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# Biotechnology and IP Protection: The Indian Approach to Balance Innovation, Ethics and Public Interest

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The evolution of biotechnology has led to significant advancements in healthcare, agriculture, and environmental science, which in turn have made the landscape of intellectual property rights (IPR) increasingly complex, particularly in the realm of patent law. This research critically explores how patent law in India has adapted to the rise of new biotechnologies, focusing on issues such as patent eligibility, the encouragement of innovation, and ethical considerations. The study advocates for a revised legal framework in India that addresses the challenges of emerging biotechnologies leading to the creation of new varieties of plants, while protecting public interests. By proposing a balanced approach that promotes both innovation and public welfare, this research aims to offer a comprehensive understanding of the legal and ethical challenges at the intersection of biotechnology and patent law in India.

**Keywords:** Agriculture, Biotechnology, Environment, IPRs, Plant Breeders' Rights, Patents

Several efforts at comprehending the ways to give protection to newly developed varieties of plants by plant breeders across the globe have come to light from time to time. Many nations have come forward to present their interest in extending protection to these novel fruits of intellectual efforts involved behind the biotechnological interference in the genetic makeup of plants. It has been seen that some nations chose to move towards the UPOV system for using it as a blueprint for formulating their national legislations, while others followed the path directed by the TRIPs Agreement.[1] On one hand, the UPOV Convention with its four versions emphasizes greatly upon the need to protect Plant Breeders' Rights (PBRs), TRIPs Agreement, on the other hand, provides three options to the members under its Article 27.3(b), *i.e.*, either to opt for patent protection or to create their own system to protect plant varieties or to take the option of a combination of both these approaches. However, the focus of this article is not the 'rights' granted by the nations under their domestic legislations, rather it is to see how India, a signatory to the TRIPs Agreement, has established a legal framework to balance the delicate relationship between biotechnology, plant breeding and IP protection in India.

Biotechnology has advanced rapidly, leading to some game-changing advancements in healthcare, agriculture, and environmental protection. The progress of genetic engineering, gene editing technologies, and a greater understanding of molecular biology has paved the way for significant advances in these fields. By allowing the manufacturing of recombinant proteins, monoclonal antibodies, and gene therapies, it has revolutionised medicines in healthcare. Also now reality are methods like those of precision medicine based on a person's genetic composition. In farming, it has produced genetically modified (GM) crops with desired traits and raised agricultural output, so supporting food security. Additionally helping with environmental solutions are bioremediation methods and biofuels made from biomass and algae. The unique qualities of biotechnological innovations as well as the interactions among several forms of IPRs produce a complex terrain. Evaluating patentability criteria becomes challenging in biotechnological breakthroughs since they often combine genetic sequences, gene editing techniques, and complex biological processes. Beyond patents, the field of IPRs in biotechnology includes PBRs, data exclusivity, and trade secrets, which demand for research on their interaction. Though efforts at harmonization—like the TRIPS Agreement—try to offer a consistent framework for IP protection, national laws still vary to some extent. Responding to developing biotechnologies by addressing patent law

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issues calls for constant legal framework adaptation. These concepts raise questions regarding access to genetic resources and healthcare as well as standard patentability rules and disclosure requirements. Further complicating matters ethically and socially are the results of biotechnological innovations. Thus, it is important to balance ethical issues with the necessity to boost innovation by means of biotechnological innovations and access to them. Influencing the direction of patent law in response to new biotechnologies depends on cooperation among stakeholders.

## Methodology

To better grasp the complicated nature of this field of research, the researchers examined the body of current literature on these subjects including scientific papers, past rulings rendered by Indian courts, and books on biotechnological discoveries and patents. To this aim, an effort has also been taken to understand the law as it is implemented in the nation. Consequently, the approach applied has doctrinal character. After a thorough review, researchers determined that the legal system had to be modified to take into account the peculiarities of the growing biotechnologies. On this basis, specific amendments to the Indian Patent Act of 1970 are recommended. These recommended changes also aim to strike a balance between supporting creativity and ensuring reasonably accessible biotechnological innovations.

