

Ethics and Intellectual Property Rights in Genetic Therapy

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ABSTRACT

Genetic technology, particularly CRISPR-Cas9, has transformed the paradigm of treating genetic diseases by offering new hope for more effective and precise therapies. However, this advancement also presents significant ethical and intellectual property rights (IPR) challenges. This article explores the impact of patents on the development and accessibility of genetic therapy, as well as the ethical issues arising from human genetic modification, especially at the germline level. Using a qualitative analytical approach that combines literature reviews and case studies, the article examines patent disputes that have emerged in the development of CRISPR and how applied patent policies can exacerbate inequities in access to critically needed medical therapies. Furthermore, the article discusses ethical concerns regarding the misuse of genetic technology and its potential impact on future generations. In conclusion, the article proposes the need for more inclusive and balanced policies that prioritize both innovation and accessibility, as well as strict regulations to ensure the safe and ethical application of genetic technology, while considering broader social and cultural impacts.

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Introduction

The rapid advancements in genetic technology over the past decades, particularly with the discovery of CRISPR-Cas9, have revolutionized the treatment of genetic diseases that were previously difficult to address. CRISPR, discovered by Jennifer Doudna and Emmanuelle Charpentier in 2012, enables highly precise and efficient DNA editing, unlocking significant potential for treating various diseases caused by genetic mutations, including sickle cell anemia, beta-thalassemia, and certain types of cancer (Guo et al., 2022). This technology allows scientists to target specific genes and modify them with far greater accuracy than previous genetic editing methods. In addition to CRISPR, other genetic therapies, such as RNA interference (RNAi) and stem cell therapy, have also been employed to treat rare diseases and genetic disorders that are difficult to address with conventional therapies.

However, despite the tremendous potential of these technologies in medicine, they also raise a host of complex ethical issues. One of the primary concerns involves intellectual property rights (IPR), particularly patents on these discoveries. Patents on technologies like CRISPR-Cas9 provide critical financial incentives to drive further innovation but also pose challenges related to accessibility, distribution, and the regulation of these technologies on a global scale. For example, the dispute between the University of California and MIT over patent rights to CRISPR created uncertainty and hindered scientific collaboration in its further development (Regalado, 2024). Moreover, patents associated with genetic therapy technologies can result in exorbitant licensing fees, limiting public access to innovative therapies, particularly in developing countries (Mercurio, 2004). Another critical ethical issue is germline modification, or changes to DNA that can be inherited by future generations. CRISPR technology enables genetic modifications that can be passed down, raising profound questions about the moral validity of such interventions. Do humans have the right to alter genetics to cure diseases or even enhance certain traits, such as intelligence or appearance? Germline modification carries the potential for unforeseen consequences on human health and, more broadly, could create new social inequities if the technology becomes accessible only to the wealthy or developed nations (Ayanoglu et al., 2020). While CRISPR-based therapies offer the potential to treat diseases caused by genetic mutations, their implications for future generations and the possibility of misuse make the technology highly controversial (Kolanu, 2024).

Additionally, ethical issues emerge with the potential misuse of genetic technology. One of the most concerning examples is the concept of "designer babies," where parents might select specific genetic traits for their children, such as intelligence, physical appearance, or particular abilities (Joseph et al., 2022). While this technology can be used to prevent debilitating genetic diseases, the question arises: to what extent should humans "design" individuals according to specific preferences, and does this risk exacerbating social inequality between those who can afford such procedures and those who cannot? On the other hand, although CRISPR offers tremendous potential for life-saving genetic therapies, many countries, particularly those with conservative views on biotechnology, are hesitant to adopt this technology for human treatments. Countries with culturally cautious approaches to new technologies, such as many in Asia and the Middle East, often face difficulties in accepting technologies like CRISPR due to concerns about the ethical and moral implications of genetic modification in humans (Abuhammad et al., 2021). Consequently, the regulation of this technology depends not only on scientific advancements and legal policies but also on evolving societal and cultural understandings at the global level.

