PATENTING LIFE: GLOBAL PERSPECTIVES ON INTELLECTUAL PROPERTY IN GENETIC AND BIOTECHNOLOGICAL INNOVATION AMIDST ETHICAL AND LEGAL CHALLENGES

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ABSTRACT

The revolutionary capabilities of genetic engineering and biotechnology can revolutionize environmental conservation, agriculture and medicine. Because of this, intellectual property (IP) rights, particularly patents, are fundamental to their development, as they incentivize innovation by protecting investments in R&D. How IP works in these domains, however, raises significant questions regarding its broader implications for biodiversity, food security and public health. This research examines the correlation between intellectual property rights and innovation in biotechnology and genetic engineering, highlighting key technologies such as genetically modified organisms (GMOs), CRISPR and biopharmaceuticals. It examines the challenges of patenting these technologies, including the monopolization of genetic resources, the inability to access life-saving medicines, and the ethical dilemmas posed by the patenting of living things. Antubam, the paper highlights discrepancies on IP governance and its implications for equitable access of developing nations as opposed to developed nations. The US BRCA gene patent lawsuit and India's Section 3(d) pharmaceutical patent policy provide important insights into these difficulties. The findings of the study state that while IPR promotes innovation, it must be balanced with public interest, or it would ultimately compromise accessibility and sustainability. Because of this, it stresses the need for such IP frameworks to be transformed so that the creation of fair licensing policies to call for licensing of underpinned technology be established as well as the development of international treaties prioritizing sustainability and global health. To ensure that the genetic as well as the

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biotechnology engineering support the sustainable as well as the inclusive development, also maintaining its ethical standards, the study at the end makes a policy proposals which aligns with the IP law as well as the SDGs.

KEYWORDS: Biotechnology, Genetic engineering, SDGs, Biopharmaceutical Patents, TRIPS.

INTRODUCTION

Environmental science, agriculture, and medicine have all seen significant changes because of the revolutionary disciplines of biotechnology and genetic engineering. To create new goods and technology that enhance people's quality of life, these fields exploit biological systems and creatures. Biotechnology and genetic engineering have proven to be essential instruments in tackling some of the most urgent issues facing the world, including food insecurity, climate change, and public health crises. They range from the development of genetically-modified crops endowed with greater resilience to the making of life-saving medicines.[37]

The protection offered by intellectual property rights (IPRs), especially patents, is one of the main forces behind innovation in these domains. Another major driver of innovation in these fields is the protection provided by IPR-patents generally. Patents give exclusive rights to scientists and companies to use their ideas for a defined period of time and therefore stimulate research and development in time-intensive and resource-intensive research and development domains such as biopharma, GMOs, and genome-editing technologies like CRISPR. Their exclusivity would thereby enhance investment into risky and expensive R&D efforts and, indeed, foster inventions. [38]

The combination of biotechnology and intellectual property has sparked debates, on issues such as the control of resources and the cost of medicines as well as the ethical considerations of patenting living organisms. Patents can potentially restrict access to technology and life saving drugs in developed countries while also serving as a means for fostering innovation[39]. Moreover there are concerns about the adequacy of existing systems, in light of the risks posed by modified organisms to biodiversity and the environment.[40] he study aims to explore the

[37] Michael Wink, *An Introduction to Molecular Biotechnology: Fundamentals, Methods and Applications* (3rd edn, Wiley-VCH 2013)
[38] Jennifer Doudna & Samuel Sternberg, *A Crack in Creation: Gene Editing and the Unthinkable Power to Control Evolution* (Houghton Mifflin Harcourt 2017)
[39] David Castle, *The Role of Intellectual Property Rights in Biotechnology Innovation* 18 (Edward Elgar Publ'g 2009)
[40] Shamnad Basheer, 'India's Patent Law and Section 3(d): A Model for Balancing Innovation and Access', (2008) 26 *Nat. Biotechnology* 483, 485

balance, between encouraging innovation through intellectual property rights and tackling concerns such as equitable access to genetic technology and issues related to public health and biodiversity conservation is the primary focus of this research project The study seeks to evaluate if current intellectual property frameworks align with broader sustainability goals by analyzing the ethical and legal dimensions of patent rights, in genetic engineering and biotechnology sectors.

