



The Need for Reform in India's Patent Law for Gene-Edited Organisms: A Comprehensive Review

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ABSTRACT :

This paper evaluates, from a legal perspective, the argument that India's patent law needs reform regarding the patentability of Gene-edited organisms (GEOs). These organisms are different from gene-modified organisms because there is no Addition of foreign genes; rather, the gene editing method modifies the existing DNA of an organism to get a beneficial outcome. Tools like CRISPR-CAS9 Transforming Biotechnology with Revolutionary Gene-Editing Applications in Medicine, Agriculture and the Environment. Gene-editing technologies, especially CRISPR-Cas9, will revolutionize biotechnology with transformative applications in medicine, agriculture, and environmental sustainability. At present, however, Section 3(j) of the Patents Act in India provides a limit on the patentability of living organisms, a potential hurdle in the commercialisation and development of gene-edited organisms. Still, it does not directly limit the patentability of the gene-edited organism itself, but it does not explicitly restrict the patentability of the gene-edited organism. This commentary discusses the legal, ethical, and scientific context calling for reform. Through a review of the current patent regime in India, an examination of best practices, global perspectives, and considerations of the influences on innovation, public health, and food security, this paper contends that reforms are needed to keep pace with the rapid growth of genetic technologies. The paper also canvasses possible routes of reform and their consequences for biotechnology in India.

Keywords: Gene-edited organism, Section 3(j) of the Indian Patent Act, Biotechnology, CRISPR, Gene-Edited Organisms, Patent Law Reform, India, Intellectual Property, Agricultural Innovation, Biotechnology Industry

I. INTRODUCTION

The rise of gene-editing technologies, especially CRISPR-Cas9, brings powerful opportunities for transformative changes in various fields of biotechnology, including but not limited to agricultural, medical, and industrial applications. Gene-edited organisms are different from gene-modified organisms because there is no addition of foreign DNA, but it has some precise editing in the organism's existing DNA. These technologies enable the accurate editing of the genomes of living entities, opening new avenues for treating hereditary diseases, increasing crop strength, and promoting sustainable development across industrial sectors. One example is that Scientists use genome editing to study diseases by altering the DNA of animals like mice and zebrafish, which share many genes with humans. At the NHGRI, the Burgess lab uses CRISPR to delete specific genes in zebrafish to understand their role in deafness, focusing on 50 genes similar to those linked to human hearing loss.¹

Yet, notwithstanding the major scientific advancements, the patentability of gene edited organisms (GEOs) continues to be a topic of debate in numerous countries, including India. If we speak of India, there is no patentability on gene-edited organisms, due to which people avoid doing research on gene-edited organisms, and the private sector avoids putting their money on any research on gene-edited organisms. The patenting of various living organisms in India, including genetically modified organisms (GMOs) and GEOs in general, is regulated through the Indian Patents Act, 1970, with special exclusions under Section 3(j).² This exception prohibits the patentability of plant and animal varieties as well as processes to produce plants and animals, which are mainly biological. This has controlled and limited the patenting of gene-edited organisms for agricultural, medicinal, and environmental applications in our country. Section 3(j), although aimed at protecting biodiversity and traditional knowledge, has a flooding legal barrier for patenting new gene-editing methods and their commercial benefit.³

The focus of this paper is to highlight that India needs to reform its patent law in light of the changing biotechnology sector and also to analyse where the non-patentability of gene-edited organisms is hindering India's progress in various fields. Through an analysis of the existing legal system, this paper evaluates the problems presented by Section 3(j) and argues that a proper application of this current legislation is insufficient for the complexities of gene-edited organisms. In addition, the paper analyses the approaches taken by different jurisdictions, including the United States, the EU and China, about the patentability of GEOs. This comparison offers useful suggestions to help India balance innovative growth while also ensuring that the public interest and ethical concerns are well-protected. With the rising international competition in the field of biotechnology, India desperately needs to bring

¹ National human genome research institute <https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-Editing>

² The Indian Patents Act, 1970, Section 3(j), Government of India.

