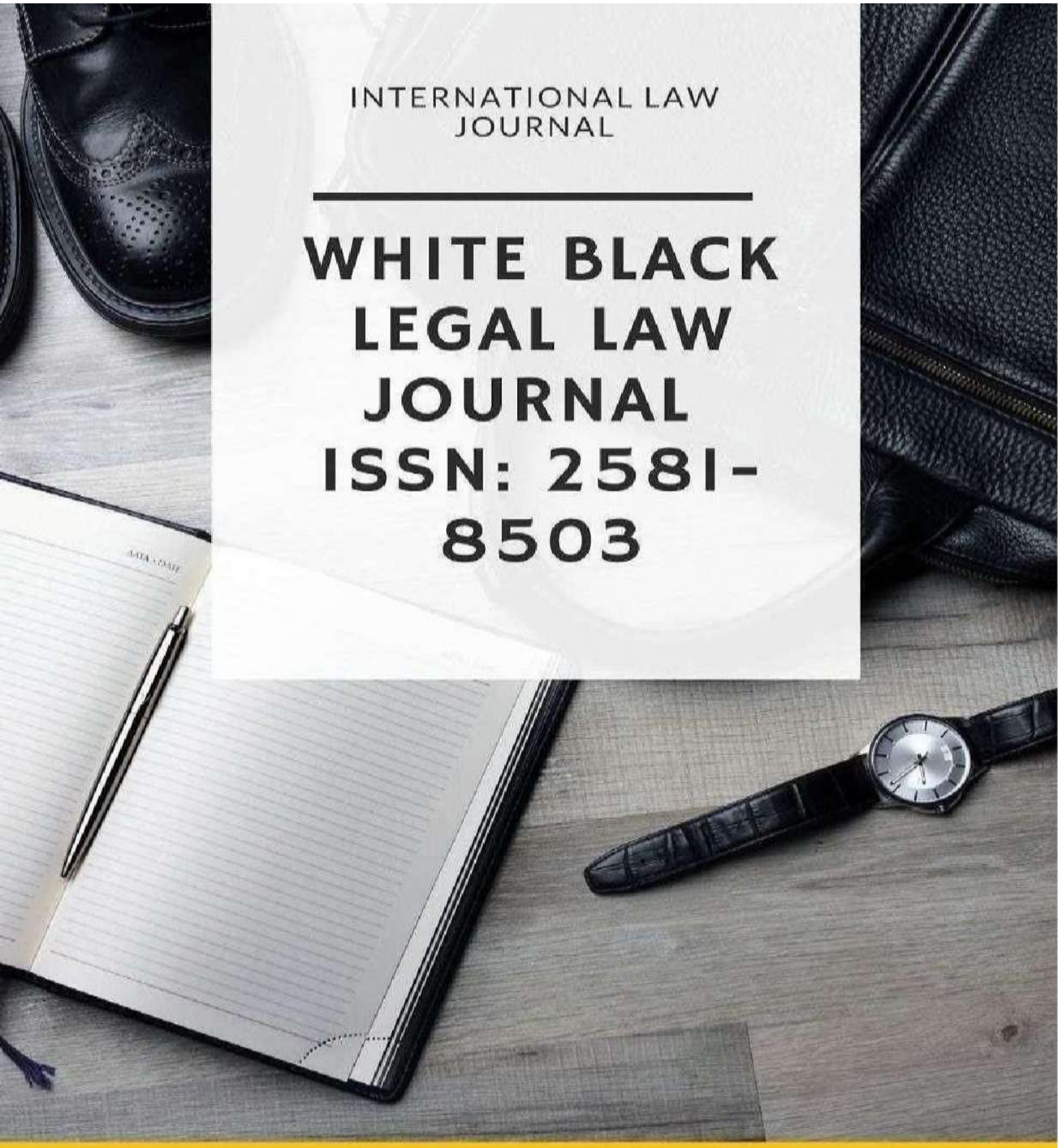

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With this thought, we hereby present to you

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"LEGAL AND ETHICAL CHALLENGES IN THE PATENTABILITY OF GENE EDITING TECHNOLOGIES: BALANCING INNOVATION, ACCESSIBILITY AND OWNERSHIP"

AUTHORED BY - R.S.RAMYA HARINI[1] & S.SHANMATHI[2]

ABSTRACT:

Biotechnology has been revolutionized by the development of gene editing technologies, especially like CRISPR-Cas9, which allow for quick, accurate, and affordable changes to genetic material. Even though these developments have enormous potential for fields like agriculture, medicine, and environmental preservation, they also bring up difficult moral and legal issues, particularly with regard to their patentability. Section 3 of the Indian Patents Act, 1970, which restrains the concept of patentability mainly on naturally occurring compounds or genes and as well as biological processes, but it also focuses on the difficulties which have been presented in it. This study critically analyses the legal framework controlling the patentability of genome editing technologies in India. This paper also compares the legal stances with other countries such as China, the US, and the EU, the study investigates how disparate patent laws influence accessibility and creativity. This paper also explores the wider implications of gene patents, such as moral issues pertaining to fairness in distribution, respect for humanity, and intellectual ownership. Finally, this paper also emphasizes the circumstances for a complicated and well-rounded approach that promotes progress in the field of genetic science while preserving moral bounds and fair access.

KEYWORDS: Gene Editing Technology, Ethical, DNA, Patent, CRISPR-Cas9, Legal, Indian Patent Act.

