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Gene Editing Technologies and Patent Landscape: Navigating Legal and Ethical Challenges in the Context of Genetic Resources

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ABSTRACT

Gene editing technologies, such as CRISPR-Cas9, have revolutionized biotechnology due to their ability to modify genes precisely and profoundly. As well as exploring possible consequences for the world's genetic resources, this study explores the ethical and legal issues raised by the patenting of gene editing technology. It examines ethical concerns, the intricate relationship between gene editing patents and biodiversity conservation, and the current legal framework.

It is important to consider ethical considerations when considering how patenting gene editing breakthroughs affects indigenous peoples. By comparing the gene-editing patent landscape across different jurisdictions and taking a closer look at international perspectives, the paper argues for regulatory harmonization to address global barriers.

By examining case studies and legal precedents, this research reveals significant challenges in the gene editing patent field. The study also evaluates how gene editing patents affect access to these ground-breaking technologies, with an emphasis on promoting innovation while guaranteeing fair access worldwide, especially for poor nations.

To strike a balance between guaranteeing the ethical, and responsible use of these technologies and promoting innovation through gene editing patents, the research concludes with legislative suggestions and potential solutions. This work adds to a nuanced understanding of the legal and ethical landscape in a field that is developing quickly, such as gene editing, and offers insightful information that will be useful in guiding future policy discussions and developments at the nexus of gene editing technologies and genetic resource protection.

***Keywords**: Gene editing technologies-CRISPR-Cas9, Ethical concerns, Legal issues, Patenting, Indigenous peoples Regulatory harmonization, Innovation, Fair access.*

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I. INTRODUCTION

Biotechnology and bioengineering are dynamic, fast-moving technologies that have transformed many industries and sectors, from manufacturing and healthcare to environmental sustainability. The persistent surge of creativity in these fields has fueled ground-breaking discoveries and unleashed the potential of innovation to influence science and technology in the future. The transformative potential of several subtopics within biotechnology[2] and bioengineering is explored in this thorough review article. These subtopics include genetic engineering advancements, bioprocessing innovations, bioinformatics and big data analytics, nanotechnology applications, synthetic biology, bioengineering human organs, bioremediation strategies, emerging therapeutic modalities, industrial applications, and bio-inspired engineering. Thanks to genome editing tools, scientists may alter DNA to affect physical characteristics like eye color and risk of illness. To achieve this, scientists employ a variety of technologies. These methods cut the DNA at a specified location, much like scissors. The DNA that was sliced can then be added to, removed from, or replaced by scientists. The late 1900s saw the development of the first genome editing technology. More recently, modifying DNA has become simpler than ever thanks to a new genome editing tool called CRISPR, which was developed in 2009. Older genome editing techniques are more complicated, time-consuming, expensive, and inaccurate than CRISPR. CRISPR is currently widely used by scientists to undertake genome editing[3]. Remarkable developments in genetic engineering, most notably the introduction of CRISPR technology, have made accurate and effective genome editing possible. This potent instrument has made it possible to modify genetic material in novel ways, leading to breakthroughs in a variety of industries, including biotechnology, medicine, and agriculture. The promise for treating genetic abnormalities, creating innovative medicines, and increasing agricultural output is enormous when it comes to the remarkable accuracy with which genes can be edited. Genetic engineering has seen a revolution in recent years with the advent of CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) technology and its uses in gene editing. The development of the potent gene-editing tool CRISPR-Cas9 has revolutionized the science by making it possible to modify genetic material precisely and effectively. This novel technique targets particular DNA sequences using a guide RNA and then uses the Cas9 protein to cut and alter the DNA at those locations. Researchers now have an easy-to-use and flexible tool for researching gene function, creating treatments, and

[2] Revolutionizing biotechnology and bioengineering: unleashing the power of innovation, July 2023, Journal of Applied Biotechnology & Bioengineering 10(3):81-88, July 202310(3):81-88, DOI:10.15406/jabb.2023.10.00332

[3] What is genome editing?, https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-Editing

improving agricultural attributes thanks to the discovery of CRISPR-Cas9.

(A) What is a Patent?

In general, a patent is a document that a government issues to an inventor or inventor's assignee, granting them "the right to exclude others from making, using, selling, or offering for sale the invention" in the manner that the inventor has claimed and specified. In return for an invention's complete public disclosure, the government awards a patent. In exchange, an inventor or the assignee of an inventor consents that the invention will enter the public domain upon the expiration of the patent term. An inventor must submit a patent application that sufficiently details the invention for someone with the necessary skills to replicate it to receive a patent. The technical merits of an invention are the only thing that patent examiners are knowledgeable about, although ethical, safety, and legal issues are significant during the creative process. It is crucial to remember that obtaining a patent does not grant the owner of the invention the right to produce, use, sell, or offer for sale the invention. For instance, an inventor cannot manufacture, use, sell, or propose to sell a product that is prohibited in their nation, even if they have a patent on it. Patents have social and economic purposes. Governments offer patent rights to inventors as an economic incentive to openly reveal scientific and technical advances rather than keeping them under wraps since an inventor is not required to disclose an invention publicly. Governments also establish patentability requirements to promote the advancement of specific technologies deemed beneficial to society and to boost the supply of novel, practical goods. In theory, governments might also deter potentially harmful inventions by denying patent protection to areas of technology that are damaging to society, but in reality, this is rarely done.[4]

A gene patent is the exclusive rights to a certain DNA sequence (a gene) granted by the government to the person, group, or business claiming to be the first to identify the gene. For 20 years from the date of the patent, the owner of a gene patent controls the use of the gene in both noncommercial (such as research) and commercial (such as clinical genetic testing) contexts. Companies now possess all the rights to genetic testing for copyrighted genes as a result of gene patents[5].

