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Balancing Innovation and Ethics: An Analysis of the Patenting of Human Genetic Material

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CHAPTER 13

Balancing Innovation and Ethics: An Analysis of the Patenting of Human Genetic Material

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The rapid growth of biotechnology, especially in the area of human genetics, has brought forth significant scientific progress while also raising serious ethical and legal concerns. Developments such as genetic engineering and CRISPR gene editing have expanded the limits of traditional patent systems, particularly when it comes to determining whether human genetic material qualifies as an invention. This phenomenon creates a continuous conflict between promoting innovation and protecting fundamental ethical values. This paper examines how Indian patent law aims to maintain this balance. It analyses the key legal provisions and judicial interpretations that restrict the patenting of naturally occurring genetic material, while still recognising the possibility for scientific advancement. In order to understand India's position, the paper compares it with the approaches that are being followed in the United States and the European Union, where the courts have taken different views on the patentability of genetic material. The paper uses a qualitative research method, where it analyses the relevant literature, case laws and statutory frameworks to identify the existing gaps and challenges that can arise in this area of study. It focuses on important issues such as the difference between discovery and invention, the ethical concerns surrounding the commercialisation of human biology, and the broader impact it has on the access to healthcare and research. Overall, this paper highlights the importance of establishing a more balanced and ethically conscious patent framework. The paper argues that while innovation is important and should be encouraged, it should not come at the cost of human dignity or the larger public interest.

Keywords: Biotechnology Patents, CRISPR, Ethics, Human Genetic Material and Section 3

1 INTRODUCTION

The intersection of biotechnology and intellectual property law has emerged as one of the most debated topics in this area of study. As the science in today's world is advancing rapidly, the legal system can struggle to keep pace.¹ This is especially clear in human genetics, where this conflict is not just commercial but also closely tied to personal, philosophical,

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¹ Bao Tran, *The Intersection of Biotechnology and Patent Law*, PATENTPC, <https://patentpc.com/blog/the-intersection-biotechnology-patent-law> (last visited Apr. 15, 2026).

and medical factors. When a researcher isolates a gene sequence linked to a hereditary disease, a lot of questions arise as to whether that is an invention or a discovery. Can a corporation own a piece of human biology? These are real questions that are asked worldwide about the same issue. We all know that patents aim to encourage invention by granting exclusive rights, but applying them to human genes or embryos raises concerns about human dignity and public welfare, where the tension arises between the ethical considerations and legal protection. This paper aims to explore how the patent systems can balance two important things, that is, the need for innovation along with the ethical safeguards.

2 STATEMENT OF PROBLEM

The main problem that the paper is aiming to identify and address is in the patenting of human genetic material, where there is a regulatory gap that is created. Traditional patent laws are drafted in a way that does not have the ability to address the daily advancements and complexities that are present in human genetics or living organisms, *per se*. The paper more importantly looks into India's approach towards this issue and tries to attempt a comparison of the approaches that are taken by other different jurisdictions, which are the United States and the European Union, in the context of human genetic material, which is distinct from the broader aspect of biotechnological patents.

3 SCOPE AND LIMITATION

The paper mainly focuses on the Indian aspect of the research gap, and that is in comparison with the jurisdictions of the United States and the European Union. These jurisdictions have important patent law models that have different approaches on the patents granted for genetics. The approaches that are taken are evident such as the Indian law specifically under Section 3 provides a set of standards, while the U.S. does it through Supreme Court rulings and EU does it through the Biotech Directive and cases from the European Patent Office. The paper's scope is only limited to these jurisdictions and does not cover a global perspective. The paper does not focus on empirical research and relies mainly on doctrinal research.

4 RESEARCH OBJECTIVE

The paper has two main objectives and they are:

- i. To analyse the Indian patent law that is dealing with the human genetic material, with the help of legal provisions and judicial interpretations.

- ii. To compare the above Indian approach with the U.S. and EU jurisdictions, showing how different jurisdictions handle the same issue.

By doing this, the paper will be able to analyse as to whether the current frameworks are able to create the balance between the concepts of innovation and the ethical concerns.

5 RESEARCH METHODOLOGY

The research that is done in this paper is a doctrinal study, where it looks into the doctrinal analysis of the patent law, case laws and articles, to understand what the legal stance is on the issue of biotechnology patent. Additionally the paper looks into other jurisdictions to have a better understanding on how different jurisdictions treat genetic patents.