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I. INTRODUCTION:

Utilizing the mechanism of patents to acquire exclusive access to a particular gene sequence or its associated functions is known as gene patenting. This gives the patent holder authority over the application, creation, and marketing of goods or procedures associated with that gene. Concerns about restricting the dissemination of genetic information and impeding research and medical progress have made gene patents a contentious issue[3]. Section 3(C) of the Patent Act, 1970, prohibits the "discovery of any living thing or non-living substance occurring in nature[4]" as a patentable subject matter in India. Furthermore, with the exception of microorganisms, Section 3(j) expands this restriction to include plants and animals[5]. In 2005, the Indian Patent Office published the Manual of Patent Office Practice and Procedure and the Indian Biotechnology Guidelines in 2013 to keep pace with biotechnology developments worldwide. The late 1900s also saw the creation of the first genome editing technology.Recently, DNA has become easier to modify than ever due to a new gene editing technology, CRISPR that arose in 2009. Compared to earlier gene editing technologies CRISPR is easier, faster, cheaper, and more precise[6].

II. EVOLUTION OF GENE EDITING TECHNOLOGY AND ITS PATENTABILITY IN INDIA:

1. FOUNDATIONS OF GENETIC ENGINEERING AND EARLY REGULATION (1970S - 1989):

The Environment (Protection) Act, 1986, and the 1989 Rules established a multi-tiered biological safety oversight system, which includes the Institutional Biosafety Committees (IBSCs), the Review Committee on Genetic Manipulation (RCGM), and the Genetic Engineering Appraisal Committee (GEAC) to regulate all GMO research, field trials, and environmental release[7]. This was made possible by the development of recombinant DNA technology in the beginning of the 1970s, which allowed scientists

[3]LEGALVIDHIYA,https://legalvidhiya.com/genetic-engineering-and-intellectual-property-legal-and-ethicalimplications/#:~:text=Examining%20legal%20considerations%20like%20patentability%2C%20infringements%2C%20and%20licensing%2C,associated%20with%20genetic%20engineering%20and%20gene%20editing%20techniques (last visited March. 30, 2025).

[4] Patents Act, 1970, § 3(C), No. 39, Acts of Parliament, 1970 (India).

[5]Patents Act, 1970, § 3(j), No. 39, Acts of Parliament, 1970 (India).

[6]ipindia.gov.in,https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf? (last visited March. 30, 2025).

[7]E-PGPATHSHALA,https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp_content/S000014ER/P000283/M025535/ET/1513150088paper13_module_18_etext.pdf (last visited Apr. 1, 2025).

to synthesise DNA from various organisms.

2. **PATENT FRAMEWORK EMERGES (1999 - 2005):**

   To meet the WTO-TRIPS Agreement, India revised its Patents Act in 1999 to permit transitional product-patent applications retroactive to 1995, in 2002 to formally include biochemical, biotechnological, and microbiological processes (including genetically modified microorganisms) in patentability, and in 2005 to repeal Section 5 restoring complete product-patent protection in all technologies, including biotechnology, while maintaining some public-interest protections[8].

3. **RISE OF PROGRAMMABLE NUCLEASES AND INDIAN TAKE UP (MID 1990S - 2012):**

   Through the advent of zinc-finger nucleases (ZFNs) in the mid-1990s, TALENs in 2010, and the revolutionary CRISPR-Cas9 system in 2012, Indian institutions such as CSIR-IGIB and NIPGR began using these genome editing tools for gene mutants, testing, and enhancement of crops by 2015–2018[9].

4. **PATENTABILITY CRITERIA FOR GENE EDITING INVENTIONS (POST 2005):**

   Enhanced microorganisms, polynucleotides, vectors, gene constructs, and gene-editing toolkits are patentable if they meet the legal requirements of novelty, inventive step, and industrial applicability, as stated in the 2013 Guidelines for Assessment of Technological Advances Utilizations for Patent. This excludes patents on plants, animals, and essentially biological processes (Section 3(j)), as well as simple innovations of naturally occurring compounds (Section 3(c)) and slight alterations without improved effectiveness (Section 3(d))[10].

5. **CRISPR PATENT LANDSCAPE IN INDIA (2022 - PRESENT):**

   On May 27, 2022, ERS Genomics, which was established together by Nobel laureate Emmanuelle Charpentier, received Indian Patent No. 397884, which covers CRISPR-Cas9 formulations and techniques for eukaryotic cell editing. The worldwide Broad vs. UC conflict is reflected in ToolGen Inc.'s post-grant objection to this patent[11]. A thorough patent surroundings study is necessary before implementing a "one nation, one license" approach to ensure studies freedom and innovation safeguards. Indian

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[8] Malathi Lakshmikumaran, Patenting of Genetic Inventions, 12 MANU 45, 46 - 49 (2007).

[9] IJLSI,https://ijlsi.com/wp-content/uploads/Gene-Editing-Technologies-and-Patent-Landscape.pdf (last visited Apr. 16, 2025).

[10] *Id*. at 2.

[11] SPICYIP, Do Indian Scientists Need to Worry about CRISPR Licences? – SpicyIP (last visited Apr. 2, 2025).

scientists navigating CRISPR-Cas9 patents face additional complexity due to uncertainty over whether Cas9 qualifies as a patentable "microorganism" or an excluded "microbiological process," unclear research exemptions that may not cover use of research tools without a license, and the risk of restrictive license terms or reach-through[12].

III. UNDERSTANDING GENE EDITING AND PATENTABILITY:

Scientists can precisely alter a living thing's genome (genetic material) due to the potent and cutting-edge technology known as gene editing. Since it makes it possible to alter particular genes to produce desired results, it has the potential to transform biology, medicine, and agriculture completely. Even though there are many gene editing methods, CRISpen-Cas9 is the most commonly employed and favored method[13]. Synthetic enzymes, sometimes called genetic scissors, are used to insert, delete or replace DNA within the genome of a living organism. Gene editing tools such as CRISpen-Cas9 enable researchers to accurately target and alter specific genes or sequences of DNA. This accuracy carries wide-ranging implications for areas as diverse as biotechnology, agriculture and health care[14].