[4] Is Gene Editing Patentable? https://journalofethics.ama-assn.org/article/gene-editing-patentable/2019-12
[5] GENETIC PATENTING; THE CHALLENGES FACING GENE PATENTS & CONCERNS THEY POSE, https://ip.com/blog/genetic-patenting-the-challenges-facing-gene-patents-concerns-they-pose/

II. Role of patents in incentivizing innovation and the potential consequences on access to genetic resources

It could secure a patent for a novel gene editing method created against accepted ethical standards since ethical considerations have no bearing on patentability. For instance, the WHO's new advice may be broken by a patent filing for a novel technique for modifying the human germline genome. If it did, Section 101 of Title 35 of the US Code would not prevent the innovation from being eligible for patent protection. If the application meets the statute's conditions for patentability, the USPTO would award a patent on this invention even if it might not pass muster with other authorities like the US Food and Drug Administration. Public health, research, and biotechnology innovation may be greatly impacted by the economic and policy concerns regarding patents on genes, nucleotide sequences, expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs), and other genetics-based discoveries. Notwithstanding these possible advantages, the earliest opposition to gene patents has centred on ethical worries about turning a portion of our bodies into a commodity.

Globally, the application of DNA sequence patents to address global illness, international development, and climate change has frequently resulted in a gap between developed and poor nations.

These worries have sparked discussion and prompted the investigation of potential legislative solutions to guarantee that gene patents do not obstruct scientific advancement and medical practice. A patent requires fulfilling certain legal conditions. First, since the public would not benefit in any way from the invention, patents are not permitted for natural items or scientific formulations. In addition, the applicant seeking a patent on a gene must demonstrate that the invention is: (1) new; (2) beneficial; and (3) nonobvious. It must include a thorough description of the invention in a manner that would enable someone with similar expertise to duplicate it. Therefore, the primary trade-off taken into account in patent law is the right to withhold the invention's use from everyone in return for the public revelation of knowledge. Currently, the European Patent Office and the United States Patent and Trademark Office (USPTO) have regarded isolated and purified nucleotide sequences as if they were the same as patentable man-made chemicals, and the U.S. Supreme Court has made it clear that genetically modified organisms may qualify as patentable subject matter. Particularly, DNA patents provide several special problems. Because DNA is inherently dualistic—it may be both tangible material and immaterial information—patent enforcement and gene patenting face both practical and legal challenges. Furthermore, it is difficult, if not impossible, to "invent around" a genetic patent to

produce an equal but non-infringing invention due to the small number of genes—roughly 23,000—in the human genome. Furthermore, innovations like genetic diagnostics may require several patents or licensing agreements, raising worries about a "patent thicket" or "anti-commons effect." The requirement for multiple license agreements may raise the price of genetic testing because of this. Human rights experts criticize allowing a firm to prevent others from testing, utilizing, or experimenting with genes that are found in every cell of our bodies. Patients lose control over their bodies since gene patents explicitly prohibit medical professionals from testing for different disorders.

III. EXAMINATION OF EXISTING PATENT LAWS AND REGULATIONS GOVERNING GENE EDITING TECHNOLOGIES

The patenting of genetics involves two primary processes[6]:

Isolation: A novel gene or genetic mutation must be separated and purified from the surrounding genetic material as soon as it is found. Usually, sophisticated laboratory methods like DNA sequencing, gel electrophoresis, and PCR are used for this.

Patent search: To ensure that no one else has already patented the same gene or genetic mutation, it is crucial to conduct a comprehensive patent search before filing a patent application. In the future, this helps to avert confrontations and legal difficulties.

“Patenting a process of manipulating DNA and chemical substances related thereto, gene sequences and fragments of gene that are not present in their natural state in nature" is the term used to describe the practice of patenting gene technology. An invention that claims to be a "discovery of scientific principle" is not deemed to be an invention and is thus not patentable, as per section 3(C) of the Patent Act of 1970. Furthermore, the same act's Section 3(j) defines as "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties, and species and essentially biological processes for plant and animal production or propagation." Nonetheless, India's patent policy has undergone some significant modifications in the last several years. The Indian Patent Office published the Manual of Patent Office Practice and Procedure in 2005 and the Indian Biotechnology Guidelines in 2013 after realizing the importance of biotechnology on the Indian economy and its worldwide developments. The purpose of these instructions and recommendations was to streamline the biotechnology patenting procedure while also accommodating the field's changing needs. According to the Manual, a genetically modified gene sequence must have a unique expression

[6] Id.

strategy, protected antibodies, and industrial use, together with a novel expression sequence and kit. It should be mentioned that the holder of a gene patent in India is entitled to the patent's commercial advantages when it is issued[7].

Following the publication of a groundbreaking paper in Science by Jennifer Doudna of the University of California Berkeley, Emmanuelle Charpentier, who was then based at Umeå University in Sweden, and their collaborators, CRISPR-Cas9's transformative potential was first made public in 2012. It was shown in the Science report that CRISPR-Cas9 can cut and (potentially) modify DNA in vitro. Among the names most closely associated with CRISPR-Cas9 were Doudna and Charpentier, as well as Feng Zhang and George Church at the Broad Institute (an independent research institute that developed from ten years of research collaborations among scientists at Harvard University and the Massachusetts Institute of Technology). Additionally, Virginijus Šikšnys' parallel work was acknowledged alongside that of Doudna and Charpentier with their joint award of the Kavli Prize in Nanoscience in 2018[8].

The increasing ubiquity of genetic technologies raises the question of whether patent rules impede access to genetic technology and, consequently, to potentially life-saving diagnostic and treatment technologies. Because they erect obstacles to manufacturing and foster dependency on the nations where patent-holding corporations are based, patents can have an anti-competitive effect. Furthermore, patent rules may enable biotechnology businesses to engage in anti-competitive practices. There currently needs to be more legally enforceable international agreements that deal with the patentability of genetic material. The Trade-Related Aspects of Intellectual Property Agreement, or TRIPS, is one possible source of regulation. Technology transfer and dissemination, as well as technical innovation, are the goals of TRIPS. The patentability of surgical, medicinal, and diagnostic procedures as well as biological processes is covered under TRIPS, among other things[9]. Many different kinds of biological materials are patentable, but only after they have undergone one of two processes: synthetic or recombinant production, or isolation from their natural habitat.

