A STUDY ON THE RELATIONSHIP BETWEEN IPR AND ACCESS TO BIOTECH INNOVATIONS IN PHARMA WITH SPECIAL EMPHASIS ON THE CRISPR-CAS9 TECHNOLOGY

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ABSTRACT

This article delves into the intricate relationship between intellectual property rights (IPR) and access to biotechnological innovations within the pharmaceutical sector, with particular emphasis on the revolutionary CRISPR-Cas9 technology. Through an indepth examination of international dynamics within the IPR landscape, the study sheds light on the challenges and opportunities faced by policymakers in developing nations in protecting national interests while promoting societal welfare.

Drawing upon a comprehensive analysis of existing literature and policy frameworks, the research elucidates the institutional capabilities of developing countries in navigating the complexities of IPR, including the coordination of policies across governmental bodies and participatory engagement in decision-making processes. Moreover, the paper explores the implications of limited financial and human resources on the implementation of new legislation and infrastructure enhancements, proposing collaborative strategies with neighbouring countries to overcome these challenges.

Furthermore, the study investigates the therapeutic potential of CRISPR-Cas9 technology in the realm of medicine, highlighting its role in treating various genetic conditions and infectious diseases. It examines the ethical considerations surrounding the use of CRISPR-Cas9 for germline gene therapy and somatic cell editing, emphasizing the need for robust regulatory frameworks to govern its application.

Overall, this article provides valuable insights into the complex interplay between IPR, biotechnological innovations, and CRISPR-Cas9 technology in the pharmaceutical industry. By elucidating the opportunities and challenges associated with these advancements, the study aims to inform policy decisions and facilitate equitable access to biotech innovations for global health and agricultural sustainability.

INTRODUCTION

Intellectual property encompasses exclusive rights granted by a nation over expressions of individuality, specifically including innovations, artistic and creative works, unique symbols, and designs used in commerce.[1]

Cutting-edge technology plays a crucial role in the healthcare industry. The utilization of the Intellectual Property framework by Small and Medium Enterprises in the medical sector heavily depends on factors such as the company's business strategy, size, resources, innovative capabilities, competitive environment, and area of expertise. Companies driven by research and innovation that aim to develop new drugs, enhance or modify existing medications, or create new pharmaceutical/medical equipment or processes often rely significantly on the patent system to ensure the recovery of investments made in research and development.

The existing Intellectual Property Rights (IPR) framework is facilitating the commercialization of seed improvement, monoculture, protection of new plant varieties, microorganisms, and genetically modified organisms. This has led to the

irreversible depletion of our diverse biological resources. A way should be found to develop an elective approach that fosters harmony between the formal Intellectual Property (IP) framework and sustainable aspects of biodiversity.

Organizations that rely on licensing for providing pharmaceutical products should be educated about the patent system to enable them to negotiate fair and equitable licensing agreements. Small and Medium Enterprises in the medical sector can utilize the wealth of information found in patent documents as crucial input for their Research & Development, for generating ideas for further innovation, for safeguarding their "freedom to operate," or for discovery purposes.

Contemporary structures, such as plant variety protection, are typically less pertinent to most Small and Medium Enterprises in the medical field. However, this may vary based on the product offerings and strategies of each organization. The Agreement on Trade Related Aspects

[1] Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual property rights: An overview and implications in pharmaceutical industry*, 2(2) J ADV PHARM TECHNOL RES. APR-JUN. 88–93 (2011) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/.

of Intellectual Property Rights (TRIPS) establishes minimum standards and guidelines concerning the categories of IPR.

BIOTECHNOLOGY- MEANING AND IMPORTANCE

Biotechnology is an innovation that uses natural frameworks, living creatures, or parts of this to create or make various items. With the improvement of a hereditary building during the 1970s, inquire about in biotechnology created rapidly as a result of the new plausibility to make changes in the life forms' hereditary material.

As many controls, biotechnology covers a wide zone of biology, such as hereditary qualities, natural chemistry, atomic science, and various others. Each year, new new innovations and items are created inside the zones of medication development of new meds and treatments, cultivation improvement of hereditarily modified plants, biofuels, organic treatment or efficient biotechnology generation of synthetic compounds, paper, materials and nourishment.

