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Article:	**Patentability of Gene-Editing Technology and Clustered Regularly Interspaced Short Palindromic Repeats: Cases based legal Analysis**
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ABSTRACT

The study aims to evaluate the patentability of Gene-editing technology, specifically focusing on "Clustered Regularly Interspaced Short Palindromic Repeats (hereinafter CRISPR)." The qualitative and empirical methodologies,is adopted to examin fundamental criteria for patentability outlined in US patent law (2015) and the American Invents Act 2011. It draws on legal precedents, with a particular emphasis on key United States Supreme Court cases such as Alice v. CLS International Bank(2014) and Myriad Genetics, Inc. v. Molecular Pathology,(2013) to explore their practical implications on CRISPR technology. The significance lies in detailed analysis; how established legal standards affect the patentability of cutting-edge gene-editing technologies. By weaving together legal frameworks and real-world implications, the study provides a comprehensive understanding of the patentability landscape surrounding CRISPR. This sheds light on the complex interplay between legal considerations and technological advancements, which is crucial for stakeholders in the biotechnology and legal sectors. The study has potential recommendations for policymakers and legal practitioners on navigating the challenges associated with the patentability of gene-editing technologies and also suggests prospective revisions to current patent laws to better accommodate technological advancements that fosters balanced innovation while protecting intellectual property rights.

Keywords

American Invent Act, Bio-legal precedents, Editing Germline Cells, Editing Somatic Cells Patent law.

Introduction

Clustered Regularly Interspaced and Short Palindromic Repeats denoted to the unique arrangement of short DNA sequences separated by spacer DNA sequences and a distinctive property of repetitive and palindromic genomic sequences; respectively. Collectively, it referred to a collection of DNA sequences discovered in the genomes of prokaryotic species such as bacteria and archaea. These sequences are critical for these species' immunological responses to invading genetic material, such as viruses. Spacer DNA sequences, in the context of CRISPR are short pieces of DNA that are unique and serve to separate the repeated palindromic sequences within the array. These spacer sequences are from foreign genetics.

Envision a prospective scenario in which major corporations employ CRISPR, a genetic editing instrument, to alter nearly each existing organism. Immaculate lawns consist of genetically-modified grasslands, individuals cherish their genetically -altered animals, and parents meticulously choose the optimal traits for their genetically-enhanced offspring (Boyle, 2016).

CRISPR-Cas9, an acronym for "Clustered Regularly Interspaced Short Palindromic Repeats" and "CRISPR-associated protein 9," stands as a revolutionary genetic-editing technology that enables precise DNA modifications (Koo, 2016). This innovation surpasses earlier genetic-editing methods with its enhanced programmability, minimizing the occurrence of off-target effects (Ledford, 2017).

The FDA has recently issued a press release cautioning against the sale of "do-it-yourself" CRISPR kits, deeming it illegal due to safety concerns associated with CRISPR-Cas9-mediated gene therapies. Chinese scientists reported utilizing CRISPR-Cas9-modified cells to inject a lung cancer patient in October 2016, while Oregon Health & Science University researchers reported effective CRISPR-mediated modifications to non-viable human embryos in August 2017 (Rana et al, 2018).

While patent battles, laws and regulations, and ethical considerations have dominated legal discourse around CRISPR-Cas9, there is a noticeable void in the discussion of the patentability of CRISPR-Cas9 therapeutic applications (Feeney, 2021). Prior studies have examined the patentability of methods for generating and translating CRISPR-Cas9, but they have not investigated the patenting of CRISPR-Cas9 systems for medical purposes by modifying human, bacterial, or viral DNA (Chen, 2018).

The eligibility of these CRISPR-Cas9 applications for patent protection becomes ambiguous when evaluated against traditional tests for patentability (Gootenberg, 2018). Adding complexity to this matter, federal law prohibits the issuance of patents "on a claim directed to or encompassing a human organism," raising uncertainty about whether CRISPR-Cas9 systems cross this regulatory boundary (America Invent act, 2011). The statutory history of the Act indicates that this establishment was crafted to prevent the patenting of "human embryos and fetuses." However, the legislative intent also acknowledges the patentability of "genes, stem cells, and animals with human genes (WIPO, 2015).