## Analysis

### The Patentability of Biotechnological Inventions

The process of deciding whether biotechnological inventions are patentable presents a number of challenges. This entails evaluating the novelty, non-obviousness, and utility (NNoU) of biotechnological innovations, which sometimes provide unique challenges because of their multifaceted character and fast development. For example, establishing novelty in biotechnology can be difficult given the abundance of already known genetic data and the swift rate of scientific development.[2] Questions arise regarding the patentability of naturally occurring biological materials, genetic sequences, and modified forms of known substances.[3] Thorough understanding of the prior art and existing knowledge boundaries is therefore, necessary.

*Another instance* is the assessment of non-obviousness of an invention. This can be difficult in biotechnological innovations since the field is interdisciplinary and several scientific disciplines converge there. Combining biological components with other technologies, such computer algorithms or nanotechnology, could provide special difficulties assessing creativity. Additionally, determining non-obviousness requires careful review of the past works as well as the degree of technical mastery and knowledge in the pertinent field.[4]

Demonstrating value in such innovations which often entails tying them to possible advantages in environmental conservation, agriculture, or healthcare can present another difficulty. But determining the degree of utility needed for patentability particularly in developing fields like gene therapies or regenerative medicine can be difficult. Thus, experimental data from biological tests or clinical trials are absolutely required.[5]

Another contentious issue has been whether biological materials including cells, proteins, and genes are patentable. Further difficulties arise in distinguishing between naturally occurring biological materials and their isolated or purified forms as well as in deciding the degree of human involvement needed for patent eligibility. Globally, the issue of patentability of biotechnological innovations is a highly intriguing one; many countries have taken different approaches to handle this challenging issue.[6] In the United States, biotechnological inventions are generally considered patentable subject matter if they meet the criteria of NNoU.[7] Landmark cases such as *Diamond* v *Chakrabarty* (1980)[8] have played a crucial role in determining the patentability of living organisms and GMOs (Genetically Modified Organisms) in the U.S. In the European Union, governed by the European Patent Convention[9] and assessed by the European Patent Office[10] and in Australia[11], biotechnological inventions are subject to specific requirements, including NNoU criterion. Canada determines the patentability of biotechnological inventions based on the criteria of NNoU[12], with higher life forms being excluded from patentability.[13] Some jurisdictions have embraced a broad approach to patenting biotechnology, while others have placed certain limitations, such as excluding the patenting of higher life forms. These differences reflect the diverse perspectives and policy considerations of each country, balancing the promotion of innovation with access to biological resources and healthcare.

Developing a thorough framework for patenting biotechnological inventions depends on an awareness of these complexities including NNoU and patent eligibility of biological materials. These factors affect current debates and biotechnology policy on patentability.

Several landmark cases have significantly influenced the patentability of biotechnological inventions in India. In the *Novartis AG* v *Union of India* (2013)[14] case, the Supreme Court denied a patent for the cancer drug imatinib mesylate, establishing the requirement of enhanced efficacy for patent eligibility. *Ferid Allani* v *Union of India* (2014)[15] addressed the patentability of GM organisms, emphasizing that GMOs could be patented based on their characteristics and novelty. The *Monsanto Technology LLC* v *Nuziveedu Seeds Ltd.* (2018)[16] case dealt with patent infringement in the biotechnology sector, highlighting the need for evidence to determine patent validity. *Monsanto Technology LLC* v *Cefetra BV* (2019)[17] addressed the enforcement of biotechnological patents concerning importation and international trade. These cases contribute to the evolving jurisprudence surrounding biotechnological patents in India by determining the demarcation between PVP and patents and highlighting the challenges that inventors and farmers face, enforcing biotech innovations while protecting farmers' rights.