The research will analyze significant issues, like GMO patents, CRISPR, and biopharmaceuticals, in an effort to achieve the above objectives. It will discuss the challenges that these patents pose, such as possible ethical concerns, exorbitant costs of patented products, and trans-border jurisdictional issues. In addition, the study will provide a comparative analysis of legal systems and case laws across different jurisdictions, highlighting the differences between developed and developing countries in terms of intellectual property management in biotechnology. For example, the historical BRCA gene patent case in the US highlights the ethical issues of monopolizing genetic information, whereas Section 3(d) of act prevents patent from evergreening to ensure that the medicines are available at the price range[41]. The findings of this research will contribute to ongoing discussions regarding IPRs' role in genetic engineering and biotechnology. It aims to provide pragmatic policy recommendations reconciling sustainability, equitable access, and protection of innovations. Ultimately, the research stresses the importance of a high-minded strategy of intellectual property management that considers the different interests of governments, creators, and the public at large.

INTELLECTUAL PROPERTY IN BIOTECHNOLOGY

ROLE OF IP IN FOSTERING INNOVATION

Intellectual property, particularly patents, significantly facilitates innovation in the biotechnology sector. Patents facilitate R&D through the provision of exclusive rights, which makes it easier for businesses and organizations to raise funds to finance expensive and time-consuming biotechnological research. Through the limited monopoly they have over inventions, patents enable innovators to recover costs and earn money for a period, typically 20 years. Since they are insulated from direct rivalry, this unique monopoly stimulates researchers and companies to invest significant assets into developing fresh technology.[42]

[41] *Myriad Genetics Inc. v Ass'n for Molecular Pathology*, [2013] 569 U.S. [576], [594]

[42] Michael A. Heller & Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science' (1998).698, 701

Where the fields are biopharmaceuticals, CRISPR technology, and GMOs, patents play an essential role. Powerful patent rights, for example, enabled genetic crops to be developed, for example, Bt cotton with pest resistance. Companies that have patented their GMO technologies, including Monsanto (now part of Bayer), can retain the sole rights to these innovations. These companies could not otherwise have afforded the large costs of developing such technologies—testing, research, and approval by regulatory bodies—without intellectual property protection.[43]

Patents have played a crucial role in ensuring intellectual ownership of ground-breaking discoveries, such as CRISPR, a gene-editing tool that permits precise alterations to DNA. The importance of patents in deciding who profits from such innovations is demonstrated by the patent fight between the University of California and the Broad Institute over the rights to CRISPR technology. In addition to facilitating commercial growth, these patents have produced important breakthroughs in industries including gene therapy, agriculture, and personalized medicine. The expansion of biotechnology startups has been aided by the protection of rights, which have further accelerated innovation in the field.[44]

In addition, patents on vaccines and life-saving drugs have been a significant source of innovation in the biopharmaceuticals sector. It is often contended that patent protection provides a financial reward for the invention of new therapies for diseases that would not be developed otherwise, despite the inflated prices which are charged by the pharmaceutical industry for patented drugs. Drugs such as the cancer drug Gleevec and the breast cancer drug Herceptin were developed under patent protection so that their producers could recoup their R&D costs and profit from their innovation.

ETHICAL AND LEGAL CHALLENGES

Certainly, intellectual property protection in biotechnology has spurred advancements but has raised a number of ethical and legal concerns. Patenting living organisms is the most contentious among them. There has been a lot of discussion among scientists, ethicists, and legislators on patentability of transgenic animals, plants, and bacteria. Patenting of living organisms brings into question control over genetic resources and monopolization of life-essential technologies, which would have profound implications for biodiversity, food security, and public health.

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[43] Doudna, Jennifer A., & Sternberg, Samuel H., *A Crack in Creation: Gene Editing and the Unthinkable Power to Control Evolution* (Houghton Mifflin Harcourt 2017).