This nuance implies that scholars aiming to develop CRISPR-Cas9 conducts for diverse human ailments must go beyond demonstrating the safety of their therapy to the FDA. They may inevitably find themselves entangled in legal disputes to determine their dealing qualifies as patentable focus matter under current state law. This underscores the need for a thorough

examination of the intricate intersection between CRISPR-Cas9 applications and the existing legal framework.

Background

Gene-editing technology has revolutionized the field of biotechnology, offering unprecedented possibilities for medical treatment, agricultural improvement, and scientific research. CRISPR has become known as a revolutionary gene-editing technology because of its preciseness, efficiency, and adaptability. CRISPR technology permits the targeted editing of the sequence of DNA in living creatures, allowing the fix of genetic abnormalities, augmentation of desirable features, and research of gene function. (Barrangou, 2016). CRISPR-Cas9 was first discovered in 2000 by experts in Spain. (Mojica,2004), Nevertheless, its potential for genetic editing became widely recognized in 2012. This acknowledgement accompanied an article in the journal by researchers from the University of California. Berkeley (Jinek, 2012).

The rapid growth of CRISPR technology has created a number of legal and ethical concerns. Adaptation to such disruptive innovations presents issues for patent law, which seeks to preserve and promote innovation. The patentability of gene-editing technologies, notably CRISPR, entails complicated challenges pertaining to innovation, non-obviousness, and utility, as well as broader factors such as the morality and societal consequences of genetic alterations. (Pugliese, 2019).

In the United States, numerous major acts and judicial judgments have changed the legal framework for patenting biotechnological inventions. The America Invents Act (AIA), passed in 2011, made major improvements to the US patent system, particularly a shift from the first-to-invent to a first-to-file model. This statute, along with rulings by the Court of Appeals and the US Patent and Trademark Office (USPTO), sets the present framework for patent eligibility. (Krishnamurthy, 2014).

The amazing value of CRISPR-Cas9 as a genome editing tool stems from its great precision. The CRISPR-Cas9 guide RNA consists of 20 nucleotides, each of which perfectly matches a nucleotide on the target DNA. This tight matching method reduces the risk of the Cas9 enzyme cleaving the DNA at an undesired place to less than one in one trillion. Ensuring that breakage only occurs at the desired target is critical since any off-target editing offers the danger of disrupting functioning DNA, ultimately resulting in serious and even fatal side effects. (Koo, 2017).

Objectives of the Study

This paper aims to give a thorough survey of the ongoing legitimate system controlling the legitimacy of licenses of quality altering innovations, with an emphasis on CRISPR. It attempts to lay out all-inclusive patentability standards and how they apply to quality altering methods. The study will examine relevant case law and administrative guidance to determine how the America Invents Act (AIA) of 2011 affects gene-editing technology patentability. Examining existing patents and case law to determine whether CRISPR technology meets the threshold for patent protection is an essential objective. In addition, the study sheds light on the complexities that arise from the connection between emerging technologies and existing patentability-affecting laws.

Significance of the Study

This study provides useful information that could have an effect on how the United States of America's patent law is changed in the future, especially for biotechnological discoveries. Legislators should be encouraged to propose amendments to better accommodate technological advancements in gene editing as a result of the study's emphasis on inconsistencies and ambiguities in the existing legal framework. Lawful professionals that practice on protected innovation can profit from understanding how CRISPR and related advancements line up with existing patent standards. This can make patent applications stronger and help defend against lawsuits.

Characterizing the patentability guidelines for CRISPR innovation could help scholastics and biotech undertakings gain licensed innovation freedoms, empowering interest in creative endeavors. The development of novel treatments and gene editing technologies could be sped up by this protection. By establishing standards for joint research endeavors, clear patent norms can facilitate collaboration between educational institutions and the industrial sector. The paper resolves the moral and moral issues of permitting quality altering innovation, advancing a decent discussion that thinks about both possible advantages and dangers. This can assist in the creation of frameworks that foster moral innovation.

The aftereffects of the review can be utilized in to advance informed banter and educate people in general about the ramifications regarding quality altering licenses and cooperation in mechanical progressions. By providing an in-depth analysis of the relationship between biotechnology and patent law, the study will make a significant contribution to the academic literature. Students, educators, and academics who study biotechnology, ethics, and law will benefit greatly from it. Biotech companies, patent attorneys, and legislators will all benefit from extensive research and the resulting data. It will walk you through the difficult process of patenting gene editing technology, ensuring that stakeholders are well-informed and prepared to address pertinent issues.

