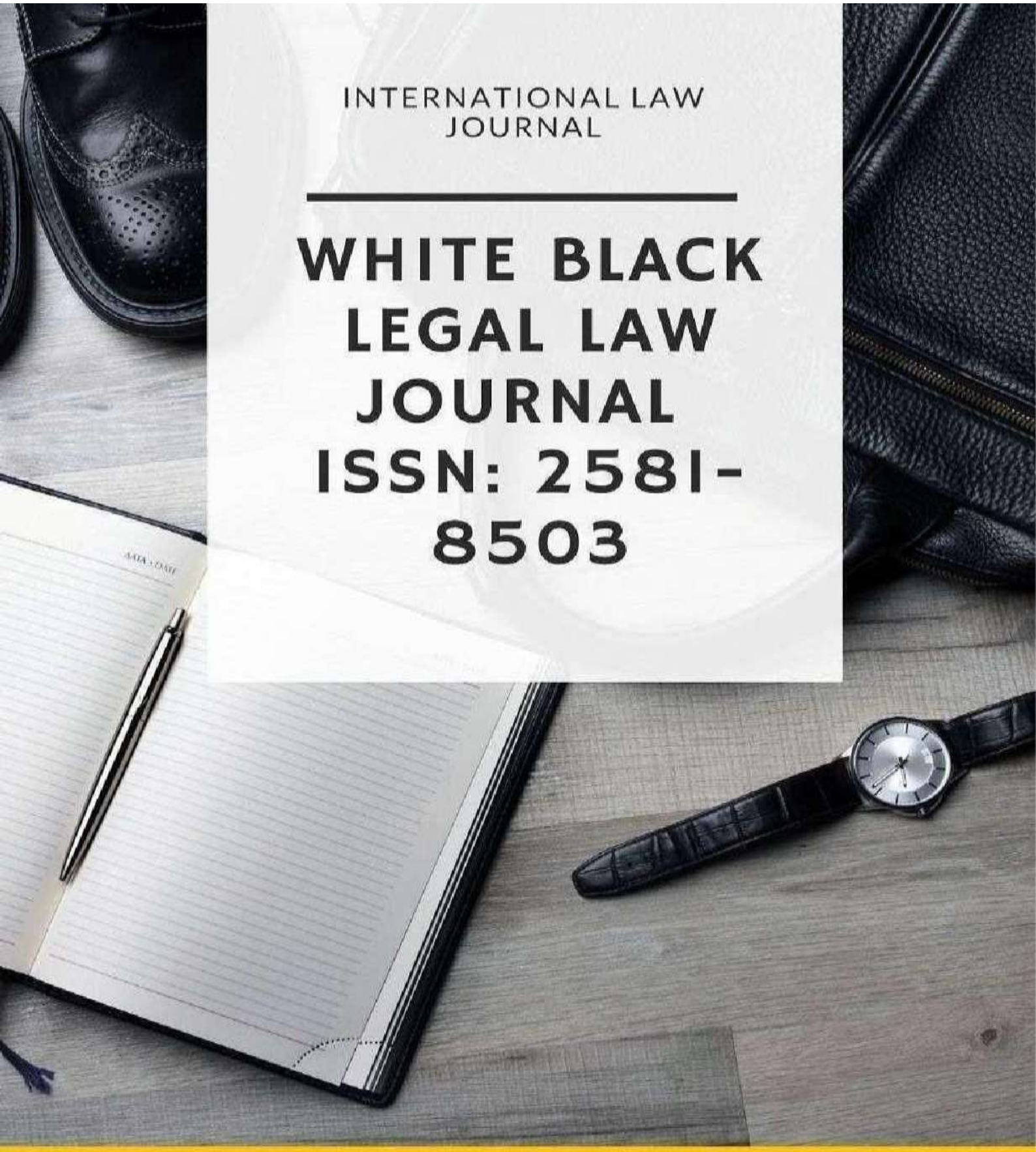

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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

THE INTERSECTION OF LAW, ETHICS, AND BIOTECHNOLOGY: REGULATING PATENTS ON LIVING ORGANISMS

AUTHORED BY - HIMANI TAK,
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ABSTRACT

The patent regime heralds an expansion of its protective umbrella to the emerging field of biotechnology, the full implications of which are only now becoming apparent. With the revolutionary and rapid growth of industry, new legal and ethical issues have emerged that necessitate meticulous and concerned deliberation. This paper explores the evolution of patenting life in the United States, Europe, and India. Additionally, the implications of each country's impact on the international patent regime in light of the TRIPS Agreement are examined. The paper also investigates the feasibility of providing similar statutory protection to living organisms manufactured with significant human intervention in India, which has so far seen a low volume of patent applications for 'utility patents'.