[44] Shamnad Basheer, 'Patents, Innovation, and the Role of Intellectual Property in Biotechnology: A Delicate Balance, 26 Nat. Biotechnology' (2008). 377, 378

The degree to which patenting can result in monopolies on life-essential genetic resources is one of the largest ethical issues. Companies holding patents on genetically engineered organisms (GMOs) or gene-editing technologies like CRISPR can charge astronomical fees for use of their inventions, making them inaccessible to poor populations or countries with little financial capability. This monopolization can sometimes result in stifling innovation and competition. Patenting of biopharmaceutical products, genetically modified seeds, etc., has been criticized as allowing the large agribusiness corporations to dominate the food supply and limiting the control of the food supply by individual farmers. They are being forced into further dependency on such firms. Even the access to lifesaving medications has been challenged through biopharmaceutical patenting.[45]

The high cost of patented drugs has been an issue for a long time, particularly in developing countries where access to essential drugs is limited. As an illustration, the Novartis AG v. Union of India case in India highlighted the issue of evergreening whereby drug manufacturers attempt to extend a drug's life on patent through small formulation updates. This practice has been criticized as keeping generic copies of the drugs out of reach and making them expensive for people in need. In addition, there are significant biodiversity-related issues with the patenting of genetic resources.

The ability to patent genes, such as those in microbes, plants, and animals, has been met with fears of biopiracy, or the act where companies appropriate genetic resources from nature without compensating the countries or people who provide them justly. For instance, in India, where the neem tree has been used for centuries because of its medicinal properties, commercialization of the tree's genetic material has become an issue. Ethical issues of ownership of genetic resources and fair compensation was raised by the foreign companies patenting neem's attributes without giving due credit to traditional knowledge. The ethical dilemmas presented by the patenting of human genes are a second issue. The multi-faceted legal and ethical dilemmas surrounding patenting of human genetic material are presented by the case of Myriad Genetics, which patented the BRCA1 and BRCA2 genes responsible for increased breast cancer risk. Because scientists may not be able to freely study the genes without licensing agreements, these patents are argued to hinder access to genetic testing and research by critics.

[45] Yash Pal, 'India's Biopiracy Dilemma: The Case of Neem and the Biotech Industry'(2017) 34 *Int'l. J. Law & Tech.* 453, 455

PATENTS ON GENETICALLY MODIFIED ORGANISMS (GMOS)

Genetically modified organism (GMO) patents make up a sizeable portion of the biotechnology sector. The Agreement TRIPS, a component WTO accords, largely shapes the legal framework for patenting genetically modified organisms. Although TRIPS permits exclusions for moral considerations, such as the patenting of human or animal life forms, it requires member nations to offer protection of patent for inventions, including those in biotechnology. Patents on genetically modified organisms (GMOs), including genetically modified crops, have been a major driver of agricultural innovation by providing businesses with protection and promoting investment in crop enhancement. For example, genetically engineered crops such as Roundup and Bt cotton Businesses like Monsanto (now Bayer) have patented ready soybeans, which have brought significant agricultural advancements.[46]

But the patenting of genetically modified organisms has generated controversy, particularly in relation to its effects on biodiversity and food security. Many contend that monopolization results from the concentration of GMO patents in the hands of a small number of multinational firms, which raises issues with access to reasonably priced seeds and food sovereignty[47]. For instance, smallholder farmers in underdeveloped nations frequently struggle to obtain patented seeds and might have to purchase new seeds every planting season rather than reusing them from a prior harvest. In areas where agriculture is the primary source of sustenance, this financial strain may jeopardize food security. Furthermore, the extensive usage of genetically modified crops has sparked worries about how they can affect biodiversity because GMOs and wild species might unintentionally spread of modified genes.

CRISPR TECHNOLOGY AND GENE EDITING

The specific editing of genes that CRISPR technology enables has revolutionized the biotechnology sector altogether. Scientists can change specific DNA sequences with the assistance of this technology, which may lead to breakthroughs in biological science, agriculture, and medicine. But the rapid evolution of CRISPR has initiated complex ethical and legal debates, notably regarding ownership and patenting. One of the most famous patent battles, for example, was between the Broad Institute and the University of California, both of which asserted ownership of the CRISPR gene-editing method. Because they determine who

[46] *Trade-Related Aspects of Intellectual Property Rights* (TRIPS), WTO, [1999] IP/C/W/161, art. 27(3)(b)
[47] Robert W. Beard, 'The Ethics of Patenting GMOs: A Global Perspective', (2015) 45 Biotechnology Law Review 154, 157

owns the commercialization of CRISPR and related products and who benefits from its progress, these patent disputes matter.

