PATENT AND GENOME EDITING TECHNOLOGIES: ISSUES AND CHALLENGES

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Abstract

Patent systems over the last century have evolved to be at par with the exponentially growing fields of science and technology to provide monetary benefits to the inventors in their niche fields of research and development which gives exuberant growth to the entire scientific field. This stimulates the perpetual loop of scientific progress. Development of the various gene editing tools such as ZFNs[1], CRISPR-Cas9[2] and TALENs[3] during the last decade have revolutionised the biotechnological industry. From enhancing food security to leapfrogging the healthcare sector, genome editing technologies have provided a convenient solution to previously cryptic Enigma codes of biology. The Indian Patent Act of 1970 has been made in synchrony with the TRIPS agreement to accommodate patenting of microorganisms in the Patents (Amendment) Act 2002. Section 3(j) of the Patents Act, 1970, allows the patentability of microorganisms. However, the new advancement in genome editing has put forth a challenge towards the existing legal framework apropos to the patenting of microorganisms at present globally. Researchers in this paper have discussed various shortcomings in patent systems. Firstly, the challenges with respect to the identification of the original inventor of a GMO (Genetically Modified Organisms) or the process of their development. Secondly, the obstacles pertinent to the assessment of the industrial working of the proposed GMOs or the process of their development are elucidated in a reformist approach to the subject. Lastly, the ethical dilemmas with regard to human rights arising from the commercial exploitation of genome editing technology have been addressed. In the end, certain safeguard mechanisms while policy formation at national as well as international levels is suggestively discussed in this paper by researchers to strike a balance between incentivising biotechnological advancements and protecting the ordre public.

Keywords: *Patent systems, CRISPR-Cas9, TRIPS agreement, Genetically Modified Organisms, Microorganisms, Genome Editing Technology, Biotechnology.*

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[1] Zinc Finger Nucleases (ZFNs).
[2] Clustered regularly interspaced short palindromic repeats, CRISPR.
[3] Transcription Activator-Like Effector Nucleases (TALENs).

Introduction

A gene's function can be understood by the controlled alteration of its DNA sequence in a cell. Numerous editing enzymes, including Zinc Finger Nucleases (ZFNs), Transcription Activator-Like Effector Nucleases (TALENs), and Homing Meganucleases, are effective; nevertheless, each target sequence necessitates a different enzyme design.[4]

However, greater sample sizes are generally required to be screened for Homologous Recombination (HR) based genetic engineering methods, hence they have lower efficiency for gene editing.[5]

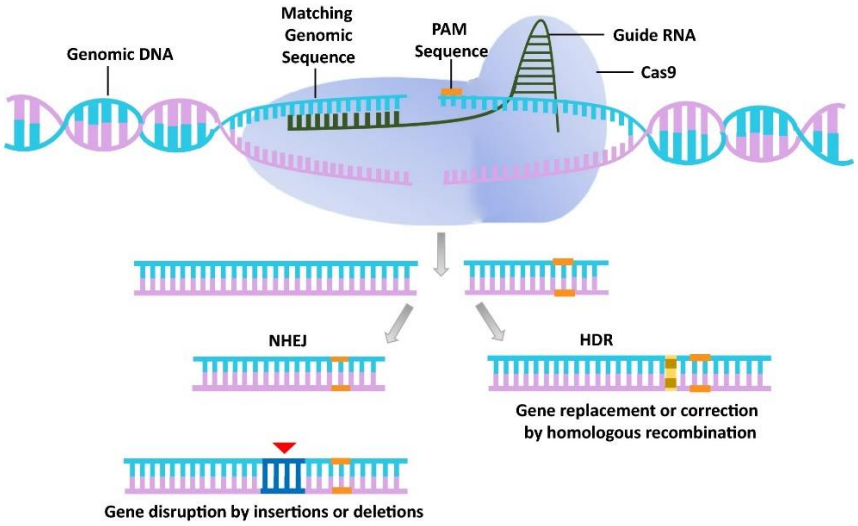

Fig. 1: Schematic of CRISPR–Cas9-mediated genome editing.[6]

Despite the increase in precision, ZFN and TALENs still required a lot of knowledge and resources, which prevented their widespread usage. This was all altered by the discovery of

