulation, promotion of R&D, international cooperation, and manufacturing activities in biotechnology.

Genetic Engineering Appraisal Committee (GEAC): Constituted under the Ministry of Environment and Forests (MoEF), the GEAC is the primary regulatory body for biotechnology in India.

Specialized Committees: Several committees with statutory authority have been established under the DBT and MoEF to regulate activities involving the handling, manufacture, storage, testing, and release of genetically modified materials. These committees are primarily staffed by members from the scientific community and personnel from DBT and MoEF, with DBT appointing the members.

Key Regulatory Committees:

Institutional Biosafety Committees (IBSC): Responsible for implementing guidelines at the local level.

Review Committee on Genetic Manipulations (RCGM): Responsible for issuing permits for genetic manipulations.

GEAC: Oversees the large-scale and commercial use of transgenic materials and is supported by State Biotechnology Coordination Committees (SBCC) and District Level Committees

(DLC).

Important Case Laws on Biotechnology

Case laws play a crucial role in shaping the legal and regulatory landscape of biotechnology, particularly concerning intellectual property, ethical considerations, and public health. These legal precedents help define the boundaries of innovation, ownership, and responsibility within this rapidly evolving field.

Here are some important case laws and incidents related to biotechnology:

1. John Moore v. Regents of the University of California (1990)⁷

"This landmark case is recognized as one of the first international legal battles concerning the patenting of human genetic material. The case brought to light significant medico-legal problems arising from the utilization of human body parts for experiments and transplants, which are integral to the development of medicine and biotechnology. While the case did not yield conclusive decisions on all key legal issues, it underscored the importance of the doctrine of informed consent in biomedical research involving human subjects and the broader role of bioethics in biotechnology research and patenting, according to international law. The re-examination of this case from Indian and international perspectives emphasizes the urgent need for specific legislation in this area."

2. Lawsuits Regarding Patents on Breast Cancer Genes (Association for Molecular Pathology v. Myriad Genetics)

"Research papers indicate that a U.S. court allowed a lawsuit to proceed against the U.S. Patent Office and a biotechnology company concerning the legality of patents awarded for two breast cancer genes. Scientists argued that these patents were illegal and hindered research (Lenzer, 2009). This situation highlights the contentious debate over whether naturally occurring human genes can be patented, a debate that has significant implications for genetic research, diagnostics, and the broader biotechnology industry".

3. The Harvard Mouse Patent Case in Canada⁸

"This case involved a significant Appeal Division decision in Canada that provided important legal arguments in favor of granting patent protection for advanced biotechnology. The decision and the preceding legal processes were also evaluated for their similarities to decisions concerning biotechnology patents in the United States, indicating a cross-jurisdictional impact

⁷ (Narayanan, 2010, pp. 82–89).

⁸ (Kamber, 2003, p. 761).

on patent law for biotechnological inventions"

4. *Impact of Case Law on Patentability of "Laws of Nature"*⁹

"Beyond specific cases, the broader body of case law has increasingly narrowed the scope of patentability for products based on "laws of nature." This development has made it more challenging to patent and license certain biotechnology products, influencing the strategies of academic medical centers and technology transfer organizations in engaging industry partners. The need for novel collaborative models that focus on early drug discovery, data exchange, and clinical trial validation has become more pronounced due to these legal shifts".

5. *Changchun Changsheng Biotechnology Vaccine Incident (China)*¹⁰

"This incident, while not a traditional court case establishing legal precedent on biotechnology per se, represents a critical legal and regulatory event concerning public health liability within the biotechnology sector. In this case, a tort debtor (Changchun Changsheng Biotechnology) entered bankruptcy proceedings while tort claims related to a vaccine incident were being settled. The Chinese government intervened by requiring the company to establish a special compensation fund to protect the rights and interests of tort creditors, as existing bankruptcy law did not adequately prioritize these claims. This approach, which is likely to be codified into law, serves as a reference for handling public health liabilities involving biotechnology companies and highlights the challenges of ensuring public safety and accountability in this industry".

Now, biotechnology is also entering the field of Pharmaceuticals are reducing different kinds of therapies by using bio-scientific techniques. Thus, all these need for regulating the same. But the question is how does one regulate biotechnology to protect human life and plants and animals for human consumption or or thread to environment and the manner in which one can achieve balance and socio-economic interest or establish ethical boundaries for manipulating life. There has been certain protocol established in 1992 by the UN on biological diversity, the objective of which is to contribute insuring and educate level of protection in the field of safe transfer, handling and use of Living Modified Organisms (LMO) resulting from Modern bio technology that may have adverse effects on the conservation and sustainable use of biological diversity taking also into account risk to human life and specifically focusing on trans boundary movements.

⁹ (Silva & Ramos, 2018).

¹⁰ (Huang, 2022).

Development in biotechnology like any other branch of science brings both good and evil because of its wide range of applications affecting many areas. Therefore, bio safety measures assume significance. Bio-safety measures may regulate trans- boundary and national movement of such products. At the international level, the Bio-safety protocol governs the trans-boundary movements. Even though Bio-safety Protocol and the Indian Hazardous Microorganisms Rules aim at regulating Genetically Modified Organisms (GMOs), there are some facts that undermine their effectiveness. The protocol covers only living modified my living modified organisms and its application is limited only to the effects of LMOs on conservation of biological diversity. All pharmaceuticals are excluded from the purview of the Protocol. The Indian rules covers GMOS, Pharmaceuticals who disturbed food stuff etc., the primary object being to protect environment, nature and health and not a regulating biotechnology and biotechnology products. Regulating biotechnology is a complex and challenging endeavor due to the numerous socio-economic factors involved. Various social and economic questions arise, such as the right to development, intergenerational equity, the rights of indigenous peoples, farmers' rights, environmental protection, and ethical and moral considerations. Efforts to regulate biotechnology may ultimately lead to addressing these broader global socio-economic issues. The true challenge of regulating biotechnology can become obscured by the multitude of indirect questions that are only tangentially related to the field. Until a comprehensive legal framework for biotechnology regulation is established, biosafety measures will serve as a valuable tool in this regulatory process.

WHITE BLACK
LEGAL