**Role of Patents in Promoting Innovation**

According to certain research findings, patents offer incentives for biotech businesses to spend on R&D and enable the creation and marketing of novel biotechnological goods. For the biotechnology industry, for instance, a study (Arora et al., 2016) revealed a favourable link between patenting and R&D spending.[18]

Patents have had a significant impact on biotechnological innovation, as demonstrated by notable case studies. One such case study is the development of recombinant DNA technology, where patents incentivised the pioneering work of Cohen and Boyer, leading to the creation of the first genetically engineered organism and the establishment of Genentech as a biotechnology company.[19] Another case study relates to the CRISPR-Cas9 gene-editing technology, in which R&D in this domain was greatly incentivised by patents awarded to the Broad Institute and the University of California, Berkeley. The patent conflict among these organisations underlined the significance of patents in allocating rights and deciding ownership of ground-breaking biotechnological discoveries.[20] The effectiveness of patent protection in promoting advancements in biotechnology is an ongoing subject of evaluation. Supporters argue that patents incentivise R&D investments, enable technology transfer, and facilitate the commercialisation of biotechnological innovations. They assert that patents provide a return on investment and encourage collaboration between academia and industry.[21] Critics, however, raise concerns about monopolies, limited access to essential technologies, and hindrance to knowledge diffusion. They argue that patent thickets and high litigation costs discourage small innovators, limit competition, and impede cumulative innovation.[22]

Research shows that patents play a significant role in incentivising R&D investments and the development of new therapeutic treatments in the pharmaceutical industry.[23] However, balancing exclusive rights with knowledge dissemination and access is crucial for cultivating a dynamic and innovative biotechnology ecosystem. Patent protection should consider the specificities of the biotechnology sector and the broader goals of promoting innovation, access to technology, and public welfare.

***Limitations in the Context of Biotechnological Inventions***

Small innovators face difficulties and the diffusion of biotechnological innovations is hampered by the often expensive and time-consuming patenting process for biotech discoveries. Complex and overlapping patents can lead to patent thickets that impede innovation and provide entrance obstacles.[24] Furthermore limiting competitiveness are blocking patents owned by non-developers.

Notwithstanding these restrictions, patents encourage creativity, defend inventors' rights, and propel biotechnology's development—benefiting many disciplines including health, food, energy, and the environment. Promoting biotechnological advancement depends on careful balancing patent protection with accessibility and competitiveness.[25]

In the context of biotechnological inventions, the influence of patents on access to healthcare, agriculture, and the environment is a major problem. Due to patent monopolies, patents on pharmaceutical items and medical treatments can limit access to cheap medications, particularly in developing nations. This emphasises the difficulty of juggling innovation

incentives with healthcare access since it reduces patient access to life-saving medications and necessary treatments.[26] Small-scale farmers and agricultural biodiversity can be impacted by patents on GM crops and agricultural biotechnology affecting farmers' access to seeds and so hindering the saving and trade of seeds. The patent system must balance safeguarding of inventors' rights with guaranteeing availability of agricultural innovations for sustainable food generation.[27] Furthermore, patents on biotechnological innovations including genetically modified organisms could concentrate ownership and control over agricultural resources, so influencing the long-term viability of agricultural methods, biodiversity, and the state of ecosystems.[28] In the field of biotechnological developments, addressing these issues and striking a balance between patent protection and accessibility is absolutely vital.

To address the limitations and challenges posed by patents in the context of biotechnological inventions, various mechanisms have been considered like compulsory licensing[29], establishment of patent pools[30], non-assertion pledges[31], Research exemptions and fair use provisions. These mechanisms offer potential solutions to address the limitations and challenges posed by patents in the biotechnological context.

***Ethical and Social Concerns in Biotechnological Inventions***

Biotechnological inventions raise important ethical considerations that require careful examination. Some key ethical concerns are herein discussed.

Genetic manipulation or modification of human embryos and germline cells through biotechnological inventions raise questions about the inherent dignity and moral status of human beings. This includes concerns about the manipulation of human genetic material and the potential for creating designer babies, which challenges our understanding of human nature and the boundaries of intervention in the natural order.[32]

In biotechnology research and innovation, informed consent is a fundamental ethical principle. It is crucial to ensure that individuals are fully informed about the potential risks, benefits, and implications of participating in biotechnological interventions. Respecting individual autonomy and allowing informed decision-making regarding genetic information and biotechnological interventions is essential.[33] The advent of biotechnological inventions and the patentability of such innovations have significant social implications as well. Firstly, access to healthcare is a major concern, especially in developing countries, as patented biotechnological inventions, particularly in the pharmaceutical field, can lead to high prices for essential medicines. This can create disparities in access to healthcare and worsen existing healthcare inequalities.[34] Secondly, the patent system can impede affordability and hinder the availability of affordable biotechnological innovations. High licensing fees and royalties associated with patented technologies can limit research, development, and implementation of new treatments, restricting their reach to those who can afford them. Lastly, biotechnological inventions can raise concerns about equality and fair distribution of benefits. Patent protection can result in monopolies and concentration of economic power, potentially limiting access to innovations and exacerbating socio-economic disparities. Ethical principles of justice and fairness should be considered in the development and distribution of biotechnological inventions.