[4] Ghosh, D., Venkataramani, P., Nandi, S. *et al.* CRISPR–Cas9 a boon or bane: the bumpy road ahead to cancer therapeutics. *Cancer Cell Int* **19**, 12 (2019); Bogdanove AJ, Voytas DF. TAL efectors: customizable proteins for DNA targeting. Science.2011;333(6051):1843-6; Stoddard BL. Homing endonuclease structure and function. Q Rev Biophys. 2005;38(1):49–95; Urnov FD, et al. Genome editing with engineered zinc finger nucleases. Nat Rev Genet. 2010;11(9):636–46. https://doi.org/10.1186/s12935-019-0726-0 (Last visited 10.01.2023).

[5] Sharan SK, et al. Recombineering: a homologous recombination-based method of genetic engineering. Nat Protoc. 2009;4(2):206–23. https://doi.org/10.1038/nprot.2008.227 (Last visited 10.01.2023).

[6] *Fig. 1*: The Streptococcus pyogenes derived CRISPR–Cas9 RNA-programmable DNA endonuclease is targeted to a DNA sequence via a single guide RNA (sgRNA) sequence, which base-pairs with a 20-nt DNA sequence upstream of the protospacer-associated motif (PAM), resulting in a 3-bp double-strand break (DSB) upstream of the NGG. The resulting DSBs are subsequently repaired either by non-homologous end joining (NHEJ) or by homology-directed repair (HDR). Repair via the error-prone NHEJ pathway, frequently leads to insertion or deletion mutations (Indels) that can lead to genome instability. Alternatively, in the presence of an exogenous donor DNA template, the DSB can be repaired via the error-free HDR pathway, which can engineer precise DNA modifications.
Ghosh, D., Venkataramani, P., Nandi, S., & Bhattacharjee, S. (2019). CRISPR–Cas9 a boon or bane: the bumpy road ahead to cancer therapeutics. Cancer cell international, 19(1), 1-10 https://link.springer.com/article/10.1186/s12935-019-0726-0#citeas (Last visited 10.01.2023).

CRISPR/Cas9, a bacterial defence mechanism against bacteriophages that was repurposed as a precise tool for genome editing.[7]

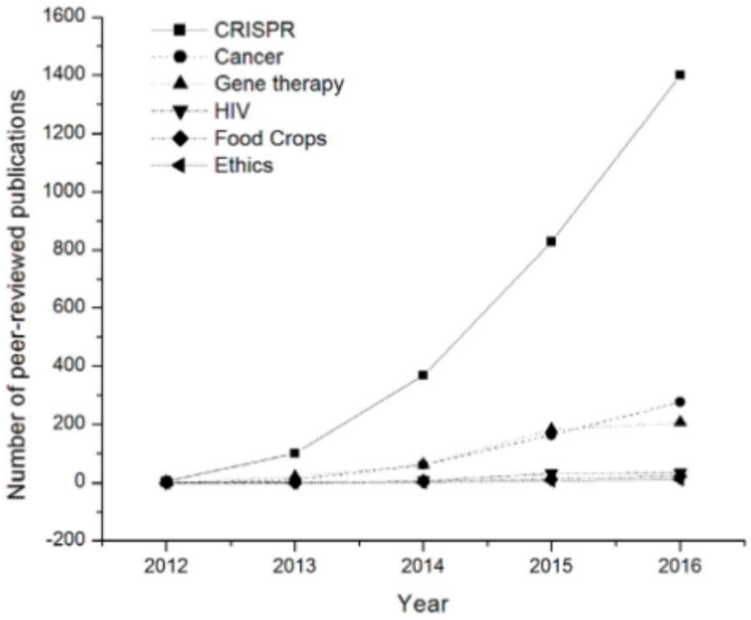

Fig. 2: Genome editing has developed into a highly active area of research since the CRISPR/Cas9 system was discovered in 2012; this can be shown by looking at the rise in papers incorporating this technology in recent years.[8]