However as genetic material is not specifically covered by TRIPS, some argue that this allows for inconsistent treatment of genetic material in terms of patentability throughout WTO

[7] The Legal and Ethical Implications of Genetic Engineering and Gene Editing Technologies On India's Intellectual Property Laws, https://thelegallock.com/the-legal-and-ethical-implications-of-genetic-engineering-and-gene-editing-technologies-on-indias-intellectual-property-laws/

[8] Access to CRISPR Genome Editing Technologies: Patents, Human Rights and the Public Interest, https://link.springer.com/chapter/10.1007/978-3-030-83114-1_4

[9] Smitha Gundavajhala, GENETIC TECHNOL TIC TECHNOLOGIES: P OGIES: PATENT PROTECTIONS & THE CASE TIONS & THE CASE FOR TECHNOLOGY TRANSFER, https://digitalcommons.law.uw.edu/cgi/viewcontent.cgi?article=1335&context=wjlta

member nations. Currently, Member States have the option to reject genetic material under Article 27. Products or methods may be patentable under Section Five of TRIPS if they are novel, incorporate an innovative step, and have potential for industrial use. Genetic technology can be copyrighted, however, genetic material has frequently not required an innovative step to be patentable. The Doha Declaration, often referred to as the TRIPS Agreement and Public Health Declaration, adds further nuance to the TRIPS Agreement. The Doha Declaration emphasizes that member nations are free to adopt actions to enable access to current medications and the development of new medications and that intellectual property safeguards under TRIPS should not preclude them from taking action to protect public health[10].

IV. RELATIONSHIP BETWEEN GENE EDITING PATENTS AND BIODIVERSITY CONSERVATION EFFORTS

The extinction of species is happening 1,000 times quicker than it did a thousand years ago, contributing to the planet's declining biodiversity. In the meanwhile, biotechnology—which includes synthetic biology—has developed recently as a set of methods that allow people to read, understand, alter, create, and manipulate DNA segments to quickly change the structures and capabilities of cells and living things. Applications of synthetic biology are already revolutionizing the commercial, manufacturing, and medical fields. The synthetic biology industry was estimated to be worth $5.3 billion globally in 2019 and is projected to reach $4 trillion annually over the next ten to twenty years. This quickly developing discipline has the power to drastically alter biodiversity protection in both positive and bad ways. When properly developed and used, several synthetic biology applications have the potential to directly lessen threats to biodiversity, which would promote biodiversity conservation.

On islands where existing methods have major limitations, male-biased reproductive sex-ratio-engineered gene-drive procedures have been offered as a means of helping to remove invading rats. Similarly, the Wolbachia incompatible insect strategy has been suggested as a way to manage invading mosquito species to shield endangered Hawaiian birds from illnesses like avian malaria. There are serious worries that communities, groups, or individual species might suffer as a result of synthetic biology. Transgenes, for instance, or genetic modifications may be able to spread horizontally between species, having unintended or detrimental effects. Such misgivings about biodiversity may be especially pertinent when the target species can interbreed with related species. The possibility that synthetic biology techniques like modified

[10] What biological inventions can be patented, https://www.ipaustralia.gov.au/patents/what-are-patents/what-biological-inventions-can-be-patented

gene drives—which are meant to be self-disseminating—may affect populations that are not intended targets is perhaps the environmental consequence that should worry us the most. [11]

V. POTENTIAL CONFLICTS AND SYNERGIES BETWEEN GENE-EDITING RESEARCH AND THE PRESERVATION OF GENETIC RESOURCES

It has been suggested that synthetic biology is "an extreme form of genetic engineering" and that its use should be banned. Recent plant science experiments at the University of Copenhagen that created vanillin in yeast sparked a heated international discussion over the welfare of native vanilla growers as well as the need to identify the vanillin as natural. Regarding human gene editing, the previously mentioned disclosure of altering human embryos by gene editing sparked a barrage of criticism, stoked concerns about a future driven by eugenics, and reignited the discussion over human enhancement.

A moratorium on using zinc-finger nucleases and CRISPR/Cas9 to modify germline genomes was demanded by two different groups of well-known scientists.[12] One might debate whether or not scientists should be permitted to alter biological systems genetically. Regardless of the potential benefits, the concept of genetically altering naturally formed life may be ethically objectionable. In this work, we shall not embrace this ethical perspective. The main concern is how to utilize technology in an ethically acceptable way, not if it is inherently immoral. In what circumstances should utilising it be permitted? What kinds of applications may one create with it? Which regulations need to be implemented? The application of CRISPR/Cas9 technology on human embryos sparked the current discussion on the ethics of gene editing.

The recommendation that followed, which called for a ban on some CRISPR/Cas9 applications, is an illustration of applying caution when using the technology in a particular area. One may argue that this is justified by the reality that moving forward will still have very unclear outcomes. According to the precautionary principle, actions should be taken to safeguard the environment and public health even in the lack of conclusive, scientific proof of harm. It stipulates two requirements. First, parties should abstain from acts that might endanger the environment in the face of scientific uncertainty. Secondly, the burden of proof for assuring the safety of an action falls on those who propose it. Gene editing presents some morally important choices that "revolve around balancing scientific freedom, governance, risk and security" because of its dual-use nature. Not only will national governments have to make these

[11] Nicholas B.W. Macfarlane, Direct and indirect impacts of synthetic biology on biodiversity conservation, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9641226/

[12] Ana Nordberg, Cutting edges and weaving threads in the gene editing (Я)evolution: reconciling scientific progress with legal, ethical, and social concerns, https://academic.oup.com/jlb/article/5/1/35/4816224?login=false

decisions, but also individual scientists who must choose what research to do and publish; research institutions that must determine how to control research inside their walls, train their researchers, and install laboratory security measures; funding agencies, which have decisions to make about the development, adoption, and/or enforcement of codes of conduct and education; professional societies that have decisions to make about the evaluation and publication of potentially dangerous papers; editors and publishers that have decisions to make about the incorporation of dual-use research and technology into their application and review processes; and international organizations that have decisions to make about world policy.