In the Indian context, ethical frameworks play a crucial role in guiding the assessment and regulation of biotechnological inventions. Several relevant ethical frameworks and principles are applicable in this context. Firstly, the principles of autonomy, beneficence, non-maleficence, and justice, as outlined in the Belmont Report, provide a foundation for ethical decision-making in biotechnology. These principles emphasize respecting individual autonomy, promoting well-being, minimizing harm, and ensuring fairness in the distribution of benefits and burdens.[35] Secondly, the Indian Council of Medical Research (ICMR) has developed comprehensive ethical guidelines that specifically address ethical considerations in biotechnological research and clinical practice in India. These guidelines cover important aspects such as informed consent, privacy and confidentiality, genetic research, and the involvement of vulnerable populations.[36]

Additionally, the socio-cultural ethical perspectives in India need to be considered, given the country's diverse cultural values. The principle of "lokasamgraha," rooted in Indian traditions, emphasizes collective well-being and the need to balance individual rights with societal interests.[37]

The application of the ethical frameworks in the Indian context requires an inclusive and participatory approach involving stakeholders such as scientists,

ethicists, policymakers, and the public. It is important to engage in a dialogue that reflects the values, cultural diversity, and societal aspirations of the Indian population to ensure that ethical considerations are adequately addressed in the patentability and regulation of biotechnological inventions.

**Challenges in India**

In the context of biotechnological inventions, India faces many challenges. The first one being 'access to healthcare' as a large portion of the population lacks affordable healthcare options.[38]

Since the patented biotechnological inventions, especially pharmaceutical products, are available at really high costs and thus create barriers to access for economically disadvantaged individuals. This further exacerbates existing healthcare disparities in the country.[39]

Second of these challenges is striking a balance between incentivizing innovation through patent protection and ensuring access to affordable medicines remains a complex task. (*Public interest* v *private rights*).[40]

Since the Novartis AG case, India has taken measures to balance public health concerns with patent protection.

S.3(d) of the Indian Patents Act provides stronger patentability standards for pharmaceutical discoveries, limiting small improvements from being patented and facilitating access to inexpensive generic drugs. Furthermore, the Act includes provisions for compulsory licencing (S.92), which allow the government to give licences to third parties to produce and sell patented items without the patent holder's approval under specific situations.[41] Voluntary licensing, technology transfer agreements, and health-related patent examination guidelines are other aspects of India's approach to striking a balance between public health and patent protection.[42]

India's dedication to public health and inexpensive medication is shown in its efforts to assure the supply of critical medicines and encourage market competition. The government recognises the necessity for intellectual property rights to stimulate innovation, but it equally recognises the need to make healthcare accessible and cheap to its citizens. With new developments in the field of biotechnology, several new ways of improving the available pool of resources and facilities have come up like Gene Editing[43] and Biopharming.[44]

The CRISPR/Cas9 system[45] in particular, has revolutionised biotechnology by allowing precise changes to an organism's genetic material. Gene editing has the potential to help agricultural development initiatives, increase crop yield, and solve food and nutrition security concerns in India. It is seen as a significant instrument for addressing the rising needs of a growing population and adjusting to the effects of climate change on agriculture.

S.3(c) of India's Patents Act reflects the country's position on gene editing technology within the IP regime. The law restricts the patentability of natural discoveries of living or non-living entities. The Manual of Patent Office Practice and Procedure, 2005, states that GM gene sequences and amino acid sequences can be patented if they meet certain criteria, including novelty, inventive step, industrial applicability, and substantial human intervention.

In addition, to keep up with worldwide biotechnology advancements, the Indian Patent Office published the Indian Biotechnology Guidelines in 2013. According to these standards, a recombinant gene with an innovative step and an industrial application is patent eligible. The rules do not expressly need the considerable human intervention criterion indicated in the Manual of Patent Office Practise and Procedure, 2005.