³ Feroz Ali Khader, *The Law of Patents – With a Special Focus on Pharmaceuticals in India* (LexisNexis, 2007), 145.

its patent laws at par to global standards; although it needs to conduct this balancing act whilst addressing the concerns of the public regarding biodiversity, public order and morality, and finally, access to technology. The following article will outline why change is needed, explain the current law, and offer ideas for how India can create a more expansive and flexible patent system for gene-edited organisms

II. THE LEGAL FRAMEWORK FOR GENE-EDITED ORGANISMS IN INDIA

The current patent law framework regarding gene-edited organisms (GEOs) in India is derived primarily from provisions within the Indian Patents Act of 1970 that were implemented to promote innovation and incentivize the development of novel products and services. Section 3 of Patents Act, on the other hand, limits the patentability of living organisms, including plants, animals and biological processes to produce plants and animals.⁴ However, it is not so much the section itself that limits the gene-edited organism, but this section is crucial in determining if a genetically modified or gene-edited organism will be considered patentable as this is due to their potential to live in the wild.⁵

Section 3(j) of the Patents Act

The most significant aspect is Section 3(j), which prohibits the patenting of any "plants and animals in whole or in part" (except microorganisms).⁶ It also does not allow the patenting of essentially biological processes to produce plants or animals. The phrasing in this section has led to significant controversy over to what extent gene-edited organisms developed using the more modern technologies such as CRISPR-Cas9 would be subject to these restrictions. Though the Indian Patent Office (IPO) had imposed this restriction only on 'genetic modifications, which is the process of creating a gene-modified organism but not gene-edited organism which it seems to be different from a gene-modified organism. "If the organism is not the direct product of conventional genetic modification, but just a more targeted genetic approach to modification at first, this creates a legal grey area here on the law's applicability to that gene-edited organism,".⁷ This key provision is designed to prevent the patenting of the biological basis of life forms or resources like food, plants, and animals, which could lead to their patenting or colonization. But gene-edited plants, animals and their products, and organisms edited with new genome-science techniques, either for the field or the treatment room, fall outside this framework. Instead, these organisms are engineered with exact genetic alterations, so should they be afforded the same limitations?

III. COMPARATIVE ANALYSIS WITH OTHER JURISDICTION

An examination of where India stands on gene-edited organisms globally requires an analysis of its approach about that of other leading jurisdictions, the US, the European Union and China. so that this comparison gives us the gaps we need to fill in our legal framework.

UNITED STATES OF AMERICA

Patenting of genetically modified organisms (GMOs) and other gene-edited organisms has long been permitted under U.S. law, and the broad view of patent eligibility for such organisms has been reinforced since the Supreme Court effectively opened the door for patenting certain types of living organisms in *Diamond v. Chakrabarty* (1980).⁸ In this case, the U.S. has notably continued to deliver patents on organisms that may be gene-edited, including plants and microorganisms that receive CRISPR-Cas9-induced genetic modifications. It is highly conducive to innovation, one of our more determining qualities, and with relatively few exceptions, patent law allows living organisms to be patented, given that it meets the general requirements of patentability such as novelty, utility and non-obviousness. The patentability of gene-edited organisms boosted the biotech innovation by innovations such as modified crops like pest-resistant corn and drought-tolerant soybeans, and as of 2024, above 90% of corn, soybeans and cotton were planted with genetically edited varieties.⁹ Advanced medical research, such as diagnosis of a disease and possible treatment, and one of the innovations of the USA using gene-edited organisms is genetically engineered bacteria that produce insulin, revolutionising diabetes treatment. There was also an improvement in the agriculture sector, as the gene-edited crops helped increase the yield and reduce pesticide use. Not only these but it also created jobs as it led to thousands of biotech startups, which eventually created jobs.

The European union

The European Union, though it provides patentability on gene-edited organisms, does so with more restrictions than the USA. The European Union (EU) has been more conservative as regards the patentability of these gene-edited organisms.¹⁰ The EPO grants patents on gene-edited organisms, whereas Directive 2001/18/EC governs GMOs in agriculture. When handling GMOs and gene-edited organisms, the EU has focused on ethical and environmental impact. The evolution of gene-editing and its implications for animal genetic resources However, in 2018 the European Court of Justice (ECJ) decided that organisms created with new gene-editing techniques (for example, by using CRISPR-Cas9) should be considered GMOs and thus fall into the GMO Directive, which imposes a "rigorous" approval process for regulatory purposes. The ruling has far-reaching consequences for the commercialization of

⁴ **Indian Patents Act, 1970**, Section 3(j), Government of India. <https://indiankanoon.org/doc/124832407/>

⁵ Aiswariya Biswas, "CRISPR, Gene Editing and the Indian Legal Framework," *Indian Journal of Law and Technology* 17, no. 1 (2021): 55–76.

