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Ethical Considerations in Bio Patents

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The ethical considerations surrounding bio patents in the field of genomics present a deeply intricate and multi-dimensional legal challenge, requiring a careful balance between proprietary rights of innovators and the overarching public interest. The complexity of this issue is particularly evident in critical sectors such as healthcare, biotechnology, and agriculture, where the patenting of genetic materials has raised profound moral, legal, and socio-economic concerns. Traditionally, IP law has been structured to incentivize scientific and technological progress by conferring exclusive rights on inventors for a limited period, allowing them to recoup investments and profit from their discoveries. However, when applied to genomics, this conventional rationale encounters substantial ethical dilemmas, particularly concerning the moral and legal implications of patenting naturally occurring genetic sequences. The fundamental question arises: should genetic materials, which constitute the very building blocks of life, be subject to private ownership through patent rights? If so, what ethical and legal limitations must be placed on such patents to ensure that they serve broader societal interests rather than leading to monopolization and inequitable access to life-saving technologies?[1]

Advancements in biotechnology, particularly in genome sequencing, gene editing, and synthetic biology, have significantly expanded the scope of genomic interventions, allowing for unprecedented modifications of human, animal, and plant genomes. While these breakthroughs hold immense potential for medical and agricultural innovations, they also raise pressing ethical concerns regarding the monopolization of essential genetic resources. One of the primary ethical challenges posed by bio patents is their impact on the affordability and accessibility of critical medical treatments. Granting exclusive patent rights over genetic sequences and biotechnological processes to corporate entities often results in exorbitant pricing, effectively limiting access to life-saving medicines and therapies. This issue is particularly pronounced in developing nations such as India, where socio-economic disparities already impede access to essential healthcare services. Bio patents, when granted without adequate ethical oversight, risk exacerbating these inequalities by placing critical medical advancements beyond the reach of economically disadvantaged populations. On the other hand, proponents argue that without robust patent protections, private-sector investment in genomic

[1] Pallavi Tripathi, “BioMEMS for Life-Saving Biomedical Technologies” 3 *Biotechnology Kiosk* 5 (2021), https://doi.org/10.37756/bk.21.3.3.1.

research and biotechnological development would decline, ultimately impeding medical and scientific progress. This argument underscores the necessity of striking a delicate balance between incentivizing innovation and safeguarding the fundamental human right to healthcare.[2]

The intersection of IPRs and bioethics is particularly contentious, as it necessitates a reconciliation of legal entitlements over genetic resources with broader ethical principles such as justice, fairness, and human dignity. One of the most significant legal debates in this context revolves around the distinction between discovery and invention. Patent law traditionally excludes natural phenomena from patent eligibility; however, various jurisdictions have granted patents for genetically modified organisms, gene therapies, and synthetic DNA constructs, thereby blurring the boundaries between what is naturally occurring and what constitutes human invention. From a bioethical standpoint, the patenting of genetic materials raises serious concerns regarding the commodification of life.[3] If genetic sequences, elements that exist naturally within the human genome, are subjected to exclusive ownership, there is an inherent risk of private entities exercising disproportionate control over fundamental aspects of human biology. The principle of beneficence, which dictates that scientific advancements should be directed toward the greater good, stands in direct opposition to the exclusivity granted by patent law. By restricting access to genomic therapies and essential biotechnological innovations, bio patents may conflict with the ethical imperative to ensure that medical advancements serve the collective welfare rather than the financial interests of a select few.

Another significant ethical challenge in bio patenting is the principle of distributive justice, which requires the fair allocation of healthcare resources, and the equitable distribution of benefits derived from scientific progress. The monopolization of genetic technologies by corporate entities risks creating insurmountable financial barriers for patients and healthcare providers in resource-limited settings. The ability of multinational corporations to secure exclusive rights over genetic sequences further exacerbates global health disparities, particularly in the context of rare genetic disorders and gene-based therapies. Additionally, bio patents frequently involve genetic resources derived from indigenous communities and traditional knowledge systems. The issue of biopiracy, whereby corporations and research institutions appropriate genetic resources without fair compensation or acknowledgment, represents a grave ethical violation. Historical cases from India, including the patenting of neem, turmeric, and basmati rice by foreign entities, exemplify the deficiencies of a legal framework that prioritizes corporate interests over the rights of local and indigenous communities. Such instances highlight the urgent need for more robust legal mechanisms to ensure that genetic resources and associated traditional knowledge are not unfairly appropriated by private entities. While international legal instruments such as the CBD & Nagoya Protocol

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[2] "{BLR 715} Bio-Technology General - Notice of Allowance - Patents" 6 *Biotechnology L. Rep.* 488 (1987), https://doi.org/10.1089/blr.1987.6.488.
[3] *Id.*

mandate PIC and ABS, enforcement mechanisms remain inadequate, leading to continued exploitation of genetic resources by powerful commercial interests.

The ethical challenges posed by bio patents necessitate the integration of comprehensive legal frameworks that safeguard public interest while ensuring that scientific innovation is not stifled. Ethical considerations must be embedded within the patenting process to prevent exploitative practices and ensure that the benefits of genomic research are distributed equitably.[4] One of the key ethical frameworks relevant to bio patenting is the precautionary principle, which advocates for caution in granting patent rights over genetic materials, particularly when potential social, environmental, and health consequences remain uncertain. This principle emphasizes the need for regulatory bodies to prioritize public welfare over commercial profit, ensuring that bio patents do not lead to unintended negative consequences. Additionally, the principle of justice mandates that bio patent policies do not disproportionately favor corporate entities at the expense of marginalized communities. It is imperative that legal structures incorporate safeguards to ensure that bio patents do not undermine fundamental human rights, particularly the right to health and access to life-saving technologies.

In the Indian context, the National IPR Policy (2016) seeks to align patent laws with ethical considerations by advocating for a balanced approach that fosters innovation while protecting public health. However, significant gaps remain in the implementation of ethical safeguards within the existing legal framework. While the policy acknowledges the importance of access to essential medicines and the need for fair benefit-sharing mechanisms, challenges persist in ensuring that these principles are effectively enforced. The lack of stringent regulations to prevent monopolization of genetic resources, combined with the limited capacity of regulatory institutions to oversee ethical compliance, underscores the necessity of continuous legal and policy interventions. To address these concerns, India must strengthen its patent laws to incorporate stricter ethical guidelines, ensuring that bio patents serve not only the interests of patent holders but also the broader public good.

PHILOSOPHICAL AND ETHICAL THEORIES IN BIO PATENTING

The ethical dilemmas associated with bio patenting are deeply entrenched in philosophical inquiries concerning justice, morality, and the fundamental legitimacy of IPRs over genetic materials. The question of whether genetic sequences, biological organisms, or biotechnological innovations should be subject to private ownership has ignited extensive debates across legal, ethical, and scientific communities.[5] At the heart of these discussions lies a critical tension between the pursuit of innovation and the ethical limitations of commodifying life itself. The legitimacy of bio patents is often justified through arguments emphasizing the necessity of incentivizing scientific progress, ensuring sustained investment in biotechnological research, and fostering advancements in medicine, agriculture, and genetic

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[4] Brad Sherman, "Which Nagoya Protocol?" *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* 249 (2022), https://doi.org/10.4324/9781003301998-20.