INTRODUCTION

In essence, a patent is a legal right that grants the patent holder the exclusive ability to commercially exploit their invention. Nevertheless, it is important to note that a patent does not inherently grant authorisation to utilise or commercialise the invention; marketing approvals must be obtained separately. A patent grants exclusive rights for a specified duration and serves as a legal method to restrict competition. The purpose of the limitation period for the monopoly is to incentivise the inventor while ensuring a fair balance between the rights of the individual and those of society.[1] It is important to recognise that patents are often disputed as a means of providing motivation for innovation and ensuring essential investment in production, marketing, and research and development (R&D).[2] Despite facing significant opposition, patent laws, which are integral to the traditional

[1] "Panel Report, Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (2000)."
[2] "Patents are often viewed as instrument of economic policy aimed at rewarding the inventor, Straus Joseph, Biotechnology and Patents, 54 CHIMIA 293 (2000)."

intellectual property rights (IPR) system, have deep national origins and are subject to additional domestic legislation.

The fundamental factors for establishing patent eligibility are novelty and practical use. The distinction between a discovery and an invention hinge on the presence of novelty, a concept that has long been emphasized in the application of the 'product of nature doctrine' in the United States and other nations. This doctrine has played a significant role in prohibiting the patenting of living organisms.

Bio-patents, which refer to patents granted on living matter such as microorganisms, genetically modified species, genes, and cell lines, are subject to different degrees of patentability across countries. The process of patenting new life hinges on the distinctions between its characteristics and uses compared to known substances. The question of whether merely isolating a microorganism or gene from its natural environment warrants a patent varies by country. In the United States, for instance, compounds that are "isolated and purified" are deemed eligible for patent protection if they meet the necessary patentability requirements. However, it is important to note that a gene patent only extends to the isolated and purified form, not the gene in its natural state. However, in the European Union, "biological material isolated from its natural environment or produced by means of a technical process, may be the subject of an invention, even if it previously occurred in nature."[3] However, regardless of the specific country's standards for granting a patent on living matter, it is clear that this is a delicate and often contentious issue.

In the midst of the legal discourse, a number of pressing public health issues have been brought to light in relation to the authorization of patents for biomedical studies. Numerous experts argue that the patenting of human gene sequences could potentially hinder advancements in medical treatments and research, while also creating a significant strain on the judicial system.

[3] "EU: Directive 98/44/EC, Art. 3.2."

RESEARCH OBJECTIVES

- To analyse the ethical, moral, and public health implications associated with the patenting of life forms.
- To study jurisprudence on life forms of United States of America and Europe to understand their compliance with and impact on the international patent regime, particularly in light of the TRIPS Agreement.
- To examine the evolution and current state of patent laws concerning life forms in India
- Recommend strategies to harmonise patent rights, public interests, and ethical concerns in biotechnological patenting practices.

RESEARCH QUESTIONS

- What are the ethical, moral, and public health considerations that arise from the patenting of life forms, and how do these affect the current patent framework?
- How does the jurisprudence on life form patents in the United States and Europe align with the TRIPS Agreement, and what impact does this have on the international patent regime?
- In what ways have patent laws concerning life forms evolved in India, and what is the current state of these laws in relation to biotechnological advancements?
- What strategies can be developed to harmonize the interests of patent holders with public and environmental concerns, ensuring ethical biotechnological patenting practices?

LITERATURE REVIEW

1) *Patenting life: Biotechnology, intellectual property and environmental ethics by Hettinger N*

The author in this article talks about the development of Biotechnology Patents, its evolution, benefits, significance and the rationale behind protecting of such innovations.

2) *DNA Patenting and Access to Healthcare: Achieving the Balance among Competing Interests by Melissa E. Horn*

The author in this article talks about relevance of Human Gene Patenting and the public Interests involved in it.

3) *The debacle of Novartis patent case in India: Strict interpretation of patentability criteria under Article 27 of the TRIPS Agreement by Dr Raju K D*

The jurisdiction of a national court to test the validity of a provision in an international agreement in the light of the Novartis case has been discussed.

4) *Biotech Patents: Equivalency and Exclusions under European and US Patent Law by Li Westerlund*

The article examines the clash between biological and technological realities with legal approaches and concepts.

Bio-Patents: The Ethical and Moral Dilemmas

The question of patenting living entities, including organisms, cells, and tissues, goes beyond mere legalities. It delves into a complex clash of interests, ideas, concepts, and worldviews. Consequently, the ensuing obstacles transform the matter into a moral deliberation above all else.[4] A discussion of moral and legal debates follows, which are regarded as critical moot points under bio-patent regimes.

The 'Invention versus Discovery 'debate

A major issue that has consistently irritated anti-bio patent advocates is whether an organism or a living end product produced by essentially using a naturally occurring product can be argued to be more than a mere discovery and thus granted patent protection as a 'novel invention'. The question is a fundamentally important issue that must be determined as a mere discovery in all patent law regimes, but it has never been protected by the patent umbrella.

