INTERNATIONAL JOURNAL OF LEGAL SCIENCE AND INNOVATION

[ISSN 2581-9453]

Volume 6 | Issue 4

2024

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Patenting of Microorganisms and Life Forms: An International Perspective

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ABSTRACT

The patenting of microorganisms and other life forms presents a complex and contentious issues, especially when comparing the approaches of nascent patent regimes like India with those of developed regions such as Europe and the USA. As it is well known that, microorganisms are found naturally, forming a part of the ecosystem and they are discoverable per se and not inventible hence, why the question of them being patented arises? Where a line should be drawn if patenting of microorganisms and life forms are allowed, in order to maintain the balance between encouraging research and development and their exploitation? This paper examines how these regimes differ in their approach to the patentability of living organisms, highlighting India's proactive stance in implementing TRIPS mandates to foster research and development in biotechnology. The paper delves into the moral, legal, and ethical dilemmas associated with bio patenting, arguing for a balanced intellectual property regime that respects both commercial interests and public welfare. It underscores the importance of situational exceptions and flexibilities in the Indian IP framework to accommodate indigenous conditions while adhering to international agreements. The need for sensitivity towards public health and ethical concerns is emphasized, alongside a caution against unfounded mistrust of commercial entities to promote scientific advancement responsibly.

Keywords*: Microorganisms, Patenting, TRIPS Agreement, Biotechnology, Ethical Dilemmas, International Patent Regimes.*

I. INTRODUCTION

As widely accepted factor in relation to grant of patents is invention, which in turn should be novel i.e., the product or process which is to be given a patent should not exist priorly (prior art). Mostly non-living things i.e., non-life forms are patented along with the processes of certain production processes. The patenting of living organisms is comparatively a recent development that has seen significant growth in recent years, particularly following the implementation of the Trade-Related Intellectual Property Rights (TRIPS) Agreement in 1995. While many countries previously did not allow the patenting of biological forms, the TRIPS

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agreement made it compulsory for WTO signatories to grant the patenting of certain life forms, such as 'microorganisms', and 'specific living processes', such as 'microbiological processes.' The unrestricted patenting of biological resources could lead to serious consequences if not properly regulated. Critics argue that using the patent system to reward scientific achievements in the realm of biological resources and processes is inappropriate because living organisms differ fundamentally from non-living materials. But, on the contrary if it is not done it might lead to a situation whereby innovation might not take place.

But, the 'patenting of life forms' is a comparatively new phenomenon, but it has started to grow at a tremendous rate in the recent years, especially since the establishment of the 'Trade-Related Intellectual Property Rights (TRIPS) Agreement in 1995. Patenting of biological resources had been prohibited by most of the countries, but patenting of at least certain life forms (microorganisms) and certain living processes (microbiological processes) had been made mandatory by TRIPS treaty for WTO member states. There can be serious consequences if floodgates are opened for patenting of biological resources without any form of checks and balances mechanisms. Many critics of patenting of life forms have argued that it is inappropriate to use the patent system to reward scientific work in the field of biological resources and processes, as living organisms are qualitatively different from non-living materials.'

This paper shall try to understand the phenomenon of how the different regimes in relation to patenting of microorganism works and how they are grant patents. It shall try to explore the other international laws and regimes with respect to patenting of life forms and microorganisms. The paper shall also try to explore the different moral, legal and ethical dilemmas relating to the 'patenting of microorganisms and other life forms.'

II. DIFFERENT INTERNATIONAL INSTRUMENTS IN RELATION TO PATENTABILITY

Article 27(3)(b) of **TRIPS Agreement** acts as a ground for signatory states to deny patents for "*plants and animals, other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes*." [2]Consequently, TRIPS mandates that all member countries grant patents for microorganisms, as well as non-biological and microbiological processes. Additionally, since animal and plant components, along with modified plants and animals, are not specifically excluded from this requirement, TRIPS might also necessitate the patenting of biological organisms.

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27(3)(b), Marrakesh Agreement Establishing the World Trade Organization, 1994 (WTO).

However, it has become obligatory to grant patents for 'microorganisms' and 'microbiological processes.' The TRIPS agreement does not define 'microorganism' nor does it specify the extent of its protection. As a signatory to TRIPS, India has made provisions in alignment with this requirement.