Biotechnology assisted the creatures with battling the affliction. As of now, there are more than 250 biotechnology medical care items and antibodies that can be accessible to patients, including a few already untreatable diseases. More than 13.3 million ranchers worldwide utilize farming biotechnology to increase yields, safeguard them from bugs and other bugs, and diminish their general effect on the climate . What's more, more than 50 biorefinery offices in Northern America are trying and refining innovations to deliver biofuels and synthetic compounds from sustainable biomass, assisting the country with diminishing outflows of outflows gas.

The Biological Diversity Act of 2002, commonly referred to as the BD Act, outlines a framework for accessing genetic resources and sharing the benefits derived from them. Section 6 of the BD Act, effective since July 1st, 2004, stipulates that obtaining Intellectual Property Rights (IPRs) through the use of biological resources in India requires approval from the National Biodiversity Authority (NBA).

This field encompasses the study of life and encompasses the application of technology, pharmaceuticals, and various other valuable resources. In modern terms, it includes genetic engineering, tissue culture, and cellular development. It spans a wide array of techniques aimed

at altering organisms for human purposes, ranging from animal husbandry to plant breeding and enhancements achieved through selective breeding and hybridization.

Understanding these fundamental natural processes involves the ability to isolate and amplify a specific gene from the vast array present in an organism's genome—the complete set of genes or genetic material present in a cell or organism. Undoubtedly, the increasing availability of complete genome sequences for a growing number of organisms holds the promise of transforming these sciences and the industries reliant upon them.

HOW INTELLECTUAL PROPERTY RIGHTS CAN PROTECT BIOTECHNOLOGY?

Intellectual property rights serve as a shield for innovation, ensuring that creators are duly recognized and protected. In the realm of biotechnology, inventors rely on intellectual property rights to safeguard their creations. However, establishing the novelty and innovation of a product is essential to secure these rights, as outlined in *Section 2(1)(j) of the Patents Act, 1970*[2], which defines the criteria for granting and protecting inventions.

Let's delve into how intellectual property rights play out in the biotechnology sector through a practical example:

Consider the pharmaceutical industry, where government protection enables companies to brand their products with the ® symbol, signifying that the trademark is registered and exclusive to them. While multiple companies may produce the same chemical compound, only one can legally market it under the trademarked name. For instance, fluoxetine hydrochloride, an antidepressant, is sold by various companies, but only Eli Lilly can market it as Prozac. Similarly, Roche has exclusive rights to the trademark Tamiflu for its flu prevention and treatment drug, Oseltamivir. Trademarks extend beyond drugs to encompass hospital names, physician practices, and other branded entities, crucial in today's business landscape where branding and image are pivotal.

Another example lies in biotechnology firms, which rely on patents to safeguard their intellectual property rights pertaining to drug delivery devices. AstraZeneca, for instance, holds

[2] The Patents Act, 1970 No. 39, Acts of Parliament, 1970 (India) available at h:ps://ipindia.gov.in/writereaddata/Portal/ev/secBons/ps2.html.

patents for the Symbicort Turbuhaler, a dry powder inhaler delivering the medication budesonide/formoterol for asthma and COPD maintenance treatment. Similarly, healthcare companies secure patents for devices such as braces, prostheses, vision testing equipment, and healthcare management computer systems, ensuring their innovations remain protected.

GOVERNMENT'S ROLE IN LICENSING OF BIOTECHNOLOGY INVENTIONS IN INDIA

The Department of Biotechnology (DBT) has crafted an innovation strategy alongside a Vision Statement on Biotechnology, aiming to provide a framework and strategic direction across various sectors to accelerate the advancement of biotechnology in developing nations. This strategic plan seeks to delineate pathways for progress in fields such as agricultural and food biotechnology, industrial biotechnology, medical and pharmaceutical biotechnology, diagnostic biotechnology, bioengineering, nanotechnology, clinical biotechnology, environmental biotechnology, as well as intellectual property rights including patent law, copyright law, trademark law, and design law.

In the realm of intellectual property, the Intellectual Property Office (IPO) views biotechnological innovations as pertaining to living organisms of natural origin, encompassing animals, humans (including parts thereof), artificial living entities like microorganisms, vaccines, transgenic animals and plants, and biological materials such as DNA, plasmids, genes, vectors, tissues, cells, and replicons. Processes related to living entities, processes related to biological material, and methods for treating human or animal bodies, biological processes, or simply biological procedures are also considered within this purview.