6 LITERATURE REVIEW

6.1 Biotechnology and Intellectual Property Rights in India: Legal Framework, Challenges and Emerging Jurisprudence²

If you look into this article, it offers a thorough examination of the Indian patent law framework as it applies to biotechnology, with a particular focus on the Section 3 exclusions under the Patents Act, 1970. The paper traces the evolution of Indian patent law from its initial exclusion of living organisms to the more expansive position it has taken post-2002, highlighting the pivotal role that was played by the case of *Dimminaco AG* in recognising the patentability of the processes that involve living organisms. The paper clearly analyses each relevant sub-section of Section 3 and provides a clear explanation as to how these provisions function in practice. The paper however does not deeply delve into the concept of human genetic material patent, this is because it is far distinct from the broader biotechnology patent.

6.2 Biotechnology Patents: Untangling the Double Helix of Innovation, Ethics and Legal Challenges³

Now, this article provides a deep analysis on the ethical and legal tension that can arise in the biotechnology patents, and the paper is structured in such a way that it includes several concepts such as the doctrine of product of nature, moral utility doctrine, property rights theory, and the concept of the sacredness of life. The paper also looks into the landmark

² Anandhi A., *Biotechnology and Intellectual Property Rights in India: Legal Framework, Challenges and Emerging Jurisprudence*, 3 LAWFOYER INT'L J. DOCTRINAL LEGAL RSCH. 645 (2025).

³ Suhana, *Biotechnology Patents: Untangling the Double Helix of Innovation, Ethics and Legal Challenges*, 9 J. INTELL. PROT. STUD. 97 (2025).

Diamond v. Chakrabarty decision to understand the approach that was taken in this case. The paper has not examined the position of India in the treatment of the cases when it comes to the discovery-invention distinction under Indian law.

7 BASICS OF HUMAN GENETICS

7.1 Meaning of Human Genetic Material

Genetic material basically refers to the biological information that is encoded in the DNA and RNA of living organisms. In human beings, this information is organised into 20,000 to 25,000 genes that are distributed into 23 pairs of chromosomes. Each of the genes carries the instructions for producing the proteins in the body that perform a specific biological function. The identification, isolation, and manipulation of these genes is the base of modern biotechnology.⁴

In the context of the patent law, human genetic material becomes very much significant when it is being isolated from its natural environment and is characterised through the laboratory methods. But this gives rise to the very question as to whether such an isolated material can constitute an ‘invention’ or is just a ‘discovery’ which is already existing in nature, and this has been the central issue for many debates.⁵

7.2 Distinction between Discovery and Invention

The patent frameworks worldwide are all based on the principle that patents are there to protect the inventions and not the discoveries as such. A discovery is the identification of something that is already existing, while an invention is something that is created and is new. The distinction between these two can be said to be easy to understand in the general sense, but when it comes to the field of genetics this general principle becomes very much complicated.

Under the Indian Patents Act, 1970, Section 2(1)(j) basically defines what an ‘invention’ is and states that it is a new product or a process that is involving an inventive step and is capable of industrial application.⁶ And it must be noted that Section 3(c) explicitly excludes from patentability “the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.”⁷

⁴ NAT'L HUM. GENOME RSCH. INST., <https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics> (last visited Apr. 16, 2026).

⁵ <https://pmc.ncbi.nlm.nih.gov/articles/PMC2220019/>.

⁶ The Patents Act, 1970, § 2(1)(j).

⁷ *Id.* § 3(c).

Both of these sections together mean that a naturally occurring gene sequence, even if it was previously unknown to science, cannot be patented in India simply because it has been identified and isolated.