The '**Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure'**[3] allows for 'deposits of microorganisms at an *international depositary authority* to be recognized for patent procedure purposes.'[4] Typically, to meet the legal requirement of sufficiency of disclosure, patent applications and patents must describe the subject matter of the invention in a clear and complete manner so that it can be replicated by someone skilled in the field. For inventions involving microorganisms, it is impossible to fully describe them. Therefore, 'a deposit of the biological material' must be prepared in a recognized institution for such inventions. This treaty ensures that an applicant does not need to deposit the biological material in every country where they seek a patent; a single deposit at a recognized institution suffices and is acknowledged by all countries party to the Budapest Treaty. Consequently, this treaty facilitates the patenting process for microorganisms.[5]

III. STATUS OF MICROBIAL PATENTING IN USA AND EUROPEAN REGIME

(A) USA

In the United States (US), the concept of patentability originated with the '**Patent Statute of 1793**.' This statute allowed patents to be granted for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof." This definition remains fundamental to the U.S. patent code. Subsequently, the term "art" was replaced by "process."[6]

The statute did not initially address the 'patenting of life forms,' but a significant precedent was established in 1889. In a landmark decision, the U.S. Commissioner of Patents denied a patent application for a fibre found in pine needles, stating that identifying the '**composition of trees** in a forest' was "**not a patentable invention, recognized by statute, any more than finding a new gem or jewel in the earth would entitle the discoverer to patent all gems**

[3] International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, WTO Agreement, 1977 (Budapest).
[4] International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Article 3 (1) (a), WTO Agreement, 1977 (Budapest).
[5] Ramkumar Balachandra Nair, Pratap Chandran Ramachandranna, Patenting of microorganisms: Systems and concerns, 16, Journal of Commercial Biotechnology volume, 337–347 (2010).
[6] Daniel J. Kevles, Patenting Life A Historical Overview of Law, Interests, and Ethics, Legal Theory Workshop, Yale Law School, 1-2 (2001).

subsequently found." The commissioner argued that, allowing patents on natural plants and trees would be "unreasonable and impossible." This decision laid the ‘groundwork for the "product of nature" doctrine, which holds that while methods developed to extract natural substances can be patented, the natural objects themselves cannot be patented, as they are not considered inventions and cannot be claimed as private property.’[7]

***Diamond v. Chakrabarty*:[8]**

Facts-

The 'product of nature' doctrine is closely linked to the patenting of inventions themselves. According to this doctrine, for something to be patented, it must result from human intervention. Nature's creations cannot be patented. Therefore, a plant or organism found in the wild cannot be patented. However, purified forms of natural products may be eligible for patent protection if they are novel and non-obvious compared to their natural counterparts. A significant shift occurred in 1980 with the ‘Supreme Court's historic ruling in Diamond v. Chakrabarty. This case involved a genetically modified bacterium designed to consume petroleum spills, for which Ananda Mohan Chakrabarty, a genetic engineer at General Electric, submitted a patent application in 1972. The ruling granted the patent, marking a change in the non-patentability status of living organisms. Ananda Mohan Chakrabarty, a genetic engineer and researcher at General Electric, submitted a patent application in 1972 for a bacterium designed to consume petroleum (oil) spills (superbug).’

According to Chakrabarty, the ‘Pseudomonas bacterium’ he engineered contained at least two stable energy-generating plasmids, each providing a distinct hydrocarbon degradative pathway. This genetically modified bacterium could break down various components of crude oil using ‘salicylate, an aromatic hydrocarbon, and naphthalene, a polynuclear aromatic hydrocarbon.’ It was asserted that this capability, which no naturally occurring bacterium possessed, made the invention useful for remediating oil spills. The effectiveness of this "novel" bacterium in degrading crude oil and other complex hydrocarbons demonstrated its adaptability. However, since living organisms could not be patented under American law at that time, Chakrabarty's patent application for the bacterium was initially denied by a **patent examiner.**

The **Board of Patent Appeals and Interferences** agreed with the initial ruling denying Chakrabarty's patent. However, the ‘**United States Court of Customs and Patent Appeals**’

[7] Ramkumar Balachandra Nair, Pratap Chandran Ramachandranna, Patenting of microorganisms: Systems and concerns, 16, Journal of Commercial Biotechnology volume, 337–347 (2010).
[8] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

overturned this decision, stating that "the fact that microorganisms are alive is without legal relevance for purposes of the patent law." The case was then appealed to the Supreme Court by the Commissioner of Patents and Trademarks, which ultimately rendered a decision in favor of Chakrabarty.