[5] Humberto E. Ortega et al., "Patents on Endophytic Fungi for Agriculture and Bio- and Phytoremediation Applications" 8 *Microorganisms* 1237 (2020), https://doi.org/10.3390/microorganisms8081237.

Volume 3, Issue 2 ISSN 2582-743X

engineering. Conversely, strong objections are raised on moral and ethical grounds, arguing that the privatization of genetic resources leads to monopolistic control, exacerbates social inequalities, and violates the intrinsic dignity of life.[6] A thorough examination of this contentious issue requires engagement with diverse philosophical perspectives, each offering a distinct lens through which the ethical ramifications of bio patenting can be assessed. Among these, utilitarianism, deontological ethics, Rawlsian justice, and indigenous or communal perspectives provide robust frameworks for analyzing the broader implications of granting IPRs over biological entities.

A utilitarian perspective, grounded in the consequentialist philosophies of Jeremy Bentham and John Stuart Mill, evaluates ethical dilemmas based on the maximization of overall societal welfare. In the context of bio patents, utilitarian reasoning predominantly supports the grant of patents on genetic inventions as a means to stimulate research and development in critical scientific domains. The rationale underpinning this viewpoint is that IP protection creates a system of incentives, encouraging private entities to allocate substantial resources toward the advancement of medical treatments, genetically modified organisms, and diagnostic technologies. Without the promise of exclusive rights, private firms may lack the financial motivation to undertake costly, high-risk research endeavors, thereby slowing down the rate of technological progress that could otherwise yield significant benefits for public health, agriculture, and environmental sustainability.[7] By ensuring that inventors and biotechnology firms can recoup their investments through temporary monopolies, patent laws ostensibly create an environment conducive to sustained innovation, ultimately resulting in breakthroughs that enhance the overall well-being of society.

Despite these advantages, the utilitarian justification for bio patenting is not without its inherent contradictions and ethical concerns. A principal challenge lies in determining the distribution of benefits and burdens arising from patent protection. While patents may incentivize innovation, they simultaneously confer exclusive control over essential genetic technologies, leading to exorbitant pricing of life-saving medicines and restricted access for economically disadvantaged populations. This issue is particularly pronounced in developing countries like India, where a significant portion of the population is unable to afford patented biopharmaceuticals. In such instances, the utilitarian principle of maximizing societal welfare becomes difficult to uphold, as the patent system, in practice, privileges the interests of corporate entities over those of vulnerable communities. Moreover, monopolistic practices enabled by patent protections often stifle competition, impeding the entry of affordable generic alternatives into the market and exacerbating healthcare disparities.[8]

To reconcile these ethical tensions, a more nuanced application of utilitarian principles necessitates balancing patent protection with regulatory mechanisms designed to mitigate

[6] Daniel K.N. Johnson, "Biotechnology Inventions: What Can We Learn from Patents?" 1999 *SSRN Elec. J.*, https://doi.org/10.2139/ssrn.181009.
[7] *Id.*
[8] Ashish Chauhan, "Bio-Prospection and Bio-Piracy" 05 *Pharmaceutica Analytica Acta* (2014), https://doi.org/10.4172/2153-2435.1000e170.

Volume 3, Issue 2 ISSN 2582-743X

inequities. Legal provisions such as compulsory licensing, price caps, and patent pools can serve as corrective measures to prevent bio patents from undermining the broader goal of public welfare. The global discourse surrounding patent waivers for COVID-19 vaccines provides a compelling illustration of the need to recalibrate IP laws in light of humanitarian concerns. While the pharmaceutical industry has defended strong patent protections as essential for fostering innovation, calls for temporary patent suspensions highlight the imperative of prioritizing human lives over corporate profits. Thus, from a utilitarian standpoint, an ethically defensible patent regime must not only encourage scientific discovery but also ensure that its benefits are equitably distributed, preventing situations where the very innovations designed to promote well-being become inaccessible to those who need them most.

In contrast to utilitarianism, which evaluates ethical issues through the lens of consequences, deontological ethics, rooted in the moral philosophy of Immanuel Kant, emphasizes the inviolability of moral principles, duties, and rights, irrespective of their outcomes. From a deontological standpoint, the patenting of genetic materials, particularly human genes and naturally occurring biological sequences, raises profound moral objections. A central tenet of Kantian ethics is the principle of human dignity, which dictates that individuals must always be treated as ends in themselves rather than as means to an economic or scientific objective. The commodification of life forms through patenting contravenes this ethical principle by reducing genetic resources to mere objects of commercial exploitation, disregarding their intrinsic moral significance.

The deontological critique of bio patenting is particularly salient in cases involving human genetic material. Patents on human genes imply a form of ownership over fundamental components of human biology, effectively transforming aspects of the human genome into proprietary assets. This moral concern was at the forefront of the landmark case of *Association for Molecular Pathology v. Myriad Genetics*,[9] wherein the US Supreme Court ruled that naturally occurring human genes could not be patented. The Court's decision reaffirmed the deontological assertion that genes, as products of nature, should remain part of the commons, rather than being monopolized by corporate interests. This ruling underscored the ethical imperative that scientific discoveries related to human genetics should be freely accessible for research and medical use, rather than being restricted under proprietary claims.

Additionally, deontologists argue that bio patents violate ethical duties concerning human health and welfare. The right to health, recognized under various international legal frameworks, imposes a moral obligation on governments and institutions to ensure equitable access to medical advancements. When patents result in barriers to essential medicines, they effectively undermine this ethical duty, prioritizing profit-driven incentives over the well-being of individuals. Consequently, deontological ethics advocate for stringent legal restrictions on the patentability of genetic materials, emphasizing that the sanctity of life should not be subordinated to economic interests.

[9] 569 U.S. 576 (2013).

Volume 3, Issue 2 ISSN 2582-743X

John Rawls' theory of justice as fairness provides yet another critical perspective on the ethical dimensions of bio patenting, particularly in relation to socio-economic equity and access to genetic resources. Rawlsian ethics emphasize the principles of equal basic liberties and distributive justice, asserting that any inequalities must be structured in a manner that benefits the least advantaged members of society. Monopolistic control conferred by bio patents often results in economic disparities, wherein pharmaceutical corporations reap substantial financial rewards while marginalized populations struggle to access vital treatments. This disparity directly contravenes Rawls' difference principle, which mandates that social and economic arrangements should be designed to uplift the most vulnerable.

Applying Rawlsian principles to bio patenting necessitates legal mechanisms that counteract the exclusionary effects of IPRs. Policies such as compulsory licensing, public sector investment in research, and restrictions on evergreening practices, exemplified by India's Sec. 3(d) of the Patents Act, 1970, seek to prevent corporations from perpetually extending patent monopolies at the expense of public access. Such legal measures align with Rawlsian justice by ensuring that IP regimes do not disproportionately favor corporate entities but instead contribute to the broader goal of social welfare.[10]

Beyond Western philosophical paradigms, indigenous and communal perspectives provide a fundamentally different approach to bio patenting by challenging the very notion of genetic ownership. Many indigenous communities regard genetic resources as elements of collective heritage rather than as commodities subject to private appropriation. This perspective underscores the principle of stewardship over privatization, arguing that genetic materials should be preserved for the benefit of all rather than being exploited for corporate gain. The historical phenomenon of biopiracy, in which traditional knowledge and genetic resources have been appropriated without consent, exemplifies the ethical failure of patent systems to recognize indigenous contributions.