Furthermore, the economic and social impacts of patents on genetic technology merit attention. Genetic therapies such as Zolgensma for Spinal Muscular Atrophy (SMA) or Luxturna for genetic blindness offer new hope for patients who previously had no treatment options. However, the exorbitant costs associated with patents on these technologies restrict their accessibility for many, particularly those in developing countries or with limited financial resources. In the case of Zolgensma, the cost of a single dose exceeds two million USD, rendering it unaffordable for most patients worldwide (Garrison Jr et al., 2021). Overly stringent patents can lead to serious issues of equitable access to treatment, further exacerbating existing social inequalities.

Given the significant challenges posed by patent policies and the ethical implications of genetic technologies, it is essential for policymakers, scientists, and

society to critically consider how these technologies should be regulated and applied. If not governed wisely, these highly promising technologies could deepen social inequalities, heighten cultural tensions, and pose unforeseen risks to human health and social justice.

According to McCullough et al. (2021), the impact of genetic therapies on healthcare systems has been transformative, particularly with CRISPR-Cas9 technology, which allows for precise genetic modifications that have the potential to cure previously untreatable diseases. They argue that while CRISPR opens new doors for gene editing, it also raises important concerns about intellectual property rights (IPR) and the potential for monopolies. Similarly, Wilson and Lawrence (2020) note that patents associated with genetic technologies, like CRISPR, often create barriers to access in developing countries due to the high cost of licensing fees, thereby limiting the global reach of life-saving treatments.

The urgency of this research arises from the rapid advancements in CRISPR-Cas9 and other genetic therapies, which have the potential to revolutionize the treatment of genetic disorders. However, these advancements come with significant ethical and intellectual property challenges that could hinder accessibility to these life-saving technologies. The issue of patent disputes and access to CRISPR-based therapies, such as Zolgensma for Spinal Muscular Atrophy, raises concerns about inequities in healthcare, particularly in developing countries. Understanding the balance between innovation incentives and fair access to these technologies is critical to ensuring that these advances benefit the broader global population.

Although existing studies have discussed the ethical concerns surrounding CRISPR technology and its patent implications, there is limited research on how patent disputes and licensing costs affect the global accessibility of genetic therapies. Most studies focus on the ethical concerns of genetic modification, such as germline editing, but few examine the practical barriers that patents create for healthcare systems, particularly in low- and middle-income countries. This study aims to bridge this gap by exploring the economic and social impacts of patent policies on the distribution of genetic therapies and their implications for global healthcare equity.

This study is novel in its exploration of the intersection between intellectual property rights and the accessibility of CRISPR-based genetic therapies. It examines how patent conflicts and exorbitant licensing fees can limit access to potentially life-saving treatments, especially in resource-poor settings. The novelty of this research lies in its comprehensive analysis of how patent policies might be reformed to ensure that genetic technologies, such as CRISPR, can be more equitably distributed and accessible, thus offering a new framework for addressing the ethical dilemmas associated with the commercialization of genetic therapies.

This article aims to explore and analyze the impact of patents on CRISPR technology and other genetic therapies, as well as how the emerging ethical issues surrounding the use of these technologies influence global policy. By employing a qualitative analytical approach and literature studies, this article will examine patent conflicts, accessibility issues, and the socio-economic impacts of genetic therapy. Additionally, it will investigate how policies implemented in various countries may exacerbate or mitigate these challenges, taking into account diverse cultural values and the ethical dilemmas faced by the scientific and medical communities.

The benefits of this research include providing policymakers, healthcare providers, and biotech companies with actionable insights into how patent systems can be adjusted

to promote both innovation and broader access to genetic therapies. Additionally, it contributes to the academic discussion on the ethical and legal challenges surrounding genetic technology, offering a pathway for more equitable healthcare solutions.

Research Methods

To understand the ethical and intellectual property rights (IPR) impacts in the context of genetic therapy, this study employs a qualitative analytical approach emphasizing in-depth analysis of relevant literature and existing case studies. This approach was chosen as it allows the authors to comprehensively explore various perspectives on the impact of genetic editing technologies such as CRISPR-Cas9 in terms of patents and their ethical implications. The qualitative approach facilitates the analysis of narratives, policies, and regulations that shape the reception and application of this technology globally in both medical and legal fields.