Gene patenting is believed to affect even the traditional practices of Indian farmers in creating, conserving, exchanging, and utilizing genetic diversity. It is further believed that the granting of gene patents to agro-biotech companies outside India can provide advantages to those companies while potentially disadvantaging Indian farmers and communities.

In India, biopharming has the potential to improve healthcare access, particularly in rural regions, while also contributing to the country's pharmaceutical sector. However, it is critical to address the regulatory, safety, and ethical concerns that come with biopharming. Some aspects of the current legal framework, such as narrow patentability standards, a prohibitive filing fee for sequence listings, onerous requirements (for example, mandatory disclosure of the source and geographical origin of biological material), and the requirement of prior approval from the National Biodiversity Authority (NBA), have hampered optimal growth in the biotech space.[46]

In addition, S.3(c)[47] states that the "discovery of any living thing or non-living substances occurring in

nature" is not considered “patentable subject matter”. This provision affects the patentability of isolated substances, such as isolated proteins, as they are considered mere discoveries of naturally occurring substances and are thus excluded from patentability. Additionally, S.3(d) poses challenges for patentability by requiring that modifications of existing substances yield a "new form of a known substance" exhibiting "enhancement of the known efficacy". The interpretation and application of S.3(d) in biotech inventions are still evolving. S.3(d) seeks to prohibit the granting of "secondary" pharmaceutical patents, such as those for novel versions of existing compounds and medications. According to previous study, "S.3(d) was initially underutilised by the Indian Patent Office.[48] However, the usage of S.3(d), including on the main claims of patent applications, has increased significantly over time, albeit it is still employed in conjunction with other sorts of patentability objections. Concerns have been expressed concerning the rising use of S.3(d) against main patent applications.[49]

The government, scientific institutions, and regulatory bodies are actively working towards developing guidelines and regulations to govern the development and deployment of biotechnological innovations.[49]

The existing regulations governing crops developed using biotechnology, including gene editing, are being examined to ensure their applicability, safety, and adherence to national and international standards. The acceptance and success of gene editing and biopharming in India depend on various factors, including political will, societal acceptance, economic viability, retailer and consumer acceptance, and scientific advancements.

Despite these challenges, a unique Gene Editing attempt is being made in India by researchers including Debojyoti Chakraborty and his colleagues at the CSIR-Institute of Genomics and Integrative Biology in Delhi for the Sickle Cell Anaemia Treatment. They aim to develop gene-editing techniques, including CRISPR, for the treatment of genetic disorders.[50]

Another notable example of gene editing research in India is the work done by scientists at the Institute of Genomics and Integrative Biology (IGIB) in New Delhi who have successfully used the CRISPR/Cas9 system to edit the genome of mosquitoes, aiming to control the spread of mosquito-borne diseases such as dengue and malaria.[51]

Gene editing, particularly using the CRISPR/Cas9 system, has emerged as a powerful tool for precise and efficient modification of the genome. This technology allows scientists to make targeted changes to the DNA sequence, offering immense potential in various applications. In India, researchers and institutions have actively contributed to the development of gene editing techniques and their applications. *For instance*, in response to the COVID-19 pandemic, Indian scientists developed a CRISPR-based diagnostic test called FELUDA. It utilizes gene-editing technology to detect the presence of the coronavirus with high accuracy and sensitivity.[50]

Biopharming involves using plants as bioreactors to produce valuable pharmaceutical products. In India, there have been efforts to explore the use of GM plants for biopharming purposes. These plants can be engineered to produce therapeutic proteins, vaccines, and other pharmaceutical substances.[52] *For instance*, researchers at the National Institute of Plant Genome Research (NIPGR) in New Delhi have been working on developing GM plants to produce therapeutic proteins. They have successfully engineered tobacco plants to produce a vaccine candidate for hepatitis B.[53] This demonstrates the potential of biopharming in India for affordable and accessible production of important biologics. However, it is worth noting that the patentability of biotechnological inventions, especially gene editing techniques, can be complex and subject to interpretation. The Indian Patent Office and courts have dealt with several cases related to biotech patents, including those involving gene sequences and GMOs.