- **Medicine:**Gene editing seems like a way to fix genetic diseases like muscular dystrophy, sickle cell disease and cystic fibrosis by correcting the underlying genetic defects.
- **Agriculture:** Gene editing can enhance food security by producing crops that are better equipped to withstand environmental stressors, diseases, and pests.
- **Biotechnology:** It makes it possible to produce gene editing organisms with desirable characteristics, such improved expansion, higher efficiency, or immunity to illness.

A Developed from a bacterial immunity system that detects and eliminates virus genomes, CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) is a potent, adaptable genome-editing tool that, when combined with the Cas9 gene enzyme and a synthetic assist RNA, is capable of targeting specific DNA sequences in order to add, remove, or alter the genetic material.

[12] Advances for India as foundational CRISPR/Cas9 gene editing patent granted | ERS Genomics (last visited Apr. 5, 2025).
[13] NHGRI, What is genome editing? (last visited Apr. 15, 2025).
[14] *Id*. at 8.

IV. LEGAL CHALLENGES IN THE PATENTABILITY OF GENE EDITING TECHNOLOGY:

A major legal challenge in gene editing is which and what is patentable. In the developing world, technology is developing in AI, robotics, and biotechnology with a strong focus on sustainability and inclusivity. Extinct animals are brought back with this technological development, as they brought dire wolves back. Technology like CRISPR-cas9 can precisely modify the DNA sequences by cutting and altering them at specific locations. It raises complex questions about whether the resulting edited DNA is a patentable invention or merely a discovery of a natural phenomenon.

A landmark judgment in the US case in gene patent law is ***Association for Molecular Pathology v. Myriad Genetics (2013)***[15], where naturally occurring material is not patentable because it has been isolated, artificially altered, or created DNA eligible for patent protection. The Court allowed patents on cDNA (complementary DNA), which is synthetically created and does not occur naturally. The court ruled that there was a significant impact on genetic and biotechnology research, and the companies drafted their patent claims by saying that their invention is truly inventive genetic modification rather than a discovery of what already exists in nature.

The European Union permits the patenting of isolated gene sequences under the Biotech Directive when the companies demonstrate the industrial application. It shows a policy stance that encourages the invention while maintaining ethical safeguards. Japan also adopted gene-related patents, including broad claims on DNA sequences and treatments like iPSCs (induced pluripotent stem cells).[16] However, Japan sets public morality clauses, and these rules exclude some biotechnology inventions that are against ethical grounds.

In India, the patent act 1970[17] in section 3[18] talks about which are not patentable. Section 3(j) says biological processes used to produce or grow plants or animals cannot be patented. Section 3(c) also excludes discoveries of natural substances, like gene sequences. Therefore, gene editing can be patented because it modifies the genes themselves. If it is a natural process it

[15] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[16] Ramesh B. Karky, Japanese Biotechnology Regulation and Life Science (Gene) Patenting, 24 J. World Intell. Prop. 404, 405-412 (2021).
[17] Patents Act, No. 39 of 1970, INDIA CODE (1970).
[18] Patents Act, 1970, § 3, No. 39, Acts of Parliament, 1970 (India).

cannot be patented. The distinction is pivotal when evaluating process vs product patents. In India process patents are recognized by the gene-editing method(like CRISPR). Granting the patent is more strict for giving to final edited DNA or organisms because of ethical and legal restrictions.[19] The Indian legal system incorporates broader ethical and social concerns. Gene editing in embryos has significant socio-economic and ethical challenges, especially regarding the misuse of non-therapeutic purposes such as creating "designer kids" who prefer changes in color, core height, or intelligence.[20] It could be a high level of social inequality, Specifically if the access is determined by affordability. The primary concerns are the high cost of technology, equitable access, and benefit-sharing remain unresolved. It needs transparency and public awareness. So it must ensure informed consent, and address data protection given to the participant.

The distinctions between process and product patents add another layer to the problem. The methods of gene editing and tools for delivery of gene editing vectors patentable as process patentability of modified gene vectors that result in biological products could be complex. This raises ethical challenges. Many countries patent delivery vectors and tools, and the company maintains secrecy. This partial disclosure approach creates ethical concerns about the transparency, accessibility, and role of patents in the influence sharing of scientific knowledge. Gene editing innovations often emerge in Cooperative settings involving research institutions, Universities, private companies, and public funders.[21] This cooperative research space leads to ownership disputes creating who holds the intellectual property.

A. Ownership Disputes:

The landmark case in the US, which is a talk about the patent dispute for the rights to CRISPR-Cas9 University of California v. Broad Institute, Inc., No. 17-1907 (Fed. Cir. 2018)[22]UC Berkeley demonstrated the CRISPR mechanism in vitro first. However, the broad institution obtained the first patent for its use in eukaryotic cells. This case highlighted how filing strategies, such as expedited patent applications and jurisdictional differences, can determine ownership rights.

[19] Ghosh & De, The Status of Patenting Plants in the Global South, 23 J. World Intell. Prop. 121, 123-135 (2020).
[20] Sarkar & Mazumder, Human Gene Editing and Its Inherent Conundrums: Legal Perspectives, 13 Indian J.L. & Just. 46, 48-64 (2022).
[21] Sherkow & Scott, The Pick-and-Shovel Play: Bioethics for Gene-Editing Vector Patents, 97 N.C. L. Rev. 1497, 1500-1503, 1543-1549 (2019).
[22] University of California v. Broad Institute, Inc., No. 17-1907 (Fed. Cir. 2018)

In India, the implications of this case clearly define who owns the intellectual property in joint biotech projects, particularly those who are supported by government programs like DBT OR CSIR. The lack of statutory protection for junior scientists and co-developers creates more complexity. Sarkar and Mazumder emphasize that India needs a transparency and strong system to prevent exploitation and promote fair innovation.[23] Such conflicts are not just legal but also involve politics and business, as they influence the licenses, academic reputation, and future funding allocations.[24] Without standardized frameworks between multiple institutions' claims, legal uncertainty can deter investment and delay the progress of gene therapies.