However, when a gene sequence is modified, engineered, or expressed in a novel context through human intervention, the position becomes more nuanced. Complementary DNA (cDNA), for instance, is synthesised in the laboratory from messenger RNA and does not occur in nature in the same form.⁸

7.3 International Agreements

The TRIPS Agreement requires member countries to grant patents for biotech inventions, but it does allow exclusions for plants, animals, and essentially biological processes. It also permits exceptions based on public order or morality. India has used these flexibilities to exclude genetic sequences from patentability, treating them as natural phenomena under Section 3 of its Patents Act. The 2024 WIPO Treaty on Genetic Resources and Traditional Knowledge introduces a mandatory disclosure requirement for patent applicants. However, the treaty has serious weaknesses. Under Article 5.3, a patent cannot be invalidated solely because the applicant failed to disclose something. Article 3.5 also prohibits patent offices from having any verification obligations.⁹ This is a concern for India, which already has strong domestic provisions under Sections 25 and 64 of its Patents Act, allowing pre-grant and post-grant opposition based on disclosure. And it must be noted that signing this treaty could actually weaken India's existing legal safeguards.

8 THE TENSION BETWEEN ETHICAL AND LEGAL ASPECTS OF HUMAN GENE PATENTING

8.1 The Concept of Ethics

The patenting of human genetic material raises one of the most extreme ethical questions that a legal system can address. At its core, the main objection is very simple, that is, can something that is intrinsic to human biology, such as a gene that exists within every person who carries it, really become the exclusive property of a corporation or research institution? Many scholars argue that gene patents amount to a form of commodification of the human body, which in some respects is comparable to the commodification of persons that the law rightly prohibits. This objection is expressed through several theoretical frameworks. The

⁸ Ramya Nagaraj, *Intersection of Biotechnology and Patent Law in India: A Critical Study on the Impact of Human Genetics Innovation*, 7 INT'L J.L. MGMT. & HUMAN. 1286 (2024).

⁹ WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, May 24, 2024, GRATK/DC/7.

doctrine of the sacredness of life holds that life forms possess an inherent dignity that is incompatible with the logic of ownership.¹⁰

In the Indian context, this can be strongly related to the cultural and religious traditions that regard that human beings cannot be used for commercial appropriations.¹¹

Gene patents incentivise the enormous investments that are required to sequence, isolate, and characterise genetic material, and to develop diagnostic tests and therapies based on that material. Without patent protection, researchers argue, the market would fail to produce the information and tools that can improve human health.¹² This is the central tension within India's patent regime and also highlights the tension between TRIPS compliance and global competition versus ethical values, biodiversity, and farmers' rights.

John Locke's labour theory of property offers something like a middle path. If a researcher has put in significant intellectual and physical effort to isolate and characterise a gene sequence that would otherwise have remained hidden from medicine, there is a reasonable argument that they deserve some form of exclusive right over that specific product of their labour.¹³ The problem is that this argument proves too much. It would justify patents on almost any isolated natural substance, no matter whether any genuine creative contribution has been made beyond simply identifying what nature had already produced.

8.2 Public Health Access

One of the most significant consequences of human gene patents is their impact on access to healthcare. When a single entity holds a patent over a gene associated with a particular disease, it acquires the power to control the use of that gene in diagnostic testing and treatment. This can result in dramatically higher costs for patients and reduced availability of testing in lower-income settings.

The controversy involving *Myriad Genetics* in the United States clearly exemplified this issue. Myriad held patents over the BRCA1 and BRCA2 genes, mutations in which are strongly associated with hereditary breast and ovarian cancer. The company's monopoly over these genes meant that it could set prices for BRCA testing at levels that were unaffordable for many patients, and it could also prevent other laboratories from developing competing tests. It was only when the US Supreme Court struck down patents on naturally occurring DNA sequences in 2013 that these barriers were lifted.¹⁴

¹⁰ Suhana, *supra* note 3, at 101–02.

¹¹ Anandhi A., *supra* note 2, at 670.

¹² *Id.* at 668–69.

¹³ Suhana, *supra* note 3, at 101.

¹⁴ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 585–86 (2013).

So any legal framework that uses monopoly rights over human genetic material to restrict access to essential diagnostic tools or treatments must be judged against this constitutional standard. The 2013 *Novartis case*, while it dealt with pharmaceutical patents rather than gene patents directly, set an important precedent. Patent protection must not compromise public health access, and this principle applies just as strongly to the genetic context as well.¹⁵

8.3 CRISPR and New Technological Advancements

The rise of CRISPR-Cas9 gene editing technology has added a new layer of complexity to the already persisting issues. CRISPR allows scientists to make precise, targeted modifications to DNA sequences with a speed and accuracy that earlier techniques could not achieve. It has applications ranging from the correction of genetic disorders in human embryos to the enhancement of agricultural crops and the development of novel therapeutic agents.¹⁶