The only definitive conclusion in such a debate is whether there has been enough human intervention to create an organism distinct and independent of the one that existed before. Bio-patents are permitted under almost all patent regimes that are directly or indirectly affiliated with the TRIPS Agreement or derive a significant portion of their municipal law from it. The argument that the subject matter is 'products of nature' has been dismissed as archaic, obsolete, and thus untenable. However,

[4] "Hettinger N, Patenting life: Biotechnology, intellectual property and environmental ethics, Boston College Environmental Law Review (1994-1995, 267 2022)."

caution should be exercised when dealing with patent laws. An excessive grant of 'utility patents' to living organisms and related structures can often raise ethical concerns.

The Issue of Informed Consent

'Every human being of adult years and sound mind has the right to determine what shall be done with his body….. '

Cardozo J., (1914)[5]

The current argument examines the legal basis of the informed consent doctrine as a means of respecting patents and people who act as research subjects, as well as the extent to which consent to patenting does and should play a role in modern patent law.

The concept of informed consent stems from the fundamental ethical principle of autonomy, which grants the patient the right to know about his own medical condition and requires the physician to respect any decision made by the patient regarding his own health care. Consistent with the autonomy principle, the goal of informed consent is to fully educate the patient about his condition, allowing him to make the best decision for himself.

However, imposing the onus of obtaining a research subject's 'informed consent' necessitates a thorough disclosure of the researcher's intentions, particularly those of a commercial nature. The John Moore case[6], handed down by the California Supreme Court, is a landmark decision that emphasizes the importance of informed consent. The case involved the removal of the appellant's spleen in preparation for an upcoming medical procedure. The spleen was later used to create an immortal spleen line, which was then patented. The Supreme Court admonished the respondents' defrauding actions, stating that the necessary information was not disclosed to the appellant, rendering his consent redundant. The validity of the patent granted to the respondents was a critical issue that went unmentioned in the court's decision.

[5] "Schloendroff v Society of New York Hospital, (1914) 105 N.E. 92, 93 (NY)."
[6] "Moore v Regents of the University of California, 271 Cal. Rptr. 146 (Cal 1990)."

The 'Environmental Ethics' Question

The term environmental ethic has been defined as the relationship between man and his surroundings that fosters a fundamental sense of respect for the land rather than merely defining it as an exploitable resource. It also aspires to create a more compatible existence for men and their fellow beings, with the latter not just bearing the brunt of an exploitation rage.

The 'Lockean' derivative in the 'fruits for labour' argument appears to be antithetical to the fundamental principles of environmental ethics.[7] While the former seeks to provide adequate benefits to any man who creates a product, the latter takes the opposite approach; it is based on the proposition that because the end product derives a valuable input from the originally innately occurring organism, the interests of this organism are of paramount ethical concern.

The authors would like to emphasise the discrepancy and fallacy in this argument. Human intervention, as stated by the US Supreme Court in Diamond v Chakarabarty, results in the creation of a novel organism, something previously unknown to mankind but which did not exist before. Even in Indian jurisprudence, emphasis has been placed on the importance of inventive steps that transform the original substance into something significantly different from its previous state.[8] The authors are adamant that a presumption of ownership in favour of the subject of research, or the person from whom the research material is extracted, over the end product, which employs human ingenuity, is false, even if the material is primarily his.

A second point of contention is an alleged failure to consider the subject's well-being. Such an argument is untenable, at least in the context of human life patents. If the aforementioned 'subject's welfare' argument is advanced with regard to human patents, it can be based on the presumption of competent consent. As a result, insofar as private individuals are concerned, the argument fails because an adequate amount of care and interest protection is provided while informing the subject of the nature of commercial interests that the researcher intends to pursue, thereby leaving the subject with the option of continuing the research.

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[7] "The argument derives its bedrock ingredients from the Lockean argument which concurs with the right to ownership of a man over any product crafted by him. The argument boils down from the 'I made it and it would not have existed without my intervention 'paradigm. For a summary on the Lockean theory of labor argument of property see Lawrence Becker, Property Rights, Chapter 4, (1997) in Hettinger N, Patenting Life: Biotechnology, Intellectual property and Environmental Ethics, Boston College. C. Environmental Affairs Law Review, 1994-1995, 267 (2022)."

[8] "Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries, AIR 1982 SC 1444."

The Questions of *Ordre` Public* and Morality

Article 27(2) of the TRIPS Agreement allows member nations to exclude inventions from patentability to enforce public order or morality. Similar provisions can be found in the Biotechnology Directive and the European Patent Convention. The complexity arises because none of the text expresses unequivocally what the essence of such a provision is. The TRIPS provision, for example, only prohibits commercial exploitation of the invention on the basis of public order or morality. This is a significant gap, given that the exception is limited in cases where certain unethical inventions are not commercialised.