B. Jurisdictional Variations:

Different countries approach gene patenting in different ways. It challenges international firms and researchers.These differences reflect each country's laws, health needs, ethics, and economic goals across jurisdictions.

1. **U.S:** After the myriad decisions, natural DNA cannot be patented, but synthetically altered sequences like cDNA can be patented. The USPTO permits patents on CRISPR tools and techniques if they meet the novelty and utility standards[25]. However still uncertain about patent claims, particularly those that overlap with naturally occurring genes and biological functions.
2. **European Union:** The European Union recognizes biotechnological inventions due to the Biotechnology Directive (Directive 98/44/EC) and allows the patenting of gene sequences, provided that their industrial applications are disclosed. The Directive categorically prohibits the patenting of human embryos and germline cell modifications on ethical considerations[26]. Although EU member nations profess to follow these regulations, the level of compliance varies greatly, so patenting procedures under this jurisdiction are more challenging.
3. **India:** Section 3(c) and Section 3(j) of the Patents Act under the Indian context prohibit the patenting of naturally occurring gene sequences and living organisms. Though gene editing technologies like CRISPR can be patented as processes,

[23] Sarkar & Mazumder, Human Gene Editing and Its Inherent Conundrums: Legal Perspectives, 13 Indian J.L. & Just. 46, 48-64 (2022).

[24]Chilukuri & Kelley, Biopower: Securing American Leadership in Biotechnology (Conclusion), Ctr. for a New Am. Sec., 61 (2025).

[25] Bagley, Race-ing Patents/Patenting Race: An Examination of the U.S. Patent System's Discriminatory Impact on Black Inventors, 92 Iowa L. Rev. 353, 383-384 (2021).

[26] Directive 98/44/EC, of the European Parliament and of the Council, on the Legal Protection of Biotechnological Inventions, arts. 3–6, 1998 O.J. (L 213) 13.

claims on edited genes or human interventions, e.g., germline editing, are ethically and legally restricted. Regulation by regulatory authorities like the ICMR and DBT further limits the application of gene editing to somatic interventions in the clinical research context.[27] The approach taken by India is one of public health, bioethics, and distributive justice, and hence gene editing becomes a tool for enhancing social equity and not a tool for enhancing commercial interests.

4. **Japan:** Japan's nation has a positive policy towards innovation and encourages the patenting of therapies derived from DNA and gene-modification-related technologies. Japan is actively engaged in harmonizing its patent legislation with that of the United States and the European Union by issuing initial guidelines concerning the patentability of biotech advancements.[28] On the other hand, Japan employs ethical limitations through its provisions of public order and morality in patent legislations that can prohibit inventions against the-existing social norms.
5. **China:** China is also emerging as a hub for biotechnology, with a dramatic increase in patent filings, especially in gene editing. Permissive of product and process patents, China has strict state control of human gene use. The legal systems are changing rapidly but are being tried out in terms of transparency, intellectual property rights, and bioethics.
6. **Global South and FTAs:** Several Global South nations, such as India, are under significant pressure from multinationals and advanced economies in the form of Free Trade Agreements (FTAs) to accept TRIPS-plus standards.[29] These standards are usually designed to increase the scope and duration of patent protection over what is offered under the WTO TRIPS Agreement. These norms can be in contradiction to national laws attempting to provide access to life-saving medicines and genetic technologies and, as such, limit the exercise of domestic regulatory autonomy.

Jurisdictional variation has significant implications for international patent policy and creates uncertainty for policymakers, companies, and scholars. Multinational firms must navigate a rich intellectual property regime diversity, which can chill innovation and impose compliance costs. For developing countries, reconciling international commitments and domestic goals is a significant challenge.

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[27] *Id.* at 15.
[28] *Id.* at 11.
[29] *Id.* at 14.

C. Patent Thickets and Innovation Stifling:

Gene editing technologies such as CRISPR involve various aspects of innovation—such as enzymes, guide RNAs, promoters, and delivery mechanisms. Each of these can be patented independently by various organizations, and this leads to patent thickets. Patent thickets increasingly deter new entrants and researchers from operating without having to negotiate complex licensing arrangements or risking infringement. It is very challenging for Indian researchers and start-ups to navigate the fragmented intellectual property terrain. Overlapping patents can curb innovation through the enhancement of the costs and the complexities of licensing arrangements. In addition, this is discouraging academic research and participation by small innovators as they do not have the financial and legal resources necessary to conduct freedom to operate analysis in multiple jurisdictions.

In addition to that, Genetic Use Restriction Technologies (GURTs) and proprietary use of data establish technical dependencies and augment corporate control. Sarkar and Mazumder caution that these paradigms not only suppress local innovation but are also a looming threat of bio-colonialism, where Indian ecosystems and genetic resources are being used without fair sharing of benefits.[30]

The ethical consequences are of significant scale. With restricted access to basic resources, innovation could be concentrated in the hands of a few powerful organizations, leading to monopolies. This is added to by strategic use of secrecy and selective disclosure in patent applications, as in the "Pick-and-Shovel Play," where companies conceal technical information while gaining substantial legal protection.[31] These practices undermine the very basic function of patents facilitating knowledge sharing by providing public access to inventions.

V. ETHICAL CHALLENGES THAT INVOLVED IN THE PATENTABILITY OF GENE EDITING TECHNOLOGIES:

From an ethical perspective, living things are considered to be divine creations and cannot be owned by human beings through the device of patents. The onus of creating and owning every living thing on Earth lies solely with God. Every living thing has inherent wholeness and

[30] *Id.* at 15.