However, certain biotechnological innovations are deemed non-patentable under Section 3 of the Indian Patent (Amendment) Act 2005. These include living organisms of natural origin such as animals, plants (in whole or in part), plant varieties, seeds, species, genes, and microorganisms, as well as any manufacturing or production process related to such living substances. Additionally, methods of treatment, whether therapeutic, surgical, medical, prophylactic, diagnostic, or remedial, for humans, animals, or similar treatments, are excluded from patentability.

Similarly, living organisms of artificial origin such as transgenic animals and plants, or any part thereof, as well as biological materials like organs, tissues, cells, and viruses, along with

processes involved in their preparation, fall under the category of nonpatentable innovations. Essentially, biological processes for the production of plants and animals, such as methods of crossing or breeding, are also ineligible for patent protection.

INTELLECTUAL PROPERTY IN BIOTECHNOLOGY AND PHARMACEUTICALS: NAVIGATING THE LEGAL LANDSCAPE

In the rapidly evolving fields of biotechnology and pharmaceuticals, intellectual property (IP) rights play a pivotal role in fostering innovation, attracting investments, and ensuring that inventors receive due recognition for their contributions. However, navigating the legal complexities surrounding IP in these sectors is a formidable task, particularly given the intricate nature of biotechnological and pharmaceutical inventions and the global emphasis on accessible healthcare.

At the core of IP protection in biotechnology and pharmaceuticals lies the patent system, which grants inventors exclusive rights to their innovations for a limited period, typically 20 years from the filing date, in exchange for disclosing their inventions to the public. However, applying patentability criteria to biotech and pharma inventions often poses intricate legal challenges.

Biotechnological inventions, spanning from genetically modified organisms (GMOs) to CRISPR-Cas9 gene editing technologies, frequently straddle the boundary between patentable inventions and naturally occurring phenomena, which are ineligible for patent protection. The landmark *U.S. Supreme Court case of Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)* addressed this issue directly, ruling that naturally occurring DNA sequences cannot be patented, while synthetic DNA (cDNA) is eligible for patenting. This ruling has had significant ramifications for biotechnology research and development, underscoring the distinction between natural products and human-made inventions.

In the pharmaceutical sector, the challenge often revolves around striking a balance between IP rights and the imperative of making medicines affordable. The case of *Novartis AG v. Union of India & Others (2013*[3]*),* decided by the Indian Supreme Court, serves as a pivotal example. The Court refused patent protection for the cancer drug Glivec, determining that Novartis failed

[3] *Novartis v. Union of India & Others (*2013) 13 S.C.R. 148 (India).

to demonstrate enhanced therapeutic efficacy over known substances. This decision highlighted the rigorous standards applied to pharmaceutical patents in India and brought attention to the global discourse surrounding "evergreening" practices, wherein companies attempt to prolong patent exclusivity by making minor modifications to existing drugs.

THE CRISPR-CAS9 TECHNOLOGY AND ITS SIGNIFICANCE IN BIOTECH AND PHARMACEUTICAL RESEARCH

CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats. It is a component of bacterial immune systems that can cut DNA, and has been repurposed as a gene editing tool. It acts as a precise pair of molecular scissors that can cut a target DNA sequence, directed by a customizable guide.

The CRISPR-Cas9 technology is a ground-breaking tool that has revolutionized the landscape of biotechnology and pharmaceutical research. Originally derived from bacterial immune systems, CRISPR, which stands for Clustered Regularly Interspaced Short Palindromic Repeats, serves as a potent gene-editing mechanism that has garnered significant attention for its precision, cost-effectiveness, and versatility.

How Does CRISPR CAS9 Technology Work?

Simply put, The CRISPR-Cas9 system is like a pair of tiny scissors and a GPS for DNA. The scissors, called Cas9, can cut DNA at a specific spot, while the GPS, called guide RNA, helps the scissors find the right place in the DNA.

The guide RNA is like a map that tells Cas9 exactly where to go. Once Cas9 reaches the right spot, it snips the DNA there. When the DNA is cut, the cell notices it's damaged and tries to fix it. Scientists can use this repair process to change or edit specific genes in the DNA.

So, basically, CRISPR-Cas9 lets scientists edit DNA like you might edit a document on a computer – making changes to specific parts to fix problems or make improvements.