⁶ Indian Patents Act, 1970, Section 3(j).

⁷ Rohan George, "Patentability of Gene-Edited Organisms: CRISPR and the Indian Context," *SpicyIP* (blog), May .

⁸ *Diamond v. Chakrabarty* 1980 https://unctad.org/ipccaselaw/sites/default/files/ipccaselaw/2020-12/Diamond%20v.%20Chakrabarty%2C%20447%20U.S.%20Supreme%20Court%20%20303%20%281980%29_0.pdf

⁹ Report: Feed and Grain https://www.feedandgrain.com/business-markets/commodities/news/15713046/genetically-engineered-crops-dominate-us-agriculture-usda-data-shows?utm_

¹⁰ European Court of Justice, "Judgment in Case C-528/16," *Court of Justice of the European Union*, July 25, 2018.

gene edited crops and organisms in the EU because it applies a cumbersome regulatory regime than the U.S.

Since February 2025, the EU is still in debate about the patenting of gene-edited plants that have used New Genomic Techniques. To limit legal uncertainties and support breeders, the European Parliament proposed a ban on patents on such plants in early 2024. As of now, gene-edited organisms (including plants developed with NGTs like CRISPR) are still patentable in the EU if they meet standard patent criteria, such as novelty, inventive step, industrial application, etc. Also, there is no final decision on the ban because many EU bodies offer different views. However, there is a probability that the legal framework may change soon because of the proposal to ban these kinds of organisms.

China

By comparison, China has welcomed gene-editing technology with open arms and is rapidly becoming an important player in the world biotechnology market. Biotechnology patents covering gene-edited organisms can be granted in China under the Chinese Patent Law so long as the subject matter meets the standards of novelty, inventiveness, and utility.¹¹ Its growing number of patent filings in gene editing has been growing much faster than the U.S. because patentability of gene-edited organisms is more flexible in China as compared to the USA or EU, and it has also been promoting CRISPR-based research. Due to patentability, basic research on gene-edited organisms in China is far ahead of India. China has performed many research studies and developed many gene-edited organisms, such as disease-resistant wheat, Tomatoes with increased glucose and fructose content by 30%, enhancing sweetness without affecting size and Fully-developed and gene-edited rice using CRISPR-Cas9 technology in China for traits like disease-resistance and yield. Over the past few years, China has developed policies that enable the patenting of genetically modified and gene-edited organisms and has undertaken this in agriculture, with the Chinese government perceiving an opening to utilize innovative technologies to improve food security and propel agricultural productivity.¹²

IV. CHALLENGES AND IMPLICATIONS

1. Ambiguity in Law and Regulatory Framework

There are many challenges, such as Uncertainty in the legal framework, which is one of the highest hurdles for patenting genetically modified organisms in India. Gene editing is not treated as a sui generis subject in patent law in India, whereas it is often confused with Section 3(j) that relies on more inclusive limitations. If we introduce a clear legal framework, then we may be able to overcome these challenges. The absence of concrete definitions and well-defined provisions for cutting-edge technologies like CRISPR-Cas9 is a barrier to innovation and deters investment in biotech start-ups and research institutes. With the changing technology and environment, the patent law of India also needs some major changes.

2. Ethical and environment concern

There are also many challenges related to ethics, including environmental concerns regarding patenting gene-edited organisms. Against this backdrop, debates about whether we should be altering the genetic stock of life (including crops and animals) are growing. Opponents say that patenting GEOs may create monopolies on critical inputs, worsen food inequality, and have an impact on local farming communities. In addition to this, the need to vigilantly evaluate the environmental release of gene-edited organisms in the long term, particularly crops with novel traits, is generating demands for more comprehensive evaluation and regulation before such products can be brought to the market.

3. Economic Consequences of the India Biotech Industry

Ambiguity on patenting has an economic bearing on India's biotechnology sector. There are many biotechnology startups in India, but an unclear patent regime on organisms whose genomes have been edited using these technologies may prevent them from attracting investments, technology licensing, and entering overseas markets. Moreover, it might be very tough for innovators in India to protect their intellectual property against global competition without a patent in place.

