Biological Inventions and the Patent Regime: Balancing Innovation and Ethics

by

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Abstract

The rise of biotechnology has redefined the scope of patent law by enabling the manipulation and creation of biological materials. This paper investigates how legal systems worldwide have accommodated biological inventions within existing intellectual property frameworks. It assesses key international instruments and judicial decisions and explores the ethical concerns raised by the commodification of life forms, particularly those involving genetic material and indigenous knowledge. While patents incentivize innovation, they may also hinder access to essential medicines and promote biopiracy. This article proposes a more ethical, globally consistent patent regime by reinterpreting existing standards for inventiveness, applying morality clauses more rigorously, and encouraging alternative models of innovation. The legal recognition of biotechnological advancements must proceed without compromising fundamental rights and social equity. A calibrated and ethically anchored patent regime is essential for ensuring that life sciences serve the broader goals of justice, dignity, and sustainable development. The fusion of biotechnology and intellectual property has ignited a complex legal and ethical dialogue on the scope of patentable subject matter. Innovations such as genetically modified organisms, synthetic DNA, and engineered stem cells challenge conventional boundaries between discovery and invention. This manuscript explores how the patent regime has evolved to address biological inventions and how it must respond to emerging ethical concerns. Through an analysis of legal frameworks like the TRIPS Agreement, the European Patent Convention, and national laws, this paper interrogates how morality clauses, inventive thresholds, and access considerations can shape equitable and sustainable innovation. The study argues for reforming the patent system to better accommodate ethical diversity, encourage socially beneficial inventions, and prevent the monopolisation of life itself.

I. Introduction

Biological inventions now occupy a central role in global innovation, particularly in medicine, agriculture, and environmental sustainability. From genetically engineered crops to stem cell therapies, these breakthroughs push the boundaries of traditional intellectual property law. Historically, patent law was devised for mechanical and chemical inventions, but it now contends with the complex moral and legal questions raised by biotechnological discoveries.

Biotechnology stands at the forefront of transformative science. From CRISPR gene-editing technologies to genetically modified crops, biology has moved from observation to manipulation. These innovations not only promise revolutionary treatments and environmental solutions but also raise profound legal questions, particularly regarding intellectual property rights. The traditional patent regime was developed in an era of mechanical and industrial innovation; its adaptation to biological inventions is both a technical and moral undertaking.

The rapid commercialisation of genetic material has generated significant economic interest and legal disputes. Central to this debate is whether life forms, or parts thereof, are merely discovered or genuinely invented. If patent law grants exclusive rights to entities claiming biological material, this potentially commodifies life and undermines principles of human dignity and equity. Historically, inventions in patent law are human-made creations that are novel, non-obvious, and capable of industrial application. The notion of "patenting life" was once unthinkable. However, judicial and legislative developments, particularly since the 1980s, have reshaped what is considered patentable. Today, isolated genes, genetically modified organisms, and laboratory-grown tissues are all considered viable subject matter under many patent systems. The controversy begins with this legal acceptance. Critics question whether life—or components of it—should be commodified through patents. Do patents incentivise innovation or restrict access to essential technologies? Are morality clauses sufficient in regulating ethically contentious inventions? What is the impact on indigenous communities whose knowledge is often expropriated through bioprospecting?

This article explores the legal foundations of patent law as it applies to biological inventions, focusing on international and regional instruments, such as the TRIPS Agreement and the European Patent Convention (EPC). It also engages with ethical critiques of current practices, such as the privatization of human genes and the misappropriation of indigenous knowledge. Drawing from these perspectives, the article recommends legal and institutional reforms to promote innovation while safeguarding ethical values. This paper investigates the intersection

of biological science, patent law, and ethics. It explores key international agreements and domestic regulations, highlights leading cases, and evaluates ethical arguments. The study proposes a model patent system that balances legal innovation with moral responsibility and public interest.