The CRISPR-Cas9 system operates through a tandem of essential molecules, facilitating the alteration of DNA. These components encompass an enzyme known as Cas9, which functions akin to a pair of microscopic scissors capable of precisely cleaving the DNA strands at a designated genomic location. This incision permits the addition or removal of DNA fragments

as needed. Accompanying Cas9 is a segment of RNA called guide RNA (gRNA), which comprises a short pre-defined RNA sequence nested within a larger RNA framework. This scaffold attaches to DNA, while the specific sequence within the gRNA acts as a navigational beacon, directing Cas9 to the intended genomic site. Consequently, Cas9 is directed precisely to the targeted region, ensuring accurate DNA cleavage.

The guide RNA is meticulously engineered to bind exclusively to a particular sequence within the DNA. Its RNA bases exhibit complementarity to those of the target DNA sequence, ensuring the guide RNA's specificity to the intended genetic locus. As a result, the guide RNA selectively binds solely to the target sequence within the genome, mitigating the risk of off-target effects.

Upon reaching the designated genomic site, Cas9 initiates a cut across both strands of the DNA, creating a double-strand break. Subsequently, the cell detects the DNA damage and initiates repair mechanisms to rectify the breach. Leveraging this innate DNA repair machinery, scientists can introduce desired alterations to one or more genes within the cell's genome.

In essence, the CRISPR-Cas9 system provides researchers with a versatile tool for precisely modifying genetic material, offering immense potential for applications ranging from basic research to therapeutic interventions

One of the key advantages of CRISPR/Cas9 lies in its simplicity and efficiency compared to earlier gene-editing techniques. Its straightforward design and ease of use make it accessible to researchers across various disciplines. Moreover, CRISPR/Cas9 boasts a wide array of real-world applications, spanning from agriculture to human health.

In the realm of human health, CRISPR/Cas9 has opened up new avenues for the treatment of genetic disorders. By targeting disease-causing mutations at the genetic level, scientists envision a future where debilitating conditions such as haemophilia and Huntington's disease can be effectively addressed. Additionally, CRISPR/Cas9 has paved the way for innovative approaches to organ transplantation, with the potential to create transgenic animals capable of producing organs suitable for human use.

The significance of CRISPR/Cas9 was underscored by the prestigious Nobel Prize in Chemistry awarded to Jennifer Doudna and Emmanuelle Charpentier in 2020, recognizing their

pioneering contributions to gene editing. However, it's essential to acknowledge the collaborative effort of countless scientists, including Virginijus Siksnys, whose collective contributions have propelled the development and advancement of gene-editing technologies like CRISPR/Cas9.

Applications and Implications

- CRISPR-Cas9 exhibits significant promise as a therapeutic tool for addressing various genetic-based medical conditions, encompassing ailments like cancer, hepatitis B, and high cholesterol.

- While many proposed applications focus on editing non-reproductive cells (somatic cells), there's considerable interest and discussion regarding the potential editing of reproductive cells (germline cells).

- Editing germline cells raises ethical concerns due to the hereditary nature of any alterations, which would affect subsequent generations.

- Currently, the practice of gene editing in germline cells is prohibited in the UK and the majority of other nations.

- Therapeutic applications of CRISPR/Cas-9 have shown promising results, particularly in the treatment of diseases like lung cancer and HIV. In a ground-breaking human trial, T-cells extracted from patients were genetically modified using CRISPR/Cas-9 to enhance their ability to fight cancer cells.

- CRISPR/Cas-9 holds potential in combating infectious diseases, including HIV. Researchers have successfully demonstrated in animal models that HIV replication can be halted and the virus eliminated from infected cells by excising the HIV genome using CRISPR/Cas-9. Additionally, the technology offers the possibility of blocking HIV entry into host cells by editing genes like CCR5, which play a crucial role in viral infection. Preliminary trials have shown promising results, indicating that edited cells may be more resistant to HIV infection compared to unmodified cells.

- In agriculture, CRISPR/Cas-9 presents a solution to address the challenges of food scarcity and environmental stressors. By genetically modifying crops, researchers aim to enhance their nutritional value, increase resilience to drought and disease, and extend shelf life. This not only helps to ensure food security but also promotes sustainable agriculture practices to meet the demands of a growing global population.[4]

- Furthermore, beyond its role in genome editing, CRISPR/Cas-9 can be utilized for gene activation and silencing. By modifying the Cas-9 protein, researchers can artificially regulate the expression of specific genes, either activating or repressing their activity. This opens up new avenues for studying gene function and developing targeted therapies for various genetic disorders. Additionally, the technology allows for the visualization and precise localization of genes within cells, enabling researchers to study their behaviour and interactions in greater detail. This advancement holds promise for advancing our understanding of cellular processes and developing novel treatments for complex diseases.