In India, CRISPR-based inventions raise particular challenges and certain questions. If the technique is used to edit a naturally occurring human gene sequence, does the resulting modified sequence constitute an invention? If so, what degree of modification is required to cross the threshold from discovery to invention? The existing framework under the Patents Act does not provide clear answers to these questions, and the ICMR's ethical guidelines, while prohibiting germline modification and the creation of designer babies, do not address the patent law implications of CRISPR research in somatic cells.¹⁷

9 JUDICIAL INTERPRETATIONS

9.1 Indian Judicial Interpretations

The Indian patent framework, particularly post-2005, has developed a unique character defined by stringent thresholds for patentability, especially concerning life forms and incremental pharmaceutical innovations. Indian case law shows a judicial effort to clarify the limits of Section 3 of the Patents Act, 1970, which outlines certain exceptions to patentability.

¹⁵ *Novartis AG v. Union of India*, (2013) 6 SCC 1.

¹⁶ Sahar Ebrahimi, Mohammad Ali Khosravi, Abbasali Raz, Morteza Karimipoor & Parviz Parvizi, *CRISPR-Cas Technology as a Revolutionary Genome Editing Tool: Mechanisms and Biomedical Applications*, 27 IRAN. BIOMED. J. 219, 219–46 (2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10707817/>.

¹⁷ Pallabi Bhattacharyya, Kanikah Mehndiratta, Souvik Maiti & Debojyoti Chakraborty, *Rare Genetic Disorders in India: Current Status, Challenges, and CRISPR-Based Therapy*, 49 J. BIOSCI. 28 (2024), <https://www.ias.ac.in/article/fulltext/jbsc/049/0028>.

9.1.1 *Dimminaco A.G. v. Controller of Patents and Designs*

The first significant judicial pronouncement on the patentability of processes involving living organisms came from the Calcutta High Court in *Dimminaco AG v. Controller of Patents and Designs* (2001).¹⁸ The case involved a patent application for a process to prepare a live vaccine for Bursitis infection in poultry. The Patent Office rejected the application on the ground that the end product contained a living virus and was therefore not a “manufacture” or a vendible substance. Reversing this decision, the High Court held that the term ‘manufacture’ should be interpreted pragmatically. If the process results in a commercially valuable product that can be bought and sold it qualifies as patentable subject matter, regardless of whether it contains living material. This decision established a foundational precedent: the presence of life per se is not a bar to patentability under Indian law if human technical ingenuity has produced a useful commercial product.

9.1.2 *The “Human Intervention” Test and Essentially Biological Processes*

A more recent and direct application of the “human intervention” standard can be found in the Madras High Court’s 2024 decision in *Sakata Seed Corporation v. Deputy Controller of Patents and Designs*.¹⁹ This case addressed the exclusion for “essentially biological processes” under Section 3(j). Sakata had developed a method for producing a cytoplasmic male sterile Eustoma plant through a process of backcrossing and screening. The Controller rejected the application, deeming the backcrossing method an essentially biological process. The High Court overturned the rejection, holding that the claimed invention was not a mere natural phenomenon. The court noted that the process involved specific human interventions that were decisive for the final result. By relying on the European Patent Office’s definition of an essentially biological process, the court found that the technical human steps moved the invention beyond the scope of the Section 3(j) exclusion. This judgment provides crucial clarity for plant and genetic innovations in India, confirming that if a claimed method involves a non-trivial technical step by a human actor, it is not excluded.

9.1.3 *The “Therapeutic Efficacy” Standard*

The landmark Supreme Court decision in *Novartis AG v. Union of India* (2013) provides the definitive interpretation of the enhanced efficacy requirement under Section 3(d).²⁰ While this case concerned a pharmaceutical compound (the beta crystalline form of Imatinib Mesylate), its reasoning is directly applicable to any patent claim over a “new form

¹⁸ *Dimminaco A.G. v. Controller of Patents & Designs*, AID No. 1 of 2001 (Cal. HC Jan. 15, 2001).

¹⁹ *Sakata Seed Corp. v. Deputy Controller of Patents & Designs*, (I)CMA(PT) No. 122 of 2023 (Mad. HC Jan. 2024).