Gene Editing Diseases and Germline Cells

i. Editing Genetic Diseases

Numerous studies have been conducted to assess CRISPR-Cas9 for editing genetic sicknesses out of humanoid cells. As CRISPR-Cas9 do not naturally exist in hominoid cells, researchers must either directly deliver the guide RNA (gRNA) and Cas9 or insert DNA encoding them into the cells, enabling the cells to produce these components themselves.

The benefits of delivering the gRNA/Cas9 molecule directly to cells include reduced off-target effects because the cells' defenses usually eradicate the complex in less than a day. Nonetheless, the efficacy of this technique is restricted since not all cells express the Cas9/gRNA complex, which has led to the general acceptance of viral transmission as the more effective way. In 2017, researchers at the University of California, Berkeley, reported a major breakthrough: they have effectively used CRISPR-Cas9 to fix the mutation that causes muscular dystrophy in mice. The researchers injected mice with muscular dystrophy with a unique delivery method they devised, a CRISPR-Gold variant. Interestingly, CRISPR-Gold successfully introduced the entire Cas9/gRNA compound into the cells, obviating the necessity for a viral method of delivery. In comparison to control groups, treated mice receiving the CRISPR-Gold treatment showed an 18-fold increase in rectification rate and a two-fold improvement in strength and agility during following tests (Chauvin, 2018).

ii. Editing Germline Cells

Notably, a viral delivery method was not necessary because CRISPR-Gold successfully delivered the Cas9/gRNA molecule into the cells intact. In later testing, the CRISPR-Gold therapy showed that treated mice had twice as much strength and agility as control groups, and an 18-fold higher correction rate. Researchers at the University of Texas used CRISPR-Cas9 to treat muscular dystrophy in mice in a study that was comparable to that carried out by Berkeley's muscular degeneration researchers. In this instance, the scientists used the CRISPR-Cas9 method to insert the genes causing muscular dystrophy into freshly fertilized mouse eggs. Even while the researchers saw a mosaicism in mature mice, they also noticed that the mice's muscles were stronger than they should have been based only on gene expression. This result implied that a critical treatment outcome would be that the mice would benefit disproportionately from even a small percentage of healthy cells (Long, 2014).

Legal Landscape on the patentability of Gene Editing Technology

The American patent classification is structured to foster intellectual exploration by safeguarding notions and inventions. Congress, in alignment with this objective, has bestowed patent protection to individuals or entities that create or uncover any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," with certain stipulated "conditions and requirements" under inventions patentable code 35 U.S. section 101. .

i. General Requirements for Patentability

The prerequisite for patent protection is set forth in Section 101 of the U.S Patent Act (2015), which states that the invention must be acceptable as patent-eligible subject matter, or something for which a patent is allowed, usually a tangible good or a method. However, ideas that just describe natural laws are not eligible for patent protection (Sherkow, 2013). In Mayo Collaborative Services v. Prometheus Laboratories, (2012) the Supreme Court of USA upheld this idea, that a method that repeats a law of nature cannot be patented unless it includes extra elements that provide real-world assurance and go beyond merely trying to monopolize the law of nature itself. Realizing that all inventions use, incorporate, or apply natural laws to some degree, The Court recognized that a patent may be granted when a natural law is applied to a well-known structure or procedure.

The Court established a two-step procedure in Alice Corp. v. CLS Bank International, (2014) to determine whether a patent inadvertently covers a law of nature. The court's first task is to ascertain whether the patent includes any abstract ideas. It must then determine whether the patent contains an adequate "inventive concept" that goes beyond just directing the application of the rule of nature. A patent is considered eligible for protection if it covers a sufficiently innovative notion and does not just specify circumstances in which the law governing nature is to be applied.

ii. America Invents Act

Researchers now have to fulfill extra requirements under the America Invents Act (AIA) 2011 in order for their ideas to be considered patent-eligible subject matter. It specifically forbids the granting of patents pertaining to or involving human organisms. It does not attempt to completely forbid patent for all inventions meant for consumption by humans or use, even though it does want to limit patent protection for specific kinds of research (WIPO Manual, 2015).