The applications of CRISPR/Cas9 are vast and continue to expand with each passing day. From curing diseases in animal models to creating transgenic organisms for research purposes, CRISPR/Cas9 has transformed the field of biotechnology and holds immense promise for the future of medicine and agriculture. As researchers delve deeper into the intricacies of CRISPR/Cas9 and refine its capabilities, the possibilities for genetic manipulation are truly endless.

Background of the Technology

Genome editing refers to the deliberate modification of DNA in living cells, involving the insertion, removal, or alteration of genetic material. The acronym CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeat, describing a unique arrangement of DNA sequences observed in prokaryotic genomes. Initially observed by Japanese scientist Ishino in 1987, these repetitive sequences with interspaced segments were later termed CRISPR by

[4] Misganaw Asmamaw and Belay Zawdie, *Mechanism and Applications of CRISPR/Cas-9-Mediated Genome Editing*, 15 BIOLOGICS 353 - 261 (2021) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8388126/.

Mojica in 1990. However, their biological significance remained unclear until 2007 when CRISPR was identified as part of the prokaryotic immune system against viruses.

During viral attacks, prokaryotes incorporate short viral DNA fragments (spacers) into their CRISPR arrays, serving as a genetic memory of previous infections. The CRISPR defence mechanism operates in three stages: adaptation, crRNA synthesis, and target interference, involving the destruction of viral nucleic acids by Cas proteins encoded by adjacent Cas genes.

Prior to the discovery of CRISPR/Cas-9, gene editing relied on techniques like zinc finger nucleases (ZFN) and Transcription activator-like effector nucleases (TALENs), both involving protein engineering and being costly and time-consuming. ZFN utilizes a zinc finger DNA binding domain and a restriction endonuclease domain to target and cleave specific DNA sequences, while TALENs offer a broader range of target sequences with a similar structure.

The elucidation of the CRISPR mechanism in prokaryotes revealed its potential as a gene-editing tool in various organisms. In 2012, Doudna and Charpentier discovered that CRISPR/Cas-9 could edit DNA with high precision by providing the appropriate template. Since then, CRISPR/Cas-9 has become the most effective and efficient genome editing tool, widely applied across different disciplines.

his review aims to delve into the mechanisms of genome editing facilitated by CRISPR/Cas-9 and explore its recent applications, recognizing it as a ground-breaking scientific discovery of the century. Additionally, it will address the current challenges hindering the widespread adoption and transformation of this technology.

PATENT-ELIGIBLE SUBJECT MATTER

Patentability under Indian Law

In Indian patent law, the notion of patentability is delineated in *Section 2(1)(j) of The Patents Act, 1970*[5], where an invention is defined as a novel product or process exhibiting an inventive step and having industrial applicability. This statutory provision necessitates that any new process or product seeking patent protection must possess characteristics of novelty, utility, and

[5] The Patents Act, 1970 No. 39, Acts of Parliament, 1970 (India) available at h:ps://ipindia.gov.in/writereaddata/Portal/ev/secBons/ps2.html.

inventive ingenuity. It mandates that the product or process sought to be patented should not be part of the public domain prior to the submission of the patent application, nor should it be obvious to a person skilled in the relevant field.

Moreover, Indian patent law also recognizes significant advancements or improvements upon existing technologies as patentable subject matter. Section 3 of the Act enumerates specific categories of inventions that are deemed eligible for patent protection. However, it also delineates certain exclusions, including inventions that contravene public morality or pose substantial risks to human, plant, or animal life, as well as to the environment.

Under *Section 3(b*[6]*)* of the Act, any invention that is contrary to morality or that poses serious threats to the well-being of living organisms or the environment is ineligible for patent protection. The manual of patent practice and procedure further elucidates that inventions such as processes for modifying the germ line of human beings may fall within the scope of this provision, thereby precluding them from patentability.

Similarly, *Section 3(i)* [7]of the Act prohibits the patenting of processes related to the medicinal, surgical, curative, prophylactic, diagnostic, or therapeutic treatment of human beings, as well as processes aimed at rendering animals free of disease or enhancing their economic value. This provision underscores the legislative intent to prioritize public health and welfare over commercial interests in the realm of patentable inventions.