[31] Sherkow & Scott, The Pick-and-Shovel Play: Bioethics for Gene-Editing Vector Patents, 97 N.C. L. Rev. 1497, 1500-1503, 1543-1549 (2019).

dignity which need to be protected and guaranteed[32]. Human beings should not disturb the right divine natural order by changing living beings. That said, as gene editing and related genetic engineering technologies raise important ethical questions, there is not sufficient attention to the ethics of such technologies in Indian intellectual property laws. These ethical implications relating to diverse technologies could shape patent eligibility, licensing terms and the political significance of intellectual property rights in genetics more widely. The following are some ethical considerations:

1. **Access to Healthcare:** Patents and other forms of intellectual property laws can make it difficult to obtain necessary medical devices. For example, patents on key genetic medicines or diagnostic technologies might exclude certain individuals who are unable to purchase the patented technology from access to genetic engineering and gene editing. This raises questions about how to balance commercial interests and the public interest fairly, and how to ensure that everyone has access to health care.
2. **Human dignity and Autonomy:**One essential aspect of any organism, including a human being, is that its genes can be edited and modified through gene editing and genetic engineering. There are ethical concerns raised by the application of these advancements to modify the human genome, including germline editing, which may challenge concepts of autonomy, human dignity, and permissible or impermissible interventions.
3. **Equity and Justice:** Advances in technology like genome editing and genetic engineering could make already-existing social and economic disparities worse. Other researchers may find it more difficult to advance or use these innovations if intellectual property rights are concentrated in the hands of a restricted number of organizations, especially in environments with limited resources. When these technologies reinforce or exacerbate already-existing inequalities, concerns are raised.

Due to patenting organisms privatizes life and considers it like property, it is considered unethical. A patent can be purchased, sold, or transferred, just like any other private property.In context of gene editing and genetic engineering technologies It is important to accept that intellectual property laws can impact the progress, promotion, and accessibility and they are not intended to provide Extensive answers to the ethical concern these technologies present.

[32] Pancham Rathod & Sheetal Tiwari, Patent And Genome Editing Technologies: Issues And Challenges, I IPR J. MNLU 93, 100.

In the context of gene editing and genetic engineering technologies It is important to accept that intellectual property laws can impact the progress, promotion, and accessibility and they are not intended to provide Extensive answers to the ethical concern these technologies present. In the case a unanimous ruling in ***Association for Molecular Pathology v. Myriad Genetics (2013)***, the Supreme Court determined that naturally occurring DNA sequences, including the BRCA1 and BRCA2 genes and their natural derivatives, are not patentable.In contrary, synthetic complementary DNA (cDNA) can be patented, because it does not occur in nature. This ruling overturned Myriad's decision to take exclusive control over the extraction and testing of BRCA genes, expanding the access to BRCA tests and allowing additional companies to engage with BRCA genes to potentially reduce patent expenses[33].

The decision, which lifted patent restrictions on natural gene sequences, promoted more extensive genetic research and innovation. However, it also raised investor concerns about the lower returns on novel genetic testing and treatments, which led some businesses to choose trade-secret tactics over patents. The Myriad ruling created ambiguity over the patentability of diagnostic techniques, similar to ***Mayo v. Prometheus***, which could deter investment in personalised genetic therapy because of concerns about inadequate patent protection[34].

VI. BALANCING INNOVATION, ACCESSIBILITY, AND OWNERSHIP:

A. The Role of Open Science and Patent Pools:

Open science has become an important framework for improving transparency, cooperation, and inclusiveness of scientific research. Open science lowers the barriers to scientific innovation by sharing data, results and methods. In the Indian context, with a large portion of research funded through public financing, open science can promote democratization of access and facilitate collective progress[35]. Patent pools act as an additional mechanism to encourage the collective management of intellectual property rights by allowing multiple patent holders to license their patents as a bundle. This approach reduces transaction costs and mitigates the problem of "royalty stacking." In

[33] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[34] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).
[35] Grunewald, S. (2019). *CRISPR's Creatures: Protecting Wildlife in the Age of Genomic Editing*. UCLA Journal of Environmental Law and Policy, 37(1), 1–58.

addition, it leads to faster diffusion of the technology[36]. The countries that need patent pools the most are those in the developing world like India, where critical sectors such as agriculture and pharmaceuticals can have substantial health ramifications driven by monopolistic existence. Patent pooling agreements under fair, reasonable and non-discriminatory (FRAND) principles provide an institutional framework that enables open science without hindering innovation through excessive ownership control.

B. Compulsory Licensing as a Mechanism for Access:

Compulsory licensing (CL) is a legal mechanism by which governments can enable individuals to utilize patented inventions without the consent of the patent holder. It is mostly employed to fulfill public health needs. An example is the Natco Pharma Limited vs Bayer Healthcare Llc on 11 July, 2019[37] case in India, where a license for a more affordable version of the cancer drug Nexavar (sorafenib) was granted because the original drug was too expensive and not available. The balance between incentivizing innovation and ensuring public availability remains tenuous. While patents provide exclusive rights that can incentivize investment in research and development, they can overly restrict follow-on innovation and access, especially for important medical treatments. Since patents in genetics and biotechnology often involve core knowledge for subsequent innovation, effective use of CL [38] probably remains crucial. For India, the flexibility of its CL framework to include new technologies like genome editing tools (e.g., CRISPR-Cas9) is essential. Extending the application of CL, such as to preventive and diagnostic technologies, can make it more effective in protecting the right to health.

C. Ethical Patentability Frameworks: Responsible Licensing and Benefit Sharing

Ethical patenting systems seek to harmonize intellectual property rights with the values of equity, justice, and sustainability. The systems promote ethical systems of licensing that are dependent on accessibility, affordability, and public good, particularly in areas influencing vital human needs like healthcare and food security[39]. India's legal regimes, as exemplified by the Biological Diversity Act of 2002 and its commitment under the

[36] Monast, J. J. (2018). *Editing Nature: Reconceptualizing Biotechnology Governance*. Boston College Law Review, 59(7), 2377–2436.