Data Collection

Data collection in this study was conducted through a review of relevant academic literature, primarily scientific articles published in medical, biotechnology, legal, and ethics journals. These articles provide profound insights into advancements in genetic technology, CRISPR applications in genetic therapy, and emerging issues related to patents and intellectual property rights. Most of the literature used consists of peer-reviewed articles, ensuring the validity and credibility of the data.

Medical and Legal Journals

In the context of genetic therapy, medical literature is essential for understanding how CRISPR and other genetic therapies are applied in clinical practice. Journals such as *Nature Biotechnology*, *Cell*, and *Science* offer up-to-date information on the latest research integrating CRISPR into treatments for genetic diseases. Legal and policy sources, such as articles in the *Harvard Law Review* and reports from the World Intellectual Property Organization (WIPO), were used to explore patent-related issues surrounding this technology. Additionally, reports from organizations like the World Health Organization (WHO) provide guidance on the global impact of genetic technology applications and policies that could be implemented internationally.

Case Studies

This research also analyzes several case studies related to patent conflicts, particularly those involving CRISPR technology. One key focus is the dispute between the University of California and MIT regarding patent rights to CRISPR. This case illustrates how patent conflicts can affect scientific collaboration, hinder the dissemination of genetic technology, and influence global accessibility (Kong et al., 2023).

Policy Reports

To provide a broader perspective, this study also examines policy reports published by international bodies like WIPO and WHO, which frequently issue guidelines on patent regulation in biotechnology and its impact on drug and therapy distribution. These reports shed light on how different countries approach patent issues in the context of biotechnology and genetic therapy and how such policies affect access to technology in developing nations.

Data Analysis

The data analysis methods employed in this study include comparative analysis and thematic analysis.

Comparative Analysis

Comparative analysis was used to evaluate the policies implemented in various countries, particularly concerning patents and genetic technologies. This approach allowed the authors to identify differences in how nations regulate the use of CRISPR and other genetic therapies. For instance, comparisons between patent policies in the United States, Europe, and several Asian countries reveal stark contrasts in how these nations handle patents within the context of genetic therapy.

Thematic Analysis

Thematic analysis was employed to examine ethical issues arising from the application of genetic technology. This analysis focuses on key themes such as genetic safety, germline modification, and technology accessibility. For example, the theme of germline modification emerges in debates about CRISPR ethics worldwide. Some countries, like China, have begun experimenting with CRISPR for germline modification, while others, such as Germany and France, have stringent laws prohibiting such research. This analysis explores how cultural differences and societal values influence national policies toward this genetic technology.

Legal Approaches

The study also adopts legal approaches to examine issues related to intellectual property rights and patents. This includes reviewing existing patent laws and comparing regulations applied across various legal systems, such as the common law system prevalent in the United States and the civil law system dominant in European countries (Shinder & Cross, 2008). Furthermore, international regulations issued by WIPO were analyzed to understand how the global legal framework seeks to govern biotechnology patents, including CRISPR.

Secondary Sources

Secondary sources play a crucial role in providing a broader context for the use and regulation of genetic technology. Books and monographs on biotechnology ethics and patents were used to deepen the understanding of the dynamics between technology, law, and ethics. A notable source is Michael Sandel's work on the ethics of biotechnology, which discusses ethical dilemmas arising from humanity's ability to genetically modify life (Michael, 2004). In addition, this study examines reports published by government agencies and international organizations such as the United Nations and the European Commission, which discuss how genetic technologies are controlled in various regions and how these policies interact with ethical and social issues. These reports offer valuable insights into global challenges in implementing these technologies and propose fairer ways to distribute the benefits of technological innovation.

Interdisciplinary Approach

This research adopts an interdisciplinary approach that integrates various fields of study, including biotechnology, law, ethics, and economics. The use of this interdisciplinary approach enables the authors to view issues related to CRISPR and genetic therapies from diverse perspectives, providing a more comprehensive understanding of how these technologies impact society and individuals. Consequently, the findings of this research not only provide legal and technical insights but also consider the social and moral implications of these rapidly evolving technologies.