Patent law is related to regulatory initiatives because it has an indirect regulatory influence. The goal of patent law, which is a form of incentive and reward structure, is to offer well-balanced incentives and rewards to guarantee that investment in innovation is sufficiently alluring to encourage the development and dissemination of new and useful products and processes to the general public. In this way, the advantage of that incentive is denied to a particular invention when an exception to patentability is applied. However, standards for patent eligibility also have a wider symbolic regulatory impact, extending the scope of a patent grant rejection beyond the innovation under consideration and even outside the patent system. For instance, denying a grant due to moral objections might set off a domino effect that reduces all forms of incentives for innovation and investment in the relevant research fields.

VI. LEGAL CHALLENGES ASSOCIATED WITH PATENTING GENE-EDITING TECHNOLOGIES

The ethical concerns raised against the use of CRISPR-Cas technology in humans primarily revolve around the potential implications of germline gene therapy, which involves making genetic alterations in gametes or embryos. This could result in genetic modifications that are carried by all cells of a resulting child and passed on to subsequent generations, impacting the human gene pool. The statement emphasizes that it would be irresponsible to proceed with any clinical use of germline editing unless safety and efficacy issues are resolved, and there is broad societal consensus about the appropriateness of the proposed application. Additionally, the statement highlights that the safety issues have not yet been adequately explored, the cases of most compelling benefit are limited, and many nations have legislative or regulatory bans on germline modification.

The decision-making process has been influenced by these concerns, leading to recommendations for a temporary moratorium on germline therapy to allow for further research on the opportunities and risks of the method and for social debate on the ethical and legal

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questions of germline therapy. This reflects a cautious approach to the potential long-term implications of genetic modifications in humans and the need for broad societal consensus before proceeding with clinical applications of germline editing. Variations in patent laws between countries can affect the scope and enforceability of gene-editing patents.

For instance, some countries may have stricter criteria for patent eligibility or different standards for determining non-obviousness.[13] The marketing of gene-edited crops and the advancement of gene-editing technologies are governed by two significant legal frameworks: GMO legislation and patent law. However, these two systems exhibit differing views of the regulatory status of the gene-edited crop in light of the moral dilemma surrounding the safety of gene-editing techniques about human health and the environment: Whereas the patent law takes a liberal stance, the GMO legislation takes a restrictive one. It will unavoidably lead to several ethical, social, and economic difficulties, especially as the EU tries to capitalize on the financial benefits of gene-editing technology while simultaneously protecting public health and the environment.

While the safety-oriented GMO legal system seeks to ban risky technologies for the public good, the innovation-oriented patent law system tends to award property rights to private corporations and enterprises. The divergent interests that the GMO and patent law systems represent draw attention to their disparate definitions and boundaries, which include "techniques/methods of mutagenesis" under the GMO legislation and "an essentially biological process" under the patent law. Because natural mutagenesis and mutagenesis techniques/methods are not covered by the patentability exclusion of essentially biological processes under the law, clever claim drafting could get around the plant variety patentability exclusion obstacles and maximize patent protection. There is a limited interpretation of the term "essentially biological process." Plant breeding techniques can be patented as long as they involve human involvement and are not the result of natural processes like crossover or selection. The public's understanding of the safety of genetically modified foods has led to a more limited GMO legal regime in the EU than under the liberal patent law system. Its extremely strict standards classify plant gene editing as genetically modified organisms (GMOs) by separating technical/method mutagenesis from natural mutagenesis. This suggests that developing methods for modifying plants' genomes is not economically viable since obtaining permission to grow genetically modified organisms is almost difficult.[14]

[13] Patent-Related Aspects of CRISPR-Cas Technology https://www.allea.org/wp-content/uploads/2016/08/Statement_CRISPR_web_final-1.pdf

[14] Li Jiang, Commercialization of the gene-edited crop and morality: challenges from the liberal patent law and

The Court of Justice of the European Union (CJEU) has ruled in a recent case that crops and other products produced using ODM or CRISPR-Cas should be subject to the same regulatory oversight as GMOs created by traditional transgenic approaches. This decision was made in light of the risk of releasing new GMOs and ensuring that all new GMO foods are fully tested and labelled. Motoko Araki and Tetsuya Ishii's 2014 assessment of 39 nations, which focused primarily on the regulation of human germline alteration, revealed a range of regulatory methods. Any interference with the germline is prohibited by law in several European nations. There are advisory recommendations in other nations. Any kind of germline alteration would be extremely challenging to carry out due to the intricate regulatory framework in the United States. Funding limitations on embryo research may also have a significant impact on the fundamental science required to even reach the stage of regulatory approval.

Furthermore, many nations have just not given the possibility any thought. Depending on how it works, gene therapy in the US is governed by a regulatory framework that treats it like a biological medication or a technology. It falls under several rules of safety, effectiveness, and infection control in addition to the extensive oversight of the FDA. The Recombinant DNA Advisory Committee and regional review bodies for research subjects are two advisory groups that the United States consults to ensure that human clinical trials are conducted in compliance with national standards and laws. Japan follows a similar process. In the well-known Novartis AG v. Union of India decision, the Supreme Court sought to keep copyrighted products from going green and to provide India's 1 billion citizens access to reasonably priced medical care. Although it would not have a major influence on the availability of generic medications, Section 3(d) attempts to prohibit patenting useless, minor medical modifications. The court ruled that patents cannot be made any greener.