It is debatable whether the provisions imply a prohibition on research in those fields or a restriction on patent issuance in the same. A conflict arises as a result, wherein patent law assumes a transcendental role that encroaches upon the domain of regulatory law. However, it is undesirable for patent law to provide a defence for something that is deemed unethical despite being a seminal piece of research.

The American Jurisprudence on Life Patents

The United States Constitution empowers Congress to secure for limited times to authors and inventors exclusive rights to their writings and inventions'[9] in order to promote innovation. The United States Patent and Trademark Office (USPTO) was established as a federal administrative unit to carry out and regulate the US patent system.[10] According to US legislation[11], there are four requirements for granting a patent: the invention must be novel, not statutorily barred from acquiring patent rights, have utility, and be non-obvious. Aside from the four prerequisites mentioned above, there is no statutory bar to the subject matter's patentable status.

The American law on the patentability of 'life patents' is 'all inclusive'. Traditionally, patents were used for mechanical instruments and the like. Adding biological materials to patentable subject matter raised concerns about their 'inventive' status and potential for private ownership of life. There is a debate over whether technological advances necessitate a new patent regime. In many ways, the

[9] "U.S. Constitution. Art. I, Section 8, Cl. 8."
[10] "35 U.S.C. Section 1."
[11] "U.S. Patent Act (35 U.S.C.). The US Patent Act is found in Title 35 of the US Code and contains the federal statutes governing patent law in the United States http://www.bitlaw.com/source/35usc/index.html."

arguments in favour of a completely new system are similar to those made 30 to 40 years ago, when polymer chemistry was a developing technology.[12] The debate extends beyond whether the current patent regime should apply to living matter or not. As Chief Justice Burger explained, the issue was "not between living and inanimate things, but between natural products—whether living or not—and human-made inventions."[13] Even today, ethical concerns are raised, albeit in a much quieter tone. With biotechnology rapidly emerging as a profitable sector, its impact on the biomedical and bio pharmacological sectors cannot be underestimated. It is reasonable to expect an increase in the number of bio-patents. It is therefore imperative that a conclusion to the debate be found sooner rather than later.

Even though patents on living organisms were not expressly excluded from the scope of patentable matter, the US Supreme Court supported such a paradigm in its landmark decision in Diamond v Chakrabarty[14]. In this case, the US Supreme Court held in a 5:4 majority decision that Congress, while drafting the enactment in question (the US Patent Act), intended to include 'anything made by man under the sun.' The Supreme Court granted legal protection to living organisms that met patentability criteria under 35 U.S.C. Section 101.

In Chakrabarty, the appellant (a microbiologist) challenged the USPTO's refusal to grant a patent on his mutated Pseudomonas bacterium, which contained at least two stable energy-generating plasmids. This human-engineered organism could help break down oil particles and control oil spills; a novel attribute on which the appellant based his arguments for the formation of an organism-generating process as well as some unique characteristics of the bacterium itself. The USPTO conceded that the organism's extraordinary characteristics made it non-natural and thus could not be classified as a 'product of nature'. The USPTO agreed with the applicant's argument that such an organism did not naturally occur in nature and therefore could not be barred from patent rights as a 'product of nature'. The patent application was dismissed solely on the grounds that the subject matter was a 'living organism’.

[12] “Melissa E. Horn, DNA Patenting and Access to Healthcare: Achieving the Balance among Competing Interests, 50 Clev. St. L. Rev. 253 (2002-2003)”
[13] “DeMott John S & Thomas Evan, Test-Tube Life: Reg. US Pat. Off., (30 June 1980)”
[14] “447 US 303 (1980).”

While considering these various arguments, the Supreme Court of the United States agreed that an engineered organism was a novel invention rather than a 'product of nature'. It also stated that the Congress could have reasonably anticipated the rapid expansion of science and technology, and that the patent umbrella can be expanded to include anything that 'man had made under the sun. The Supreme Court agreed that a challenge to two previous legislations that prohibited certain types of plants from being patented should not prevent the appellant from successfully patenting his novel organism.[15]

The Supreme Court in Funk Bros Seed Co v Kalo Inoculant Co[16] expanded the functional framework of Section 101, ruling that novel products with previously unknown characteristics would meet the clause's requirement. The Supreme Court disagreed with the then-prevailing imperative nature of the 'product of nature' doctrine. USPTO used it to deny patent protection and inventor rights to the vast majority of patent applications relating to living organisms. However, following this landmark decision, the Supreme Court has reversed the age-old doctrine and declared that life forms are patentable until they are significantly altered through human intervention.[17]

\To summarize, the legal position on life patents in the United States is currently in transition. Currently, the interpretation of statutory and regulatory principles governing life patents is liberal. Utility patents require disclosure of the novel invention's proposed or unique function in the patent application. Without disclosure, the patent application is likely to be rejected and the application process terminated. However, disclosure is required only for one specific usage technique, not for all possible ways to secure patent protection

The European Jurisprudence on Life Patents

The European patent system demonstrates a disciplined but inclusive regime for granting patent rights to biotechnology and its numerous offspring. The guidelines for European nations regarding municipal patent laws are incorporated in two primary documents: the European Patent Convention (EPC) and the Biotechnology Directive of 1998[18].