Clustered regularly interspaced short palindromic repeats, or CRISPR, are small pieces of viral DNA that have been inserted into the genome of bacteria. They serve as spacers and as a template for the synthesis of an interference RNA that can recognise specific locations in the genome of an infecting virus and identify the sites that should be cut by nucleases.[9] The most well-known of these nucleases is Cas9, although others, such Cpf1(also known as CRISPR-Cas12a), have recently been found, increasing the genetic engineering toolkit. If the development of recombinant DNA technology represented a step forward, then CRISPR represents a quantum leap for genetic engineering as well as for the developing biotechnologies of synthetic biology, nanotechnology, xenotransplantation, gene therapy, and population control through gene drives. These apparent emerging biotechnologies mark the next phase in

[7] Maxmen A., Three technologies that changed genetics. Nature, 528, S2, 2015 https://www.nature.com/articles/528S2a (Last visited 10.01.2023).

[8] *Fig. 2*: The data shows the number of publications in 5 different fields where CRISPR/Cas9 was involved; research on the disease being the most sought application of CRISPR/Cas9. The search was performed using PubMed, data were retrieved between November 28th and December 5 of 2016. Keywords included CRISPR and the combination of CRISPR plus cancer/gene therapy/HIV/crops or ethics.
Caballero-Hernandez, D., Rodríguez-Padilla, C., & Lozano-Muñiz, S. (2017). Bioethics for biotechnologists: from Dolly to CRISPR. Open Agriculture, 2(1), 160-165. https://www.researchgate.net/publication/316067580_Bioethics_for_biotechnologists_From_dolly_to_CRISP(Last visited 10.01.2023).

[9] Gaj T., Gersbach C.A., Barbas C.F., ZFN, TALEN, and CRISPR/ Cas-based methods for genome engineering. Trends Biotechnol., 2013, 31(7), 397-405 https://doi.org/10.1016/j.tibtech.2013.04.004 (Last visited 10.01.2023).

the development of biotechnology, one that aims to create new products for human use and consumption by not only using living things as a source of material but also by customising organisms through genome editing or synthetic biology techniques.

CRISPR is a powerful tool for editing genes, and as such, it has the potential to revolutionize many areas of medicine, agriculture, and more. However, the technology also raises some significant challenges with regard to Intellectual Property Rights (IPR). There are currently multiple patent disputes over the use of CRISPR, with different companies and institutions claiming ownership of the technology. This has led to confusion and uncertainty in the industry, and it could slow down the development and commercialization of CRISPR-based products.

Simultaneously, there are also several other ethical concerns emerging regarding the use of CRISPR-based products for vanity purposes, inaccessibility to the technology by the developing world, concerns of biopiracy and lack of regulations safeguarding the use of such technology.

Background

CRISPR technology has had a significant impact on the Indian patenting system. The Indian Patent Office has faced challenges in determining the patentability of CRISPR-related inventions due to the complexity of the technology and the ongoing patent disputes in other countries. In May 2020, the Indian Patent Office granted the patent application to ERS Genomics, co-founded by Dr. Emmanuelle Charpentier, 2020 Nobel Prize winner for gene-editing for "Methods and compositions for RNA directed target DNA modification and for RNA directed modulation of transcription".[10]

On the other hand, Indian companies and research institutes have started to focus on CRISPR research and development. They have filed a large number of patent applications related to CRISPR-based inventions, such as diagnostic kits and gene therapy. In 2020, India's Council of Scientific and Industrial Research (CSIR) granted a patent for CRISPR Cas-9 in India, which is considered a significant development for Indian researchers and companies.[11] However, the Indian patenting system is still trying to navigate the complexities of CRISPR technology and the ongoing patent disputes, but it appears that the Indian government is taking steps to promote the growth of CRISPR-based research and development within the country.

[10] The Regents of the University of California, University of Vienna., assignee. Methods and compositions for RNA directed target DNA modification and for RNA-directed modulation of transcription. IN397884. 2995/KOLNP/2014. 15/03/2013 https://ipindiaservices.gov.in/publicsearch (Last visited 10.01.2023).

[11] Gulati, S., Maiti, S., & Chakraborty, D.. Low-cost CRISPR diagnostics for resource-limited settings. *Trends in Genetics, 37*(9), 776-779, (2021). https://doi.org/10.1016/j.tig.2021.05.001 (Last visited 10.01.2023).