Ethical concerns regarding CRISPR are also increasingly common. The editing of human embryos is one of the most significant issues. While CRISPR technology can be used to cure genetic diseases, others fear that it can be misused for non-clinical purposes, like producing designer babies.[48] The modification of animal genomes is another ethical dilemma. The long-term effects of gene editing on animal well-being and environmental balance are yet to be determined, although genetically engineered animals can contribute to research and agriculture. Tight regulations and ethical guidelines for the use of CRISPR technology have been called for due to these concerns.[49]

BIOPHARMACEUTICALS AND LIFE-SAVING DRUGS

Patents play a critical role in the biopharmaceutical sector by promoting innovation as they protect new therapies and drugs. However, achieving a balance between innovation promotion and ensuring access to life-saving drugs is always a challenge. Patents provide pharmaceutical companies with the financial motivation they require to invest in developing new drugs, but they also provide such drugs with monopolies, which makes them expensive and often unavailable in poor countries.[50] For instance, prior to the availability of generic equivalents, facilitated by the lapse of patent protection, patented HIV/AIDS drugs were a principal disincentive to treatment in the developing world.

The struggle between medication availability and patent protection is best illustrated by the case of Novartis' oncology drug Gleevec. Novartis argued that its creation had saved lives and tried to renew its patent for the drug to prevent generic versions from being sold in India. The Supreme Court of India, however, ruled that the Gleevec patent could not be extended; this was hailed as a public health victory. This case highlights the need for achieving a balance between access to affordable drugs and protection of rights, especially in the situation of life-saving drugs.

COMPARATIVE JURISDICTIONAL ANALYSIS

Intellectual property laws vary extensively across jurisdictions, with industrialized nations generally having more robust IP protection systems compared to developing nations. Focusing

[48] Michael J. McCoy, 'The Monsanto Patent Wars: Biotechnology and the Law'[2012], 53 *Harvard Law Review* 200, 202-206

[49] Nita A. Farahany, 'The Ethical and Legal Implications of CRISPR Gene Editing',(2017) 38 Journal of Law and the Biosciences 225, 228

[50] *Gleevec Patent Decision, Novartis AG v Union of India,* [2013] SCC OnLine SC 2210.

on industrialized nations such as the United States and developing nations like India, this section explores the differences in handling intellectual property in biotechnology and genetic engineering. By considering key case studies, we can understand the different approaches and lessons for future legal regimes.

Intellectual property laws regulating biotechnology and genetic engineering are quite different in jurisdictions, particularly between industrialized nations and developing or poor nations. Industrialized nations, like the United States, often apply a robust IP system with exclusive emphasis on patent protection in a bid to foster innovation. The contentious question of gene patenting has been discussed, for example, in the well-known case of Association for Molecular Pathology v Myriad Genetics, in which the US Supreme Court held that natural occurring DNA sequences are not patentable.[51] This ruling demonstrated a harmonious balance between promoting innovation as well as protecting public access to genetic information.

Conversely, however, most developing nations such as India have implemented intellectual property legislations designed to ensure accessibility and affordability. Section 3(d) of India's Patents Act bars the "evergreening" of pharmaceutical patents, ensuring that minor alterations to existing drugs with little clinical benefit cannot be patented[52]. This policy has been lauded for providing access to low-cost generic pharmaceuticals while ensuring a fair competitive market. This reflects the problem in the biotech field about the governance of international property, wherein developed governments value incentives to innovate while poor countries place public health and equitable access first. In a flexible, integrated framework for TRIPS, provisions like compulsory licensing[53] may overcome such gaps in development in terms of equality among all.

DEVELOPED COUNTRY: MYRIAD GENETICS AND BRCA GENE PATENTS

One notable instance of IP in biotechnology in the US is the Myriad Genetics lawsuit. The BRCA1 and BRCA2 genes, which associates with the high risk of ovarian and breast malignancies, were patented by Myriad Genetics. The corporation was able to dominate genetic testing for these genes thanks to these patents, which gave them a monopoly on testing and raised questions about pricing and accessibility. The Association for Molecular Pathology v.

[51] *Association for Molecular Pathology v Myriad Genetics*, [2013] 569 U.S. 576

[52] The Patents Act 1970, s 3(d)

[53] *Trade-Related Aspects of Intellectual Property Rights* (TRIPS), WTO, [1999] IP/C/W/161, art 31, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C (15 April 1994)

Myriad Genetics case decided by the U.S. Supreme Court in 2013[54] prohibited the patenting of naturally occurring genes.