V. RECOMMENDATIONS FOR REFORM

1. clean definitions and instructions in patent law of India

Gene editing should be clearly defined in Indian patent law. New provisions should be created to distinguish between traditional GMOs and gene-edited organisms to provide for positive developments in biotechnology that also avoid a monopoly over the food supply and ethical issues. Also the ambiguity created by 3(j) of Indian patent law must be cleared.

2. Alignment with international standards.

India needs patent laws consistent with international norms for biotechnology patents. National engagement with international stakeholders is required to help bring patent provisions in line with global expectations, specifically regarding patentability and regulation of biological innovation. India should align its patentability standards with WIPO and TRIPS-compliant frameworks. If India provides patents for gene-edited organisms, there are chances of more innovations in the edited field, and there is a possibility that the private sector will start investing in this research. India should adopt the international framework to make sure that it does not lag in the innovation or advancement of biotechnology and be able to walk in steps with other countries

3. Expanding the Role of Regulatory Bodies

Gene-editing technologies are always going to be best housed under innovation and public health oversight. Biotechnological inventions have the potential

¹¹ State Intellectual Property Office of China. "Guidelines for Patent Examination in Biotechnology." *CNIPA*, April 2019.

to cause long-lasting harm to the environment and human health; therefore, regulatory oversight shall be an integral part of patent examination by the NBA and DBT. These bodies would need to be equipped to respond to patent applications related to genomically edited organisms with input from scientific advisory and Establish and enforce unequivocal biosafety requirements for innovators, such that patents are awarded only after the identification of specific biosafety risks.

VI. CASE STUDIES AND PRECEDENTS

Monsanto v. Nuziveedu (2006)

The legal battle between Nuziveedu Seeds Ltd. and Monsanto Technology LLC centres on the patentability and use of genetically modified (GM) cotton seeds in India. In 2002, an agricultural biotechnology company called Monsanto entered a legal dispute with the government of India regarding whether BT cotton, a genetically modified organism, could be patented.¹³ At the same time, the case raised fundamental questions about patenting of life, the public good in agricultural diversity, and control of essential resources. The case also showcased a polarisation of views on what constitutes a property right in more than one sense of the term. While the case specifically dealt with GMOs, it established precedents that have been carried over into later discussions on the patentability of gene-edited organisms and the application of India's patent law to living organisms.

Syngenta Participations AG v. Controller General of Patents (2017)¹⁴

The case of Syngenta Participations AG v. Controller General of Patents (2017) involved Syngenta's patent application for a genetically modified plant with improved traits. The Controller of Patents rejected the application based on Section 3(j) of the Indian Patent Act, which excludes the patenting of plants and biological processes. However, the Intellectual Property Appellate Board (IPAB) ruled in Favor of Syngenta, stating that the plant, created through a biotechnological process (not purely biological), was eligible for patent protection. The case clarified that genetically modified organisms (GMOs), resulting from biotechnological methods could be patented in India, even if they involved plant modifications, provided the process wasn't purely biological, thus boosting biotech innovation in the country.

VII. CONCLUSION

With the changing environment, we need changes in our patent law, too. Recent advances in gene-editing technology, such as CRISPR-Cas9, are being used to redefine the boundaries of biotechnologies, and it is vital that the Indian law threatens to keep up with this scientific progress. And while India's current patent regime in general, and indeed Section 3(j) of the Patents Act in particular, reflects a cautious and protectionist approach to patents intended to safeguard biodiversity and farmers' rights, they also create ambiguity and limitations that may stifle innovation around gene editing. In comparison to jurisdictions such as China, which have and continue to usher in gene-edited innovations through friendly patent and regulatory regimes, the stall in India threatens to leave the biotechnology sector at a competitive disadvantage.

The TRIPS Agreement allows India room to devise its patent laws within ethically acceptable measures that also encourage technological advancement. But effectively leveraging gene-editing for national progress, particularly in the realms of agriculture and healthcare, will require India to introduce clearer definitions, regulatory updates, and balanced policies that foster both innovation and public welfare. Strengthening IPR in this manner will not just provide legal certainty to innovators but will also enhance India's standing on the global biotechnology map.

¹³ Monsanto v. Nuziveedu <https://www.bananaip.com/nuziveedu-v-monsanto-patentability-gene-sequences-india-case-brief-comments/>

¹⁴ Syngenta participation AG v. controller general of patent <https://indiankanoon.org/doc/82745184/>