[15] "ibid, 310-318."
[16] "333 US 127"
[17] "In Re Allen, (846 F.2d 77, Fed. Cir. 1988); Genetics Institute, Inc. (927 F.2d 1200, Fed. Cir. 1991)"
[18] "The European Biotechnology Directive; directive 98/44/EC of the European Parliament and the Council on the legal protection of biotechnological inventions."

The EPC highlights four criteria for determining the patentability of any subject matter. According to the EPC, for successful patent protection, the subject matter must be patentable, have novelty and an inventive step, and demonstrate industrial usage. These four criteria were reaffirmed by the Directive of 1998. In fact, for the purposes of ensuring compatibility between the EPC and bio-patents, the Directive explicitly states in Article 3.2 that biological material, after significant human processing and intervention, cannot be excluded from the scope of patent protection simply because its initial existence is inherent in nature.

A new feature of the EPC is the inclusion of a 'public order and morality' clause under Section 53(a). The provision prohibits the granting of patent protection to any invention that violates public order and morality. This position contrasts with American patent law, which lacks any such 'morality' clause. Section 53(b), which supplements this clause, prohibits patents for any variety of plants, animals, or natural processes.

The decision in Harvard/Onco mouse[19] represents the European Patent Office's (EPO) adoption of these attributes. In this case, the inventor successfully patented the Onco mouse, a transgenic organism that was mutated and altered through sufficient human and technical intervention to become a novel organism. The Onco mouse was receptive to breast cancer, allowing for an earlier diagnosis. The EPO considered Harvard's application to secure a patent for the 'Onco mouse'. However, the EPO dismissed this because the subject matter was deemed 'a variety of animals' and thus ineligible for patent protection under Section 53(a). On appeal, numerous parties submitted briefs to the motion before the appellate body, which did not uphold the EPO's decision to classify Onco mouse as an animal variety. However, it recommended that the patent office consider the enjoined parties' briefs and determine whether the invention in question violated public order or morality. In 1994, the EPO ruled in favour of the applicants, granting them the disputed patent. Du Pont, the primary sponsor of the organism's research and development, was also granted patent rights.

The Harvard/Onco mouse case demonstrates Europe's willingness to grant patents for adequately human-engineered biological products. Again, in 1995, the Court granted a patent for a DNA

[19] "Harvard College v Canada (Commissioner of Patents) 2002 SCC 76"

sequence encoding a human protein produced by pregnant women to aid in the pregnancy.[20] The subject matter in question was deemed more than a mere discovery because it 'had to be isolated from its surroundings and a process had to be developed to obtain it.' This case limited the application of the 'products of nature' doctrine.

All of this is not to say that the European patent regime is as 'all inclusive' as the American regime. The European regimes explicitly prohibit inventions of plant and animal varieties, naturally occurring processes, those that are contrary to public order and morality, and certain other subject matters listed in Section 52(2) of the EPC. The European disposition on bio-patents has been liberal and draws heavily on the TRIPS Agreement. Article 27.1 of TRIPS requires that the subject matter of a patent application be defined as an invention rather than a mere discovery; the invention must also be sufficiently 'new, innovative, and capable of industrial application.' Despite this liberal inclination among the common European patent instruments, namely, the EPC and the Directive, the national IP laws of the majority of European nations remain in a state of aberration, with a more rigorous and stringent approach to the grant of life patents. This is due primarily to the fact that both of the aforementioned documents are subject to municipal laws.

Life Patents: The Indian Perspective

The Indian Patents Act of 1970 governs patent protection in India. It was gradually amended between 1999 and 2005 to meet India's international obligations under TRIPS. TRIPS aims to remove perceived barriers to 'free-trade' by establishing minimum IPR standards around the world. It directs member countries to provide product patents for all technologies and microorganisms. It also makes noncompliance with WTO statutes subject to prosecution and severe punitive action, such as sanctions or fines. Despite the safeguards and other flexibilities provided in the form of preferential treatment for developing and least developed countries, most developing members believe that the scope of patentability outlined in TRIPS is far too broad.[21] They argue that overly strong intellectual property rights with broad scopes and durations of protection are undermining the TRIPS Agreement's

[20] "Hormone Relaxin, 1995 O.J. E.P.O. 388 (Opp. Div.)"