Results and Discussions

CRISPR Patents and Patent Disputes

One of the key findings of this study is the complexity arising from patent disputes over CRISPR-Cas9 technology, which has introduced significant uncertainty in the scientific community and the biotechnology industry. In 2012, scientists Jennifer Doudna and Emmanuelle Charpentier developed the CRISPR-Cas9 system for precise and efficient genetic editing. This technology enables researchers to edit DNA with unparalleled accuracy, making it an invaluable tool for medical, agricultural, and biotechnological research. However, shortly after this discovery, another scientist, Feng Zhang from MIT, also patented the use of CRISPR in scientific applications, leading to a dispute over who holds the rightful patent to this technology (Aquino-Jarquín, 2022). This conflict has created widespread uncertainty among researchers and companies attempting to develop and commercialize CRISPR-based technologies.

The patent dispute between the University of California and MIT affects not only the parties involved but also the entire biotechnology industry that depends on this technology. Overlapping patents between these institutions have delayed the full utilization of CRISPR for various applications, particularly in genetic medicine. This delay stems from the high licensing fees required for using the technology. Many biotech companies and researchers face significant barriers due to the ambiguity over patent ownership, resulting in uncertainty about the use of CRISPR for therapeutic purposes (Kim et al., 2023).

In this context, the CRISPR patent conflict highlights how the existing patent system can hinder the rapid and efficient progress of scientific advancements. Although patents are designed to provide financial incentives for inventors, they often impede the technology's further development. Researchers aiming to develop practical applications must first ensure they do not infringe on existing patents, which entails paying substantial licensing fees. This creates a financial burden, especially for small research institutions or developing nations that lack the resources to afford these costs (Gubby, 2020).

Moreover, these overlapping patents restrict the collaboration among scientists that is crucial for medical research. With technology that could revolutionize the treatment of genetic diseases such as sickle cell anemia and beta-thalassemia, delays in accessing CRISPR due to patent disputes harm patients in urgent need of innovative genetic therapies. For instance, many researchers are deterred from using CRISPR for medical applications because they must wait for patent disputes to be resolved or avoid further development due to the prevailing legal uncertainty (Liu et al., 2021).

This situation also raises concerns about potential patent monopolies within the intellectual property rights system. When a single entity or group of research institutions controls critical patents, they wield significant power to dictate who can use the technology and under what conditions. This can lead to inequities in the distribution of life-saving medical technologies, especially considering CRISPR's immense potential for addressing severe genetic diseases (Subica, 2023). Furthermore, limited patent control concentrated in a few entities exacerbates disparities in access to new therapies, compounding global healthcare inequities.

While patents serve to reward inventors and promote further innovation, their influence over control and access to genetic technology poses significant challenges for medicine and research. For example, Zolgensma, a genetic therapy for Spinal Muscular Atrophy (SMA), illustrates how exorbitant prices driven by patents can restrict access to essential technologies, especially in developing nations. Such stringent patents hinder

innovation and worsen inequities in the distribution of highly needed healthcare technologies (Ogbonmide et al., 2023).

These findings suggest that while CRISPR patents offer clear incentives for further development, the issues arising from these patents demand closer attention from policymakers. Patent systems must be carefully considered in a global context to ensure that highly promising genetic technologies are accessible to a broader population, not just those with financial means. Thus, when formulating IPR policies for genetic technology, it is essential to balance protecting inventors' rights with ensuring that these innovations are accessible to as many people as possible, especially those in greatest need (Saul, 2024). By addressing patent disputes and access challenges, future research should investigate the best ways to regulate patents in biotechnology, particularly for innovations with substantial potential for global health. A more flexible and inclusive legal framework is needed to accelerate scientific collaboration and the distribution of medical technologies without compromising inventors' rights to their discoveries (Khachigian, 2020).

Accessibility of Genetic Technology and Patent Impacts

A significant challenge linked to patents in genetic therapy is the limited accessibility of these technologies, often constrained by the high costs imposed by intellectual property rights (IPR). One of the most prominent examples of inequities caused by patents is Zolgensma, a genetic therapy for Spinal Muscular Atrophy (SMA), a genetic disease that leads to progressive muscle weakness in children. Zolgensma is a groundbreaking therapy, as a single dose can correct the underlying genetic defect, offering hope to children who previously had limited treatment options (Ogbonmide et al., 2023). However, with a price of around \$2 million per dose, the therapy remains out of reach for most patients, especially those in developing countries or from low-income families.