In recent years, India's IP law has seen developments to address the evolving landscape of biotechnology and gene editing. The guidelines and decisions by patent authorities and courts have provided clarity on the patentability of biotechnological inventions, including genes and GMOs. *For instance*, in 2013, the Indian Supreme Court clarified that naturally occurring gene sequences without specific applications are not patentable. However, if a gene sequence is isolated, purified, and has industrial applications, it may be eligible for patent protection.[54]

India's IP law adapts to biotechnological advancements, offering protection for gene editing and biopharming. Patent authorities and court decisions clarify guidelines, promoting innovation.

Challenges remain, such as unclear patentability criteria, lengthy prosecution, and data exclusivity in the growing biotech industry. Various biotechnological inventions, including GM crops, stem cell research, biosimilars, nanotechnology applications, biomarkers, vaccines, agricultural biotech, and animal innovations, encounter legal challenges in patentability and regulatory approval.[55]

**Updating the Legal Frameworks in India**

India's biotechnological advancements require an updated legal framework with stakeholder engagement to strike a balance between innovation and public interest. Regular monitoring would assess effectiveness, responding to dynamic biotech advancements. With this, India can build an environment supporting innovation, equitable healthcare access, and safeguard public health. Current issues in Indian Patent law pose hurdles for biotechnological inventions. The patentability criteria, particularly the restrictive interpretations of non-patentable subject matter under Ss. 3(b), (c), (d), (e), (h), (i), (j), and (p) create uncertainty and inconsistency, impeding the progress and protection of innovative biotechnological inventions. Section 3(d) poses further challenges for biotechnological innovations, as the interpretation of "enhanced efficacy" remains ambiguous and subjective, potentially obstructing novel biotechnological creations. Meeting the disclosure requirements under Section 8 proves challenging for biotechnological inventions due to their complex nature. Demanding extensive information, including foreign filings and experimental data, at the time of filing can be impractical and hinder disclosure. Moreover, the time-consuming examination process delays patent grants and obstructs the timely protection and commercialisation of innovative biotechnological solutions. Additionally, the absence of specific data exclusivity provisions in the Indian Patent law, particularly in the pharmaceutical and biopharmaceutical sectors, can discourage investment in R&D of innovative biotechnological products, hindering progress and market introduction.

Given the evolving intersection between biotechnology and IP law in India, it is crucial to undertake several legislative amendments to address the current challenges. There is an urgent need to revise Section 3(b) of the Patent Act to provide a clearer definition of what constitutes inventions that are "contrary to public order or morality" and those that "cause serious prejudice to human, animal, or plant life or health or to the environment," particularly in the context of biotechnological innovations. An *explanation* to that effect may be inserted within the provision itself. This clarification would potentially help delineate the boundaries of patent eligibility more effectively.

Similarly, Section 3(d) requires a more precise interpretation to prevent undue restrictions on the patentability of incremental or secondary biotechnological inventions. By refining this section, India can better support innovation in the field without stifling valuable advancements due to overly stringent criteria.

The language in Section 3(j) also needs to be amended to address the ambiguities surrounding the patentability of biotechnological inventions, including microorganisms, plants, seeds, varieties, and species. Introducing a proviso that explicitly states that GMOs are patentable, provided they meet the established patentability criteria and ethical standards, will bring much-needed clarity to this area of patent law.

To facilitate more efficient processing of patent applications, Section 10(4) should be updated to incorporate electronic filing and online submission procedures. Streamlining the filing process through digitization of forms and documentation will make it easier for applicants to comprehend the patent system.

The provisions for patent revocation under Section 64 should be strengthened to address issues such as non-working of patents, public health emergencies, anti-competitive practices, and violations of ethical standards. Expanding the grounds for revocation will help ensure that patents are not misused and that public interests are adequately protected.

Furthermore, Section 146 needs to be revised to empower patent authorities to conduct inspections, seize infringing materials, and take appropriate action against unauthorized use of patented biotechnological inventions. This will enhance enforcement capabilities and help maintain the integrity of the patent system.

