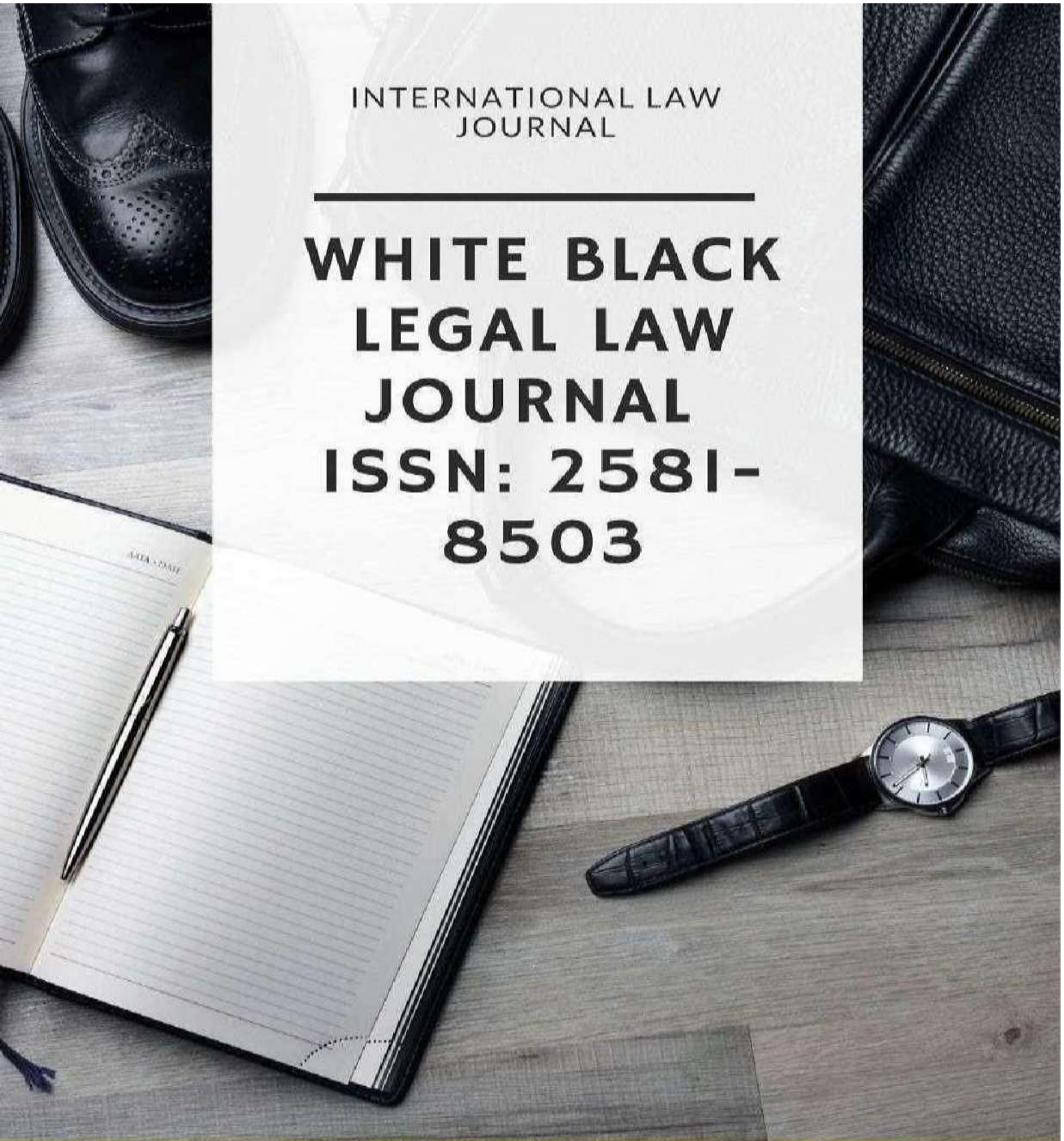




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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provided dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and 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

GENE EDITING AND PATENT ELIGIBILITY IN INDIA: LEGAL AND MORAL IMPLICATIONS OF CRISPR-BASED INNOVATIONS

AUTHORED BY - D. KANNABIRAN* & G. KARISHMAA**

ABSTRACT:

The theory of CRISPR-Cas9 represents a sizable step forward within biotechnology providing targeted modifications to living beings that may have further applications in agriculture, medicine, or natural conservation. Patentability for CRISPR-made innovation is vital from legal and moral views for a developing country like India, trying to reconcile the fast pace of advancement through science and related socio- economic development. Section 3 of the Patents Act of India, established in 1970, sets out exclusions for the patenting of life forms. It is in this ambiguous territory that certain gene-edited organisms enter, with dubious patentability. The paper, therefore, diverges to critique the urine patent regime of gene editing in India, extending to pioneering judicial interpretations and accounting for ethical issues from life commodification, access to that technology, and environmental devaluation. It crafts reform policy suggestions through cross-country comparisons and India's obligations under the TRIPS Agreement, balancing innovation with public interest protection. It also recommends the establishment of a more humane patent system taking into consideration Indian culture, ethics, and development issues.

1. INTRODUCTION:

The CRISPR-Cas9 technology- low-cost yet powerful gene-editing system made this possible: biotechnology has advanced into the arena of editing gene continuities of animals, plants, and humans (Doudna & Charpentier, 2014)¹. Agriculture would benefit from CRISPR in creating plants resistant to dry spells. At the same time, medicine makes use of CRISPR for the treatment of genetic disorders, and ecology favors CRISPR in using microbes for

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¹ Doudna, J. A., & Charpentier, E. (2014). The new frontier of genome engineering with CRISPR-Cas9. Science, 346(6213). <https://doi.org/10.1126/science.1258096>

bioremediation. Such developments raise a lot of issues relating to IP rights, especially for courts like India where patent law is a very delicate balancing act trying to push innovation ahead while protecting the public good. Concerning gene-manipulated animals and patents, India faces particular challenges because it is a world leader in both generic cultivation and medications. The Indian Patents Act, 1970 Section 3(j)² does not view animals and plants as objects for patent but leaves the door open for granting patents for microorganisms on specific grounds with genetically modified forms of life having the possibility of being thereby granted patents (Government of India, 1970). Secondly, India is obligated under the TRIPS Agreement to protect inventions concerning biotechnological use, and that puts into question its somewhat traditional-leaning approach to patents on living organisms (WTO, 1994)³. Besides legality questions, gene editing raises ethics regarding the commodification of life, fair access to technology, and possible ecological imbalance-associated societal concerns to India's large diverse populace. This research explores the legality and ethics of CRISPR-based patenting in India. This research raises the following questions:

- How is India's Patent Law enabling or limiting CRISPR-based gene editing innovations?
- What are the ethical implications of gene editing living organisms for patents in a developing country like India?
- How can India develop a balanced patent system with an innovative public domain and environmental goals?

2. CRISPR-Cas9: TECHNOLOGY AND APPLICATIONS

CRISPR-Cas9, drawn from bacterial immune systems, enables scientists to modify DNA with a level of accuracy hitherto unimaginable before by targeting the desired genes and making changes (Jinek et al., 2012)⁴. In contrast to other prior gene-editing systems such as zinc-finger nucleases, CRISPR is scalable, affordable, and adaptable and thus within the accessibility of research labs worldwide, including Indian ones.

2.1 India applications

India's USD 80 billion biotech sector in 2022 will apply CRISPR to revolutionary applications

² THE PATENTS ACT, 1970 (ACT NO. 39 OF 1970), s.3(j)

³ WTO | intellectual property - overview of TRIPS mAgreement. (n.d.). https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

⁴ Jinek, M., Chylinski, K., Fonfara, I., Hauer, M., Doudna, J.A. and Charpentier, E. (2012) A Programmable Dual-RNA- guided DNA endonuclease in adaptive bacterial immunity. *Science*, 337, 816-821. - References – Scientific Research Publishing. (n.d.). <https://www.scirp.org/reference/referencespapers?referenceid=2180262>

(IBEF, 2023)⁵:

- Agriculture: CRISPR will create climate-resilient crops, like water-thirsty rice or disease-resistant millet, critical to India's 58% rural population (FAO, 2021)⁶. For instance, the Indian Agricultural Research Institute is exploring CRISPR-edited wheat to boost crop yields in case of water shortages (IARI, 2022)⁷.
- Medicine: Gene editing provides therapies for inherited disorders such as sickle cell anemia, which are common among India's tribal population. Indian companies like Eyestem are employing CRISPR in treating ocular diseases (Eyestem, 2023)⁸.
- Environmental Sustainability: Microbes can be engineered to combat pollution, i.e., plastic degradation, according to India's Swachh Bharat campaign (CSIR, 2023)⁹.