These exorbitant costs demonstrate how patents can create barriers to accessing vital medical technologies. Although this therapy offers a potential cure for children with SMA, only a few can afford its immense cost, creating a divide between those who can access the treatment and those who cannot. In developed nations with robust healthcare systems, the cost might be covered by insurance or government subsidies, but in many developing countries, the therapy is virtually inaccessible due to the lack of government support or insurance coverage (Kruk et al., 2018). This raises ethical concerns about the fair distribution of medical technologies that can save lives but are restricted by patent-driven pricing.

Similarly, Luxturna, a gene therapy used to treat blindness caused by mutations in the RPE65 gene, highlights the inequity caused by patent systems. While the therapy offers new hope to patients without prior treatment options, its cost of \$850,000 per eye renders it unaffordable for many (Darrow, 2019). Like Zolgensma, Luxturna's high cost exacerbates access disparities, leaving patients in developing countries or those with limited financial means unable to access life-changing treatments.

Although patents play a crucial role in incentivizing innovation, they often limit the distribution of transformative technologies for genetic diseases. Consequently, while patents reward innovation and fund further research, they can also create severe inequities in access (Chien, 2022). For therapies like Zolgensma and Luxturna, patent policies rarely account for the social and economic impacts of restricted access.

These inequities are particularly pronounced in developing countries, where resources to afford such therapies are scarce. In many cases, the costs of genetic therapy

extend beyond the price of the drug itself to include medical procedures, post-treatment care, and logistical requirements. Patents on innovative genetic therapies result in profound social injustices, as only those who can pay the high costs can benefit from life-saving medical discoveries (on Patenting, 2008). Reconsidering the existing patent structures in genetic therapy, particularly for essential treatments, is critical to ensuring fair access.

Even in developed countries, patents create tensions between healthcare providers and biotechnology companies. In some cases, excessively high pricing policies limit access even when sufficient resources exist to fund treatment. For example, in the United States, while some patients may access genetic therapy through health insurance, insurers often struggle to cover the immense costs, potentially influencing whether patients can receive therapy (Wong et al., 2023). High-priced patents also increase healthcare system costs, further restricting access for many who need the therapy.

Overall, while patents in genetic therapy aim to compensate inventors and fund further research, their associated high costs often create severe inequities in access to essential therapies. These inequities exacerbate disparities between rich and poor nations and contribute to broader social injustices, where those unable to afford high costs miss opportunities for life-saving treatments. Policymakers and international regulatory bodies must explore ways to balance patent rights with the need to ensure fair access to innovative genetic therapies that offer significant global health benefits (Souto et al., 2024).

Ethical Issues in Genetic Therapy: Germline Modification and Technology Misuse

The ethical issues associated with genetic therapy are highly complex and require serious consideration, particularly given the extensive implications for human life. A major concern is germline modification, which refers to genetic changes made to DNA that offspring can inherit. In this context, CRISPR-Cas9 has unlocked extraordinary potential for genetic repair, such as addressing serious genetic conditions like beta-thalassemia and sickle cell anemia, both caused by hereditary mutations (Kolanu, 2024). This technology enables scientists to precisely cut and replace faulty DNA sequences, offering more effective and targeted treatments for genetic diseases.

However, germline modifications—altering the DNA of eggs or sperm—mean these changes are passed to future generations, raising profound ethical questions. One primary concern is the unforeseen risks of such genetic changes, which could lead to harmful side effects not only for the treated individual but also for future generations (Rubeis & Steger, 2018).

Additionally, germline modification poses a broader moral dilemma: Do humans have the right to alter their genetic lineage? Given that these changes affect multiple generations, many ethicists argue that principles of caution and equity should constrain such interventions. Designer babies, or the potential use of CRISPR to select specific traits like intelligence or physical appearance, exemplify how this technology could be misused for unethical modifications (Andoh, 2017). In conclusion, while CRISPR and similar technologies hold immense promise, they also demand robust ethical, legal, and policy frameworks to address their potential misuse and ensure equitable and responsible application.