II. Legal Framework of Biological Inventions

A. Defining Patentability in Biotechnology

Under most patent regimes, an invention must be novel, non-obvious, and industrially applicable. In biotechnology, determining whether a biological product meets these thresholds requires specific analysis. The European Union's Directive 98/44/EC allows patenting biological material that is isolated from its natural environment, even if previously existing in nature.[1] This has enabled patents over genes, cell lines, and genetically modified organisms (GMOs).

The US Supreme Court's ruling in *Diamond v Chakrabarty* marked a foundational shift. The Court held that a genetically modified bacterium was patentable because it was "a product of human ingenuity" and not a natural phenomenon.[2] This ruling expanded the scope of patent-eligible subject matter to include living organisms altered by humans.

B. The TRIPS Agreement

The TRIPS Agreement permits WTO members to exclude from patentability inventions that are contrary to "ordre public or morality,"[3] providing a legal foothold for national exceptions based on ethical considerations.

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes baseline global standards for intellectual property protection. Article 27(1) mandates that patents be available for "any inventions, whether products or processes, in all fields of technology," provided they are new, involve an inventive step, and are capable of industrial application.[4] This language includes biological inventions.

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[1] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13.

[2] *Diamond v Chakrabarty* 447 US 303 (1980)

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C, 1869 UNTS 299, art 27(2).

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C, 1869 UNTS 299, art 27(1).

However, Article 27(2) provides exceptions, allowing member states to exclude inventions from patentability where it is necessary to protect ordre public or morality. Article 27(3)(b) further allows exclusions for diagnostic, therapeutic, and surgical methods for treatment of humans or animals, and for plants and animals other than microorganisms.

Thus, TRIPS permits considerable discretion in ethical and public interest-based exclusions, allowing countries to adopt moral filters within their patent laws.

Beyond TRIPS, the Nagoya Protocol on Access and Benefit-Sharing (2010) complements the Convention on Biological Diversity by requiring countries to adopt measures ensuring fair sharing of benefits from the use of genetic resources.[5] While not a patent treaty, it influences IP frameworks by encouraging disclosure of origin and prior informed consent in patent applications involving biological materials.

C. European Legal Framework: The EPC and the Biotech Directive

The European Patent Convention (EPC) explicitly bars patenting inventions that are "contrary to ordre public or morality."[6] The scope and interpretation of this provision were clarified by Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech Directive).[7] This directive allows patenting of biological material isolated from its natural environment, including gene sequences, provided a specific industrial application is disclosed.

However, it also excludes certain subject matter: processes for cloning human beings, modifying the germ line genetic identity, and using human embryos for commercial purposes.[8]

In *Brüstle v Greenpeace*, the Court of Justice of the European Union ruled that an invention involving the destruction of human embryos was unpatentable, even for scientific or therapeutic purposes, reflecting a strict interpretation of morality exclusions.[9]

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[5] **Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) to the Convention on Biological Diversity** (adopted 29 October 2010, entered into force 12 October 2014) UN Doc UNEP/CBD/COP/DEC/X/1.

[6] European Patent Convention 1973, art 53(a)

[7] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13.

[8] ibid art 6.

[9] Case C-34/10 *Brüstle v Greenpeace* [2011] ECR I-09821.

Additional EU mechanisms, such as the Unitary Patent and the Unified Patent Court, aim to centralise and streamline patent enforcement but retain the ethical boundaries defined by the EPC and Biotech Directive.

D. The US Approach

In *Diamond v Chakrabarty*, the United States Supreme Court held that a genetically engineered bacterium was patentable subject matter, establishing that "anything under the sun made by man" could be patented.[10] This decision opened the floodgates for patenting living organisms and genetic material.

However, in *Association for Molecular Pathology v Myriad Genetics*, the Court later clarified that naturally occurring DNA sequences are not patentable, although synthetic complementary DNA (cDNA) is, as it does not occur naturally.[11] This established a boundary between discovery and invention.