Additionally, the court defends the rights of common people and prohibits pharmaceutical firms from charging exorbitant prices for drugs that are beyond the of reach the average person. Companies are not allowed to commercialize identical pharmaceuticals by simply changing the substance's molecular structure, according to Section 3(d) of the Patent Act. The absence of an "innovative step" in imatinib mesylate prohibits patents from being constantly greened. The only person with the exclusive permission to use a patented medication is the patent holder, who also has the exclusive right to profit from their creation. India's agricultural economy is mostly based on farming, yet communities and farmers may suffer as a result of strong legal protection for genetic engineering in plants. Agro-biotech corporations may profit from gene

the strict GMO law in the EU, https://www.tandfonline.com/doi/full/10.1080/14636778.2019.1686968

patenting in foreign nations, which might encourage bio- and cultural piracy. Respect for human dignity, ethical behaviour, and responsible research are examples of ethical considerations. To advance healthcare fairness and democratize the advantages of new technologies, it is imperative to address pricing and accessibility. To effectively manage these intricacies, India's regulatory bodies need to establish strong supervision frameworks and foster global cooperation to fully use the revolutionary possibilities of these technologies.[15]

The drawbacks of gene patents include moral conundrums, most notably the question of whether businesses ought to have legal ownership rights over human genes that arise spontaneously. The idea of possessing a portion of human DNA prompts serious concerns about the moral boundaries of life's commercialization. Gene patents can also inhibit competition by prohibiting other businesses from exploiting the protected gene to create rival commercial products. This restriction on possibilities might lead to a monopoly, which could raise final product costs in the absence of market competition's checks and balances. The prospective withholding of patents has significant ethical ramifications in addition to economic ones. This is made all the more painful when one considers how many more options there are for those with hereditary problems. Access to genetic information and the pursuit of medical improvements for the greater good present complicated ethical challenges due to the conflict between proprietary interests and the needs of the community. [16]

VII. ISSUES RELATED TO EQUITABLE ACCESS, POTENTIAL MISUSE, AND SOCIETAL IMPLICATIONS

Gene patents are a source of concern because of the possibility that they may impede advances in science and medicine. There is a widespread concern that the exclusive rights bestowed by patents might hinder or postpone the identification and advancement of vital diagnostic tools and treatments. This worry stems from the possibility that gene patents' restricted character may restrict access to crucial genetic data, impeding cooperative efforts and obstructing scientific advancement. It becomes more difficult to strike a careful balance between the preservation of intellectual property and the larger objective of expanding scientific and medical knowledge.

Opponents fear that an overemphasis on proprietary interests may obstruct collaborative research and free information interchange, lowering the rate of genomics innovation and

[15] R. ALTA CHARO, The Legal and Regulatory Context for Human Gene Editing, https://issues.org/legal-and-regulatory-context-fhuman-gene-editing/
[16] What are gene patents and are they ethical? https://minesoft.com/what-are-gene-patents-and-are-they-ethical/

perhaps limiting the creation of novel therapies and technologies. This persistent conflict highlights the need for a balanced approach to gene patenting that encourages creativity while making sure that medical and scientific information is kept as a common resource for the sake of society at large.

IPRs are based on the idea of limiting access to content. This gives inventors and producers the ability to control and manipulate who has access to the content for the appropriate amount of time and under the terms of protection. Paying the rightsholder for access is a common way to leverage access when the content is valuable enough to be in demand. In principle, the chance to benefit from access is meant to encourage creators to create worthwhile content. It is believed that this temporary limitation will best serve the long-term interests of the public, society or the community at large because it will lead to the creation and dissemination of additional subject matter. Narrow restrictions on that bundle of exclusive rights suit the short-term public interest. To provide long-term advantages in the public interest, IPR logic consequently depends on striking a balance between access and temporary limitations. [17]

Genes, gene sequences, gene fragments or expressed sequence tags, the proteins that these genes express, and single nucleotide polymorphisms—which are frequently employed in the study of genetic disorders—are now examples of patentable upstream discoveries. While the patenting of discoveries made upstream has led to a significant inflow of private investment cash, downstream application inventors will probably cross many patent borders, which will need the "stacking" of royalties to patent holders. This could reduce the value of all patents, vastly increase legal costs and inhibit innovation. In comparison to discoveries that would maximize benefits to society, a disproportionate amount of effort is focused on discoveries that would maximize revenues to the inventor by aiming for huge, potentially profitable markets. This makes treatment discrepancies between industrialized and developing nations, as well as across socioeconomic and ethnic groups within countries, even more pronounced.

Furthermore, studies into genetic "solutions" can take precedence over studies into the less glamorous but no less significant roles that some individuals play in illness prevention. Modifiable behavioural variables, including obesity, inactivity, and smoking, are responsible for more than 70% of strokes, over 80% of coronary artery disease cases, and over 90% of adult-onset diabetes cases. A smaller and more expensive variety of solutions will be produced if these innovation objectives are ignored than may occur. Also, High licensing fees and royalties may constrain the number of laboratories prepared to provide a particular test. There

[17] Walsh, K., Wallace, A., Pavis, M. et al. Intellectual Property Rights and Access in Crisis. IIC 52, 379–416 (2021). https://doi.org/10.1007/s40319-021-01041-1

is a finite amount of money that society can allocate to social services like health care. The socially optimal amount of money to be spent on any one therapy considers the possibility that, beyond a certain point, investing in other areas may result in higher health benefits. The patent holder, on the other hand, aims to increase sales of its creation. This creates pressure to include more patients than what is socially optimum in the pool of patients deemed eligible for a test or therapy.

Enough safeguards must be in place to reduce the possibility of monopoly power misuse. It will need federal leadership to make the present patent laws easier to understand. To meet societal demands for innovation and reasonably priced access to these advances, nations must endeavour to radically modify these rules. All parties involved in this endeavour, including the medical community and the general public, must be involved. To make sure that practical and long-lasting solutions are discovered, the national and provincial medical organizations have significant responsibilities to play as advocates for physicians and patients.[18]

(A) How gene editing patents may affect traditional knowledge holders and indigenous communities

The word "biopiracy" has recently been used by activists and certain non-governmental organizations (NGOs) to refer to traditional knowledge about the incorrect or unlawful usage of biological resources. Additionally, the increasing number of patents indicates increased research on biopiracy. Indian neem tree lawsuits have demonstrated that patents are essential to biopiracy. These international consultants are dubious about the overuse of biopiracy to characterize particular instances of unfair or false intellectual property claims over biological resources and traditional knowledge, although there has been much international discussion on disputes of intellectual property and assets, traditional knowledge, and heritage. The word "bioprospecting" was coined recently to refer to the responsible use of natural resources, the protection of indigenous peoples' rights, and the identification and marketing of bioproducts. The literature on biotech patents about globalisation and the rights of indigenous peoples is dominated by two topics in particular. First, traditional indigenous knowledge may be used as a basis for creating a useful product, like a medication.