Because it allowed other laboratories to conduct genetic testing, this ruling was welcomed as a public health success because it opened up the field to greater competition and lower prices. This case states the tension between public access and rights and points to need for clearly defined legal limits to exclude monopolization in the biotechnology industry.

DEVELOPING COUNTRY: INDIA'S APPROACH TO BIOPHARMACEUTICAL PATENTS UNDER SECTION 3(D)

India, on the other hand, has adopted a more cautious stance regarding biopharmaceutical patents, especially in light of Section 3(d) of the Patents Act[55]. New versions of known substances cannot be patented under this provision unless they lead to improved efficacy. The Supreme Court of India rejected the patent for the cancer medication Glivec (Imatinib mesylate) in *Novartis AG v Union of India*,[56] a noteworthy case that illustrates India's strategy, on the grounds that it was only a novel formulation of an already-approved treatment with no appreciable increase in therapeutic efficacy. The Court's ruling upheld the nation's position against the practice of pharmaceutical companies extending their patent spans by making minor changes to already-approved medications, or "evergreening." This ruling guarantees that life-saving medications continue to be accessible and reasonably priced in India, emphasizing the importance of balancing IP protection with public health needs.

LESSONS FROM INTERNATIONAL TREATIES: TRIPS, UPOV AND NAGOYA PROTOCOL

Frameworks for IP protection in biotechnology are provided by international treaties such as the Nagoya Protocol, the International Convention for the Protection of New Varieties of Plants (UPOV), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[57] TRIPS ensures that patenting methods are standardized globally by establishing the minimal requirements for IP protection, including biotechnological innovations. However, as demonstrated by India's approach to biopharmaceutical patents, it enables nations to modify their intellectual property laws to meet their evolving needs. Fair benefit-sharing is crucial, particularly in developing nations that supply genetic resources, according to the UPOV and

[54] *Association for Molecular Pathology v Myriad Genetics*, [2013] 569 U.S. 576
[55] *Supra* note 53
[56] *Novartis AG v Union of India*, [2013] 6 SCC 1
[57] *Supra* note 47

Nagoya Protocols, which regulate plant variety protection and access to genetic resources, respectively.

RECOMMENDATIONS

The confluence of genetic engineering, biotechnology, and intellectual property law presents difficulties that need for creative and internationally inclusive policy solutions. These suggestions seek to close ethical and legal loopholes, guarantee the fair application of genetic technology, and align IP regulations with the demands of global development. Intellectual property legislation policy reform is needed for fair access to biotechnology and genetic engineering as it follows a set of values that uphold morality. This especially calls for establishing a balance between innovation and the greater good, where the constraints come in from monopoly and accessibility.

First, there are restrictions to ban "evergreening" wherein countries must make provisions such as Section 3(d) of India's Patents Act restrict patents on incremental developments lacking substantial efficacy.[58] This deters unjustified monopolies but encourages actual innovation. Compulsory licensing systems should be strengthened to make lifesaving medicines and biopharmaceuticals available at a lesser cost in the low-income regions.[59] Second, differential pricing mechanisms must then be used for fair access to critical biotechnological developments like GMOs and CRISPR-based medicines.[60] Such methods can keep the innovation wheel spinning for pharmaceutical corporations while keeping up with marginalized communities.

International agreements, like TRIPS, must provide more room for public health concerns, especially for developing countries.[61] This can be done by inserting clauses that obligate cheap licensing of critical technology and prohibit monopolistic practices by exploiting genetic resources. To ensure that biodiversity-rich countries are protected, the mechanisms of benefit sharing must be applied accordingly, with regard to the Nagoya Protocol.[62]

Global governance systems are complex enough to resolve ethical challenges, but open-access genetic research databases and CRISPR licensing arrangements could democratize access to scientific progress. Universal ethical principles for biotechnological research will also assure the sustainability and inclusivity of this scientific field. Lastly, IP laws need to be aligned with

[58] Patents Act 1970, s 3(d)
[59] Supra note 47
[60] Danzon, Patricia M., et al.: *The Economics of Biopharmaceutical Pricing and Reimbursement* (NBER Working Paper No. 16297. 2010)
[61] Doha Declaration on the TRIPS Agreement and Public Health, World Trade Organization, [2001]
[62] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, Oct. 29, 2010, United Nations Treaty Series, vol. 30619

the goals that guide the UN's SDGs, such as: global health, food security, and innovation. Policymakers must focus on international cooperation in the way they align IP frameworks so that biotechnological inventions are for the betterment of society at large rather than individualistic groups.[63]

HARMONIZING IP LAWS WITH GLOBAL NEEDS

Aligning IP frameworks with the Sustainable Development Goals (SDGs) of the UN, especially those pertaining to innovation, food security, and health, is the first step. Legislators should create plans to promote biotechnology breakthroughs while guaranteeing that everyone has access to them. To unify IP laws and create exceptions for the public good, international cooperation is needed.