E. Morality and Public Policy Exceptions

Article 53(a) of the EPC and Article 6 of the Biotech Directive prohibit patents for inventions that offend morality or public policy.[12] These provisions have served as legal checks against the unregulated patenting of life.

A leading case is *Brüstle v Greenpeace*, where the Court of Justice of the European Union held that inventions involving the destruction of human embryos for research purposes were unpatentable, regardless of scientific or commercial value.[13] The decision reinforced the moral limitations imposed on biotechnological patents.

Patent authorities like the European Patent Office (EPO) apply these principles through ethical assessments of controversial technologies, although critics argue that implementation is inconsistent and often swayed by economic interests.

F. Jurisdictional Differences and Policy Autonomy

While the EPC and TRIPS provide a common framework, countries retain discretion in applying moral exceptions. India's Patents Act excludes inventions contrary to public morality and prohibits patents on living organisms or biological processes for the production of plants

[10] *Diamond v Chakrabarty* 447 US 303 (1980).
[11] *Association for Molecular Pathology v Myriad Genetics, Inc.* 569 US 576 (2013).
[12] European Patent Convention 1973, art 53(a); Directive 98/44/EC, art 6
[13] Case C-34/10 *Brüstle v Greenpeace* [2011] ECR I-09821.

and animals.[14] Brazil similarly restricts patenting of parts of the human body and indigenous biological resources.[15]

Such policy autonomy enables legal systems to align IP law with constitutional and ethical values. However, it also creates inconsistencies that complicate global enforcement and technology sharing.

G. India: Emphasizing Access and Sovereignty

India has taken a rights-based and public health-driven approach to biotech patents, using TRIPS flexibilities to shape a robust domestic framework. Section 3 of the Indian Patents Act, 1970 excludes:

- Inventions "contrary to public order or morality" (s.3(b));
- The mere discovery of a living thing or non-living substance occurring in nature (s.3(c));
- Methods of agriculture or horticulture (s.3(h));
- Biological processes for production or propagation of plants and animals (s.3(j)).[16]

India's most globally discussed IP decision came in *Novartis AG v Union of India*, where the Supreme Court refused to grant a patent for a modified form of the cancer drug *Imatinib Mesylate*, on grounds that it did not meet the enhanced efficacy threshold under Section 3(d).[17] This case affirmed India's stance against "evergreening" and was hailed as a victory for access to affordable medicine.

India's Traditional Knowledge Digital Library (TKDL) is another innovation, compiling traditional medicinal knowledge to prevent misappropriation and unjust patenting of traditional formulations, especially by foreign applicants.

[14] Patents Act 1970 (India), s 3(b) and 3(j).
[15] Lei da Propriedade Industrial (Brazil), Law No 9.279/1996, art 10.
[16] **The Patents Act 1970** (India), ss 3(b), 3(c), 3(d), and 3(j).
[17] *Novartis AG v Union of India* (2013) 6 SCC 1 (SC).

H. Brazil and Latin America: Biodiversity as a Legal Priority

Brazil's legal system integrates IP with constitutional commitments to biodiversity and indigenous rights. Law No. 9.279/1996 (Industrial Property Law) explicitly prohibits patents on natural living beings, biological materials found in nature, and parts of the human body.[18]

Brazil has also implemented strict compliance mechanisms under the Nagoya Protocol. The Genetic Heritage Law (Law No. 13.123/2015) requires that users of genetic resources from Brazil obtain prior informed consent and share benefits with local communities.[19]

Other Latin American countries such as Bolivia and Ecuador have similarly emphasized the inalienability of biological wealth. Ecuador's Constitution (2008) recognizes nature (Pachamama) as a rights-bearing subject and rejects the commodification of biodiversity, influencing its approach to patent exclusions.