The second is the capacity to patent gene sequence and gene-product data derived from living things, particularly humans. Although these two difficulties could be connected (for instance, if genetic data is sourced from an indigenous community), it is more lucid to try to conceptually

[18] Patenting of genetic material: Are the benefits to society being realized?, Donald J. Willison and Stuart M. MacLeod, https://www.cmaj.ca/content/167/3/259

distinguish between them. In the first, Western nations' alleged "biopiracy" of indigenous knowledge is questioned. Because of this, it directly affects the rights of Indigenous peoples, even if the majority of these problems are avoidable if a few fundamental ideas of patent law are understood. In addition to raising significant ethical concerns, the second problem raises basic issues for patent law and policy—particularly when it comes to data on the human genome.[19]

The issue of biopiracy is best shown by the way big pharmaceutical firms use knowledge from indigenous peoples about the therapeutic benefits of plants or other natural substances to create patented, widely used drugs. Whether or to what extent it is appropriate for outsiders to utilize, and especially profit from, this information is the central question. It's critical to distinguish between using an informational resource and a physical resource while analyzing the biopiracy issue. Physical resources are finite; once used, they are no longer available to other people.

In the sense that one person's use of knowledge does not restrict another from using it in the same or different way, informational resources are nondepletable (infinitely versatile). Because of this, intellectual property differs from tangible property in essential ways, and the laws on it must likewise reflect these differences. Intellectual property experts know this argument well—in fact, it's practically cliché—but it frequently appears to be missed in the literature on biopiracy. [20]

VIII. COMPARATIVE ANALYSIS OF GENE EDITING PATENT LANDSCAPES IN DIFFERENT JURISDICTIONS

"The expansion of patent law into the protection of life forms" is "closely linked" to the biotechnology (biotech) industry's growth. Legislators, judges, and patent offices have worked together to promote more patent protection in the US and the EU; this tendency may be the outcome of political pressure to draw in biotechnology investment by relaxing patent laws. Patents are "a signalling device to stock markets that biotech companies have control over vital or fundamental technologies," according to biotech corporations. To draw in biotech investment, patent offices and courts—particularly those in several industrialized nations—are more likely to award patents freely.[21]

[19] Intellectual Property Rights: Bioprospecting, Biopiracy and Protection of Traditional Knowledge - An Indian Perspective, Bency Baby T and Timmakkondu Narasimman Kuppusami Suriyaprakash, https://www.intechopen.com/chapters/78249

[20] Biotech Patents and Indigenous Peoples, Dennis S. Karjala, https://core.ac.uk/download/pdf/217199549.pdf

[21] Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate, Molly Jamison, https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1086&context=cjil

With 87% of all patents worldwide, the United States, China, Japan, the Republic of Korea, and the United Kingdom are the top five nations in terms of patent production. With more patents than any other country, the US leads the globe in this regard, holding 56% of all patents worldwide. Since 2002, China and the Republic of Korea have been more involved in the field of gene therapy. The advancement of gene therapy is significantly impacted by social, legal, and policy concerns. The patentability of gene modification technologies is highly restricted under the European Union's gene patent policy. [22]

A small number of pharmaceutical corporations produced the majority of the top 20 innovators. The majority originated from Bayer AG and Ionis Pharmaceuticals. Other innovators were affiliated with organizations including Idera Pharmaceuticals Inc., Marina Biotech Inc., and Alnylam Pharmaceuticals Inc. Inventors that have been actively working recently include Yang Cheng-gang, Metzger W. James, Li Hong-Liang, Manoharan Muthiah, and Freier Susan M. According to Swiss intelligence business Centredoc, there are already over 11,000 families of patents on CRISPR-related technology. Other notable participants include the Chinese Academy of Sciences, Toolgen Inc., Sigma-Aldrich, Vilnius University, and Cellectis. These organizations either own early fundamental patents or contest the priority of the Broad and CVC patent applications. Corteva Agriscience, which was once a part of DowDupont, is said to have accumulated the greatest number of CRISPR-related patent rights, primarily through licensing, with an emphasis on the agriculture industry. MPEG LA is a licensing firm that has been marketing its "patent licensing pool" and has promised CRISPR patentees technological collaboration and administrative convenience as well as a (possible) one-stop shop for license seekers. Although Broad has independently urged CVC to participate in talks for a coordinated licensing plan or patent pool, it is unclear whether any patent pool would be approved by the relevant parties. This month, Sigma-Aldrich and genOway established a partnership to serve as a one-stop shop for sublicensing the intellectual property rights related to Sigma-Aldrich CRISPR. [23]

IX. NEED FOR INTERNATIONAL COLLABORATION AND REGULATORY HARMONIZATION TO ADDRESS GLOBAL CHALLENGES

A patent has a geographical scope. Since companies frequently operate across borders, they must patent their innovation in the nations in which they intend to do business. varied nations

[22] Human gene therapy: A patent analysis, Wuyuan Zhou a, Xiang Wang, https://www.sciencedirect.com/science/article/pii/S0378111921004844

[23] Life sciences A to Z - G is for gene-editing: The CRISPR landscape, https://www.shlegal.com/news/g-is-for-gene-editing-the-crispr-landscape

have varied patent regimes, which frequently causes issues for them. They frequently avoid entering nations with little to no protection for their invention. Therefore, neither the company nor the nation benefits from patents. "Every nation has its distinct systems for valid reasons. These cover topics beyond only technical ones, occasionally encompassing political ones as well, such as a country's history, social and economic circumstances, and so on. However, in the modern day, with the majority of economic activity being international, distinct.[24]