These technologies highlight the capability of CRISPR to solve the development problems of India but remain only commercially viable on the assumption of patent protection, an issue that creates legal as much as ethical concerns.

3. PATENT REGIME OF INDIA FOR BIOTECHNOLOGICAL INVENTIONS

Indian patent regime under the Patents Act, of 1970, as modified by the Patent Amendments of 2002 and 2005 to meet the requirements of TRIPS, adopts a conservative policy towards biotechnological inventions. Subsequent paragraphs evaluate important provisions from the gene-edited organism's point of view.

3.1 Section 3(j): Exception of Plants and Animals

The sub-section of Section 3(j) declares that "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals" would not be patentable (Government of India, 1970). The subsection reflects India's orientation to having biodiversity and not monopolizing natural resources. Adding microorganisms to the realm of patentable

⁵ Biotechnology in India, Biotech companies in India | IBEF. (n.d.). India Brand Equity Foundation. <https://www.ibef.org/industry/biotechnology-india>

⁶ The State of Food Security and Nutrition in the World 2021. (2021). In FAO, IFAD, UNICEF, WFP and WHO eBooks. <https://doi.org/10.4060/cb4474en>

⁷ IARI Annual Report 2022, ICAR-Indian Agricultural Research Institute, New Delhi – 110 012, India. ISSN 0972-6136

⁸ <https://eyestem.com/>

⁹ Annual Report | Council of Scientific & Industrial Research. (2025, April 17). <https://www.csir.res.in/annual-report>

subject matter, while, though, leaving gene-edited objects in the balance, may even undermine the distinction between man-made and naturally occurring living entities.

3.2 Microorganisms and Patentability

The Patents Act was amended in 2002 to necessitate TRIPS so that microorganisms shall constitute patentable subject matter in the case they were new, involved an inventive step, and had an industrial application (WTO, 1994). *Dimminaco A.G. v. Controller of Patents* (2002)¹⁰ ruled that a live vaccine of altered microorganisms was patentable, setting a precedent for biotechnology inventions (Calcutta High Court, 2002). However, "microorganism" is not specifically defined under the Act, and it is not entirely clear whether organisms that have been gene-edited, like CRISPR-edited bacteria or plants, fall within the meaning of the Act.

3.3 Section 3(c): Naturally Occurring Substances

Section 3(c) excludes "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature" (Government of India, 1970). This does not make it obvious whether CRISPR-edited organisms, which may include small alterations to naturally occurring genes, would be included within this exclusion.

3.4 TRIPS Obligations

India is committed under Article 27.3(b) of TRIPS to grant patent protection for microorganisms and non-biological or microbiological processes (WTO, 1994). TRIPS permits flexibility of maneuver in the exclusion of animals and plants, and India avails itself of this so that it can devote more attention to the public interest. Patents on gene editing are conditioned in India's situation by the conflict between TRIPS obligation and national policy.

4. ETHICAL ISSUES OF PATENTING GENE-EDITED ORGANISMS

The question of patents on CRISPR-made products is an important ethical issue in India, particularly because religious, cultural, and socioeconomic factors influence attitudes toward biotechnology.

¹⁰ CHAKARABORTY, S., BASU, P., I.P. MUKHERJEE, & S.S. SARKAR. (2001). *DIMMINACO A.G. v. CONTROLLER OF PATENTS AND DESIGNS & OTHERS*. In *IN THE HIGH COURT AT CALCUTTA*. <https://spicyip.com/wp-content/uploads/2013/11/Dimminaco-A.G.-v.-Controller-of-Patents-Designs.pdf>

4.1. Commodification of Life

The patenting of organisms through gene editing is seen as a way to commodify life, an extreme deviation from the Indian cultural ethos of respect for nature as in philosophies such as Jainism and Hinduism (Chakrabarty, 2003)¹¹. Those criticizing living organism patents decry it for stripping living organisms of their inherent value, with the added fear that CRISPR can make them into artificial organisms.

4.2. Equitable Access

Presumably, India, a lackluster-dominated healthcare sector that thrives on cheap drugs for the world, would have to display high murkiness for some of the CRISPR technologies such as gene-edited stem cells which will become unaffordable for her own 1.4 billion population, 70% of whom rely on state health (WHO, 2023)¹². Should CRISPR cures for sickle-cell anemia be patented, there is a high chance its application will cause even further widening in health inequalities among deprived societies.