A gene editing technology like CRISPR is inevitably going to increase Patent applications claiming Genetically Modified Microorganisms (GMMs). The criteria governing the prerequisites for depositing microorganisms under the Budapest Treaty, of which India has become a member, and the availability of that microbe from the depositories, determine whether patents are granted in relation to microorganisms.[12] According to proviso (ii) of section 10(4) of the Patents Act, the microorganism must be deposited by the patent applicant before the International Depositary Authority under the Budapest Treaty within three months after making an application in India, if it is not completely and particularly described and is not accessible to the public. For the purpose of appropriately identifying the microorganisms, the specification must include all pertinent information, including any available features and information about the depositary institutions. Only after the application date in India must additional access be made available.[13]

Original Inventor

The first genetically modified organism (GMO) was created in 1973 by Herbert Boyer and Stanley Cohen. They used recombinant DNA technology to transfer a specific gene from one organism into another, resulting in the creation of the first genetically modified bacterium. This marked the beginning of the field of genetic engineering.[14]

The patent for CRISPR-based genetic editing technology is the subject of ongoing legal disputes. The Broad Institute, Harvard University, and the Massachusetts Institute of Technology (MIT) hold several patents for the use of CRISPR-Cas9 in eukaryotic cells, including plants and animals. However, the University of California, Berkeley and its affiliated research foundations have also filed for patents on the use of CRISPR-Cas9 in all cells, including bacteria. The outcome of these legal battles will determine which organization ultimately holds the exclusive rights to commercialize CRISPR-based genetic editing technologies. In 2012, the Broad Institute, Harvard University, and MIT filed for a patent on the use of CRISPR-Cas9 in eukaryotic cells, which was granted in 2014. The University of

[12] TREATY, B. World Intellectual Property Organization: Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. https://www.wipo.int/treaties/en/registration/budapest/ (Last visited 10.01.2023).

[13] India. (2001). *The patents act, 1970*. Universal Law Publishing. https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf(Last visited 10.01.2023).

[14] COHEN, S., & BOYER, H. (2001). The Gene Del. *Genetics And Genetic Engineering*, 58. https://www.sciencehistory.org/historical-profile/herbert-w-boyer-and-stanley-n-cohen (Last visited 10.01.2023).

California, Berkeley and its affiliated research foundations filed for a patent on the use of CRISPR-Cas9 in all cells, including bacteria, in 2012 and 2013, which were granted in 2017.[15] The U.S. Patent and Trademark Office (USPTO) has been conducting an interference proceeding to determine who was the first to invent the CRISPR-Cas9 technology. On February 15, 2019, the Patent Trial and Appeal Board (PTAB) of the USPTO ruled in favour of the Broad, Harvard and MIT and found that the University of California did not prove that they were the first to invent the CRISPR-Cas9 gene-editing technology. The Berkeley team (referred to as CVC in the most recent USPTO ruling) submitted its initial patent application in 2012, a few months before Harvard's Broad Institute. However, the USPTO at that time granted patents based on who invented a technique first rather than who filed a patent first, and the two teams have been at odds over who invented CRISPR-Cas9 gene editing for years. (The USPTO amended its procedures in 2013 and the USPTO now awards patents based on who files the application first, much like the world's other patent offices. For developing CRISPR-Cas9 gene editing, Doudna and Charpentier shared the 2020 Nobel Prize in Chemistry; nevertheless, patents and Nobel prizes are not often evaluated using the same standards.[16] Hence, there is yet no such clarity in regards to the first inventor of CRISPR.

CRISPR-Cas9, a genetic editing tool that allows scientists to make precise changes to DNA, has the potential to revolutionize medicine, agriculture and many other fields. So, the patent of this technology is very valuable and these legal battles will have a significant impact on the field of genetic engineering.

Assessing the Working of Patents

Patent examiners face several challenges when assessing the industrial working of a patent on Genetically Modified Organisms (GMOs) which includes the GMMs. GMOs involve complex genetic engineering techniques and a detailed understanding of the underlying biology is required to evaluate the patent claims. This can be challenging for examiners who may not have a background in genetics or molecular biology.[17]

Examining prior art (previously existing knowledge or technology) is essential in determining the novelty and non-obviousness of a patent. However, the field of genetic engineering is

[15] Feeney, O., Cockbain, J., Morrison, M., Diependaele, L., Van Assche, K., & Sterckx, S. (2018). Patenting foundational technologies: Lessons from CRISPR and other core biotechnologies. *The American Journal of Bioethics*, *18*(12), 36-48. https://doi.org/10.1080/15265161.2018.1531160(Last visited 10.01.2023).