Countries can, for instance, enact clauses like Section 3(d) of the Patents Act of India, which prohibits patents from evergreening by prohibiting small adjustments to current technology that do not result in a discernible increase in efficacy[64]. Furthermore, establishing tiered pricing structures for patented biopharmaceuticals could guarantee affordability in low-income areas without stifling creativity. To further balance IP rights and community requirements, multilateral accords like the TRIPS Agreement should include clear protections for public health.[65]

ADDRESSING ETHICAL AND LEGAL GAPS

Patenting living forms and monopolizing genetic resources are two ethical conundrums brought on by biotechnology and genetic engineering. A worldwide regulatory system is required to monitor the use of genetic technology in order to allay these worries. Ethical guidelines for patenting biotechnological advancements, such as refraining from patents that impede research or worsen inequality, should be included in this framework. A worldwide licensing scheme, for instance, would safeguard patent holders' rights while facilitating open-access research.

Furthermore, protections are necessary to avoid genetic resource monopolization, particularly in emerging nations with abundant biodiversity. A paradigm for fair benefit-sharing between nations that supply genetic resources and those that use them is provided by the Nagoya Protocol on Access to Genetic Resources.[66] This guarantees that biotechnology advancements

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[63] United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development', [2015] A/RES/70/1

[64] *Novartis AG v Union of India*, (2013) 6 SCC 1; Section 3(d), Patents Act, 1970 (India)

[65] Trade-Related Aspects of Intellectual Property Rights (TRIPS), WTO, [1999] IP/C/W/161, art 27

[66] Nagoya Protocol: Genetic *Resources and the Fair and Equitable Sharing of Benefits* (2010)

benefit all parties involved, especially indigenous groups whose traditional knowledge supports genetic research.

CONCLUSION

The front line of scientific progress is biotechnology and genetic engineering, which hold vast promise to address challenges such as environmental sustainability, public health, and food security. However, these technologies also pose significant ethical, legal, and societal concerns, particularly with respect to the role of Intellectual Property rights. The report highlights the need to balance stimulating innovation and ensuring equitable access and sustainable use.

The research highlights the way patents on biopharmaceuticals, CRISPR technology, and GMOs stimulate R&D. Intellectual property rights stimulate private investment, leading to revolutionary breakthroughs such as disease-resistant crops and life-saving drugs.[67] Yet due to their expense and monopolistic tendencies, these innovations often make them inaccessible, particularly in developing countries. For instance, the morality of privatizing public genetic resources is challenged by life form patenting.[68]

Comparative analysis of jurisdictions identifies industrialized nations such as the US as using sweeping patent statutes that encourage innovation but potentially close up access and competition.[69] Conversely, third-world countries such as India place restrictions, such as Section 3(d) of the Patents Act, to encourage innovation in the public good and prevent monopolies.[70] These differing perspectives underscore the need for global cooperation to harmonize intellectual property regulations. Models for finding a balance between innovation and the common good are established by multilateral agreements such as the TRIPS Agreement and the Nagoya Protocol.[71] The research also highlights how important it is to integrate ethical and sustainable considerations in IP governance. This balance is achievable with equitable benefit-sharing mechanisms, ethical patenting requirements for living organisms, and protection against monopolies. For the formulation of universally usable standards that advance the SDGs of the UN, policymakers need to prioritize international cooperation highly.[72]

[67] *Diamond v Chakrabarty*, [1980] 447 U.S. 303
[68] *Association for Molecular Pathology v Myriad Genetics, Inc.*, [2013] 569 U.S. 576
[69] *Supra* note 66
[70] *Novartis AG v Union of India*, [(2013] 6 SCC 1; The Patents Act 1970, s 3(d)
[71] *Ibid*
[72] United Nations, *Sustainable Development Goals*, Goal 9: Industry, Innovation and Infrastructure