I. Japan and China: Balancing Commercial Growth with Cultural Norms

In Japan, the Patent Act allows patenting of microorganisms and isolated gene sequences if they meet industrial applicability requirements. However, the Japan Patent Office (JPO) excludes patents that are "liable to contravene public order, morality or public health," which has been interpreted to exclude human cloning and embryo-destructive processes.[20]

China's approach has evolved rapidly. The Chinese Patent Law (as amended in 2020) includes morality exclusions but provides broad patentability for gene sequences, GMOs, and medical biotechnologies. However, the Revised Guidelines for Patent Examination (2021) require specific disclosure and function claims for gene-related patents, and the government has strengthened regulations concerning human genome editing after the *He Jiankui* scandal.[21]

J. Emerging Trends in Global Patent Governance

Across jurisdictions, several trends are emerging:

1. Stronger morality scrutiny: Courts and legislatures are more willing to reject patents that raise ethical concerns, especially those involving human biology.

[18] **Lei da Propriedade Industrial (Industrial Property Law), Law No 9.279 of 14 May 1996** (Brazil), art 10.
[19] **Lei da Biodiversidade (Biodiversity Law), Law No 13.123 of 20 May 2015** (Brazil), arts 12 and 26.
[20] **Patent Act 1959** (Japan), art 32.
[21] *Patent Law of the People's Republic of China* (2020 amendment), art 5.

2. Benefit-sharing obligations: Biodiverse countries are increasingly demanding disclosure of genetic resource origins and prior informed consent.
3. Diagnostic patent uncertainty: Judicial retrenchment on diagnostic method patents, particularly in the US, has created legal uncertainty, potentially discouraging investment.
4. Synthetic biology and CRISPR dilemmas: With CRISPR-Cas9 technology, multiple parties hold overlapping patent claims, leading to "patent thickets" that complicate licensing and access.
5. Patent pooling and open licensing: Models like the Medicines Patent Pool and Open COVID Pledge suggest a move toward more collaborative and equitable innovation regimes.

The legal frameworks governing biological inventions demonstrate both convergence and divergence. While international instruments like TRIPS set a common baseline, the diversity in national implementation reflects broader socio-ethical values and policy goals. As biotechnology continues to challenge the legal imagination, patent systems must evolve—not only to protect innovation but to uphold public interest, equity, and the dignity of life itself.

III. Ethical Challenges in Patenting Life

A. Commodification of Human Genetic Material

Perhaps the most sensitive ethical issue in biotechnology patents is the treatment of human genetic material as property. The isolation and sequencing of genes, while scientifically significant, raise questions about the ownership of what many believe should remain part of the common heritage of humanity.

Lori Andrews and other scholars warn of a "body market" where human tissue, cells, and genetic data are monetised without adequate consent or regulation.[22] Though patents do not confer ownership of humans, they do provide control over their biological components, creating a framework that resembles commodification.

[22] Lori B Andrews, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (Crown 2001).

In *Myriad Genetics*, the US Supreme Court ruled that naturally occurring DNA sequences are not patentable, though synthetic cDNA can be.[23] This nuanced ruling recognises the distinction between discovery and invention, a vital ethical boundary in patent law.

Granting patents over biological materials raises the concern that life becomes commodified. While patents confer exclusive commercial rights—not ownership—they enable control over access, use, and profit from life-related inventions.

When genes or cellular lines are patented, researchers, clinicians, and even patients may face barriers to use. Critics argue that this violates human dignity and instrumentalises human biology. This is especially controversial when applied to embryonic stem cells or human tissue samples obtained without informed consent.

Bioethicists such as Lori Andrews contend that the commercialisation of human biological material contributes to a "body economy," where tissues and genetic codes are traded as proprietary commodities. This undermines the principle of autonomy and consent in biomedical ethics.

The commodification of biological materials through patenting raises fundamental ethical and philosophical questions. While patents confer exclusive commercial rights—not legal ownership of life—they effectively control the use, distribution, and benefit of biological entities and processes. This authority can have far-reaching implications for how human and non-human life is conceptualized and valued.