International legal frameworks such as the CBD and the Nagoya Protocol seek to rectify these injustices by mandating benefit-sharing agreements and PIC from indigenous communities. However, weak enforcement mechanisms allow exploitative patenting practices to persist. Strengthening legal protections that uphold indigenous rights over genetic materials is essential to ensuring that bio patents do not erode communal knowledge systems or contribute to the unjust exploitation of traditional genetic resources.

PATENTING OF GENETIC MATERIALS: MORAL AND ETHICAL DEBATES

The legal and ethical dimensions of bio patenting, particularly concerning genetic materials, have been a subject of intense debate, shaping legal frameworks, public policy, and global jurisprudence. At its core, the issue raises fundamental questions about the nature of genetic sequences, the boundaries of IPRs over biological entities, and the societal consequences of

[10] "Interpreting 'Diagnostic' Under Section 3(i) of the Patents Act", *Cam*, Dec. 14, 2023, *available at*: https://corporate.cyrilamarchandblogs.com/2023/12/interpreting-diagnostic-under-section-3i-of-the-patents-act/ (last visited on Mar. 21, 2025).

Volume 3, Issue 2 ISSN 2582-743X

granting exclusive ownership over the fundamental building blocks of life. These debates extend beyond the technical requirements of patent law, engaging broader philosophical and ethical considerations regarding the commodification of human biology, the right to access genetic information, and the moral limits of proprietary claims over naturally occurring substances. The controversy surrounding bio patents is largely shaped by the legal distinction between discovery and invention, as well as concerns over the monopolization of essential genetic sequences, the exploitation of indigenous genetic resources, and the adequacy of informed consent mechanisms in the collection and use of genetic data. Landmark judicial decisions, such as *Association for Molecular Pathology v. Myriad Genetics*,[11] have played a crucial role in shaping global legal precedents, reinforcing the principle that products of nature should not be subject to private ownership and challenging the extent to which biotechnology corporations can assert exclusive rights over genetic innovations.

One of the central legal and philosophical questions in the patenting of genetic materials concerns the classification of genetic sequences as either patentable inventions or mere discoveries. Traditional patent law, as codified in various national statutes and international agreements such as the Agreement on TRIPS, mandates that an invention must meet the criteria of novelty, non-obviousness, and industrial applicability to qualify for patent protection. However, the application of these criteria to genetic materials has remained contentious, as DNA sequences exist in nature and are merely identified, sequenced, and isolated by researchers rather than being synthetically created. Proponents of genetic patenting argue that the processes involved in sequencing, isolating, and purifying DNA require significant human ingenuity, technical expertise, and investment, thereby transforming genetic materials into patentable inventions. According to this perspective, the act of isolating a gene, determining its function, and applying it in medical or agricultural biotechnology represents a sufficiently inventive step to warrant proprietary claims. This argument is rooted in the broader principle that scientific advancements should be incentivized through patent protection, as granting temporary exclusivity to inventors to foster investment in research and development, ultimately benefiting society through new medical treatments, genetically modified crops, and diagnostic technologies.[12]

Conversely, critics of genetic patenting contend that the mere isolation of a gene does not fundamentally alter its intrinsic characteristics and that allowing proprietary claims over genetic sequences effectively grants monopolistic control over elements that are naturally occurring. This legal argument gained substantial judicial validation in the *Myriad Genetics* case, where the US Supreme Court ruled that naturally occurring DNA, even when isolated from the human genome, remains a product of nature and is therefore not eligible for patent protection. The Court emphasized that while Myriad's identification of the BRCA1 and BRCA2 genes was a significant scientific achievement, it did not involve the kind of human

[11] 569 U.S. 576 (2013).

[12] Lara Cartwright-Smith, "Patenting Genes: What Does Association for Molecular Pathology V. Myriad Genetics Mean for Genetic Testing and Research?" 129 *Pub. Health Reps.* 289 (2014), https://doi.org/10.1177/003335491412900311.

Volume 3, Issue 2 ISSN 2582-743X

ingenuity required to convert a product of nature into a patentable invention. However, the Court distinguished between naturally occurring DNA and complementary DNA (cDNA), which is synthetically created and, therefore, eligible for patent protection. This distinction has had far-reaching implications for global bio-patent jurisprudence, reinforcing the legal principle that fundamental components of life should not be subject to private ownership. The *Myriad* decision has influenced legislative and judicial approaches in various jurisdictions, including India & EU, where patent laws increasingly reflect a restrictive stance on the patentability of naturally occurring genetic sequences.

Beyond the legal classification of genetic sequences as either inventions or discoveries, the ethical ramifications of granting patents over genetic materials have been the subject of extensive debate, particularly concerning the monopolization of essential biological elements that serve as the foundation for medical research and therapeutic advancements. The granting of exclusive rights over genetic sequences enables corporations and research institutions to exercise monopolistic control over critical biotechnological applications, thereby limiting access to diagnostic tests, gene therapies, and life-saving treatments. The ethical concerns associated with such monopolization are particularly acute in the context of public health, where patents on genetic sequences can lead to excessive pricing, restricted availability, and systemic disparities in healthcare accessibility.

A notable example of this monopolization was Myriad Genetics' enforcement of patents on the BRCA1 and BRCA2 genes, which are associated with hereditary breast and ovarian cancer. By securing exclusive rights over these genetic sequences, Myriad was able to prevent other laboratories from conducting genetic testing for BRCA mutations, effectively controlling the market for cancer diagnostics and charging prohibitively high fees for their patented test. This monopolistic practice was widely condemned for prioritizing corporate profits over public health, as it restricted access to crucial cancer screenings, particularly for economically disadvantaged patients.[13] The *Myriad* case underscored the ethical conflict between patent protection and the principle of distributive justice, which demands fair and equitable access to healthcare resources. If bio patents enable corporations to restrict access to genetic technologies, they serve to entrench socio-economic inequalities, particularly in developing countries such as India, where access to affordable medicines and diagnostic tools remains a pressing public health concern.

In response to these ethical challenges, legal frameworks in India have sought to impose constraints on the patentability of genetic materials to prevent excessive monopolization. Sec. 3(d) of the Indian Patents Act, 1970, plays a crucial role in restricting the patenting of biological materials unless they demonstrate significant therapeutic efficacy. This provision has been instrumental in preventing "evergreening", a practice wherein pharmaceutical companies make minor modifications to existing genetic sequences to extend patent monopolies without making substantive improvements to the underlying technology. Despite these safeguards, concerns

[13] Kurt Samson, "Multi-Gene BRCA Testing Identifies Mutations Other than BRCA Variants" 37 *Oncology Times* 44 (2015), https://doi.org/10.1097/01.cot.0000475713.34955.cc.