The drafters of America Invents Act, 2011 made it clear that patents ought to continue to apply for genes, which stem cells, animals that carry human genes, and a variety of non-biologic goods that are used by people. This distinction suggests that patent protection is still available for medications, notwithstanding their close relationship to human organisms. But the AIA expressly states that human embryos are not eligible for patents (Russo, 2014).

It's interesting to note that the (America Invent Act, 2011) did not significantly alter the United States Patent and Trademark Office's (hereinafter USPTO) position on the patentability of living things. In an e-mail to Congress, USPTO Director James Rogan stressed that the AIA is consistent with the agency's long-standing policy of prohibiting patents on human beings and their forms (Chauvin, 2018).

iii. Laws applied on Human Biology

USPTO policies and the limitations set forth by the America Invents Act (AIA) 2011 have not acted as a complete barrier to the issuance of patents covering technologies related to human biology. Despite these policies, valid patents have been granted for inventions involving human DNA and human stem cells (Ass'n for Molecular Pathology v. Myriad Genetics, Inc, 2013).

a. Deoxyribonucleic acid (DNA)

The Supreme Court, in the case of Association for Molecular Pathology v. Myriad Genetics, Inc (2013), established a distinction in patentability between naturally taking place and genetically modified human DNA. The court of law ruled that while naturally occurring DNA is considered a product of nature and is not eligible for patent protection, DNA sequences that do not occur naturally can be patented. The case involved Myriad Genetics, a company that discovered the genetic sequence associated with a patient's susceptibility to breast and ovarian cancer. Myriad sought a patent for the typical DNA order initiate in these genes, which would have granted them exclusive rights to isolate these genes for assessing cancer risk. But the Court decided that Myriad was not entitled to a patent on the DNA sequences as they were found in nature. Crucially, the business was able to get a patent for laboratory-created synthetic DNA thanks to the Myriad ruling. Myriad created complementary DNA (cDNA) that was devoid of introns, or non-coding areas, and only had exon segments, or coding regions. The Court concluded that Myriad was allowed to patent the cDNA because, although cDNA is produced from naturally existing sequences of DNA, the exon-only strands of DNA do not occur naturally.

A subsequent case, had a similar justification. For prenatal diagnostics, Sequenom had developed a technique for separating cell-free fetal DNA (cffDNA) from mother blood. The Sequenom patent failed both prongs, according to the court's application of the Alice test. The court determined that Sequenom's procedure lacks an adequate "inventive concept" to warrant patentability because cffDNA was declared "naturally occurring" and the method steps were ruled "well-understood, conventional, and routine"(Ariosa Diagnostics, Inc. v. Sequenom, 2015)

b. Stem Cells

Human stem cells have continuously been given patent protection by the USPTO during the last thirty years. The federal government's position on studies on stem cells has changed over time, nevertheless. Federal funding was prohibited from supporting research that involved

the development or destruction of human embryos between 1996 and 2009 (Davey, 2015). The US Patent and Trademark Office and the legal system have continuously approved patents on different stem cell technologies, even though claims on stem cells from embryos are still controversial and frequently the subject of dispute. Notably, the number of patent filings pertaining to therapeutic stem cell technologies has increased recently. This is not the case with the European Patent Office (EPO), which views stem cell patents as unlawful because of issues with human body parts, human dignity, and the use of embryos for commercial purposes. The United States' readiness to provide patents for specific stem cell therapies raises the possibility of patents covering certain CRISPR-Cas9-based therapies as well (Servick, 2018).

CRISPR Eligibility for Patent Protection

It is unclear to what degree patent law, in particular the AIA (2011), permits the protection of patents to be extended to CRISPR-Cas9 systems used for therapeutic purposes. CRISPR-Cas9-based therapies face a number of obstacles in the patent application process: the applicant must show that the therapies are either (1) not found in nature or (2) contain a sufficiently innovative concept or (3) aren't "aimed to or involving a human organism." While some CRISPR-Cas9 therapeutic uses may be able to fulfill these requirements, others might not. This section argues that patent protection should be granted to CRISPR-Cas9 therapeutic uses that are similar to current disease therapies, such as CRISPR-Cas9 treatments for bacterial and viral infections. On the other hand, technologies like somatic and germ cell editing that do not yet have a therapeutic counterpart may not be eligible for patent protection.