[21] "When the Uruguay Round was launched, several developing countries resisted the entry of Intellectual Property Rights (IPRs) into the agenda. But under pressure from the U.S. (and its S.301 threats) they yielded, resulting in the agreement on Trade- Related Intellectual Property Rights (TRIPS) as part of the WTO agreements. 'The industrialized countries (and the industries of the North that were the driving force behind TRIPS) succeeded in setting rules that were viewed by several economic experts of developing countries as having the potential to cause most damage to development prospects', Failure of TRIPS: A time for review, The Hindu, 21 April 2001."

very object and purpose. India has always maintained that '...patent rights should be exercised coherently with the objectives of mutual advantage of patent-holders and users of patented medicines, in a manner conducive to social and economic welfare and the balance of rights and obligations.'[22]

Despite strong civil society opposition, India joined the WTO in 1995, and TRIPS was an essential component of the agreement. The then-national policymakers hoped that the overall benefits of stronger ties with the global trading community would outweigh any potential risks of accepting a stricter intellectual property regime.[23]

Navigating Patent Reforms and International Obligations

In a remarkable display of legislative prowess, India has recently enacted three momentous revisions to the long-standing Patents Act of 1970, deftly navigating a decade-long transition period. The inaugural amendment, unveiled in 1999, boldly ushered in the era of exclusive marketing rights (EMRs) and paved the way for the introduction of mailbox applications for pharmaceutical and agrochemical patents, effective from January 1, 1995. Building upon this triumph, the subsequent amendment of 2002 astutely sanctioned the grant of patents for microorganisms. It is worth noting that even prior to this monumental amendment, the judiciary had astutely interpreted the patent regime, albeit without alteration, to encompass the protection of living organisms, much to the chagrin of the esteemed Indian Patent Office. In Dimminaco A G v Controller of Patent Designs & Ors[24], a Swiss company approached the Hon'ble High Court of Calcutta after being denied a process patent for the preparation of a live vaccine for Bursitis. The granting of a patent was denied by the Patent Office due to the presence of a living organism, which is considered ineligible for patenting according to Section 2(1)(j). The Patent Office argued that the use of a living organism in the production of a vaccine does not qualify as an article, substance, or method of manufacture. They maintained that since the vaccine involved the manipulation of certain microorganisms, it was merely a natural process. Although the Indian Patent Act of 1970 did not explicitly prohibit it, patents were traditionally only awarded to non-living inventions that met the criteria for patentability. The appellant claimed that this decision violated the rule of law as discretionary administrative policy

[22] "K. M. Gopakumar, Mashelkar Committee Report: A Critique, Center for Trade and Development (CENTAD), 2003
[23] V R Krishna Iyer, O Chinnappa Reddy, D A Desai & Rajinder Sachar, Peoples 'Commission on GATT, Centre for Study of Global Trade System and Development (1996)."
[24] "Dimminaco A G v Controller of Patent Designs & Ors 2002 IPLR 255 Cal. H.C"

took precedence over the statutory definition of what constitutes an invention, which did not disallow the patenting of a process for manufacturing a vaccine containing a live virus.

The Court, in its ruling, determined that the term 'manufacture' was not explicitly defined in the Act. By consulting dictionary definitions, it was established that the process of creating a vaccine was indeed original and eligible for patent protection under specific sections of the Patent Act. Utilizing the vendibility test, the Court confirmed that the patented process resulted in a marketable product, meeting the criteria for being considered a substance post-manufacturing. Additionally, the case of M/s Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries Station was referenced to further clarify the requirements of novelty and utility in patent eligibility.

The Court's decision to legalize the patentability of living matter in India was seen as bold by many, despite their cautious approach. It is worth noting that the case focused on a process patent for a manufacturing process, rather than the living matter itself. This distinction is important, as it only allowed for patenting a process that resulted in a product containing living matter. Unlike gene patenting, which raises concerns about hindering research, this case specifically involved a process patent for a vaccine. The implications of gene mutations being covered by a single patent and the impact on competitive research are more pronounced under a product patent system.

Moreover, in the Appellant's favor, the Court's decision left room for future cases to be judged based on their unique circumstances. It emphasized the importance of thoroughly analyzing the facts of each case to determine if a patent claim truly constitutes an invention. This ruling by the Calcutta High Court aligns with the approach taken in the United States and many EU nations, where biotech inventions are deemed patentable.