Volume 3, Issue 2 ISSN 2582-743X

persist that multinational corporations may exploit legal loopholes to maintain control over genetic technologies, necessitating more stringent regulatory oversight and judicial scrutiny to ensure that patent laws align with public interest considerations.

Another critical dimension of the ethical debate on bio patenting concerns the ownership of human genetic data and the principle of informed consent. Unlike synthetic chemical compounds, genetic sequences are inextricably linked to human identity, ancestry, and health, raising fundamental questions about individual autonomy and the rights of communities over their genetic information. A significant ethical issue in this regard is the extraction and commercialization of genetic material without proper consent, often seen in cases of biopiracy and unauthorized genetic research. The exploitation of indigenous genetic resources without informed consent has led to international controversies, such as the Havasupai Tribe case in the US, where genetic samples were collected for one purpose but later used for unauthorized studies without the knowledge or approval of the participants. Such cases highlight the inadequacies of existing legal protections in safeguarding individuals and communities from the unauthorized appropriation of their genetic information.[14]

In India, growing concerns over genomic data sovereignty have underscored the need for robust legal mechanisms to regulate the use of genetic materials in research and commercial applications. The Biological Diversity Act, 2002, seeks to address these concerns by mandating PIC and ABS agreements for access to biological resources. However, challenges remain in ensuring the effective enforcement of these provisions, particularly in preventing the exploitation of indigenous knowledge and genetic materials by multinational biotechnology firms. Furthermore, the rapid expansion of commercial genetic testing companies has raised concerns regarding data privacy, security, and the potential for unauthorized commercialization of genetic information. Ethical frameworks such as the UNESCO’s Universal Declaration on the Human Genome and Human Rights (1997) affirm that the human genome should not be reduced to a commodity, reinforcing the necessity of stronger legal safeguards against the privatization of genetic data.

The *Myriad Genetics* case stands as a defining precedent in the global debate on genetic patenting, serving as a pivotal moment in bio-patent jurisprudence by establishing that naturally occurring genetic sequences are not eligible for patent protection. The ruling has set a legal and ethical standard that continues to influence policy decisions worldwide, compelling lawmakers to reconsider the balance between incentivizing innovation and ensuring equitable access to genetic technologies. In India, the principles underlying the *Myriad* decision align with the restrictive provisions of the Patents Act, reinforcing the need for robust regulatory frameworks to prevent the monopolization of essential medical and biotechnological advancements. As the field of genomics continues to evolve, alternative IP models, such as patent pools, open-source genetic research initiatives, and public-private partnerships, may provide more ethically and

[14] T. Hart Anderson, “Taxing United States Patents” 11 *J. Indus. & Eng’g Chemistry* 938 (1919), https://doi.org/10.1021/ie50118a016.

Volume 3, Issue 2 ISSN 2582-743X

legally sustainable pathways for fostering innovation while ensuring that the benefits of genetic discoveries remain accessible to all.[15]

EQUITY AND ACCESS TO GENOMIC TECHNOLOGIES

The ethical and legal discourse surrounding bio patents is deeply intertwined with broader questions of equity, access, and the moral limits of IPRs, particularly in the context of genomic technologies that hold transformative potential for medicine, agriculture, and biotechnology. Patent laws, by design, seek to incentivize innovation by granting exclusive rights to inventors for a limited duration, allowing them to recover research and development costs. However, in the realm of genetic and biotechnological innovations, the exclusivity conferred by patents often results in monopolistic market structures that prioritize proprietary control over broader public welfare. This monopolization creates a profound ethical dilemma, whether granting private entities exclusive control over genomic advancements aligns with the fundamental principles of distributive justice, human rights, and global healthcare equity. The implications of bio patents extend far beyond the domain of commercial interests, as they influence the affordability and accessibility of life-saving treatments, the ethical boundaries of commodifying genetic resources, and the global disparities in healthcare. The concentrated control of genetic technologies, particularly in developing nations such as India, exacerbates existing socioeconomic inequalities by placing essential medical and agricultural innovations beyond the reach of vulnerable populations. These realities necessitate a rigorous ethical and legal examination of the extent to which contemporary patent regimes serve the collective interests of society rather than reinforcing structural disparities in access to healthcare and biotechnological advancements.[16]

The ethical concerns surrounding bio patents primarily stem from their impact on affordability and accessibility, as patent protections frequently result in exorbitant pricing structures that create significant financial barriers for economically disadvantaged populations.[17] This issue is particularly pronounced in the fields of precision medicine, gene therapy, and genomic diagnostics, where patented technologies are predominantly controlled by multinational pharmaceutical corporations, thereby limiting the ability of public healthcare institutions to provide cost-effective treatment options. In India, where a substantial portion of the population relies on publicly funded medical services, the imposition of rigid patent protections exacerbates systemic inequities by placing cutting-edge genomic therapies beyond the financial reach of most citizens. The monopolization of transformative genetic technologies, such as CRISPR-based gene editing, monoclonal antibody therapies, and genetically modified crops, raises profound moral and legal questions regarding the prioritization of corporate profit motives over public health and food security. The ethical dilemma becomes even more acute when considering the disproportionate impact on marginalized communities, particularly in

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[15] "Reflecting on 10th Anniversary of AMP v. Myriad", *Amp, available at*: https://www.amp.org/advocacy/reflecting-on-10th-anniversary-of-amp-v-myriad/ (last visited on Mar. 21, 2025).

[16] Alain Pottage, "The Inscription of Life in Law: Genes, Patents, and Bio-politics" 61 *Mod. L. Rev. 740* (1998), https://doi.org/10.1111/1468-2230.00177.

[17] *Id.*

cases where patent-induced pricing structures deprive patients of access to potentially life-saving treatments and restrict small-scale farmers' access to improved crop varieties.

One of the most critical manifestations of the ethical tensions surrounding bio patents is evident in the domain of cancer immunotherapy, where genomic-based treatments have revolutionized oncology but remain financially inaccessible to the vast majority of patients due to restrictive patent protections. CAR-T cell therapy, a groundbreaking form of gene therapy used to treat leukemia, exemplifies the adverse consequences of patent exclusivity, as its exorbitant costs, ranging between $300,000 and $500,000 per treatment, effectively render it unavailable to most cancer patients in developing nations.[18] The exclusive patent rights held by multinational pharmaceutical corporations have significantly delayed the introduction of cost-effective domestic alternatives, further widening the healthcare divide between affluent populations with access to cutting-edge treatments and economically disadvantaged patients who continue to suffer due to patent-induced pricing barriers. A similar ethical concern arises in the domain of genetic diagnostics, where proprietary sequencing technologies remain prohibitively expensive for public healthcare programs. This issue is particularly relevant in India's ongoing efforts to integrate genomic medicine into its national healthcare infrastructure, as foreign patent holders retain exclusive control over essential genetic sequencing tools, restricting the ability of domestic institutions to develop affordable diagnostic alternatives. While initiatives such as the Genome India Project seek to promote indigenous genomic research, the overwhelming concentration of IPRs in the hands of Western corporations continues to hinder India's ability to establish cost-effective, large-scale diagnostic solutions for genetic disorders and early disease detection.