[37] Natco Pharma Limited v. Bayer Healthcare Llc, (2019) 262 DLT 284.

[38] Yotova, R. *Regulating Genome Editing under International Human Rights Law*. International and Comparative Law Quarterly, 69(3), 653–684 (2020).

[39] Samyuktha, A., & Sadhana, S. (2023). *Navigating Intellectual Property Rights in the Dynamic Landscape of the Food Industry*. International Journal of Law Management & Humanities, 6, 2987–2998.

Nagoya Protocol, form the basis for equitable sharing of benefits from bioprospecting and use of traditional knowledge. Such legislative measures call for equitable sharing of benefits from use of biological resources and associated traditional knowledge by local communities.[40]

Also, ethical standards propose the inclusion of provisions in licensing agreements that prevent patent abuse and advance humanitarian objectives. These are non-exclusive licensing conditions in third world countries, price limitations, and technology transfer arrangements. Monast (2018) asserts that embracing a resource management approach in intellectual property management can assist in ensuring ethical issues, such as intergenerational equity and maintaining the environment, are not overlooked in the pursuit of profit maximization.[41]

D. Encouraging Innovation Without Creating Monopolies:

The problem of spurring innovation but not the creation of monopolies is the core part of the intellectual property problem. Extensive patent protection may spur innovation through a window of exclusivity; nevertheless, unchecked monopolization may discourage competition and restrict access to vital goods and technologies[42] . In the Indian context, this equilibrium is seen in the framing of its intellectual property legislation, which aims to encourage innovation while possessing protective elements, as seen in Section 3(d) of the Indian Patents Act. This section prevents the grant of patents for incremental innovations that lack increased efficacy. These measures serve to avoid the threats of "evergreening" and ensure that monopolistic practices are not prolonged without justification. Various incentive strategies, such as open-source drug development, prize funding, and publicly financed research and development with conditions for access, can foster innovation without relying solely on proprietary rights[43]. Moreover, public-private partnerships and programs that promote shared infrastructure and collaborative research can reduce duplicated efforts and make innovation accessible to everyone. Regulatory frameworks have to adjust to address the issues brought about by emerging technologies. For example, CRISPR and other gene

[40] Unnikrishnan, A. (2024). *Analyzing the Impact of Emerging Technologies on Intellectual Property Rights (IPR)*. Law & World, 29, 66–79.

[41] Monast, J. J, *Editing Nature: Reconceptualizing Biotechnology Governance*. Boston College Law Review, 59(7), 2377–2436 (2018).

[42] Mowzoon, M, *Access Versus Incentive: Balancing Policies in Genetic Patents*. Arizona State Law Journal, 35(3), 1077–1104 (2003).

[43] Grunewald, S, *CRISPR's Creatures: Protecting Wildlife in the Age of Genomic Editing*. UCLA Journal of Environmental Law and Policy, 37(1), 1–58 (2019).

editing tools pose some ethical and environmental issues. As Yotova (2020) argues, the use of international human rights principles in regulation of biotechnology is necessary to ensure innovation is respectful of basic rights and does not exacerbate inequalities.[44]

VII. EXAMPLE OF GENE EDITING TECHNOLOGIES:

Some of the leading gene-editing technologies currently in use are as follows:

1. **Meganucleases:**
   Naturally occurring "molecular scissors" (e.g. LAGLIDADG homing endonucleases) that are engineered to cleave long (12–40 bp) DNA sequences and produce site-specific double-strand breaks for targeted gene modification.
2. **Zinc-Finger Nucleases (ZFNs):**
   Chimeric proteins that integrate user-tailorable zinc-finger DNA-binding domains with the FokI nuclease; cause DSBs at user-specified loci to initiate repair through NHEJ or HDR.
3. **Transcription Activator-Like Effector Nucleases (TALENs):**
   Comparable to ZFNs, but with less context restrictions and higher specificity, TALE repeat domains fused to FokI are employed for DNA recognition.
4. **CRISPR-Cas9:**
   Cas9 is directed to a 20 nt target next to a PAM sequence by a single guide RNA in an RNA-guided endonuclease system, which produces accurate DSBs allowing flexible editing in almost any organism.

VIII. CASE STUDIES:

Important genetic engineering court cases in India have illuminated the intersection between innovative ideas and regulatory structures. The ***Basmati rice*** patent controversy was a milestone in bringing into focus the need for clarity regarding patentability criteria for genetic resources[45]. Likewise, fights over gene patents reflect the difficulties of applying conventional intellectual property legislation to fast-developing biotechnologies. These cases have ramifications for defining a legal environment that promotes innovation while protecting ethical concerns and national interests. Ethical concerns for researchers in India are highlighted

[44] Yotova, R. *Regulating Genome Editing under International Human Rights Law*. International and Comparative Law Quarterly, 69(3), 653–684 (2020).
[45] The Legal And Ethical Implications Of Genetic Engineering And Gene Editing Technologies In India's Intellectual Property Laws » Lawful Legal (last visited Apr. 14, 2025).

by the need to reconcile scientific advancement with responsible practice. Matters of informed consent, cultural sensitivities, and transparency in research practices remain persisting challenges. The evolving dynamics of genetic engineering present concerns over unforeseen impacts, misuse, and fair access to benefits, compelling researchers to tread a fine ethical line in order to ensure the integrity of their work.