The Patents Amendment Act of 2002, enacted in response to a significant court ruling, brought about changes to the existing legislation. One notable alteration was made to the definition of 'invention'. Previously, in addition to the essential criteria of novelty and utility, an invention had to fall under various categories such as art, product, process, method of manufacture, or a machine or substance generated through manufacturing, including any valuable improvements thereof. However, these additional requirements have now been eliminated, resulting in a more simplified definition. Presently, the only prerequisites for obtaining a patent are that the product or process must be new,

non-obvious, and useful. Although there may be differing opinions on the matter, this subsequent ruling highlights the judiciary's hesitancy to reject patent applications solely on ethical grounds. However, it is uncertain whether the addition of Section 3(j),[25] which excludes from patentability biological processes for producing plants and animals, or plants and animals in whole or in part other than microorganisms, would derail the benefits for future applicants, if the subject of patent application was adjudged to be a non-microscopic organism.[26] In order to have a clear understanding of what constitutes a 'microorganism', it is necessary to establish a definitive definition through either legislative clarification or a pronouncement by the judicial system. The national working group on patent laws has conducted a thorough examination of the draft manual of patent procedures and has determined that the term "microorganism" requires precise definition. In a specific section of the manual, it is stated that any microorganism found in nature cannot be patented. However, an amended act suggests that all 'microorganisms' can indeed be patented. If such inconsistencies are not resolved, the judiciary may invalidate the guidelines outlined in the draft manual, as they cannot override the statute and are merely administrative instructions.

In the year 2005, an amendment was made to the Act, specifically removing Section 5. This particular section used to permit the granting of patents solely for chemical processes, encompassing those of a biochemical, biotechnological, and microbiological nature. Furthermore, it encompassed substances that were intended for or had the potential to be utilized as food or medicine. It seems that the esteemed High Court's aim with this decision is to facilitate the patenting of products containing living microorganisms.

In the year 2005, a groundbreaking addition was made to patent law with the introduction of Section 3(d), which aimed to restrict patent eligibility by barring the patenting of a new version of a known substance that does not enhance its effectiveness. Despite an attempt by Novartis to challenge the constitutionality of Section 3(d) in the esteemed High Court of Madras, their efforts proved to be in vain.

[25] "Patents (Amendment) Act Section 4(e) (June 25, 2002); Section 3 (j) was developed along the lines of Article 27(3) (b) it states that plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable."
[26] "The Patents (Amendment) Act, 2005, No. 15 OF 2005, Section 3"

The overall expansion of patentability criteria has resulted in an increase in the number of patent applications, and thus an increase in the number of patents granted in the field of biotechnology. According to the Indian Patent Office's annual reports (2022 Annual Report)[27], the number of applications has steadily increased since 2000-01, when four applications were submitted but no patents were granted. In 2005-06, 1525 patent applications were filed, and 51 patents were granted. In 2022-23 (the most recent report available), there were 3758 applications and 903 grants.

	2000-01	2005-06	2010-11	2015-16	2020-21	2022-23
Patents application filed	4	1525	1497	887	3368	3758
Patents Granted	0	51	165	185	574	903

Trends in Patents Applications Filed and Patents Application Granted in the field of Biotechnology in India

According to India's insistence on a thorough review of Article 27.3, support for the African group's proposal on Article 27.354[28] presented in 1999 (which suggests that 'patents on life, including those on microbiological processes, should be prohibited'). The Indian government does not appear to be particularly interested in allowing patents on living things. In July 1999, India emphasised the importance of focusing on two complementary dimensions, one of which was the fundamental political question of whether patenting life is ethically acceptable.[29] India has also taken a more conservative European approach to patents, opting to use the morality clause in TRIPS. It is in stark contrast to the US approach, which argues that patenting life forms has enormous benefits.[30]

[27] Indian Patent Office, Annual Report 2007-08, https:ipindia.gov.inwritereaddataPortalIPOAnnualReport1_85_1_1_38_1_annual-report-07-08.pdf.

[28] "The African Group 's comprehensive proposals have received much support from other developing countries in the WTO, civil society groups, and NGOs, WT/GC/W/302."

[29] "The developing countries which had little or no say in drafting most TRIPS provisions viewed the review process scheduled every 4 years as a means to make their demands heard. See, Review of Article27.3(b), Paper IP/C/W/369/Rev.1."

[30] "TRIPS, Biological Resources and Public Health: Documents and Discussion Papers Presented at the ICTSD - Africa Group Roundtable on 12 June 2001, https://www.iprsonline.org/ictsd/docs/IPR_collection.pdf"

Despite the growing number of applications, the Indian political system continues to enforce a more rigorous patent system for safeguarding living organisms compared to its American counterpart. India, along with other developing nations, still has options available to them if they are hesitant to extend patent protection to living matter. While Article 27.1 of TRIPS prohibits discrimination, it does allow for differentiation. This non-discriminatory provision does not prevent member countries from establishing patentability thresholds that apply to all areas of technology, ensuring fairness. TRIPS grants member countries the flexibility to determine the most effective way to implement its provisions and define key elements that dictate the extent of patentability. According to Carlos Correa, the TRIPS Agreement does not impose an obligation to adopt a broad definition of 'invention', as is common in many developed countries today. Specifically, the Agreement does not require Members to consider whether naturally occurring substances, whether biological or otherwise, are eligible for patent protection, even if they are isolated and claimed in a purified form.[31]

In Novartis AG v Adarsh Pharma and Anr[32], One of the arguments raised was the potential conflict between Section 3(d) and Article 27 of TRIPS, which requires all WTO member states to offer patent protection across all technological fields without discrimination, thus potentially violating the TRIPS Agreement. However, the court did not address this issue and instead suggested utilizing the WTO dispute settlement mechanism, which was ignored. The Court did confirm the constitutionality of the provisions through Article 14. Additionally, Article 8 allows signatories of TRIPS to refuse patents in order to uphold 'public order and morality'. India has consistently maintained, with support from Paragraph 4 of the Doha Declaration, that any interpretation of the agreement's provisions must align with Article 8.