A new provision should be introduced under Section 10(5) to allow for expedited examination of biotechnological inventions in exchange for an additional fee. This provision would enable applicants to accelerate the review process and bring innovations to market more swiftly.

Section 25(2) should also be amended to impose stricter requirements for post-grant patent revisions

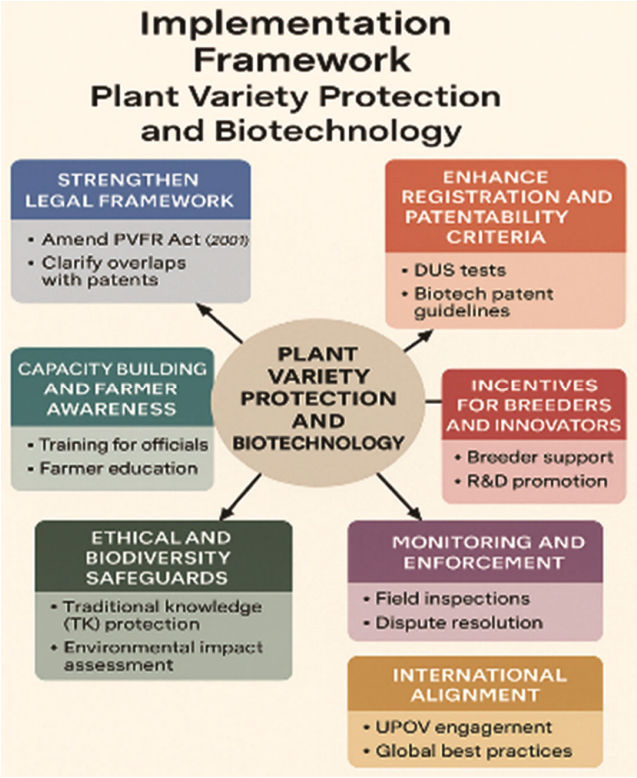


Fig. 1 — Implementation framework plant variety protection and biotecnology

and to limit extensions of patent periods for biotechnological innovations. These changes will help ensure that patents remain relevant and do not impede further innovation unnecessarily.

Finally, Section 48 should be broadened to include special provisions for compulsory licensing of biotechnological innovations, taking into account public health concerns, national emergencies, and the need to balance innovation with accessibility. This broader scope will ensure that the patent system supports both progress and public welfare.

To implement these changes effectively, India should engage with stakeholders, legal experts, and industry representatives to align the amendments with international best practices and the needs of the biotechnology sector. In addition to traditional patent protection, exploring alternative mechanisms such as public investment, prize systems, open innovation, patent pools, and differential pricing can help advance innovation while safeguarding public interests. A rigorous examination process will ensure that only genuine inventions are patented, contributing to a balanced and inclusive innovation ecosystem (Fig. 1).

## Conclusion

The rapid evolution of biotechnologies poses challenges and opportunities in patent law, necessitating a nuanced understanding of legal and ethical issues to strike a balance between innovation and the public interest. Some biotech inventions have obtained patent protection in India, including the Rotavirus Vaccine, CRISPR-Cas9 and TALENs genome editing tools, biofertilizers, biosensors, diagnostic kits, probiotic formulations, and gene therapy technologies for treating genetic disorders. India has also seen some unique biotechnological inventions like Bt cotton, recombinant insulin, vaccines for numerous diseases, biofortified crops, GM crops, tissue culture techniques, biopesticides, biomaterials, and bioplastics, showcasing their diverse applications in various sectors.

Updating the legal framework is essential to address the challenges posed by emerging biotechnologies, focusing on enhancing patentability criteria, incentivising innovation, and protecting the public interest. India can steer through the varied complexities of biotechnologies, advance innovation, and protect the public interest by adopting a holistic approach that considers legal, ethical, and social perspectives. Careful examination of patent law and IPRs in biotechnological inventions is thus vital, for ensuring a balance between incentivising innovation, protecting public interest, respecting traditional knowledge, and enabling access to affordable healthcare and agricultural technologies. Such modifications to IP laws should be based on comprehensive research, stakeholder consultations, and international best practices to create a conducive and sustainable environment for biotechnological innovations in India.