[16] Ledford, H. (2022). Major CRISPR patent decisions won't end the tangled dispute. *Nature*, *603*(7901), 373-374. https://www.nature.com/articles/d41586-022-00629-y(Last visited 10.01.2023).

[17] Sherkow, J. S., *Who owns gene editing? Patents in the Time of CRISPR, Biochemist*, *38*, 26 *(April 5, 2016).*. https://doi.org/10.1042/BIO03803026 (Last visited 10.01.2023).

rapidly evolving, and it can be difficult for examiners to keep up with the latest research and developments.

To assess CRISPR patenting scenario at the Indian Patent Office, search results of PATENTSCOPE are filtered out and a total of 177 patent applications have been filed at the Indian Patent Office.[18] The obstacle that these applicants must clear is proving that the claims do not fall under section 3 of the Indian Patents Act, which lists categories of inventions that are not patentable, in addition to demonstrating that the claimed inventions are novel, inventive, and suitable for industrial application.

Section 3(b), addresses inventions that violate moral principles or seriously harm people, animals, plants, or the environment. The Manual of Patent Office Practice and Procedure lists a method for human cloning as one example of an invention that does not qualify as one under section 3(b) of the Act because its primary or intended purpose is likely to offend established social, cultural, and legal norms of morality.[19] The examination guidelines also provide a few more non-exhaustive instances of innovations that might be subject to the patentability bar under section 3(b), including "(a) a process for cloning human beings or animals; (b) a process for modifying the germ line of human beings; (c) a process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical or other benefit to man or animal, and also animals resulting from the such process; (d) a process for preparing seeds or other genetic materials comprising elements which might cause adverse environmental impact; (e) uses of human embryos for commercial exploitation.".[20] These Guidelines further creates hurdles for the Patent applications filed in Indian Patent Office pertinent to CRISPR-based products.

The guidelines make it clear that products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc. that are directly isolated from nature are not patentable subject matter under section 3(c), which concerns scientific principles or abstract theory or the discovery of living things or non-living substances. However, section 2(1)(j) which defines

[18] https://patentscope.wipo.int/search/en/result.jsf?_vid=P12-LDAJQ9-95110 (Last visited 24.01.2023).

[19] Indian Manual of Patent Office Practice and Procedure (2016). New Delhi, India: Controller General of Patents, Designs and Trade Marks. https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf (Last visited 10.01.2023).

[20] Indian Patent Office. (2015). Guidelines for examination of biotechnology applications for patent. http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelines/1_108_1_biotech-guidelines-2015.pdf(Last visited 10.01.2023).

invention as a new product or process involving an inventive step and capable of industrial application of the Indian Patent Act may apply to how these products are isolated.[21]

The assessment of industrial working of a patent on GMOs requires a multidisciplinary approach and specialized knowledge of genetics, molecular biology, safety, and environmental and ethical considerations.

Ethical Dilemma for Using Gene Editing Technologies

Genome editing could be used to violate human rights in various ways. There are concerns that genome editing could be used to create "designer babies" or to select certain traits, leading to the possibility of a new form of eugenics raising concerns about the basic right to life. This could result in the creation of a class of genetically-enhanced individuals, which could be seen as a violation of the right to life of those who are not (naturally) selected or edited.[22]

There are Biopiracy concerns regarding CRISPR, as the genome editing technology could be used to collect, store and share genetic data of indigenous communities without consent, leading to potential breaches of privacy and confidentiality. The scholar-activist Pat Mooney, who claimed that trade agreements and already-existing multinational organisations worsened disparities in (genetic) resource access and control between the Global North and the Global South, coined the term "biopiracy." Thus, the term "biopiracy" refers to both inequitable gene flows and a claim of global (in)justice.[23] Novel gene editing methods such as CRISPR are rapidly being developed to allow plant breeders to use genetic markers as a guide for trait-level changes in individual genomes. D.S.I. (Digital Sequence Information) is necessary for CRISPR so that inventers can locate which genes are desirable for editing further necessitating the availability in the public domain to curb biopiracy.[24]

