Popular Agriculture **1(5) 50-53 (September, 2025)**
Published at popularagriculture.com

POPULAR ARTICLE

Genome editing and IPR issues current scenario

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Manuscript received: August 15, 2025; Decision on manuscript, August 28, 2024; Manuscript accepted: September 10, 2025

Genome editing raises intellectual property (IP) issues primarily related to patenting, which can lead to corporate control, high costs, and potential monopolies over essential technologies, potentially hindering access for farmers and researchers. Complex patent thickets around tools like CRISPR can also create legal hurdles, increasing costs and slowing down innovation and application. Balancing the need to reward inventors with the goal of open innovation and equitable access to these vital technologies for global challenges like food security and health is a key challenge.

Genome editing is a technology that allows scientists to make specific changes to an organism's DNA, such as adding, removing, or altering genetic material. It acts like molecular "scissors" that can cut DNA at a specific location, enabling the repair or modification of genes. The CRISPR-Cas9 system is a widely used genome editing tool that is faster, cheaper, and more accurate than older methods.

Actual working of the genome editing technology

Targeting: A guide RNA molecule finds and binds to the target DNA sequence in the genome.

Cutting: An enzyme called Cas9 is attached to the guide RNA, and it cuts the DNA at the specific location where the guide RNA is bound.

Editing: The cell's natural repair mechanisms are then used to either disable a gene or to insert, delete, or replace a segment of DNA.

Genome editing presents issues including safety concerns like unintended, off-target mutations, which could cause health problems such as cancer. Ethical challenges include the potential for misuse in creating "designer babies" or exacerbating social inequalities, particularly through irreversible germline editing that could affect future generations. Other issues include lack of global regulation and questions about accessibility and informed consent.

Safety concerns

Off-target effects: Editing may cause unintended changes to the DNA at locations other than the intended site, potentially leading to serious health issues like cancer.

Unpredictable outcomes: The effects of genome editing, especially regarding epigenomic changes, are not fully understood and could interact with other genes in unpredictable ways.

Genetic mosaicism: Edits may not occur in all cells, leading to a mixture of edited and unedited cells in the same individual, which can cause side effects.

Irreversible changes: Once introduced, especially in germline cells, changes can be passed down to future generations, and it would be difficult to remove a harmful edit from the population.

Ethical and social issues

Eugenics and enhancement: There are concerns that genome editing could be used to enhance non-therapeutic traits (e.g., intelligence or appearance) rather than treat disease, potentially creating a genetically stratified society.

Inequality: If the technology is expensive, it could only be accessible to the wealthy, increasing existing disparities in health care and other areas.

Germline editing: Making heritable changes to sperm, eggs, or embryos is particularly controversial because the effects would be permanent and passed down through generations, with potentially unforeseen consequences.

Informed consent: For germline editing, it is not possible to obtain consent from the individuals who will be most affected in the future the future generations.

Legal and regulatory issues

Lack of global legislation: There is a need for clear, worldwide regulations to guide the use of this technology, though some countries have already banned certain applications, such as heritable germline editing.

Liability: Legal frameworks are needed to determine who is responsible if something goes wrong, especially with changes that can be passed to future generations.

Ecological and security risks

Ecological imbalance: In non-human applications, gene-edited organisms could spread resistance genes through horizontal gene transfer, disrupting ecosystems and potentially spreading antibiotic resistance to other species.

Bioweapons: The technology could be misused to create biological weapons, posing a global security threat.

IPR issues related to genome editing

Patent thickets and complexity: Overlapping patents on gene editing technologies like CRISPR create a complex legal landscape. This can lead to "patent thickets" where multiple companies hold rights, making it difficult and expensive for others to use the technology without infringement.

Monopoly and access: Owning patents can grant companies exclusive rights, potentially leading to high prices for treatments or seeds. This can create a monopoly and limit access, especially for developing nations and farmers, leading to dependency on foreign technologies and potentially impacting food security.