Over the past few decades, there has been a general trend toward harmonization of patent law around the world. Patent systems are becoming more and more similar among nations, despite the wide differences in sectors, values, and economic stages between them. The passage of other international treaties, such as the TRIPS agreement, is largely responsible for this drive towards uniformity. The "pendulum has been swinging towards greater harmonization among countries" since the adoption of the Paris Convention for the Protection of Industrial Property (Paris Convention) in 1883, which calls for further standardization in the requirements for patentable subject matter. Coordination of procedural patent protections has been achieved through substantial and mostly effective international patent cooperation. Offering "the same opportunity to receive and enforce patent rights [to other signatories] as they offer to their nationals" was a pledge made by signatory nations to the Paris Convention." The format of patent applications, the application process, and the periods of protection have all been standardized as a result of subsequent treaties. However, "uniform patent laws throughout the world" was the original meaning of the phrase "international patent harmonization," which called for more consistent procedural and substantive standards."

In the past, multiple sources have called for "full harmonization," in which patent applicants would complete a single patent application and receive global protection." The main benefits of globally harmonizing patent law include the facilitation of international trade by providing uniform protection of intellectual property, reducing administrative burden and redundancy in prosecuting international patent applications, and evenly spreading the costs of obtaining international patents among participating nations. Additionally, a harmonized patent system would allow for a patent to be registered for all members of a particular region, subject to one interpretation worldwide, and potentially reduce costs for obtaining patents in multiple countries.

Furthermore, harmonization would save time and money for independent inventors and university researchers, expanding their zone of protection to nations that were previously

[24] THE ADVANTAGE/DISADVANTAGE OF THE HARMONIZATION OF THE PATENT SYSTEM, https://www.ipindia.gov.in/writereaddata/images/pdf/mohanty_report_oct_mar_2008.pdf

inaccessible under isolationist patent systems. Finally, a harmonized patent system would enable legal innovation and alternate dispute resolution, potentially lowering the cost of patent enforcement actions. The patent laws of the United States and those of other countries differ in terms of patentable subject matter and the first-to-file vs. first-to-invent systems. In the United States, patent protection is extended to any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement. This includes protection for computer programs when entwined with a patentable process, genetically engineered non-human organisms, and therapeutic methods of treating humans. [25]

However, many other countries, both developed and developing, do not provide such extensive protection. Regarding the first-to-file vs. first-to-invent systems, the United States operates on a first-to-invent system, awarding patents to the first person to invent, while essentially all other countries operate on a first-to-file system, awarding patents to the first person to file a patent application. This conflict can lead to situations where a patent for the same invention could be awarded to different parties in the United States versus other countries. Additionally, the first-to-invent system in the United States results in complicated and expensive interference proceedings, which would be unnecessary under a first-to-file system. Adoption of the first-to-file system is considered superior and would bring predictability, simplify the patenting process, and potentially benefit small companies and independent inventors. In summary, the United States and other countries differ in their approach to patentable subject matter and the first-to-file vs. first-to-invent systems, highlighting the need for global patent law harmonization.

The historical international agreements and treaties that have influenced the development of global patent law harmonization include the Paris Convention for the Protection of Industrial Property, which was established in 1883 to reduce fears of having inventions stolen or exploited. This treaty was a precursor to modern multinational protection for intellectual property. Additionally, the Patent Cooperation Treaty (PCT) was created in the late 1960s to minimize duplicative patent applications and examinations worldwide, taking effect in 1978. The PCT allows inventors to prosecute a single international patent application to obtain patent protection in multiple regions. Furthermore, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has played a significant role in achieving harmonization aspects faster than previously predicted, demonstrating the potential for political will and skilled negotiators to overcome local biases. The TRIPS Agreement establishes criteria for the

[25] Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate, Molly Jamison, https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1086&context=cjil

patentable subject matter and applies the most favoured nation principle in affording patent protection, among other provisions. These agreements and treaties have laid the groundwork for the development of global patent law harmonization.[26]

X. MECHANISMS TO BALANCE PATENT PROTECTION WITH THE PROMOTION OF WIDER ACCESS

A sophisticated strategy that incorporates legal, ethical, and practical issues is required to strike a balance between the necessity of expanding access to CRISPR technology and the urgency of patent protection. A crucial tactic is licensing agreements, in which patent holders specify conditions about the application of CRISPR technology. These contracts frequently include terms on royalties, access limitations, and the range of allowed applications. Specifically, giving priority to non-exclusive licensing agreements can democratize access by allowing a wide range of stakeholders—from academic researchers to nonprofit organizations and entities committed to addressing urgent global challenges—to utilize the technology for a variety of purposes, such as scientific research, medicinal development, and innovative agricultural practices.

Another way to expedite access and reduce transaction costs related to acquiring individual licenses is through patent pooling. Using patent pooling programs, many patent owners jointly grant licenses under their patents, offering interested companies a single point of contact for CRISPR technology. These cooperative projects seek to achieve a careful balance between promoting wider technological distribution and protecting intellectual property rights. Commitments to the public domain or open-access licensing frameworks, when combined with licensing tactics, may be extremely important in increasing accessibility. Patent holders support a more diverse innovation ecosystem by choosing to grant specific patents or technologies to the public domain or by implementing liberal open-access licensing. This strategy not only promotes cooperation and knowledge exchange but also highlights a dedication to advancing scientific progress.

Furthermore, financing and assistance programs from the government have a big impact on accessibility. Governments may support efforts to democratize access to CRISPR technology by providing funding for infrastructure development, research, and capacity-building initiatives. Open access ideals may be given top priority by publicly financed research programs and organizations, boosting the advantages that science brings to society while

[26] GLOBAL PATENT LAW HARMONIZATION: BENEFITS AND IMPLEMENTATION , https://mckinneylaw.iu.edu/iiclr/pdf/vol13p605.pdf

maintaining standards of accountability and openness. The implementation of strong governance structures and ethical principles is essential to these tactics. These guidelines help to guarantee ethical research practices, protect against any abuse or injury, and advance fair access to the advantages of CRISPR technology.