Beyond the issue of affordability, the ethical dilemmas associated with bio patents extend to their broader impact on scientific research and innovation. The privatization of key genetic resources through exclusive patent rights creates legal and bureaucratic hurdles that impede collaborative research efforts, particularly within the public sector. Public research institutions and independent scientists must navigate complex licensing agreements and financial constraints to access patented genomic tools, thereby stifling innovation and limiting the development of new therapeutic and diagnostic technologies. This monopolization of genetic knowledge runs counter to the fundamental principle that scientific discoveries, especially those with significant implications for public health, should be regarded as a collective intellectual common rather than proprietary assets for corporate exploitation. In response to these concerns, the Indian Patents Act, 1970, incorporates certain safeguards designed to prevent the excessive monopolization of medical and biotechnological innovations. Notably, Sec. 3(d) of the Act seeks to curb "evergreening" strategies, wherein pharmaceutical companies obtain successive patents for minor modifications of existing drugs to prolong market exclusivity without providing significant therapeutic advancements. While this provision serves as an important legal mechanism to prevent the abuse of patent protections, it remains

[18] Zoufang Huang et al., "CAR T cells: engineered immune cells to treat brain cancers and beyond" 22 *Molecular Cancer* (2023), https://doi.org/10.1186/s12943-022-01712-8.

Volume 3, Issue 2 ISSN 2582-743X

insufficient in addressing the broader ethical concerns surrounding the privatization of genetic and biotechnological resources.

The ethical and legal implications of bio patents can be further illustrated through case studies that exemplify the tangible impact of exclusive patent rights on public health. One of the most widely recognized examples is the case of Myriad Genetics, which held patents on the BRCA1 and BRCA2 genes, mutations of which are associated with hereditary breast and ovarian cancer. By securing exclusive patent rights over these genes, Myriad Genetics effectively monopolized the market for BRCA genetic testing, thereby preventing other laboratories from offering more affordable alternatives. This monopolization resulted in prohibitive costs, with Myriad's genetic test priced at over $3,000, placing it beyond the financial reach of many at-risk individuals. The ethical backlash against this restrictive patenting practice culminated in the landmark US Supreme Court ruling in *Association for Molecular Pathology v. Myriad Genetics,*[19] which invalidated Myriad's patents on the grounds that naturally occurring human genes cannot be subject to private ownership. While this decision established an important legal precedent, numerous genomic technologies remain under patent protection, limiting their accessibility in developing nations such as India, where the affordability of diagnostic testing remains a pressing public health concern.

Addressing the ethical challenges posed by bio patents necessitates the implementation of legal mechanisms that promote equitable access to genomic technologies while preserving incentives for innovation. One such mechanism is the establishment of patent pools, wherein multiple patent holders voluntarily license their patents to a collective entity, thereby facilitating shared access to critical technologies at reduced costs. In the field of genomic medicine, patent pools could enable broader access to gene-editing tools, diagnostic assays, and biopharmaceutical advancements by promoting collaborative research rather than exclusive proprietary control. A notable precedent for such an approach is the Medicines Patent Pool (MPP), which has successfully negotiated voluntary licenses for essential medicines, thereby increasing access to life-saving treatments in developing countries. A similar model could be applied to genomic technologies in India to ensure that patent protections do not unduly restrict the availability of gene therapies and precision medicine.

Compulsory licensing, as recognized under Sec. 84 of the Indian Patents Act, 1970, represents another critical legal mechanism for ensuring ethical access to essential biotechnological innovations. This provision allows the government to issue licenses to domestic manufacturers to produce patented drugs at reduced costs when public health considerations warrant such intervention. The landmark *Natco Pharma v. Bayer*[20] case exemplifies the effective use of compulsory licensing in promoting affordable access to essential medicines, as the Indian government granted a compulsory license for the cancer drug Nexavar, reducing its price by over 95%. Extending the principles of compulsory licensing to genomic technologies could enable broader access to gene therapies and diagnostic tools, particularly in cases where patent-

[19] 569 U.S. 576 (2013).

[20] 2014 (60) PTC 277 (BOM).

induced exclusivity creates insurmountable barriers to essential healthcare services. However, the implementation of such measures is often met with resistance from multinational corporations and is further complicated by stringent IP protection standards imposed by international trade agreements such as the TRIPS framework.

ETHICAL DILEMMAS IN AGRICULTURAL BIOTECHNOLOGY

The interplay between bio patents and agricultural biotechnology represents a deeply complex legal and ethical issue, particularly in agrarian economies such as India, where a substantial proportion of the population depends on agriculture for survival. The patenting of genetically modified (GM) seeds, proprietary plant varieties, and advanced biotechnological innovations has sparked fierce debates over farmers' rights, food security, corporate monopolization, and the broader consequences of privatizing biological resources. Proponents of bio patents argue that such IP protections foster innovation by incentivizing research into high-yield, climate-resilient, and pest-resistant crops, thereby contributing to food security and sustainable agriculture. However, critics emphasize the risks posed by the monopolization of agricultural inputs, the erosion of farmers' traditional rights, and the heightened economic dependency of smallholder farmers on multinational agribusinesses. These concerns are particularly significant in developing countries where seed sovereignty and equitable access to agricultural resources play a crucial role in rural economies. The legal and ethical discourse surrounding bio patents necessitates a thorough examination of their impact on agricultural autonomy, food security, biodiversity conservation, and the long-term sustainability of farming communities.[21]

The Effect of Bio Patents on Farmers' Rights and Food Security

One of the most contentious aspects of bio patents in agriculture is their effect on farmers' rights and traditional farming practices. Historically, Indian farmers have engaged in seed-saving, exchanging, and reusing practices, which have been instrumental in maintaining biodiversity and ensuring sustainable agricultural production. These customary practices allow farmers to retain control over seed selection and cultivation, reducing their dependence on external inputs and fostering resilience against environmental fluctuations. However, the advent of genetically modified seeds and hybrid plant varieties protected under patent laws has fundamentally disrupted these traditional practices. Patent protections often prohibit farmers from saving or replanting patented seeds, compelling them to repurchase new seeds for each cultivation cycle. This restriction not only increases production costs but also creates a cycle of economic dependency on multinational agribusinesses, which hold proprietary control over seed technologies.

From a legal perspective, the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act) was enacted in India as a counterbalance to the restrictive implications of patent laws. Unlike the more rigid patent laws that govern industrial and pharmaceutical inventions, the PPVFR Act provides explicit protection for farmers, recognizing their right to save, replant,

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[21] Dennis J. Cheek & Dan Brazeau, "Genetically modified" 22 *Nursing Mgmt.* 13, (2015), https://doi.org/10.7748/nm.22.3.13.s13.

Volume 3, Issue 2 ISSN 2582-743X

and exchange protected seed varieties under certain conditions.[22] However, the effectiveness of these provisions has been frequently challenged by multinational biotechnology corporations, which often impose contractual restrictions and licensing agreements that limit farmers' ability to exercise these legal rights in practice. These corporate-driven constraints create a legal grey area, where farmers technically retain statutory rights but face practical barriers in asserting them due to the dominance of corporate seed suppliers and the threat of litigation.