Discussion

Patents, while providing necessary incentives for innovation in genetic therapy, can also hinder technological progress if not managed wisely. In many cases, overlapping patent systems or exorbitant licensing fees restrict access to critically needed

technologies. The most striking examples of this phenomenon are the therapies Zolgensma and Luxturna, which, despite their remarkable potential to save lives, remain inaccessible to many due to their high costs imposed by patent holders. This leads to social inequality, where only a small number of wealthy individuals or countries with advanced healthcare systems can access these therapies, while those from lower economic backgrounds or developing countries are denied the opportunity for life-saving treatments. This inequality has become a significant global concern, requiring careful attention from policymakers and patent regulators (Braveman & Gottlieb, 2014).

Balancing Innovation and Accessibility

It is crucial to design a patent system that not only benefits inventors and companies developing genetic therapies but also ensures the sustainability of access to these technologies for the broader population. An effective patent system should consider both the financial interests of inventors and the broader, fairer distribution of innovative technologies. In this way, innovation would not remain the domain of elites or developed countries but could also benefit those most in need, especially in developing nations vulnerable to genetic diseases (Mazzoleni & Nelson, 1998).

Furthermore, the safety and validity of CRISPR-Cas9 technology in genetic therapy are significant considerations. While this technology offers great promise in treating genetic diseases, the long-term effects of genetic modifications in humans remain uncertain. One of the most concerning aspects is the impact of germline modifications, which involve changes to DNA that are inherited by future generations. Such changes could lead to unforeseen side effects that affect the long-term health of human descendants. This raises profound ethical questions about whether humanity has the right to make permanent alterations to the human genome, which may have consequences not just for the modified individuals but also for generations to come (Almeida & Ranisch, 2022).

Ensuring Safety and Transparency

Strict oversight and clear guidelines for implementing this technology are essential to ensure that every genetic intervention is conducted safely and avoids unintended negative impacts on future generations. Long-term research is necessary to evaluate potential side effects, both short-term and long-term. Additionally, the scientific community must continue to promote the development of this technology transparently, based on robust scientific evidence, to ensure that CRISPR-based treatments are both safe and effective. With cautious application and proper regulation, CRISPR-based therapies have the potential to revolutionize the treatment of genetic diseases.

Cultural Considerations in Genetic Technology

The cultural approach to genetic technology also influences its acceptance and application across different countries. In nations with conservative values, such as many in the Middle East and Asia, the acceptance of human genetic modification tends to be slower and more controversial compared to countries in North America or Europe, which are more open to adopting new technologies. In countries like China, where research involving CRISPR is more widely accepted, experiments with germline modifications have already begun, despite global concerns about the potential misuse of this technology (Peng et al., 2022). Conversely, nations like Germany and France have strict and conservative regulations regarding the use of this technology, explicitly prohibiting germline modifications in humans.

It is important to incorporate cultural values into the design of international policies governing genetic technologies. Such policies must account for the moral, social, and

religious views prevalent in different parts of the world to ensure the ethical and socially acceptable implementation of genetic technologies. Comprehensive international policies based on global consensus are essential to regulate the ethical and fair use of this technology, particularly in light of the diverse cultural perspectives across nations. International cooperation in designing regulations that encompass various moral and social viewpoints is critical to ensuring that genetic technology benefits humanity as a whole (Hernández Guzmán & Hernández García de Velazco, 2024)

While CRISPR-Cas9 offers extraordinary potential in treating genetic diseases, the challenges associated with technology accessibility and ethical considerations must be addressed meticulously. Policies are needed that support innovation and ensure that access to this technology is extended to all, particularly to those most in need. Balancing patent rights, technological safety, and cultural sensitivity is essential to ensure that advancements in genetic therapy provide broad and equitable benefits for all humanity.

Conclusion

Genetic technology, particularly CRISPR-Cas9, offers immense potential for treating various genetic diseases and improving the quality of life for many people. With its precise and efficient genetic editing ability, this technology opens opportunities to address previously untreatable diseases such as sickle cell anemia, beta-thalassemia, and certain cancers (Kolanu, 2024). This rapid progress has the potential to revolutionize medicine, enabling more personalized and targeted interventions based on an individual's genetic makeup. However, significant challenges related to intellectual property rights (IPR) and ethics must be addressed alongside these rapid developments. One major issue is how patents on this technology can impede scientific collaboration and restrict access to critically needed technologies for the broader public.