IX. CASE LAWS:

1. **Diamond v. Chakrabarty (U.S., 1980):**

   Utilising recombinant DNA methods, scientist Chakrabarty created a new breed of bacteria that can metabolise hydrocarbons in a way that isn't found in naturally occurring organisms. The microbes showed a lot of potential for cleaning up oil spills. The Patent Office rejected the plaintiff's patent application, stating that the microorganisms were unpatentable because they were natural goods. The Board of Appeals affirmed. The United States Supreme Court granted a patent held that genetically modified, human- made living organisms are patentable under section 101[46].

2. **Association for Molecular Pathology v. Myriad Genetics, Inc. (U.S., 2013):**

   The precise position and structure of two human genes, BRCA1 and BRCA2, whose mutations greatly enhance the risk of breast and ovarian cancer, were identified by Myriad Genetics, Inc. where for this Myriad obtained a patent and that had been challenged by Association for molecular pathology and other medical professionals and researchers, arguing that it is a product of nature so it can't be patentable. The U.S Supreme Court held that naturally occurring DNA sequences even if it is isolated are not patentable due to there being products of nature. However, since cDNA is not found in nature, it is patentable[47].

3. **Monsanto Co. v. Schmeiser (Canada, 2004):**

   Monsanto is a well known biotech company who got a patent for a genetically modified Roundup Ready Canola. Which has been sued by Canadian Farmer Percy Schmeiser for a patent infringement. Later, he discovered herbicide-resistant canola and planted it again without a license. The Court decided that the Monsanto patent was legitimate and ruled in favour of the company[48]. As well as Schmeiser infringed the patent by growing

[46] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[47] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).
[48] Monsanto Canada Inc. et al. v. Schmeiser et al., (2004) 320 N.R. 201 (SCC).

rapidly and profiting from the patented genetically modified canola plants, Schmeiser violated the patent.

4. **Novartis AG v. Union of India:**

   Novartis AG is a Swiss pharmaceutical company that developed a cancer drug called Glivec (Imatinib Mesylate). For this invention, Novartis applied for a patent, but it was rejected by an Indian patent officer by stating that a new form of a known Substance can't be patentable (Section 3(d)). As a consequence of this, Novartis challenged the decision which was given by the patent officer. The Supreme Court of India had upheld the decision of the patent officer and ruled that Novartis' invention is not new, it is just an altered or modified form of a known substance[49].

5. **Harvard College v. Canada (Commissioner of Patents), 2002:**

   During the 1980s, Harvard college delivered a genetically engineered mouse which is known as "Oncomouse". The reason for its modification was to carry out a cancer-promoting gene, which is valuable for conducting research purposes. For this invention Harvard made an application before the Canadian Patent Office, but they stated that the patent be granted for process but not for mouse itself because it is a life form so it can't be patentable. The Supreme Court maintained the patent office's ruling[50].

6. **Broad Institute v. UC Berkeley:**

   The central controversy pitted UC Berkeley's May 2012 patent application for applying CRISPR–Cas9 in prokaryotic (test-tube) systems against the Broad Institute's April 2014 patents on its use in eukaryotic (animal and human) cells. In February 2017, the U.S. Patent Trial and Appeal Board determined "no interference in fact," and the Federal Circuit subsequently upheld that the two groups of claims are patentably distinct[51]. The decision places moral control over a game-changing technology in private hands by giving the Broad Institute exclusive rights to eukaryotic-cell CRISPR, potentially resulting in unequal access and circumventing democratic monitoring. Allowing the Broad Institute to enforce "ethical licensing" limitations allowed for quick private management of CRISPR uses while avoiding democratic accountability and public involvement.

[49] Novartis AG v. Union of India, (2013) 6 SCC 1.
[50] Harvard College v. Commissioner of Patents (Can.), (2002) 296 N.R. 1 (SCC).
[51] University of California v. Broad Institute, Inc., No. 17-1907 (Fed. Cir. 2018).

X. RECOMMENDATIONS AND FUTURE PATHWAYS:

1. To ensure that only true human ingenuity is eligible for patent protection and that essential genetic information is still available to researchers and healthcare providers, patent rules should be changed to clearly distinguish between naturally occurring gene sequences and man-made inventions.
2. To ensure that the Countries and the companies are actively engaged in gene editing technologies, it should operate with full transparency and collaborate closely with international bodies such as the United Nations. So, this partnership can aid in establishing global standards and monitoring systems to ensure that the gene editing technologies are being used in an ethical way only and also exclusively for peaceful purposes. Transparent practices and UN oversight can prevent the misuse of this powerful technology for harmful objectives like biological warfare, and instead promote its use in advancing global health and development.
3. To encourage cooperation, avoid monopolistic control in genetic testing, and safeguard consumer interests by lowering obstacles such licensing costs and onerous patent terms, support open-access projects and fair licensing standards.
4. Enhance public awareness and lobbying to encourage universal, equal access to genetic technologies and information and to enlighten communities about their rights with regard to genetic testing.
5. To Promote government participation and public-private partnerships to put public health ahead of business, lowering the cost of genetic testing, and guaranteeing widespread access to genetic data.

XI. CONCLUSION:

There are many ethical issues around gene patenting, illustrating the complex interplay between innovation, access, and equity. On the one hand, patents encourage research and development in the field of genetics, driving innovation in diagnostics and treatments that can save lives. On the other hand, the exclusivity granted by patents tends to create monopolies, increasing prices and restricting access to vital genetic tests and therapies, especially for disadvantaged populations and nations. Establishing a regulatory framework that strikes a balance between the needs of innovation and people's fundamental right to healthcare is crucial as the field of gene patenting develops to guarantee that the advantages of genetic breakthroughs are shared fairly throughout society. Several instances of ethical issues are respect for human dignity,

moral conduct, and reliable research. In order to democratize the advantages of new technologies and advance healthcare fairness, affordability and accessibility must be addressed. India's regulatory bodies must establish strong oversight procedures and international cooperation to properly use the transformational potential of new technologies in order to successfully negotiate these challenges.