4.3. Environmental Risks

Upon release into the environment, CRISPR-induced crop or microbe casualties for genetic mutation could collude with biodiversity, a worrying phenomenon in mega-diverse India (MoEFCC, 2021)¹³. This patenting policy could very well inflate premature releases without prior detailed bio-safety testing, reminiscent of past Bt crops issues (Greenpeace India, 2020)¹⁴; the patent policies have meant, therefore, the grafting of ethics onto the balance of innovation and ecological responsibility.

4.4. Indigenous Knowledge

Biopiracy CRISPR technologies have been built on the genetic resources of Indian biodiversity; worries about biopiracy are thus quite justified. The fate of neem and turmeric patenting abroad indicates the need to protect local knowledge (Shiva, 1997)¹⁵. Ethical patent

¹¹ Organisation for Economic Co-operation and Development. (2002). Genetic Inventions, Intellectual property rights and licensing Practices: Evidence and policies [Book]. <https://www.oecd-ilibrary.org/docserver/9789264034730-en.pdf?expires=1728397902&id=id&accname=guest&checksum=5BAA8C364391510589EA2E5F3F75ACF4>

¹² World Health Statistics. (n.d.). <https://www.who.int/data/gho/publications/world-health-statistics>

¹³ Government of India, "Annual-report-2021-22" (Ministry of Environment, Forest and Climate Change)

¹⁴ Greenpeace India. (n.d.). The difference we make - Greenpeace India. <https://www.greenpeace.org/india/en/success-stories/>

¹⁵ Shiva, V. (1997). Biopiracy The plunder of nature and knowledge. Boston, MA South End Press. - References - Scientific Research Publishing. (n.d.). <https://www.scirp.org/reference/referencespapers?referenceid=783423>

laws need to contain mechanisms such as benefits sharing with local communities and conform to the Biological Diversity Act, 2002 based on respect for indigenous communities.

5. GLOBAL COMPARISONS

India's gene-editing patent policy is a departure from the international norm and has a transformational impact.

5.1 United States

The U.S. allows patents on genetically modified crops, animals, and microbes, as affirmed in *Diamond v. Chakrabarty* (1980), allowing a patent on a genetically modified bacterium (U.S. Supreme Court, 1980)¹⁶. The U.S. Patent Office has already allowed CRISPR patents on gene-edited crops and medicine, driving innovation but causing monopoly issues (USPTO, 2023)¹⁷. India's policy of restriction is the reverse of this liberal policy of public access rather than corporate control.

5.2 European Union

The EU does not provide patents on plant and animal derivatives of primarily biological processes but issues patents on genetically altered microorganisms and technological steps (EPO, 2020)¹⁸. The risk-averse stance of the EU, for ethical reasons, is like India's but includes more specific gene editing regulations that India lacks to date.

5.3 China

China strongly patents CRISPR technologies, especially for agriculture, to improve food security (SIPO, 2022)¹⁹. Although India is also faced with such agri issues, its patent regime crushes such innovation, negatively impacting competitiveness. The disparity means India must harmonize its patent principles of gene editing by taking the best global practices without compromising its public interest ideology.

¹⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). (n.d.). Justia Law. <https://supreme.justia.com/cases/federal/us/447/303/>

¹⁷ Patent Public Advisory Committee of the United States Patent and Trademark Office, Harrison, S., Nebel, H. S., Caltrider, S. P., Braden, S. G., Brown, D., Duan, C., Darden, L., Hadad, H., Tsai, O., Patent Office Professional Association (POPA), National Treasury Employees Union (NTEU, Chapter 243), & National Treasury Employees Union (NTEU, Chapter 245). (2023). 2023 Patent Public Advisory Committee Annual Report. <https://www.uspto.gov/sites/default/files/documents/PPAC-2023-Annual-Report.pdf>

¹⁸ Guidelines | EPO.org. (n.d.). <https://www.epo.org/en/legal/guidelines>

¹⁹ China National Intellectual Property Administration 2022. (n.d.). <https://english.cnipa.gov.cn/col/col3261/index.html>

6. SOCIO-ECONOMIC IMPACTS IN INDIA

Patenting inventions on the basis of CRISPR has enormous socio-economic implications for India's economy, agriculture, and healthcare.

6.1 Economic Growth

It will be able to attract foreign investment and finance India's USD 150 billion biotech industry by 2025 (IBEF, 2023). Over-regulation will deter startups and MNC businesses and decelerate innovation.