i. Patent Protection for Gene -Editing Technology

Patent protection should be granted to CRISPR-Cas9 medicines intended to treat bacterial and viral illnesses. These treatments meet the requirements for patentability since they are not found in nature, they haven't become so popular that their creative notion hasn't been lost, and they don't contravene the AIA (2011) prohibition against "directed to or encompassing a human organism."

ii. CRISPR Treatment for Viral Diseases

First and foremost, humans do not normally use CRISPR-Cas9 to fight viral infections, as the Supreme Court's ruling in the Myriad case illustrates. This decision establishes that proving an invention's absence in nature is a relatively straightforward requirement, necessitating a demonstration that the specific invention is not naturally occurring. In the case of Myriad, despite the cDNA sequence's nucleotide order being derived from naturally occurring DNA, Myriad successfully obtained a patent by excluding introns current in the natural DNA order (Sherkow, 2018).

Although CRISPR-Cas9 systems are used by several organisms as a part of their innate immune response, the immune system of humans does not naturally include these systems. As an immunological response in bacteria, CRISPR-Cas9 first appeared, and there is no evidence that it is a normal part of the human immune system. Because CRISPR-Cas9 systems are not normal elements of the human immune response, the Myriad standard states that inventors should be able to patent these systems for the purpose of treating viral infections (Davey, 2015).

The methods used to introduce CRISPR-Cas9-based therapeutics into cells are still very new, even in the event that a court rules that they are naturally occurring. This situation requires a sufficiently creative idea, so meeting the second requirement of the Alice assessment. Researchers cannot simply introduce gRNA into cells infected with virus and expect the gRNA

to eradicate the viruses since human cells do not normally produce Cas9 proteins. Rather, it is a difficult issue for researchers to figure out how to bring the whole Cas9/gRNA compound into the cell. Furthermore, CRISPR-Cas9 systems' antiviral uses are not regarded as "directed to or encompassing a human organism" in the sense of the AIA.

iii. CRISPR Treatment for Bacterial Diseases

Patent protection ought to be available for CRISPR-Cas9 antibacterial applications, just like it is for its antiviral uses. The analysis is similar to that of apps that fight viruses. CRISPR-Cas9 systems are mostly focused on fighting viral infections rather than bacteria, despite the fact that they naturally occur in bacteria as an immune response. Consequently, CRISPR-Cas9 antibacterial applications are not found in nature (Lin, 2021).

Since they were created so recently, the delivery methods for antibacterial CRISPR-Cas9 therapy are not commonly used. It is more advantageous to introduce a whole Cas9/gRNA complex, a technique that has not yet been thoroughly explored in humans, even though certain microbes might already have Cas9 protein that can be linked with an inserted gRNA. Crucially, as CRISPR-Cas9 treatments targeting bacteria exclusively destroy bacterial DNA without affecting human DNA, they do not violate the provisions of the America Invents Act (AIA) 2011. Consequently, antibacterial applications of CRISPR-Cas9 should be considered patentable (Duardo, 2017).

iv. Limitation of Patent Protection for Gene Technology

Contrastingly, CRISPR-Cas9 therapies intended for editing somatic and germline cells would not be eligible for patent. Despite meeting both aspects of the Alice analysis by not naturally occurring in nature and necessitating an inventive concept, these therapies fall within the scope of being "directed to or encompassing a human organism," thereby violating the provisions of the America Invents Act (AIA) 2011. As a result, patent protection for CRISPR-Cas9 therapies directed at somatic and germline cell editing is not warranted (Ormond, 2017).

a. Editing Somatic Cells

The Myriad standard and other reasonable criteria demonstrate that CRISPR-Cas9-mediated somatic cell modification is not a natural phenomenon. As was previously said, CRISPR-Cas9 is unique to bacteria and developed as an immunological response in those organisms. Although CRISPR-Cas9 is found in bacteria by nature, it is not innately capable of editing human somatic cells. Using CRISPR-Cas9 to edit somatic cells, researchers are radically changing the natural function of this event, in contrast to Myriad researchers who eliminated particular regions of naturally existing DNA (Ass'n for Molecular Pathology v. Myriad, 2013).