To enhance its legal framework and better balance the interplay between biotechnology, plant breeding, and IP protection, India should implement several targeted reforms. First, as discussed, the Patent Act should be revised to provide clearer guidelines on the scope of patentable biotechnological inventions, particularly those related to plant varieties and GMOs. *For instance*, the European Union has established a detailed framework that defines patentable biotechnological inventions and plant varieties while maintaining rigorous ethical standards.[56] By refining the definitions in Sections 3(b) and 3(j) in a similar manner, India can ensure that innovations in plant breeding are recognised and protected while

safeguarding public interests. It is not like India is not making attempts at better governance over this issue, in fact, for instance, some key priorities listed in India's Draft National Biotechnology Development Strategy 2020–25 include improving gene editing capacity, increasing biopharmaceutical R&D, and supporting public-private partnerships to create an indigenous innovation ecosystem.[57]

This shows that India has a formal and forward-looking setup for biotechnology, albeit, it is merely a strategy, therefore, it is non-binding, and more of a vision-document than an regulation or an enforceable law. Secondly, the strategy mentions IP protection and related ethical governance in general terms, rather than pointing out more concrete mechanisms to clarify the timelines, policy tools or institutional roles in this area.

Additionally, the legal framework needs to be updated to facilitate more efficient patent examination and application processes. The United States, *for instance,* has successfully implemented measures for electronic filing and expedited review of biotechnological patents, significantly streamlining the submission of documents and making the system more responsive to emerging innovations.[58] Adopting similar provisions in India, such as electronic filing and expedited review processes, will enhance accessibility and efficiency.

Furthermore, India should consider expanding the grounds for compulsory licensing to address public health concerns and national emergencies more comprehensively. *For instance,* Brazil has incorporated specific provisions in its IP laws that allow for compulsory licensing in cases of public health crises, ensuring that patent protections do not unduly restrict access to essential biotechnological advancements.[59] By integrating such provisions into its own framework, India can strike a balance between encouraging innovation and ensuring accessibility.

The Plant Variety Protection and Biotechnology framework must be operationalised through a comprehensive set of interlocking components. This entails improving the legal framework by means of amendments to the Protection of Plant Varieties and Farmers's Rights (PPV&FR) Act, 2001, so clarifying its overlaps with current patent laws. Improvements to registration and patentability criteria have to be embraced concurrently, especially DUS (Distinctness, Uniformity, and Stability) tests and biotechnology-specific patent guidelines.

Targeted training of officials and more farmer education on biotechnology and plant variety rights will be necessary under a farmer-centric implementation. Strong incentives also are required for breeders and inventors supported by R&D systems.

Standardising monitoring and enforcement procedures including field inspections and dispute resolution systems helps to guarantee regulatory compliance. Inclusive innovation depends on the inclusion of ethical and biodiversity protections including protection of traditional knowledge and environmental assessments.

Ultimately, ensuring competitiveness and compliance in cross-border biotechnology partnerships depends on alignment with international standards including UPOV and global best practices.

India recently approved the release of its first two genome-edited rice varieties in a notable change of policy. Though not labelled as genetically modified organisms (GMOs), these variants—developed using the SDN-1 genome-editing technique—show improved productivity and disease resistance. This regulatory acceptance sets a precedent for fast agricultural innovation and intellectual property inclusion of genome-edited crops, so matching India with progressive biotechnology governance. Legal systems like the PPV&FR Act must reflect these changes if they are to remain future-ready. Harikishan Sharma, “For the first time, 2 new genome-edited rice varieties: Why is this such a major breakthrough for ICAR and India’s agriculture?”[60]

Lastly, engaging with stakeholders, including researchers, industry experts, and legal professionals, in the revision process will ensure that the updated legal framework aligns with international best practices and the needs of the biotechnology sector. *For instance*, Canada’s approach to stakeholder engagement in its IP reform process has helped create a balanced and inclusive system.[61] Such collaborative efforts will help India create a robust and balanced IP regime that encourages innovation in plant breeding while upholding ethical standards and public welfare.

Note: The article is based on Major research project “An Empirical Account of the Farmers’ Rights Situation in India within the contours of Intellectual Property Regime: A Case Study of Northern India” by Indian Council of Social Science Research (ICSSR).

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