Informed consent is another critical concern. In the Moore v Regents of the University of California case, the court acknowledged that while the patient had no proprietary claim to his own cells once removed, the lack of informed consent in their commercial use raised legal and ethical red flags.[24] Such cases reveal a tension between scientific utility and individual rights.

Bioethicists such as Lori Andrews, Donna Dickenson, and Evelyne Shuster argue that the increasing commercialization of the human body fosters a "biomedical market" where tissue, genes, and reproductive materials are seen not as parts of persons, but as commodities to be

[23] *Association for Molecular Pathology v Myriad Genetics, Inc* 569 US 576 (2013).
[24] *Moore v Regents of the University of California* (1990) 793 P 2d 479 (Cal Sup Ct).

traded.[25] This undermines ethical principles of respect for persons, especially when materials are obtained from vulnerable populations without meaningful consent or benefit-sharing.

B. Biopiracy and Indigenous Knowledge

Biopiracy refers to the appropriation of biological resources and traditional knowledge from indigenous communities without permission or compensation. Patents based on indigenous knowledge—such as the healing properties of plants—often fail to acknowledge or benefit the original custodians of this knowledge.

Examples include patents on the neem tree and turmeric, both traditional remedies in India. These were eventually revoked after challenges, but the cases highlighted systemic flaws in the international IP system.[26]

The Convention on Biological Diversity (CBD) and the Nagoya Protocol aim to address these issues by requiring prior informed consent and fair benefit-sharing. However, enforcement remains weak, and traditional knowledge is still underrepresented in IP databases and patent examinations.

Biopiracy refers to the extraction of biological materials or traditional knowledge from indigenous communities without authorization or fair compensation. Patents are often granted on medicinal plants, traditional formulations, and agricultural practices long known to local populations.

The neem and turmeric cases in India are classic examples. Foreign entities filed patents for the antifungal properties of neem and the wound-healing properties of turmeric, despite their well-established traditional uses. Legal challenges led to the revocation of these patents, but only after extensive effort and mobilisation.

To address biopiracy, the Nagoya Protocol requires prior informed consent and equitable benefit-sharing for the use of genetic resources. However, patent systems in many jurisdictions still lack mandatory disclosure requirements about the origin of biological material, enabling continued exploitation.

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[25] Lori Andrews, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (Crown 2001); Donna Dickenson, *Body Shopping: Converting Body Parts to Profit* (OUP 2009); Evelyne Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337 *New England Journal of Medicine* 1436.

[26] Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press 1997).

Efforts such as India's Traditional Knowledge Digital Library (TKDL) and Peru's National Commission Against Biopiracy offer national-level responses. They catalog traditional knowledge to provide "defensive protection" against misappropriation. However, these efforts are reactive, and global patent systems still lack effective mechanisms for positive protection—that is, enabling indigenous communities to assert ownership or co-authorship over innovations derived from their resources or knowledge.[27]

The issue also intersects with broader concerns of cultural sovereignty, epistemic justice, and environmental ethics. Recognizing indigenous knowledge systems as legitimate and valuable requires a shift not just in law, but in the philosophy of innovation.

C. Access to Medicine and Social Equity

Patents can lead to monopolies that restrict access to affordable healthcare. This has been most evident in the context of antiretroviral drugs for HIV/AIDS and newer biologics for cancer and rare diseases. The high cost of patented drugs often places them out of reach for patients in low-income countries.

The Doha Declaration on the TRIPS Agreement and Public Health confirmed that IP rights should not interfere with access to essential medicines.[28]^11 It reasserted member states' rights to issue compulsory licenses and promote public health, especially during emergencies.

The COVID-19 pandemic further reignited debates about IP waivers for vaccines and diagnostics. Proponents of open licensing and public-private partnerships argue for a more equitable innovation system that does not sacrifice access for profit.

Patent monopolies can lead to unaffordable pricing for essential medicines, especially in developing countries. Pharmaceutical companies argue that high prices recoup research investments, but critics note that much foundational research is publicly funded.