Beyond farmers' rights, the implications of bio patents on food security further complicate ethical and legal discourse. The ICESCR enshrines the right to food as a fundamental human right, emphasizing states' obligations to ensure equitable access to essential food resources. However, the monopolization of seed technologies through bio patents jeopardizes this objective by driving up the cost of essential agricultural inputs, making them less affordable for smallholder farmers who form the backbone of food production in developing nations. By restricting access to seeds, bio patents create barriers to self-sufficiency and food sovereignty, placing control over agricultural production in the hands of a few corporate entities rather than local farming communities. The resulting market concentration in the seed industry further exacerbates economic disparities, as small-scale farmers find themselves increasingly marginalized in an industry dominated by large agribusinesses. The potential consequences of such market-driven agricultural policies are far-reaching, posing risks to national food security, rural livelihoods, and sustainable farming systems.

Seed Patents and the Debate Over Farmers' Autonomy

The legal and ethical conflicts surrounding seed patents fundamentally revolve around the conflict between corporate control and farmers' autonomy. Traditionally, farmers have exercised complete independence in selecting, cultivating, and saving their seeds, ensuring self-sufficiency in agricultural production. However, the extension of IP protections to GMOs and hybrid crops has led to a paradigm shift, where control over seed technology has been transferred from farmers to corporate entities. Seed patents grant exclusive rights to biotechnology firms, allowing them to dictate the terms of seed usage and prohibit the reuse of harvested seeds.[23]

The legal enforcement of seed patents often takes the form of contractual agreements, which farmers must sign before purchasing patented seeds. These agreements typically contain provisions that prohibit seed-saving and replanting, requiring farmers to repurchase new seeds for each cultivation cycle. The economic ramifications of these restrictions are profound, as farmers are forced into a cycle of perpetual dependence on corporate seed suppliers, often leading to financial strain and debt accumulation. This practice has been widely criticized as a form of "seed serfdom", wherein farmers lose their traditional autonomy and become economically subjugated to corporate agribusinesses. The broader ethical question that arises

[22] Ujwal Prabhakar Nandekar, "The Protection of Plant Variety and Farmers Rights Act, 2001" 2012 *SSRN Elec. J.*, https://doi.org/10.2139/ssrn.2208399.
[23] *Supra* note 38.

Volume 3, Issue 2 ISSN 2582-743X

is whether patents on life forms, particularly seeds, should be permitted at all, given their essential role in human survival and food production. The principle of distributive justice, as articulated by John Rawls, suggests that legal frameworks should be structured to benefit the least advantaged members of society. Applying this principle to bio patents would necessitate legal reforms that prevent excessive corporate control over seeds and ensure that IP laws do not undermine the rights and economic stability of small-scale farmers.

The Monsanto v. Nuziveedu Case and Its Ethical Implications

A landmark legal dispute that highlights the tensions between bio patents and farmers' rights is *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.*,[24] wherein Monsanto, a global agribusiness corporation, held patents for Bt cotton technology, a genetically modified crop engineered to resist pests. Indian seed companies, including Nuziveedu Seeds, entered into licensing agreements with Monsanto to use this patented technology. However, a dispute arose over royalty payments, leading to litigation concerning the validity and enforceability of bio patents in India.

The Supreme Court of India ultimately ruled that Monsanto's patent on Bt cotton seeds was unenforceable under Indian law, specifically under Sec. 3(j) of the Patents Act, 1970, which excludes plants, seeds, and biological processes from patent eligibility. This decision reinforced India's long-standing policy that patents should not be extended to life forms, particularly those integral to food security and agricultural sustainability. The ruling aligned with India's PPVFR Act, ensuring that biotechnological advancements in agriculture remain accessible and do not lead to exploitative monopolies.

The case also underscored the ethical conflict between corporate patent rights and public interest considerations. If patent laws were to fully recognize genetically modified seed patents, companies like Monsanto would wield excessive power over food production, potentially undermining the economic sovereignty of smallholder farmers. The ethical principle of common heritage, which asserts that biological resources should remain accessible to all and not be monopolized for private gain, was a central consideration in the court's ruling.

Hence, the legal and ethical challenges posed by bio patents necessitate a careful balance between promoting innovation and protecting the rights of farmers. While IP protections play a critical role in fostering scientific advancements in agriculture, they must not come at the cost of equitable access to essential agricultural inputs, food security, and farmers' autonomy. India's legal framework, as exemplified by the PPVFR Act and the Supreme Court's ruling in the Monsanto case, reflects a commitment to preserving farmers' traditional rights and preventing monopolistic control over seeds. However, the ongoing expansion of corporate influence in agricultural biotechnology underscores the need for stronger regulatory mechanisms to ensure that bio patents do not exacerbate rural economic inequalities or threaten the sustainability of agrarian communities. The future trajectory of agricultural biotechnology

[24] AIR 2019 SUPREME COURT 559.

Volume 3, Issue 2 ISSN 2582-743X

in India will depend on legal and policy interventions that safeguard farmers' rights while fostering ethical and inclusive innovation.

BIOPIRACY AND ETHICAL CONSIDERATIONS IN TRADITIONAL KNOWLEDGE

The issue of biopiracy represents one of the most profound ethical, legal, and economic challenges in contemporary IP law, particularly in developing nations such as India, where rich biodiversity and centuries-old traditional knowledge systems have formed the foundation of agricultural, medicinal, and ecological practices. Biopiracy, in its broadest sense, refers to the unauthorized extraction, commercial utilization, and monopolization of biological resources and indigenous knowledge by multinational corporations, research institutions, and foreign entities without providing due recognition, compensation, or benefit-sharing to the communities that have preserved and nurtured these resources for generations.[25] This phenomenon has led to serious concerns regarding the exploitation of traditional knowledge by powerful corporate actors who, under the guise of scientific innovation, obtain patents over naturally occurring substances and their applications, often without substantive modifications, thereby depriving indigenous communities of their rightful ownership and economic participation in the commercialization of these resources.