REFERENCES

STATUTES:

1. Patents Act, No. 39 of 1970, INDIA CODE (1970).
2. Patents Act, 1970, § 3, No. 39, Acts of Parliament, 1970 (India)
3. Patents Act, 1970, § 3(C), No. 39, Acts of Parliament, 1970 (India).
4. Patents Act, 1970, § 3(j), No. 39, Acts of Parliament, 1970 (India).

BOOKS AND ARTICLES:

1. 5th edition william cornish, Cases and materials (Sweet & maxwell 2006)
2. Malathi Lakshmikumaran, Patenting of Genetic Inventions, 12 MANU 45, 46 - 49 (2007).
3. Sherkow & Scott, The Pick-and-Shovel Play: Bioethics for Gene-Editing Vector Patents, 97 N.C. L. Rev. 1497, 1500-1503, 1543-1549 (2019).
4. Ramesh B. Karky, Japanese Biotechnology Regulation and Life Science (Gene) Patenting, 24 J. World Intell. Prop. 404, 405-412 (2021).
5. Nordberg et al., Cutting Edges and Weaving Threads in the Gene Editing (R)evolution, 5 J.L. & Biosciences 35, 36-45 (2018).
6. Sarkar & Mazumder, Human Gene Editing and Its Inherent Conundrums: Legal Perspectives, 13 Indian J.L. & Just. 46, 48-64 (2022).
7. Chilukuri & Kelley, Biopower: Securing American Leadership in Biotechnology (Biorevolution), Ctr. for a New Am. Sec., 6-9 (2025).
8. Chilukuri & Kelley, Biopower: Securing American Leadership in Biotechnology (Recommendations), Ctr. for a New Am. Sec., 48-50 (2025).
9. Chilukuri & Kelley, Biopower: Securing American Leadership in Biotechnology (Conclusion), Ctr. for a New Am. Sec., 61 (2025).
10. Ghosh & De, The Status of Patenting Plants in the Global South, 23 J. World Intell. Prop. 121, 123-135 (2020).

11. Bagley, Race-ing Patents/Patenting Race: An Examination of the U.S. Patent System's Discriminatory Impact on Black Inventors, 92 Iowa L. Rev. 353, 383-384 (2021).
12. Vandersloot, Genetic Use Restriction Technologies and Sustainable Agriculture in Developing Countries, 20 Geo. Int'l Envtl. L. Rev. 271, 282-285 (2008).
13. Grunewald, S. *CRISPR's Creatures: Protecting Wildlife in the Age of Genomic Editing*. UCLA Journal of Environmental Law and Policy, 37(1), 1–58 (2019).
14. Monast, J. J. *Editing Nature: Reconceptualizing Biotechnology Governance*. Boston College Law Review, 59(7), 2377–2436 (2018).
15. Mowzoon, M. *Access Versus Incentive: Balancing Policies in Genetic Patents*. Arizona State Law Journal, 35(3), 1077–1104 (2003).
16. Samyuktha, A., & Sadhana, S. *Navigating Intellectual Property Rights in the Dynamic Landscape of the Food Industry*. International Journal of Law Management & Humanities, 6, 2987–2998 (2023).
17. Unnikrishnan, A. *Analyzing the Impact of Emerging Technologies on Intellectual Property Rights (IPR)*. Law & World, 29, 66–79 (2024).
18. Yotova, R. *Regulating Genome Editing under International Human Rights Law*. International and Comparative Law Quarterly, 69(3), 653–684 (2020).

BIBLIOGRAPHY:

1. Directive 98/44/EC, of the European Parliament and of the Council, on the Legal Protection of Biotechnological Inventions, arts. 3–6, 1998 O.J. (L 213) 13,Directive 98/44/EC PDF on EUR-Lex**. (**March 26,2025)
2. LEGALVIDHIYA,https://legalvidhiya.com/genetic-engineering-and-intellectual-property-legal-and-ethicalimplications/#:~:text=Examining%20legal%20considerations%20like%20patentability%2C%20infringements%2C%20and%20licensing%2C,associated%20with%20genetic%20engineering%20and%20gene%20editing%20techniques (last visited March. 30, 2025).
3. ipindia.gov.in,https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf? (last visited March. 30, 2025).
4. E-PGPATHSHALA,https://epgp.inflibnet.ac.in/epgpdata/uploads/epgp_content/S000014ER/P000283/M025535/ET/1513150088paper13_module_18_etext.pdf (last visited Apr. 1, 2025).

5. IJLSI,https://ijlsi.com/wp-content/uploads/Gene-Editing-Technologies-and-Patent-Landscape.pdf (last visited Apr. 16, 2025).
6. SPICYIP, Do Indian Scientists Need to Worry about CRISPR Licences? – SpicyIP (last visited Apr. 2, 2025).
7. Advances for India as foundational CRISPR/Cas9 gene editing patent granted | ERS Genomics (last visited Apr. 5, 2025).
8. NHGRI, What is genome editing? (last visited Apr. 15, 2025).
9. The Legal And Ethical Implications Of Genetic Engineering And Gene Editing Technologies In India's Intellectual Property Laws » Lawful Legal (last visited Apr. 14, 2025).

CASES:

1. Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
2. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
3. Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).
4. Monsanto Canada Inc. et al. v. Schmeiser et al., (2004) 320 N.R. 201 (SCC).
5. Harvard College v. Commissioner of Patents (Can.), (2002) 296 N.R. 1 (SCC).
6. University of California v. Broad Institute, Inc., No. 17-1907 (Fed. Cir. 2018).
7. Natco Pharma Limited v. Bayer Healthcare Llc, (2019) 262 DLT 284.
8. Novartis AG v. Union of India, (2013) 6 SCC 1.