²⁰ *Novartis AG v. Union of India*, (2013) 6 SCC 1.

of a known substance,” which could include modified or isolated genetic sequences. The Court held that the term “efficacy” in Section 3(d) must be interpreted as “therapeutic efficacy”, which basically means the capacity of the substance to produce a desired or intended beneficial change in the patient. Novartis’ claimed invention offered improved flow properties and thermodynamic stability but did not demonstrate enhanced therapeutic benefit over the known form of the drug. Consequently, the patent application was rejected. This ruling establishes a significantly higher bar for incremental innovations in India compared to the United States or Europe. For human genetic material, this suggests that merely isolating a gene or creating a structurally modified variant (e.g., a new crystalline form of a protein) may not be patentable unless the applicant can demonstrate a genuine improvement in its therapeutic function.

9.2 United States Judicial Interpretation

In contrast to India’s detailed statutory exclusions, United States patent law is governed by the broad language of 35 U.S.C. § 101, which provides for the patentability of “any new and useful process, machine, manufacture, or composition of matter.”²¹

9.2.1 *Diamond v. Chakrabarty*

The foundational case for biotechnology patents in the United States is the Supreme Court’s 1980 decision in *Diamond v. Chakrabarty*.²² The Court was tasked with determining whether a genetically engineered bacterium capable of breaking down crude oil was patentable. In a landmark ruling, Chief Justice Burger famously declared that the distinction is between natural products, whether living or inanimate, and human-made inventions. The Court held that Chakrabarty’s bacterium was a non-naturally occurring manufacture or composition of matter and was a product of human ingenuity. This decision expanded the view on genetically modified organisms, cell lines, and, eventually, isolated human genes.

9.2.2 *Property Rights and the Human Body*

A crucial ethical counterpoint to the expansive patentability doctrine was provided by the Supreme Court of California in *Moore v. Regents of the University of California* (1990).²³ John Moore’s physician had used his spleen cells to create a valuable, patented cell line without his informed consent regarding the commercial use. The court held that Moore had no property right in his excised cells, a decision intended to avoid hindering socially important medical research. However, the court simultaneously ruled that physicians have a fiduciary

²¹ 35 U.S.C. § 101.

²² *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

²³ *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120 (1990).

duty to disclose any research or economic interests they may have in a patient's biological materials. This case embodies a balance which is basically facilitating the commercialization of human tissue for innovation but imposes strict informed consent requirements as an ethical safeguard.

9.2.3 *Mayo v. Prometheus and Myriad Genetics*

The expansive framework that was set in the case of Chakrabarty was significantly curtailed by a pair of Supreme Court decisions in the 2010s. First, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012), the Court invalidated patents on a method for optimizing drug dosage based on metabolite levels in the blood.²⁴ The Court reasoned that the correlation between metabolite levels and drug efficacy was an unpatentable law of nature, and the additional steps (administering the drug and measuring the metabolites) were merely routine and conventional activities. And in order to be patent-eligible, a claim that incorporates a law of nature must add "significantly more" than an instruction to "apply it."

This principle was applied directly to human genes one year later in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013).²⁵ Myriad had secured patents on the isolated BRCA1 and BRCA2 gene sequences, giving it a monopoly on diagnostic testing for hereditary breast and ovarian cancer. The Supreme Court unanimously held that a naturally occurring DNA segment is a product of nature and is not patent-eligible merely because it has been isolated. The Court drew a critical distinction, however, holding that complementary DNA (cDNA), which is synthesised in a laboratory from mRNA and is not naturally occurring, is patent-eligible. The Myriad decision had an immediate and profound public health impact, dismantling Myriad's testing monopoly and lowering costs for patients, but it left open many questions regarding the patentability of other modified genetic materials and diagnostic methods.

9.3 European Union Judicial Interpretation

The European approach, embodied in the European Patent Convention (EPC) and the EU Biotechnology Directive (98/44/EC), represents a middle path.

9.3.1 *Monsanto Technology LLC v. Cefetra BV*

The scope of protection afforded by a gene patent in the EU was clarified by the European Court of Justice (ECJ) in *Monsanto Technology LLC v. Cefetra BV* (2010).²⁶ Monsanto held a European patent for Roundup Ready (RR) soybeans. When soy meal produced from

²⁴ *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012).

²⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

²⁶ *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. I-06765.