At the heart of biopiracy lies a fundamental asymmetry in power dynamics between traditional knowledge holders, who have often been marginalized in global economic structures, and multinational corporations, which possess vast legal and financial resources to navigate IP regimes in a way that secures exclusive proprietary rights over biological resources. The commodification of traditional knowledge through patents and other forms of IP protection not only erodes indigenous sovereignty over biological heritage but also raises serious questions about the legitimacy of patenting life forms and naturally occurring compounds. The problem is further exacerbated by the fact that most traditional knowledge is transmitted orally across generations and is rarely documented in formats that meet the patent eligibility criteria set by Western IP systems, which emphasize novelty, inventive step, and industrial applicability. This disconnect creates a legal vacuum wherein indigenous knowledge, despite being widely known and used for centuries, becomes vulnerable to misappropriation by entities that merely document or slightly modify existing formulations before seeking patent protection.[26]

India has been at the epicenter of numerous high-profile biopiracy cases that have drawn international attention to the exploitative nature of bio-patenting. Among these, the cases of neem (Azadirachta indica), turmeric (Curcuma longa), and basmati rice (Oryza sativa) are particularly significant, as they underscore the global struggle to prevent corporations from monopolizing naturally occurring substances and the traditional knowledge associated with them. The neem case exemplifies how corporate entities have attempted to assert exclusive rights over biological resources that have long been integral to Indian agriculture and medicine. Neem, a tree native to the Indian subcontinent, has been traditionally used for its potent

[25] *Supra* note 33.
[26] *Supra* note 32.

pesticidal, antifungal, and medicinal properties. However, in the 1990s, W.R. Grace, a US-based agribusiness corporation, obtained a patent from the European Patent Office (EPO) for a fungicidal product derived from neem, claiming it as an innovation. This sparked outrage among Indian environmental activists, scientists, and policymakers, who argued that the pesticidal properties of neem had been common knowledge in Indian society for centuries and that the patent unjustly appropriated traditional wisdom. Led by the Research Foundation for Science, Technology, and Ecology (RFSTE), the patent was legally challenged on the grounds that the claimed invention lacked novelty and was merely an adaptation of pre-existing knowledge. After years of litigation, the EPO ultimately revoked the patent in 2000, acknowledging that neem's pesticidal applications were already in the public domain and, therefore, did not qualify as a patentable innovation. This case was a landmark victory in the global fight against biopiracy, demonstrating that collective resistance and strategic legal action could successfully overturn exploitative patents.

A similar controversy arose in the turmeric case, where foreign researchers attempted to claim IP rights over a widely used traditional medicinal practice. Turmeric, a spice deeply embedded in Indian culture, has been used for thousands of years in traditional medicine, religious rituals, and cuisine. It is particularly valued for its anti-inflammatory, wound-healing, and antiseptic properties, which have been extensively documented in Ayurvedic texts and traditional medical practices. Despite this well-established history, in 1995, two researchers from the University of Mississippi Medical Center were granted a U.S. patent for the use of turmeric in wound healing. This move sparked widespread criticism, as the patent essentially sought to privatize a well-known medicinal application that had been in practice for millennia. In response, the Council of Scientific and Industrial Research (CSIR) of India initiated legal proceedings to challenge the patent, submitting extensive documentary evidence from ancient texts and scientific literature that demonstrated turmeric's wound-healing properties were already part of the public domain. Following a rigorous review by the USPTO, the patent was revoked in 1997, setting an important precedent in the protection of traditional medicinal knowledge from unethical patenting practices.[27]

The case of basmati rice further illustrates the economic implications of biopiracy, particularly in the context of agricultural biodiversity and trade interests. Basmati, a unique variety of aromatic rice cultivated for centuries in India and Pakistan, is renowned globally for its distinct flavor, aroma, and long grain structure. However, in 1997, Ricetec Inc., a US-based company, was granted a patent by the USPTO for certain basmati rice varieties and their breeding methods, claiming exclusive rights to market them as 'American Basmati.' The patent not only attempted to appropriate India's agricultural heritage but also posed a severe economic threat to Indian farmers, as it could have restricted India's ability to export basmati rice under its original name, thereby affecting millions of livelihoods. The Indian government, along with agricultural and trade organizations, mounted a legal challenge, arguing that the patent was overly broad, misleading, and based on pre-existing knowledge. Under intense legal and

[27] "USPTO Web Patent Database" 1999 *Biofutur* 53 (1999), https://doi.org/10.1016/s0294-3506(00)87180-x.

Volume 3, Issue 2 ISSN 2582-743X

diplomatic pressure, the USPTO eventually narrowed the scope of Ricetec's patent, preventing it from monopolizing the basmati name and related strains. However, the case highlighted the vulnerabilities of traditional agricultural products in the global patenting system and underscored the necessity for stronger GI protections to safeguard indigenous crop varieties from biopiracy.[28]

The ethical challenges posed by biopiracy necessitate a comprehensive legal framework that prioritizes the rights of indigenous communities, ensures equitable benefit-sharing, and prevents the monopolization of biological resources. Central to this effort is the principle of PIC, which mandates that local communities must have a say in whether their traditional knowledge and genetic resources can be used for research, commercialization, or patenting. In addition, the principle of ABS, as outlined in the Nagoya Protocol under the CBD, requires that any commercial gains arising from the use of traditional knowledge must be equitably shared with the knowledge holders.

India has taken proactive legislative measures to combat biopiracy through the Biological Diversity Act, 2002, which regulates access to biological resources, enforces PIC, and ensures fair benefit-sharing. The Act mandates that foreign entities seeking to exploit Indian biological resources must seek prior approval from the National Biodiversity Authority (NBA) and that any revenues generated from such resources must be fairly distributed to local communities. The Act also prohibits unauthorized bio-patenting of Indian genetic resources and mandates the establishment of Biodiversity Management Committees (BMCs) at the local level to oversee conservation efforts. Despite these legal safeguards, enforcement challenges persist, as corporations frequently exploit legal loopholes or enter into private agreements that bypass these regulatory frameworks.

The broader global debate on biopiracy underscores the need for international cooperation in strengthening legal protections against the exploitation of traditional knowledge. Many indigenous communities lack the financial and legal resources to challenge patents filed by multinational corporations, making it imperative for governments, international organizations, and advocacy groups to work together in creating more accessible legal redress mechanisms. Enhanced documentation efforts, such as India's TKDL, play a crucial role in defensively preventing unethical patents by providing a publicly available repository of prior art, thereby preempting wrongful patent claims.

Hence, biopiracy remains a pressing challenge at the intersection of IPRs, indigenous rights, and global trade regulations. The cases of neem, turmeric, and basmati rice exemplify the predatory nature of corporate-driven bio-patenting and the necessity of robust legal frameworks to counteract such exploitation. Strengthening community participation, enforcing stringent legal protections, and ensuring equitable benefit-sharing are essential in upholding ethical

[28] *Supra* note 32.

Volume 3, Issue 2 ISSN 2582-743X

standards and preserving the integrity of traditional knowledge systems against commercial appropriation.[29]

ETHICAL GUIDELINES AND INTERNATIONAL FRAMEWORKS

The ethical considerations surrounding bio patents transcend national jurisdictions and encompass a broad spectrum of legal, social, and moral dimensions. These considerations are deeply embedded in international human rights law, global public health frameworks, and biodiversity conservation treaties. The growing commercialization of genetic resources, the rise of biotechnological innovations, and the increasing application of genomics in medical, agricultural, and industrial domains have given rise to complex ethical dilemmas. These dilemmas revolve around questions of ownership, equitable access, informed consent, and the fair distribution of benefits derived from genetic research. While IPRs serve as an important legal mechanism to incentivize innovation, the monopolization of genetic material through bio patents raises profound ethical concerns about accessibility, affordability, and the exploitation of indigenous resources.