An additional measure of protection lies in the existence of a worldwide repository for genetic information, as required by the Budapest Treaty and the Convention on Biological Diversity. The Microbial Type Culture Collection and Gene Bank (MTCC) at the esteemed Institute of Microbial Technology (IMTECH) in Chandigarh ensures that all microbial data is securely stored, revealing its geographic availability, and made accessible for research and other pertinent purposes following the publication of a patent application. Meanwhile, repositories utilized in the study of the human genome

[31] "Panel Report, European Communities and their Member States, WT/DS 114/R (17 March 2000)."
[32] "Novartis AG v Adarsh Pharma and Anr 2004(3)CTC95"

serve a similar function, for once information is divulged or made widely known, its novelty diminishes and it becomes ineligible for patenting.

Mashelkar committee on Patent Law

In the spring of 2005, the esteemed Mashelkar Committee was convened to evaluate India's adherence to TRIPS regulations after a significant amendment in 2005, and to determine if the steps taken to achieve compliance were in the country's best interests. Among the matters deliberated by the Committee was the question of whether it was permissible under TRIPS to exempt microorganisms from patent protection. In the winter of 2006, the Mashelkar committee presented a report, only to retract it subsequently due to errors in data and instances of plagiarism.[33] In the spring of 2009, the revised edition of the report was presented, its contents kept under wraps until recently, when it was finally unveiled to the general public. To a great extent, this revised rendition echoes the earlier conclusions of the Committee, which had been chastised for their neglect in taking into account public health objectives. The Committee resolved that it would constitute a breach of TRIPS to entirely prohibit the patentability of microorganisms, instead asserting that microorganisms which involve human intervention and possess utility are indeed eligible for patent protection under the TRIPS Agreement, as long as they satisfy the prescribed criteria for patentability. The Committee has faced criticism for its lack of a definitive position on the issue. It justifies the expansion of patents in the field of biotechnology based on three primary factors. Firstly, it aims to enhance the potential for foreign direct investment and contractual research and development by enticing international collaboration within India's flourishing and lucrative bio-tech industry, which thrives in the country's rich biodiversity.

The authors wish to emphasize that India's potential to attract FDI and reap associated advantages hinges on the absence of comparable incentives offered by other nations. It is noteworthy that several nations boasting advanced biotechnology sectors, including the United States, the Republic of Korea, Japan, China, and various European countries, already offer significantly greater patent safeguards concerning living organisms compared to India.

[33] "Dr Raju K D, The debacle of Novartis patent case in India: Strict interpretation of patentability criteria under Article 27 of the TRIPS Agreement, INDIAN JOURNAL OF INTELLECTUAL PROPERTY LAW, 1 (1) (2008)."

The second reason provided by the committee was their concern over the potential patenting of Indian biological matter by foreign entities. However, this argument is flawed as India is already a signatory to the Convention on Biodiversity (CBD), which dictates that prior informed consent and material transfer agreements must be implemented to acknowledge the country of origin when utilizing materials from a specific country. India should prioritize upholding the CBD to prevent biopiracy rather than pursuing alternatives that would impose an unsuitable system on the nation. Additionally, the committee references TRIPS obligations to support their suggestions, but fails to acknowledge the existing flexibilities under TRIPS, such as the absence of clear definitions for patentability criteria like novelty, non-obviousness, and usefulness. These flexibilities enable India to define the extent of patentable subject matter in more restrictive terms.

Conclusion

In recent years, there has been a noticeable increase in lobbying efforts to enhance intellectual property protection for biotech inventions, especially those involving living organisms. This trend has accelerated, particularly in developing countries striving to comply with TRIPS regulations. Despite this progress, there is still debate over whether to offer the same level of protection as seen in more developed nations, with concerns about potential economic benefits and ethical considerations weighing heavily on both sides. In light of these conflicting perspectives, the authors argue for a balanced approach that considers both individual commercial interests and broader societal concerns. They suggest that while TRIPS implementation is important, there is room for flexibility to accommodate the unique circumstances of the Indian intellectual property system. It is crucial to address public health and ethical issues while also promoting scientific knowledge and temperament, in line with the fundamental duties of every citizen.

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