6.2 Agricultural Productivity

CRISPR-edited plants can help augment the production of 150 million Indian farmers and improve food security for a rising population (FAO, 2021). Patents have to find a middle ground between business and farmer interests to maintain seeds, as envisioned under the Protection of Plant Varieties and Farmers' Rights Act, of 2001.

6.3 Healthcare Access

Gene medicines are patentable for triggering R&D but in the name of leaving out the poor. Indian application of a compulsory license to drug drugs such as Nexavar indicates respect for access through the application of CRISPR therapy (Natco Pharma v. Bayer, 2012)²⁰.

6.4 Global Competitiveness

Due to inadequate patent protection, India risks falling behind the world in the biotech race while the U.S. and China are leading by way of CRISPR patents (WIPO, 2023)²¹. India risks becoming a global leader in ethical biotech by virtue of policy balance.

7. POLICY RECOMMENDATIONS

To cross the legal and moral bar of patenting CRISPR-related innovation, the following must be done by India:

1. Define "Microorganism" in the Patents Act Amend Section 3(j) so that whether

²⁰ Sood, M. (2013). NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA. In NUJS LAW REVIEW (Vol. 6, Issue NUJS L. rev. 99). <https://nujslawreview.org/wp-content/uploads/2016/12/mansi.pdf>

²¹ World Intellectual Property Organization (WIPO), Tang, D., Bergquist, K., Khan, M., Lamb, R., Le Feuvre, B., Zhou, H., Aleman, M., Fink, C., Button, P., Huerta-Casado, Y., Besse, A., International Union for the Protection of New Varieties of Plants (UPOV), Turrin, E., Grazioli, A., Gragnani, M., & Jezequel, A. (2023). World Intellectual Property Indicators 2023. World Intellectual Property Organization. <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-941-2023-en-world-intellectual-property-indicators-2023.pdf>

organisms whose genes are edited with the use of genetic engineering, i.e., plants and animals, are microorganisms or not is established. A clear definition, as in TRIPS, would avoid confusion and spur innovation.

2. Develop Ethical Guidelines Form a biotech ethics committee in the Department of Biotechnology to screen CRISPR patents for ethical content, as befits society norms and public interest.
3. Make Access a Mandated Right Make provisions under compulsory licensing of gene-modified drugs to make India's citizens accessible to them at affordable prices, as in the Nexavar case.
4. Enrich Biosafety Laws Equate patent grants to biosafety tests according to the Environment Protection Act, 1986, to avert ecological damages due to genetically modified organisms.
5. Protect Indigenous Knowledge Establish regimes of benefit sharing according to the Biological Diversity Act, 2002, to avoid biopiracy and reward people with incentives of CRISPR technology originating out of Indian genetic resources.
6. Develop Public-Private Partnerships Encourage cooperation among research institutes (such as ICAR, CSIR) and private sector industries for creating low-cost CRISPR technology with patents sketched in terms of public use orientation.

8. CASE STUDIES

8.1. Dimminaco A.G. v. Controller of Patents (2002)

In *Dimminaco A.G. v. Controller of Patents* (2002), the Calcutta High Court held that biotechnological processes that lead to new microorganisms are patentable subject matter, but only if they are under human control and not a discovery. While important in opening the way for patenting of microorganisms such as those used in live vaccines, the ruling left the term "microorganism" even more vague, raising doubts with respect to patentability of gene-edited plant or animal.

Dimminaco A.G. applied for a patent on a method for producing a live vaccine made up of a living virus. The application was refused by the Controller of Patents & Designs on the basis that the invention was a discovery and not a "manner of manufacture" within the Patents Act. The rejection was set aside by the Calcutta High Court, holding that the process was one that involved human intervention and thus was patentable. The process resulted in a new microorganism which was not natural and was substantially manipulated by human

intervention, held the court.

This ruling was a first in Indian law, setting the precedent for patentability of microorganisms that are biotechnologically produced. It set a precedent for future patent applications on microorganisms, such as those employed in CRISPR-based technologies.

The court did not, however, determine the scope of "microorganism." That vagueness leaves questions open to patentability of higher organisms, e.g., genetically modified plants or animals, where the changes go beyond the microbial level.

Although the decision reaffirmed patentability of microorganisms, such uncertainty about scope of "microorganism" is a contentious issue and the subject of legal controversy in biotech patenting.