Balancing innovation and access: There is a tension between protecting the intellectual property of inventors to incentivize innovation and ensuring equitable access to transformative technologies for the public good.

Impact on farmers: In agriculture, IP issues can lead to concerns that farmers will become dependent on seed companies that own the patents for gene-edited crops, rather than having the freedom to save and reuse seeds.

Slowing down research: The complexity of IP can slow down research and development in areas like therapeutics, as companies must dedicate significant resources to legal and strategic planning to avoid infringement.

Solutions being explored: To address these issues, some propose solutions like creating global patent pools or open-source platforms to make the technology more accessible and reduce patent disputes.

Farmer and food sovereignty: Proprietary gene-editing tools and patented seed varieties are raising concerns about farmers' ability to save and replant seeds, potentially creating dependence on foreign technology and compromising national food sovereignty, according to Rice News Today and Down To Earth.

"Patent thickets": The overlapping nature of patents for various gene-editing technologies, such as CRISPR, creates complex licensing landscapes that can lead to legal disputes, delayed development, and increased costs for companies.

Commercialization and access: Navigating a complex web of patents can hinder the development and deployment of new technologies, especially in therapeutic areas.

Impact on biodiversity: The release of new gene-edited varieties could threaten the diversity of native species, potentially impacting trade possibilities for non-GM varieties, notes Down To Earth.

Ethical considerations: The concentration of IPR in the hands of a few large companies raises broader questions about corporate power, fairness, and the integrity of the food system, says the National Institutes of Health.

Challenges in patenting: The novelty and complexity of genome editing technologies have created challenges for patent offices, including in India, in determining patentability and managing existing disputes.

Ethical and other concerns

Beyond IP, other issues are associated with genome editing:

Safety and environmental risks: Concerns exist about unintended consequences, such as the possibility of modified genes spreading to wild relatives in agriculture or the potential for harmful off-target edits in humans.

Germline editing: The editing of human germline cells (sperm, eggs, embryos) raises unique ethical questions because the changes are heritable and could be passed down to future generations.

Eugenics: A fear exists that gene therapy could be misused to create a eugenics movement, which would select for certain traits and reject individuals who do not meet those standards.

Future prospects for gene editing related to IPR issues

These include potential cures for genetic diseases, improved crops for climate change resilience, and treating chronic diseases. However, significant ethical, technical, and societal challenges remain, such as off-target mutations, unpredictable effects on the gene pool, the need for stricter regulations, equitable access, and the risk of misuse for non-medical enhancements.

Curing genetic diseases: Gene editing is moving towards mainstream treatment for inherited disorders like sickle cell anemia, cystic fibrosis, and hemophilia, with ongoing research showing positive clinical trial outcomes.

Treating chronic diseases: In the future, gene editing may be used to target the genetic components of chronic diseases such as heart disease, cancer, and diabetes.

Agriculture and climate change: The technology can improve crops for better yields, nutritional value, and resistance to pests and climate change impacts, contributing to global food security.

Developing new therapies: Advanced techniques like base editing and prime editing are enhancing precision, while new delivery methods like lipid-based systems are being developed to improve safety and control.

Issues and overall challenges faced while adopting the technology

Technical challenges

Off-target mutations: There is a risk of unintended edits at other locations in the genome, which could lead to serious health issues, including cancer.

Delivery mechanisms: Safely and efficiently delivering the editing machinery to the correct cells is a major obstacle, with viral vectors sometimes causing immune responses and non-viral methods still being optimized.

Ethical and societal concerns

Unpredictable consequences: The long-term effects of germline editing on the human gene pool are unknown and potentially uncontrollable.

Equity and access: Ensuring that these advanced and potentially expensive treatments are accessible to everyone and not just a privileged few is a major societal challenge.

Regulation and misuse: There is a need for robust regulatory frameworks to govern its use and prevent its application for non-medical purposes like "enhancements," which could exacerbate social inequalities.

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