Moreover, somatic cell editing with CRISPR-Cas9 requires an innovative leap to pass the second pillar of the Alice standard because it does not use commonly used procedures. Researchers are unable to merely introduce gRNA into cells and expect the modifications to take place since human cells do not naturally produce Cas9 proteins. Rather, a new strategy is needed to figure out how to get the whole Cas9/gRNA compound into the cell. Consequently, CRISPR-Cas9 systems intended for somatic cell modification shouldn't be covered by patents (Koo, 2017).

A limitation on patents for CRISPR-Cas9 systems intended for somatic cell editing is found in the AIA's clause prohibiting the issuance of patents for technologies "directed to or encompassing a human organism." Since the primary goal of CRISPR-Cas9 systems is to alter

human biology, this clause naturally applies to those systems when editing DNA in somatic cells.

b. Editing Germline Cells

Patent protection for CRISPR-Cas9 systems meant for modifying germline cells ought to be denied in a similar manner. The study is similar to that conducted in somatic cell systems: such germline modifying systems meet the first two patentability requirements, but they fail to meet the third. Not only does CRISPR-Cas9 not naturally occur in humans, it does not modify germline cells in the natural world. Beyond the Myriad threshold, CRISPR-Cas9's exclusive function in bacteria, its native environment, is the destruction of viral DNA. Additionally, CRISPR-Cas9 genome editing does not make use of commonly used methods, necessitating creative thinking. Human germline cells are not currently being genetically edited on a large scale (Devi2024).

Compared to somatic cells, the argument against CRISPR-Cas9-mediated genome cell editing being "directed to or encompassing a human organism" is additionally stronger. From an academic and therapeutic perspective, germline editing is advantageous because, if mosaicism problems are resolved, the modified DNA may be expressed in all adult body cells. Unquestionably, an invention that radically modifies the DNA of each and every cell in the body qualifies as being "directed to... a human organism." Furthermore, the modified DNA might be inherited by the children of edited persons, guaranteeing its incorporation into their genome. Significant ethical issues probably keep the USPTO from awarding patents for technology that have the potential to drastically change an individual's genetic makeup. (Chauvin, 2018).

Conclusion and Recommendations

According to the study, patenting CRISPR-Cas9 systems is a difficult and legal, scientific and ethical consideration. The precision of this technology in gene editing and numerous Utilizations, such as therapeutics and significant alterations to human biology, present complicated difficulties. For current patent rules. CRISPR-Cas9 therapeutics, particularly those focusing on viral and bacterial illnesses might be able to be patented. Patents on are banned by the America Invents Act (AIA). Technology involving humans, resulting in an unpredictable regulatory environment. Differentiating determining between processes that occur naturally and those that contain creative elements it’s hard to get a patent.

Debate grows when it comes to altering germline cells, posing not only scientific and medicinal potential, as well as ethical issues The exchange of adjusted hereditary material to Future generations add complexity, and the patent office is likely to be affected by ethical issues.

In contrast, therapeutically altering somatic cells is more in line with established patent principles, fulfilling models for inventiveness and innovative ideas. However, the AIA's the restriction of technology aimed at humans is a significant obstacle, especially as improved delivery systems like CRISPR-Gold emerge. Navigating these the patent system must strike a delicate balance between encouraging complex problems and solving ethical issues associated with innovation, protecting intellectual property, and fundamental shifts in the biology of humans. As CRISPR-Cas9 keeps on altering hereditary in determining the future, editing, constant legal and ethical scrutiny will play a crucial role. Environment for patenting this groundbreaking technology.

To ensure clear guidelines for patent eligibility, the findings of the study suggest that policymakers clarify the distinction between inventive elements and naturally occurring processes. This separation is urgent to stay away from uncertainty and to guarantee that main genuinely creative headways get patent insurance. In addition, in order to strike a balance between scientific advancement and moral responsibility, ethical issues need to be addressed, particularly when editing germ lines. It is essential to adapt the regulatory environment to support the patentability of therapeutic uses of CRISPR technology as it continues to evolve. This will guarantee that these applications can develop unimpeded, fostering the creation of novel medical treatments and breakthroughs. In light of the unique challenges and opportunities presented by gene editing technologies, it is recommended to further modify the current patent laws. These modifications would better accommodate these innovations, ensuring that the patent system fosters innovation while protecting intellectual property and addressing the ethical implications of altering human biology.

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