Patents on genetic technologies such as CRISPR incentivize inventors and companies to continue innovating, but if not managed wisely, they can slow broader scientific progress. For instance, the patent conflict between the University of California and MIT over rights to CRISPR technology demonstrates how overlapping patents can lead to legal uncertainty and restricted access to life-saving technologies (Kim, 2024). Excessive patents or high licensing fees for using this technology often prevent researchers or small companies from utilizing CRISPR to develop more affordable and accessible therapies. This creates social inequality, where only certain groups benefit from this technology while many others, particularly in developing countries or low-income groups, remain excluded. Additionally, using genetic technology for human modifications raises serious moral questions. Germline modifications, which involve changes to human DNA that can be inherited, present unique challenges. While this technology can treat hereditary genetic diseases, such as beta-thalassemia or sickle cell anemia, germline changes may also result in unintended side effects that affect the long-term health of human descendants (Rubeis and Steger, 2018).

The ethical complexity deepens when genetic technology is used beyond disease treatment, such as in creating "designer babies" with traits selected by parents, including intelligence or physical appearance. This raises tensions between individual freedom to choose and the broader implications for social equality and justice. If technologies like CRISPR are used to enhance human capabilities non-medically, the risk of greater inequality arises, with wealthier individuals or countries gaining disproportionate access to such advancements (Bulathwela et al., 2024).

Moving forward, policymakers must design policies that balance innovation with equitable access for all. Flexible but stringent regulations are necessary to ensure that CRISPR technology is used safely, ethically, and accessibly. With the right policies, this technology can address widespread health issues, particularly in developing nations most vulnerable to genetic diseases. Policies ensuring that the benefits of genetic technology are accessible to all societal strata will be crucial to reducing global disparities in healthcare access (Smith, 2016).

Additionally, international regulations that unify globally recognized ethical and legal standards will be necessary to prevent the misuse of genetic technology. Sensitivity to different cultural values will play an important role in developing a fair and effective framework for applying genetic technologies worldwide (Zhong et al., 2021).

Overall, while CRISPR-Cas9 offers extraordinary potential in genetic disease treatment and improving human life quality, it also presents significant challenges in ethics, intellectual property rights, and access distribution. To maximize its benefits, policies must not only support innovation but also ensure that this technology is accessible fairly and ethically to all. Through careful regulation, genetic technology can serve as a transformative force for humanity, benefiting all and not just a privileged few.