To address these concerns, various international legal instruments, regulatory frameworks, and ethical guidelines have been established to ensure that patenting of genetic material does not lead to the erosion of fundamental human rights, exacerbating health disparities, or undermine biodiversity conservation efforts. These frameworks emphasize the need for a delicate balance between fostering scientific and technological advancements while maintaining ethical obligations such as equitable benefit-sharing, preventing biopiracy, securing PIC, and ensuring non-discriminatory access to biotechnological innovations. As the legal landscape of bio patents evolves in response to rapid advancements in genetic research, it is imperative to critically examine how international ethical frameworks interact with national patent laws and regulatory mechanisms to ensure that genomic innovations are developed and utilized within a framework of justice, equity, and sustainability.

One of the most significant ethical instruments in the realm of bio patents is the Universal Declaration on the Human Genome and Human Rights (UDHGHR), adopted by UNESCO in 1997 and subsequently endorsed by the UN General Assembly in 1998. This declaration establishes fundamental ethical principles concerning the legal and moral status of the human genome, reinforcing the view that genetic material in its natural state should not be subject to financial gain or commercial monopolization through patent rights. The declaration explicitly states that the human genome, as the common heritage of humanity, must not be commodified. This principle challenges the patentability of genes, particularly in jurisdictions where corporate entities have attempted to claim exclusive rights over naturally occurring genetic sequences.

The legal implications of this ethical stance were most notably reinforced in the landmark case of *Association for Molecular Pathology v. Myriad Genetics*,[30] wherein the court ruled that

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[29] *Supra* note 9.
[30] 569 U.S. 576 (2013).

naturally occurring DNA sequences could not be patented, as they are products of nature rather than human-made inventions. The ruling invalidated Myriad Genetics' patents on the BRCA1 and BRCA2 genes, which had previously restricted access to affordable breast cancer screening and diagnostics. The case set a significant precedent in international patent law, aligning with UNESCO's ethical position that the human genome should not be subjected to monopolistic control.

India's domestic legal framework reflects a similar ethical position through Sec. 3(c) of the Patents Act, 1970, which explicitly prohibits the patenting of naturally occurring living organisms, including genetic sequences. However, the application of this provision remains ambiguous in cases involving synthesized genetic sequences, biotechnological derivatives, and gene-editing technologies. With the advent of CRISPR-Cas9 gene editing, synthetic biology, and bioengineered genetic materials, new ethical and legal challenges have emerged concerning whether artificially modified genetic sequences should be eligible for patent protection. While India's legal framework seeks to prevent the monopolization of human genetic resources, the growing complexity of modern biotechnology necessitates comprehensive regulatory oversight to ensure that bio patents do not infringe upon fundamental ethical principles.[31]

Beyond concerns of monopolization, gene patents raise critical public health accessibility issues, as emphasized by the WHO. The WHO has consistently maintained that IPRs must not create unjustified barriers to healthcare, particularly in relation to essential medicines, diagnostic tools, and life-saving biotechnologies. In its 2006's report on IPRs and Public Health, WHO highlighted the adverse impact of excessive patent protection in genomics, emphasizing how monopolistic control over genetic information can lead to inflated pricing and restricted access to critical medical technologies.

The ethical implications of gene patents on public health were prominently highlighted in the case of Myriad Genetics, where patents on the BRCA1 and BRCA2 genes resulted in exorbitantly priced genetic tests for breast cancer susceptibility. The patents prevented competitors from offering more affordable testing options, thereby disproportionately affecting economically disadvantaged populations. This case exemplified how gene patents can lead to healthcare inequities by restricting access to vital medical diagnostics.

In India, the compulsory licensing provisions under Sec. 84 of the Patents Act, 1970 serve as an important legal safeguard to override patents in cases of public health emergencies. However, global pharmaceutical corporations often resist such measures through TRIPS-plus agreements, which impose additional restrictions on national patent laws. WHO has strongly advocated for a more flexible and ethically guided approach to patent laws, urging countries like India to implement policies that prevent gene patents from hindering medical access while still encouraging scientific progress.

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[31] "BRCA Screening" 111 *Obstetrics & Gynecology* 1205 (2008), https://doi.org/10.1097/aog.0b013e3181726f91.

Volume 3, Issue 2 ISSN 2582-743X

Apart from human genetic resources, ethical concerns related to biopiracy, and biodiversity conservation have also been central to international legal discourse, particularly in relation to the CBD, 1992, & Nagoya Protocol (2010). The CBD establishes ABS principles, which recognize the sovereign rights of states over their biological resources and ensure that local communities receive equitable benefits from the commercial utilization of their genetic materials. The Nagoya Protocol further reinforces these provisions by introducing legally binding guidelines for ensuring fair benefit-sharing agreements and preventing the exploitation of indigenous genetic resources.[32]

From an ethical standpoint, the CBD and Nagoya Protocol challenge the legitimacy of bio patents that fail to acknowledge the contributions of indigenous communities or that lead to the privatization of genetic resources without fair compensation. India has integrated these principles into its national legal framework through the Biological Diversity Act, 2002, which mandates PIC and equitable benefit-sharing agreements before any commercial exploitation of Indian biodiversity is undertaken.

However, despite these legal protections, biopiracy remains a significant challenge, as evidenced by historical cases involving neem, turmeric, and basmati rice. In each of these cases, multinational corporations attempted to secure patents over biological resources that had long been utilized by Indian farmers and traditional healers. These cases highlight the ethical imperative to ensure that bio patents operate within a framework of justice and sustainability, rather than serving as tools of corporate exploitation.

In the context of genetic research and bioethics, Institutional Review Boards (IRBs) and bioethics committees play a critical role in ensuring that genetic studies adhere to ethical principles such as informed consent, transparency, and accountability. In India, bioethical oversight is primarily exercised by the Indian Council of Medical Research (ICMR) and various institutional ethics committees responsible for reviewing research protocols. However, enforcement challenges persist due to inconsistencies in bioethical compliance across institutions, leading to cases where genetic materials have been patented without the knowledge or consent of research subjects or indigenous communities.

While the ICMR guidelines provide an ethical framework, their implementation remains fragmented, resulting in ethical lapses in research governance. Strengthening bioethical oversight through legally binding regulatory mechanisms, enhanced IRB powers, and stricter compliance measures is essential to prevent unethical genetic commodification.

The ethical implications of bio patents necessitate a robust alignment between national patent laws and international ethical frameworks. UNESCO's Universal Declaration on the Human Genome and Human Rights establishes an ethical precedent against the monopolization of genetic materials, while WHO's guidelines emphasize the importance of ensuring that IPRs do not create barriers to medical access. The CBD and Nagoya Protocol underscore the ethical

[32] Carmen Richerzhagen, "The Nagoya Protocol: Fragmentation or Consolidation?" 3 *Resources* 135 (2014), https://doi.org/10.3390/resources3010135.

Volume 3, Issue 2 ISSN 2582-743X

necessity of biodiversity conservation and equitable benefit-sharing, while bioethics committees and IRBs serve as crucial safeguards against unethical research practices.[33]

For India, aligning domestic patent laws with these international ethical principles is essential to fostering a just, equitable, and sustainable approach to bio patents. Ethical considerations must not be subordinated to economic and corporate interests but should be embedded within legal frameworks to ensure that genetic innovations serve humanity without violating fundamental rights to access, equity, and dignity.

[33] *Supra* note 14.