RR soybeans in Argentina (where no patent protection existed) was imported into the EU, Monsanto sued for infringement. The ECJ, interpreting Article 9 of the Biotech Directive, held that a patent on genetic information only extends to material in which the DNA “performs its function.” Because the DNA in the processed soy meal was “dead material” that no longer performed its function of herbicide resistance, there was no infringement. This judgment represents a significant policy choice to limit the downstream reach of gene patents on commodity products, thereby protecting trade and food security.

9.3.2 *Harvard Oncomouse*

The European Patent Office (EPO) has developed a sophisticated “balancing test” to assess the morality exclusion under Article 53(a) EPC. In the *Harvard Oncomouse* case, the EPO granted a patent for a transgenic mouse genetically engineered to be susceptible to cancer.²⁷ The Board of Appeal reasoned that the immense potential medical benefit of having a reliable animal model for cancer research outweighed the ethical concerns regarding animal suffering. Conversely, in a later case concerning a transgenic mouse for hair loss research, a patent was denied on the grounds that the limited medical benefit could not justify the animal suffering involved.

9.4 Comparative Analysis

The judicial approaches of India, the United States, and the European Union reveal fundamentally divergent philosophies toward human genetic patenting. Indian courts, guided by Section 3 of the Patents Act, have adopted the most restrictive stance. The *Dimminaco* decision established that living organisms could be patented only where human intervention produces a commercially valuable product, while *Sakata Seed* reinforced the “human intervention” test for biological processes. The *Novartis* ruling further tightened standards by requiring demonstrated “therapeutic efficacy” for incremental innovations, creating a substantially higher threshold than Western jurisdictions.

The United States initially embraced expansive patentability through Chakrabarty’s “anything under the sun made by man” doctrine, but the Supreme Court dramatically reversed course in *Mayo* and *Myriad*, holding that isolated naturally occurring DNA sequences are unpatentable products of nature. The Court preserved patentability only for synthetic cDNA, reflecting a belated recognition of ethical concerns.

The European Union occupies a middle ground. Through the Biotech Directive and EPO decisions like *Harvard Oncomouse*, EU jurisprudence employs a utilitarian balancing test weighing medical benefits against ethical costs. The *Monsanto* decision further limited

²⁷ Case T 0019/90, *Harvard/Onco-mouse*, [1990] O.J. EPO 476.

gene patent scope by requiring that patented DNA “perform its function” for infringement to occur. Collectively, these jurisdictions demonstrate an evolving global consensus toward restricting genetic patentability while preserving incentives for genuine biotechnological innovation.

10 CONCLUSION AND RECOMMENDATIONS

This paper has demonstrated that the patenting of human genetic material occupies a precarious intersection between incentivising scientific progress and safeguarding fundamental ethical values. India’s statutory framework, particularly Sections 3(c) and 3(j) of the Patents Act, provides robust exclusions against patenting naturally occurring genetic sequences. Judicial interpretations in *Dimminaco*, *Sakata Seed*, and *Novartis* have further clarified that only inventions involving substantial human intervention and demonstrated therapeutic efficacy merit protection. However, significant regulatory gaps persist, particularly concerning CRISPR-based technologies and the precise threshold at which modified genetic material becomes patentable subject matter.

The comparative analysis reveals that while the United States has retreated from its historically permissive *Chakrabarty* era through *Myriad* and *Mayo*, and the European Union maintains a calibrated balancing approach, India’s framework offers stronger ethical safeguards but lacks clarity regarding emerging biotechnologies. The 2024 WIPO Treaty on Genetic Resources, despite introducing disclosure requirements, contains concerning limitations under Articles 3.5 and 5.3 that could potentially weaken India’s existing domestic safeguards.

Based on these findings, the following recommendations are proposed:

First, the Indian Patent Office should issue comprehensive guidelines specifically addressing CRISPR-related inventions, establishing clear thresholds distinguishing unpatentable discoveries from patentable human interventions.

Second, Parliament should consider amending Section 3 to explicitly address synthetic biology and gene-editing technologies, ensuring the law keeps pace with scientific advancement.

Ultimately, the patent system must remain a servant of human welfare rather than an impediment to it. Innovation deserves encouragement, but never at the cost of commodifying human biology or restricting access to life-saving diagnostics and treatments.

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