CRISPR Under Indian Patent Law

The CRISPR gene editing tool represents a significant innovation within the framework of The Patents Act, 1970, falling under the purview of Section 2(1)(j). This cutting-edge technology, exemplified by the CRISPR-Cas9 system, marks a substantial advancement in genome editing methodologies. Its simplicity, employing RNA for DNA recognition, distinguishes it from previous options like ZFNs and TALENs. The ability to introduce multiple guide RNAs facilitates simultaneous modifications across various genes, thus embodying novelty in its approach.

[6] Section 3(b), The Patents Act, 1970 (India).
[7] Section 3(i), The Patents Act, 1970(India).

CRISPR technology holds immense promise in the realm of disease treatment across human, animal, and plant domains. With its potential to address genetic disorders such as Cystic Fibrosis and Huntington's disease, its applications continue to broaden. Analysis of CRISPR's functionality and utility reveals elements of inventive ingenuity and industrial applicability. However, the prospect of modifying the human genome at early developmental stages raises ethical concerns under sections 3(b) and 3(i) of The Patent Act, 1970.

While modification of the human germ line for desired traits may conflict with public morality, prudent measures can mitigate such risks, allowing for legitimate applications of the technology. By emphasizing the intended uses and implementing safeguards, patentees can navigate potential obstacles under section 3(b). Nonetheless, the primary hurdle to patentability lies within section 3(i), which restricts processes aimed at treating humans or animals.

To address this limitation, applications of the technology can be tailored to focus on plant-based interventions, circumventing the restrictions of section 3(i). For instance, CRISPR's utility in enhancing plant resilience against pests or altering flower colours for pollinator attraction showcases viable avenues for patent protection. By aligning claims with non-human applications, patentability barriers under section 3(i) can be effectively circumvented.

ETHICAL CONSIDERATIONS IN THE INTERSECTION OF IPR AND BIOTECH INNOVATIONS:

The conundrum emerging at the crossroads of intellectual property rights (IPR) and human rights revolves around the potential impediment to accessing knowledge and information. A notable discrepancy in technological advancement exists, with certain regions leading innovation while others lag behind. The quandary surfaces when advanced technologies, safeguarded by stringent IP regulations, remain out of reach for populations in less developed nations. Consequently, striking a delicate balance between these two realms and ensuring equitable access to knowledge, information, and technological progress poses a formidable challenge.

The debate surrounding patent rights and access to life-saving medications has perennially sparked controversy. According to the 2017 joint report by the World Health Organization (WHO) and World Bank, over half of the global population, surpassing 7.3 billion individuals, lacked access to essential medicines and fundamental healthcare services. The right to life

encompasses the right to a healthy existence, which is a fundamental moral imperative, and any denial of this right, regardless of justification, fundamentally violates the essence of life itself. It is imperative to incentivize individuals who invest their resources in research endeavours, as their encouragement fosters continued innovation. However, the innovation loses its essence if it fails to safeguard human lives. The question arises: what value does innovation hold if it does not prioritize human well-being?

The early 2000s witnessed a significant clash between pharmaceutical industry giants and the plight of 12 million HIV patients in Africa. In a remarkable turn of events, Cipla successfully advocated for a global patent waiver to supply anti-HIV AIDS drugs to Africa at an affordable price, setting a precedent for aligning economic interests with humanitarian concerns.

Cloning encompasses a broad spectrum of practices, ranging from home cloning of plants using cuttings to industrial cloning of animals. While cloning yields cells or organisms genetically identical to the original, the patenting of biological methods employed in plant and animal production is prohibited under *Section 3(j) of the Act*.[8]Moreover, any innovation that contravenes public morals or poses harm to individuals or the environment is deemed illegal under *Section 3(b)*[9]. Critics highlight numerous health concerns associated with animal cloning, including abnormal organ development, accelerated aging, and compromised immune systems, as evidenced by the case of Dolly the Sheep.

Stem cells, renowned for their remarkable adaptability and potential to differentiate into various cell types, offer promising prospects in disease treatment. However, ethical concerns surrounding their embryonic exploitation persist. While adult stem cells lack the versatility of embryonic counterparts, ethical and environmental considerations prevent the patenting of inventions related to stem cells.

Biotechnology has introduced genes with beneficial traits, such as insect resistance, to enhance plant growth, exemplified by genetically modified seeds. Despite the prohibition on patenting plants, plant varieties, or seeds, the Patents Act permits the patenting of modified genes, facilitating the creation of transgenic seeds. Although seed patents may constrain farmers' seed-

[8] Guidelines For ExaminaBon of Biotechnology ApplicaBons for Patent, Office of the Controller General of Patents, Design and Trademark, March 2013.