Furthermore, encouraging cooperative research projects among many stakeholders promotes multidisciplinary dialogue, quickens the pace of innovation, and increases the group's ability to tackle difficult social issues. All things considered, the quest for a fair approach to patent protection and increased accessibility to CRISPR technology calls for a complex plan based on ethical, legal, and cooperative considerations. Through the implementation of inclusive licensing policies, support of open access policies, and encouragement of cooperative research projects, interested parties may work together to promote the ethical advancement and fair distribution of CRISPR technology for the benefit of society.

XI. NOTABLE LEGAL PRECEDENTS

1. Patent dispute over CRISPR-Cas9:

The disagreement between the University of California, Berkeley and the Broad Institute/MIT serves as an example of the complexity of gene editing patent disputes. The fundamental CRISPR-Cas9 technique for precise gene editing was at the centre of this case. The focus of the legal disputes was inventorship, with each side asserting that they had first dibs on inventing the invention. Determining the concept of an inventor and evaluating the contributions of different researchers participating in the creation of CRISPR-Cas9 were important legal concerns. The resolution of this conflict has a significant impact on who owns and uses CRISPR technology commercially.

2. Editas Medicine vs. Intellia Therapeutics:

A patent dispute about CRISPR-Cas9 applications in the realm of human therapeutics involved two well-known biotechnology companies: Editas Medicine and Intellia Therapeutics. Patents on particular gene editing methods and their possible uses in the treatment of hereditary illnesses were at issue in this case. Patent infringement, validity, and claim scope were the main topics of legal debates. The case served as a reminder of how crucial it is to design patents precisely and how new and non-obvious gene editing innovations must be proven.

3. European Patent Office v. Broad Institute v. University of California:

The conflict between the Broad Institute and the University of California, Berkeley went beyond American borders to Europe. When deciding whether CRISPR-Cas9 patent

applications filed by rival parties should be prioritized, the European Patent Office (EPO) encountered a similar difficulty. Legal actions in Europe brought to light the difficulties in unifying intellectual rights in the international biotechnology environment and raised concerns about how patent rules are interpreted in different countries.

4. Monsanto vs. DuPont Pioneer:

The court struggle between Monsanto and DuPont Pioneer for patents of genetically modified crops provides insights into gene editing patent conflicts in agriculture, even if it is not specifically connected to CRISPR technology. Patents covering characteristics of genetically modified crops, such as insect and herbicide resistance, were at issue in this case.

Legal disputes in the field of agricultural biotechnology centred on patent infringement, validity, and enforceability. The case's conclusion had an impact on the technologies and seed licenses for genetically modified organisms.

(A) Recommendations for fostering innovation while ensuring responsible and equitable use of gene-editing technologies

Although genetic engineering is extremely risky, it also has a lot of potential. It is essential to develop responsible use and rules surrounding this technology to ensure an ethical approach:

To ensure safety and reduce the possibility of misuse, transparent and thorough norms governing genetic engineering processes must be created.

To develop frameworks that handle possible ethical issues, governments should consult with experts and ethical committees. Campaigns for public awareness should be launched to inform people about the dangers of genetic engineering and to encourage making ethical decisions. We can uphold public confidence and guarantee the moral uses of this revolutionary technology by putting strong laws into place and encouraging a culture of responsible use.

A crucial component of moral genetic engineering is diversity. We must make sure that everyone is included and that no one is left behind to establish a just future:

To prevent prejudices and guarantee the inclusion of many viewpoints, diverse representation in research and development activities should be promoted. To guarantee that genetic engineering is successful in many ethnic groups and to prevent potential biases, research studies should cover a wide range of ethnicities. To guarantee that everyone has equal access to healthcare and opportunity, efforts should be undertaken to redress historical injustices and imbalances in the field.

We can overcome the obstacles and prejudices that may surface during the use of genetic

engineering and build a more just society by embracing tolerance and variety.

It is important to take future generations' perspectives into account while talking about genetic engineering. Important ethical factors to think about include:

Empowering people to make knowledgeable decisions on genetic changes for themselves and their offspring to respect their right to self-determination. ensuring that, before being used, the long-term implications of genetic alterations are well studied and comprehended.

Weigh the possible advantages and disadvantages of genetic engineering to prevent unanticipated events and unintentional injury. Future generations' rights and well-being should come first so that we may build an ethical framework that directs the ethical application of genetic engineering.

XII. CONCLUSION

Gene patents offer several benefits, particularly in incentivising innovation and supporting the financial viability of genetic research and development. Before being granted a patent, gene sequences must prove their utility, demonstrating a practical application. This demonstrated utility becomes a pivotal point for securing funding for further research and development. In certain areas, this financial support can lead to the discovery and development of new life-saving treatments. Moreover, gene patents serve as a protective mechanism for companies that invest substantial resources in researching the applications of specific gene sequences. The patent provides a legal framework that safeguards their investment, enabling them to potentially recoup costs in a commercial setting down the line. It’s crucial to note that having a gene patent doesn’t equate to unrestricted freedom for the patent holder; government bodies retain the authority to intervene and override patents if they deem it essential for the public good, ensuring a balance between private interests and public welfare. Working together becomes our guiding concept as we attempt to use CRISPR for the benefit of mankind. We can negotiate the difficulties of CRISPR with wisdom and foresight, making sure that its advantages are achieved fairly and ethically, by encouraging communication between scientists, politicians, ethicists, and stakeholders. Let's embrace the collaborative and creative attitude and pave the way for a time when CRISPR technologies are used ethically and to everyone's advantage. By doing this, we pay tribute to the innovative heritage of CRISPR and provide the foundation for a future in which scientific advancements are achieved in a way that upholds justice, fairness, and human dignity.

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