There are concerns that genome editing could be used to exploit the genetic resources of indigenous communities, leading to biopiracy and violation of their human rights. Also, Human Rights of people with disabilities are relevant to the emerging gene editing medical technologies. There are concerns that genome editing could be used to eliminate or "cure"

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[21]Indian Patents Act, 1970. (n.d.). https://www.ipindia.nic.in/writereaddata/Portal/IPOG/Patent_Act_1970.pdf(Last visited 10.01.2023).

[22] Baird, S. L. (2007). Designer Babies: Eugenics Repackaged or Consumer Options? *Technology and Engineering Teacher*, *66*(7), 12. https://eric.ed.gov/?id=EJ774191 (Last visited 10.01.2023).

[23] Mooney, P. R. "Why We Call It Biopiracy." In Bioprospecting: From Biodiversity in the South to Medicines in the North, 37–44 (H. Svarstad and S. Dhillion, ed., 2000). Also: Spartacus Forlag AS.Moore, Gerald, and Witold Tymowski. "explanatory Guide to the International Treaty on Plant and Genetic Resources for Food and Agriculture." IUCN Environmental Policy and Law Paper No. 57 https://doi.org/10.1080%2F01436597.2022.2079489(Last visited 10.01.2023).

[24] Nehring, R. (2022). Digitising biopiracy? The global governance of plant genetic resources in the age of digital sequencing information. *Third World Quarterly*, 1-18. https://doi.org/10.1080/01436597.2022.207948 (Last visited 10.01.2023).

certain genetic conditions, leading to a devaluation of the lives of people with those conditions and a violation of their human rights.

Given that the same CRISPR-Cas9 laboratory techniques would be used, the shift from performing gene editing in "somatic" cells (such as healthy liver cells or cancers with damaging mutations) to performing it in "germ" cells may seem simple. The technique of snipping out a detrimental mutation, adding a "normal" DNA sequence, and then zipping the DNA back up again sounds physiologically beneficial, but that assumption hides the challenges of transferring technology from the lab to the patient's bedside. Separating hype from reality and far-off possibilities from immediate, useful applications is thus a challenge surrounding the technology. The therapeutic use of "genome surgery" is still a long way off for humanity.[25]

Conclusion

"Intellectual Property has the shelf life of a banana", the statement as quoted by Bill Gates[26] finds a significant relevance especially in the field of biopharmaceuticals. The research for a new drug development, that drug passing the pre-clinical and the clinical trials, as well as satisfying all the regulatory standards of multiple authorities of territories where the new drug is subjected to be commercially introduced, consumes a significant portion of the time awarded as the term of a patent. To strike the right balance between incentivising biotechnological advancements and protecting public interest, amelioration of the existing patent systems as elaborated in the suggestions discussed in this paper are need of the hour. With certain refinement and homogeneity in the patent laws worldwide with specific regards to genome editing technologies especially such as CRISPR-Cas9. Similar to any emerging technology, CRISPR-Cas9 while having enormous medical advantage as discussed in this paper, also raises a lot of complications, apprehensions, important ethical, legal, and social questions that need to be addressed to ensure that the technology is used responsibly and in a way that respects human rights. But just like all the technologies that have existed so far, regulations in the form of legal reforms especially in Patent Laws, would eventually mitigate the ethical dilemmas and safeguard the interest of humanity. It is important to have regulations and oversight in place to prevent the misuse of genome editing technology and to ensure that human rights are protected.

Suggestions

In view of the above conclusion, the researchers would like to propose few suggestions, which if considered, could provide possible solutions to various issues as discussed above. There are

[25] Rojahn S. Genome surgery. *MIT Tech Rev* 2014. https://www.technologyreview.com/s/524451/genome-surgery/(Last visited 10.01.2023).

[26] Bill Gates Quotes. BrainyQuote.com, BrainyMedia Inc, 2023. https://www.brainyquote.com/quotes/bill_gates_382175, accessed April 7, 2023.

several policy changes that could be made to patent laws to better protect genetically modified microorganisms (GMM). Broadening the definition of GMMs must be the first step. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) declares in the first half 2 of Article 27(3)(b) that "Members may ... exclude from patentability… (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes."