[9] Guidelines For ExaminaBon of Biotechnology ApplicaBons for Patent, Office of the Controller General of Patents, Design and Trademark, March 2013.

saving and trading practices, the 2001 Act to Protect Plant Varieties and Farmers' Rights safeguards the development and dissemination of transgenic plant varieties and seeds.

Relevant Case Laws:

In the legal landmark of ***Novartis v Union of India (AIR 2013 SC 1311),*** [10]the Supreme Court of India made a seminal ruling that prioritized the accessibility of life-saving medications over the protection of patent rights. The case revolved around Novartis Pharmaceutical Company's challenge to the constitutionality of *Section 3(d)* of the Patent Act, 1970, in its pursuit of a patent for a cancer treatment drug containing imatinib mesylate. The court's verdict, which denied Novartis' patent application, hinged on the interpretation of Section 3(d) and its requirement for patent eligibility. The court's interpretation clarified that the mere discovery of a new form of a known substance does not constitute sufficient grounds for patentability under Section 3(d). This judicial elucidation reaffirmed the constitutional validity of Section 3(d) and signalled a significant shift in the jurisprudence surrounding patents and life-saving pharmaceuticals.

The ruling in the Novartis case underscored the imperative to balance intellectual property rights with public health considerations, particularly in the context of access to essential medicines. By upholding Section 3(d) of the Patent Act, the court upheld the principle that innovation in the pharmaceutical sector should prioritize the development of genuinely novel and beneficial medications. This decision reflects a global consensus on the ethical imperative of ensuring equitable access to life-saving treatments, irrespective of corporate interests.

Furthermore, the Novartis judgment highlighted the adverse impact of pharmaceutical monopolies on public health outcomes, particularly in developing countries where access to affordable medications is often limited. By affirming the constitutionality of Section 3(d), the court sent a clear message that pharmaceutical companies must prioritize public welfare over profit-seeking endeavours.

[10] Mohd. Rehan Ali & Khan Obaida, *Striking A Balance Between Intellectual Property Rights And Human Rights In The Era Of Technology And Innovation* available at https://www.livelaw.in/lawschool/articles/intellectual-property-rights-human-rights-technology-andinnovation-252986

In another matter, In the case of ***Bayer Corporation v Union of India and others*** [11]an essential legal precedent was set when a compulsory license was granted to NATCO Pharma Ltd., a generic drug manufacturer, allowing them to manufacture and distribute Nexavar. This landmark decision underscored the paramount importance of public interest in matters concerning access to essential medications. The judiciary's ruling sent a resolute message that India is committed to safeguarding the welfare of its citizens and will not tolerate the exploitation of vulnerable populations by pharmaceutical giants.

By granting the compulsory license, the court demonstrated a firm stance against practices that hindered access to life-saving treatments due to exorbitant pricing or monopolistic control. The decision highlighted the judiciary's role in ensuring equitable access to healthcare and promoting competition in the pharmaceutical sector.

Moreover, the case emphasized the need for a balance between protecting intellectual property rights and safeguarding public health interests. By prioritizing public welfare over corporate profits, the judiciary reaffirmed India's commitment to upholding the right to health as a fundamental human right.

PATENT-RELATED ASPECTS OF CRISPR-CAS TECHNOLOGY

The driving force behind the pursuit of patents related to the CRISPR–Cas9 system was the potential for financial gain, which was understandably attractive to both individual scientists and the institutions involved in its study. An early patent application was jointly filed by the University of California at Berkeley, representing Doudna, and the University of Vienna, where one of the lead authors of a seminal publication on CRISPR–Cas9 was affiliated, along with Charpentier as an individual inventor, following the guidelines of the University of Umeå in Sweden, where Charpentier was employed at the time of the article's publication. This initial filing occurred in May 2012, coinciding with a separate patent application submitted by Zhang and the Broad Institute in December 2012, just as Zhang's paper on editing human cells was accepted for publication in Science.