The HIV/AIDS crisis in sub-Saharan Africa brought this issue into sharp focus, as patients were priced out of life-saving drugs. The Doha Declaration on TRIPS and Public Health affirmed that member states could use compulsory licenses to override patents in the interest of public health.

[27] Graham Dutfield, *Protecting Traditional Knowledge: Pathways to the Future* (UNCTAD-ICTSD 2006).
[28] WTO, *Declaration on the TRIPS Agreement and Public Health* (Doha, 2001), WT/MIN(01)/DEC/2.

Despite this flexibility, many countries face political pressure or lack the infrastructure to manufacture generics. Ethical concerns persist about the prioritisation of profit over human lives.

IV. Reforming the Patent Regime: Balancing Innovation and Ethics

A. Reinforcing Inventive Thresholds

To prevent the overreach of patent protection, legal systems should tighten the standard for inventiveness in biotechnology. Simply isolating or purifying a gene that exists in nature should not meet this threshold without significant human intervention.

The EPO requires a "technical contribution" beyond mere discovery. Similarly, judicial interpretations in *Myriad* and other cases reflect a growing recognition that patents must not encompass what nature has already provided.

B. Enhancing Morality Oversight

The EPC's morality clause and similar provisions in national laws must be applied more consistently. Ethics committees—composed of legal experts, scientists, and ethicists—could serve as advisory bodies to patent offices reviewing morally sensitive applications.

These committees could evaluate applications involving human embryonic material, indigenous knowledge, or biodiversity concerns. Their decisions, though not binding, could guide patent examiners in ethically fraught contexts.

C. Alternative Innovation Models

Innovation does not always require exclusionary rights. Open-source biotechnology, patent pools, and creative commons licensing offer alternative pathways to encourage research and product development.

The Human Genome Project exemplifies how publicly funded research and open data sharing can yield breakthroughs without patent exclusivity. The Open COVID Pledge invited companies to license relevant patents royalty-free during the pandemic, promoting rapid dissemination of technology.

Governments and multilateral institutions should support such models through funding, tax incentives, or preferential treatment in procurement processes. These strategies align innovation with global public interest, particularly in health and sustainability.

V. Conclusion

The legal treatment of biological inventions must reconcile the objectives of innovation with the imperatives of ethics and equity. While patents are vital for encouraging investment and research, their extension to life forms, genes, and traditional knowledge raises pressing moral concerns.

This article has shown that international frameworks like the TRIPS Agreement and the EPC already contain mechanisms—such as morality clauses and flexibilities—that allow for ethical regulation. However, the effectiveness of these mechanisms depends on political will, institutional capacity, and judicial interpretation.

Moving forward, patent regimes must emphasise genuine inventiveness, apply moral standards more rigorously, and explore alternative innovation systems that prioritise public welfare. The challenge is not merely legal but philosophical: to ensure that human creativity is rewarded without commodifying life itself.

In an era where science advances rapidly, legal systems must act as ethical anchors. A reformed, inclusive patent system—sensitive to both innovation and integrity—is essential for ensuring that biotechnology contributes to a just and sustainable future.

Patents on biological inventions walk a fine line between incentivizing research and enclosing elements of life within legal monopolies. While the patent system has adapted to accommodate advances in biotechnology, it must now evolve to accommodate ethical pluralism and social justice.

This paper has shown that existing frameworks like TRIPS and the EPC provide sufficient legal grounds for regulating unethical or inequitable patents. However, enforcement, interpretation, and institutional support remain lacking. Reform efforts should aim to:

(1) refine the inventive step requirement;

(2) enforce morality exclusions;

(3) mandate disclosure of genetic resources; and

(4) encourage open innovation.

Biotechnology holds the promise of solving critical global challenges—from disease to climate change—but only if governed wisely. The patent regime must be recalibrated not to stifle innovation, but to ensure that its fruits are shared ethically and equitably.