References

- Abuhammad, S., Khabour, O. F., & Alzoubi, K. H. (2021). Researchers views about perceived harms and benefits of gene editing: a study from the MENA region. *Heliyon*, 7(4).
- Almeida, M., & Ranisch, R. (2022). Beyond safety: mapping the ethical debate on heritable genome editing interventions. *Humanities and Social Sciences Communications*, 9(1), 1–14.
- Andoh, C. T. (2017). Genome editing technologies: ethical and regulation challenges for Africa. *International Journal of Health Economics and Policy*, 2(2), 30–46.
- Ayanoğlu, F. B., Elçin, A. E., & Elçin, Y. M. (2020). Bioethical issues in genome editing by CRISPR-Cas9 technology. *Turkish Journal of Biology*, 44(2), 110–120.
- Braveman, P., & Gottlieb, L. (2014). The social determinants of health: it's time to consider the causes of the causes. *Public health reports*, 129(1_suppl2), 19–31.
- Chien, C. V. (2022). The Inequalities of Innovation. *Emory LJ*, 72, 1.
- Darrow, J. J. (2019). Luxturna: FDA documents reveal the value of a costly gene therapy. *Drug discovery today*, 24(4), 949–954.
- Garrison Jr, L. P., Jiao, B., & Dabbous, O. (2021). Gene therapy may not be as expensive as people think: challenges in assessing the value of single and short-term therapies. *Journal of managed care & specialty pharmacy*, 27(5), 674–681.
- Gubby, H. (2020). Is the patent system a barrier to inclusive prosperity? The biomedical perspective. *Global Policy*, 11(1), 46–55.
- Guo, N., Liu, J.-B., Li, W., Ma, Y.-S., & Fu, D. (2022). The power and the promise of CRISPR/Cas9 genome editing for clinical application with gene therapy. *Journal of Advanced Research*, 40, 135–152.
- Hernández Guzmán, D., & Hernández García de Velazco, J. (2024). Global Citizenship: Towards a Concept for Participatory Environmental Protection. *Global Society*, 38(2), 269–296.
- Joseph, A. M., Karas, M., Ramadan, Y., Joubran, E., & Jacobs, R. J. (2022). Ethical perspectives of therapeutic human genome editing from multiple and diverse viewpoints: a scoping review. *Cureus*, 14(11).
- Khachigian, L. M. (2020). Pharmaceutical patents: reconciling the human right to health with the incentive to invent. *Drug Discovery Today*, 25(7), 1135–1141.
- Kim, D., Kock, M. A., Lamping, M., Batista, P. H. D., Hilty, R., Slowinski, P. R., & Steinhart, M. (2023). New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector. *Max Planck Institute for Innovation & Competition Research Paper*, 16–23.
- Kolanu, N. D. (2024). CRISPR–Cas9 Gene Editing: Curing Genetic Diseases by Inherited Epigenetic Modifications. *Global Medical Genetics*, 11(01), 113–122.
- Kong, J., Zhang, J., Deng, S., & Kang, L. (2023). Knowledge convergence of science and technology in patent inventions. *Journal of Informetrics*, 17(3), 101435.
- Kruk, M. E., Gage, A. D., Arsenault, C., Jordan, K., Leslie, H. H., Roder-DeWan, S., Adeyi, O., Barker, P., Daelmans, B., & Doubova, S. V. (2018). High-quality health systems in the Sustainable Development Goals era: time for a revolution. *The Lancet global health*, 6(11), e1196–e1252.
- Liu, W., Li, L., Jiang, J., Wu, M., & Lin, P. (2021). Applications and challenges of CRISPR-Cas gene-editing to disease treatment in clinics. *Precision clinical medicine*, 4(3), 179–191.
- Mazzoleni, R., & Nelson, R. R. (1998). The benefits and costs of strong patent protection:

- a contribution to the current debate. *Research policy*, 27(3), 273–284.
- Mercurio, B. C. (2004). TRIPS, patents, and access to life-saving drugs in the developing world. *MArq. intell. Prop. l. reV.*, 8, 211.
- Michael, S. (2004). The Case Against Perfection. *The Atlantic Monthly*, 293(3), 51–62.
- Ogbonmide, T., Rathore, R., Rangrej, S. B., Hutchinson, S., Lewis, M., Ojilere, S., Carvalho, V., & Kelly, I. (2023). Gene therapy for spinal muscular atrophy (SMA): A review of current challenges and safety considerations for onasemnogene abeparvovec (Zolgensma). *Cureus*, 15(3).
- on Patenting, E. W. P. (2008). Patenting and licensing in genetic testing. *European journal of human genetics: EJHG*, 16(4), 405–411.
- Peng, Y., Lv, J., Ding, L., Gong, X., & Zhou, Q. (2022). Responsible governance of human germline genome editing in China. *Biology of Reproduction*, 107(1), 261–268.
- Rubeis, G., & Steger, F. (2018). Risks and benefits of human germline genome editing: An ethical analysis. *asian bioethics review*, 10, 133–141.
- Saul, J. (2024). Gene Patents: Striking the Right Balance Between Incentive and Innovation. *Fordham Law Review*, 92(6), 2765.
- Shinder, D. L., & Cross, M. (2008). *Scene of the Cybercrime*. Elsevier.
- Souto, E. B., Blanco-Llamero, C., Krambeck, K., Kiran, N. S., Yashaswini, C., Postwala, H., Severino, P., Priefer, R., Prajapati, B. G., & Maheshwari, R. (2024). Regulatory Insights into Nanomedicine and Gene Vaccine Innovation: Safety Assessment, Challenges, and Regulatory Perspectives. *Acta Biomaterialia*.
- Subica, A. M. (2023). CRISPR in public health: the health equity implications and role of community in gene-editing research and applications. *American Journal of Public Health*, 113(8), 874–882.
- Wong, C. H., Li, D., Wang, N., Gruber, J., Lo, A. W., & Conti, R. M. (2023). The estimated annual financial impact of gene therapy in the United States. *Gene Therapy*, 30(10), 761–773.