8.2. Monsanto v. Nuziveedu seeds (2019)²²

The Indian Supreme Court interpreted Section 3(j) of the Indian Patents Act, 1970 in a technical manner in *Monsanto v. Nuziveedu*, prohibiting the patenting of plants and animals. The Court determined that Monsanto's Bt cotton, which involves artificial genetic modification, is patentable to the extent that it circumvents Section 3(j) limitations. This decision brought to light conflicts between Monsanto's contractual royalty clauses and government pricing limitations on biotech (GM) seed trait costs. Price limits help farmers by maintaining low prices, but they can also hinder biotechnology innovation and investment by undermining private contracts, which may discourage firms like Monsanto from creating new technologies. The decision complies with India's duties under the TRIPS Agreement, which include safeguarding biotechnological innovations. However, opponents contend that the Court failed to give a more comprehensive picture of the scope of TRIPS' Article 27(3)(b), which excludes plants and animals but guarantees the patentability of microbes and specific procedures. A more precise interpretation may have given stakeholders more assurance by bringing India's patent law closer to international norms. This case highlights the fine line that separates promoting innovation from granting the general public access to low-cost agriculture solutions.

²² Sampathkumar, S. (2022, January 12). *Monsanto Technology LLC v. Nuziveedu and Ors.* IP Matters. <https://www.theipmatters.com/post/monsanto-technology-llc-v-nuziveedu-and-ors>

8.3. Novartis. V. Union of India (2013)

The Novartis v. Union of India(2013)²³ case set the precedent that Indian law under Section 3(d) demands greater therapeutic efficacy for incremental innovation, thus making it hard to patent minor improvements over a known drug. Even though the case is not directly related to gene editing, it can have implications for CRISPR patents since small-scale differences in the genetic code may not be able to meet the "inventive step" test. Indian courts in granting patents on inventions concerning long-term human presence in the field of biotechnology are reluctant to recognize CRISPR at present.

Novartis Case and Section 3(d):

The case was for a beta crystalline structure of imatinib mesylate patent, an anti-leukemia drug. The patent was denied by the Supreme Court as it could not establish substantial improvement in therapeutic efficacy over the native.

Section 3(d) and "Inventive Step":

The section 3(d) of the Patents Act, of 1970 has proclaimed that patents for the new form, new use, or derivatives of known compounds shall be granted only if they embody a substantive difference in efficiency. The innovation has to be anything but an infinitesimal difference. Implications for CRISPR Since CRISPR gene editing involves making relatively modest changes to existing genes, it can be difficult to define the "improved efficacy" required under Section 3(d).

Substantial Human Intervention:

Indian courts have in the past had a propensity to grant patents for inventions that imply considerable human intervention and alteration of the natural form of things beyond the natural biological process.

Uncertainty for CRISPR The ambiguous rulings on CRISPR technology in Indian courts make it difficult to predict how patents on genetically modified organisms will be treated. The examiners are cautious and will deny claims unless they clearly lie within the microorganism exception.

²³ AIR 2013 SUPREME COURT 1311

9. CONCLUSION:

The patentability of CRISPR-Cas9 gene-edited organism is a single opportunity for India to use the latest biotechnology without facing stringent legal, ethical, and socio-economic issues. India can promote innovation without violating cultural values and public health by removing contradictions in Section 3(j) of the Patents Act, 1970, and issuing clear, CRISPR- specific guidelines for patents.

A new patent system would have to incorporate strong ethical oversight to rule out objections to the commodification of life, facilitate global access to its 1.4 billion citizens to CRISPR-based therapy and crop technology, and protect biodiversity from ecological harm generated by genetically modified animals.

Learning from other models elsewhere in the world like the European Union's conservative attitude towards gene-altered crops or Canada's patent tier system India can adopt a model most appropriate for entrepreneurs, farmers, and weaker sections of society. Furthermore, patent policy harmonization with international commitments under the TRIPS Agreement and access routes such as compulsory licensing and access-benefit-sharing under the Biological Diversity Act, 2002, will ensure India's sovereignty over its gene resources and preclude biopiracy.

Public consultation with indigenous communities, farmers, and civil society is needed to create trust-building and make CRISPR innovations stay in the public good. By leading the way with a vision, inclusive, and ethical patent system, India can guide the world towards responsible biotechnology, applying scientific progress to solve priority issues in agriculture, health, and sustainability while promoting equity and respect for life culture. This trailblazing effort will not only enable India to meet the needs of its diverse citizens but also set an example for other countries closing the gene editing ethics gap.