Initially, it was Zhang's patent application that succeeded, resulting in a patent being granted in April 2014, while Doudna's application remained pending. Disagreement ensued from

[11] ***B****ayer CorporaBon v. Union of India*, 162(2009) DLT 371 (India)

Doudna's team, leading to a protracted dispute between the two parties involving appeals and court hearings, resulting in an uncertain landscape regarding CRISPR–Cas9 licensing. By 2019, both parties held patents in the field, leading to biotech companies using the CRISPR–Cas9 system on human cells obtaining licenses from either Doudna's team or Zhang's. However, in February 2022, the U.S. Patent and Trademark Office Appeal Board reaffirmed the priority of Zhang and the Broad Institute as the patent holders for CRISPR–Cas9 use in human cells. This decision elicited disappointment and frustration from Doudna's side and created financial complexities for companies licensed by her team.

Nevertheless, Doudna and Charpentier emerged victorious in a similar dispute in Europe and currently hold significant patents for the technology's use in various countries, including the U.K., China, Japan, Australia, New Zealand, and Mexico.

The emergence of recombinant DNA technology during the 1970s marked a pivotal moment in the field of molecular biology and genetics, initiating a profound revolution that continues to shape scientific advancements to this day. Alongside the concurrent development of essential supporting techniques, the advent of modern biotechnology has facilitated valuable genetic modifications in various organisms, including microorganisms, plants, and animals. These advancements have yielded a plethora of novel therapeutics and diagnostics, contributing significantly to scientific progress and medical innovation.

Since the outset of these transformative developments, there has been a pressing need to address fundamental questions regarding the eligibility of inventions related to living matter for patent protection. In response to these inquiries, the European Union implemented the EU Directive on the Legal Protection of Biotechnological Inventions 98/44 on July 6, 1998. This directive serves as a comprehensive framework, delineating detailed provisions on patent eligibility and instituting specific measures aimed at safeguarding against the granting of patents for inventions that may impinge upon human dignity and ethical concerns.

Ever since scientists uncovered the existence of a RNA-mediated adaptive defence mechanism known as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) in bacteria and archaea, along with the associated Cas proteins, they recognized its potential for protecting organisms from viral and plasmid invasions. This discovery sparked considerable interest in the scientific community due to the implications it held for gene-targeting and genome editing applications. CRISPR-Cas technology quickly became the focal point of scientific discourse,

primarily because it offered a revolutionary means of directly manipulating the genetic material of living organisms with unprecedented ease, affordability, and precision.

WHY WE SHOULD BE INTERESTED IN CRISPR-CAS9?

The CRISPR-Cas9 gene-editing system represents a transformative tool with the capability to revolutionize genetic manipulation across diverse organisms, as articulated by Professor Jake Sherkow. Its versatility holds the promise of unlocking deeper insights into cellular gene function, paving the way for novel and more efficient medical interventions to combat various debilitating diseases. By rectifying underlying genetic anomalies, CRISPR-Cas9 offers the potential not only to treat these ailments but also to prevent their hereditary transmission to future generations, thereby reshaping the landscape of genetic inheritance.

Moreover, its application extends beyond medicine to encompass agriculture and industry, where it holds the potential to bolster the development of disease-resistant crops and livestock. The societal implications of such advancements are profound, promising improved food security and economic sustainability.

Currently, researchers worldwide are leveraging CRISPR-Cas9 technology to manipulate genomes across a spectrum of organisms, ranging from edible mushrooms and corn to experimental models like mice, monkeys, and even human embryos. The recent approval of clinical trials by the U.S. National Institutes of Health for CRISPRCas9 applications in cancer treatment underscores the growing momentum in translating this technology into tangible therapeutic solutions. Similarly, the UK's Human Fertilization and Embryo Authority has sanctioned its use for permanent genetic modifications in human embryos, signalling a significant stride towards realizing its clinical potential.

However, despite its immense promise, the current iteration of CRISPR-Cas9 technology is not without its challenges and ethical implications. Concerns persist regarding its accuracy and the efficient delivery of genetic modifications to human cells, necessitating further refinement and optimization. Additionally, the profound implications of altering the human genetic blueprint demand careful ethical scrutiny and deliberation.

In response to these ethical considerations, initiatives such as the issuance of "ethical licenses" by institutions like the Broad Institute aim to mitigate potential risks associated with the misuse

of CRISPR-Cas9 technology. By imposing restrictions on certain activities deemed contrary to the public interest, these measures serve as a proactive means to regulate and monitor the ethical dimensions of emerging biotechnologies. As we navigate the ethical and regulatory landscape surrounding CRISPR-Cas9, thoughtful deliberation and responsible stewardship are paramount to harnessing its transformative potential for the betterment of society.