Accordingly, the boundary of patentable subject matter is drawn. Plants, animals, and essentially biological processes used to produce plants and animals are the only things that can be exempt from patent protection. Member states are expressly prohibited from excluding non-biological and microbiological processes and microorganisms from patent protection. The terminology employed in Article 27(3)(b) implies that it is possible to distinguish clearly between microorganisms and plants and animals.[27] And the verbatim has been ratified in the Section 3(j) after the 2005 amendment of the Indian Patents Act 1970.[28] It follows a presumption that, on the surface, there is a standard definition for the word "micro-organism" that is acceptable to all the member states of the TRIPS Agreement and this definition is considered as sufficient for determining what can be patented and what cannot be patented.

It would be wrong to presume that there is an actual definition that is widely used. There is "no one fits all" scientific definition of "microorganisms". Moreover, the practise of not employing a definition for patent law purposes has been adopted by developed country patent laws appears to be due to the lack of a standard scientific definition.

Patent laws currently define GMMs as living organisms that have been genetically modified. However, this definition could be broadened to include non-living GMMs, such as enzymes, viruses and other bioproducts.

Patent laws could be amended to include special regulations for GMMs, such as mandatory safety and environmental assessments, and more stringent requirements for patentability. SPS (Sanitary and Phyto-Sanitary), the TRIPS (Trade Related Aspects of Intellectual Property Rights), the TBT (Technical Barriers to Trade), without making any specific mention of the GMO case, agreements relating to intellectual property have been reached inside the GATT/WTO framework. However, they can still be used whenever the agreed-upon multilateral free access to markets conflicts with national unilateral rules and regulations.

[27] World Trade Organization (1994). Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (Last visited 10.01.2023).

[28] Indian Patent Office, Guidelines for examination of biotechnology applications for patent, (2015) http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelines/1_108_1_biotech-guidelines-2015.pdf(Last visited 10.01.2023).

Contrarily, the Convention on Bio Diversity (CBD) and, more importantly, the Bio-Safety Protocol (PBS) directly address the problems brought on by the introduction of GM crops into the environment and by the protection of intellectual property rights on living materials, particularly in light of potential risks for biodiversity.[29]

Simultaneously, Patent laws outside India could be amended to encourage open access to GMM technologies, such as by creating a "compulsory licensing" system as established by the section 84 of the Indian Patent Act 1970 that would allow other researchers and companies to access the technology under certain conditions such as a global pandemic. International cooperation is absolutely necessary in order to amend Patent law, such as by creating a system for harmonizing patent laws across different countries to make it easier for companies and researchers to protect their GMM inventions in multiple jurisdictions.

To promote innovations and stimulate the development or advancement of genome-wide analysis and engineering technologies with the objectives of making them accessible plus affordable for greater utilisation, the Department of Biotechnology established an exclusively dedicated Task Force on "Genome Engineering Technologies and Their Utilizations" in 2014. Additionally, it is more sophisticated to better develop the infrastructure for initiatives that support research and future technologies like gene editing. Establishing such a task force shall pave a way to develop regulations for disruptive technologies in the niche of biotechnology such as CRISPR.

In conclusion, the patent laws for protecting GMMs should balance the need to promote innovation and economic growth with the need to protect the safety, ethical and human rights concerns. These laws should be implemented to promote responsible development and use of GMMs, and ensuring that the benefits of the technology are widely accessible and shared equitably.

[29] Esposti, R., & Sorrentino, A. Policy and regulatory options on genetically modified crops: Why USA and EU have different approaches and how WTO negotiations can be involved. *International Consortium on Agricultural Biotechnology Research (ICABR)*, (2002) https://www.researchgate.net/publication/242708308_POLICY_AND_REGULATORY_OPTIONS_ON_GENETIC ALLY_MODIFIED_CROPS_WHY_USA_AND_EU_HAVE_DIFFERENT_APPROACHES_AND_HOW_WTO_NEGOTIATIONS_CAN_BE_INVOLVED (Last visited 24.01.2023).