Issues-

The patent claims made by Chakrabarty were of three types:

- ‘Process claims for the method of producing the bacteria.’
- ‘Claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria.’
- ‘Claims to the bacteria themselves.’

‘The patent examiner allowed the claims of the above first two categories, but rejected claims for the bacteria.’ The decision rested on two grounds:

1. ‘That microorganisms are products of nature,’ and
2. ‘That as living things they are not patentable subject matter under 35 U. S. C. 101.’

Because, microorganisms are living things, the Patent Office Board of Appeals reiterated the examiner's finding that they are not within the ambit of US law.

Ratio Decidendi-

The Supreme Court, in a narrow 5-4 decision, ruled in favor of Chakrabarty and affirmed the patent, stating that: ‘A live, human-made microorganism is patentable subject matter under US law. As according to the law, the respondent's microorganism is a "manufacture" or "composition of substance."

According to the judges of the SC, interpretation of 35 U.S.C. 101, which says:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

Hence, microorganism in certain cases are patentable.

(B) Europe

The European patent system illustrates a well-organized yet comprehensive approach to granting patent rights for biotechnology and related fields. Two important treaties, the

Biotechnology Directive of 1998[9] and the European Patent Convention (EPC)[10], include the directive recommendations for the European countries with regard to local patent laws.

A distinctive aspect of the **EPC** is the inclusion of "**public order and morals**" under section 53(a). This clause prohibits granting patent protection to any invention that breaches moral standards or public order. This perspective contrasts with **American patent law**, which lacks a **"morality" clause**. Additionally, section 53(b) of the EPC prohibits the granting of patents for any species of plants, animals, or natural processes.

The European Patent Office (EPO) adopted these principles in the ***Harvard/Onco mouse*** [11]ruling. In this case, the inventor successfully patented the Onco mouse, a transgenic organism that had undergone significant technical and genetic modifications to become a novel entity. Due to its susceptibility to breast cancer, early diagnosis became feasible. Harvard's application to patent the "Onco mouse" was under consideration by the EPO. However, the EPO initially rejected it, deeming the subject matter "a variety of animals" and thus ineligible for patent protection under Section 53(a). During the appeal process, many parties submitted briefs, and the appellate panel ultimately overturned the EPO's decision, ruling that the Onco mouse was not "an animal variety" and granting the patent to the petitioners.

In a 1995 case, a court granted a patent for a '**DNA sequence encoding a human protein** produced by pregnant women,' which aids in pregnancy.[12] The court ruled it was more than a mere discovery because the material had to be isolated from its natural surroundings and a method had to be developed to extract it. This limited the application of the "products of nature" doctrine. However, it should not be assumed that the European patent system is as inclusive as the US system. The European system explicitly prohibits patents on new species of plants and animals, the use of natural processes, inventions that are against morality and public order, and other subjects listed in Section 52(2) of the EPC.

The TRIPS Agreement has greatly impacted the European stance on bio patents, which has been generally liberal. According to Article 27.1 of TRIPS, 'the primary requirement for granting a patent is that the subject matter must be classified as an invention rather than a mere discovery.' Additionally, the invention must be sufficiently "new, original, and capable of

[9] DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the legal protection of biotechnological inventions, 98/44/EC, 1998 (European Union).
[10] CONVENTION ON THE GRANT OF EUROPEAN PATENTS (EUROPEAN PATENT CONVENTION), No. 16208, 1973 (European Union).
[11] Ameen Jauhar and Swati Narnaulia, Patenting Life the American, European and Indian Way, 15, Journal of Intellectual Property Rights, 55-65, (2010).
[12] Hormone Relaxin, 1995 O.J. E.P.O. (388 Opp. Div.).

industrial application."[13]

The 'national IP laws' of the majority of 'European countries are still in aberration and follow a more severe and stringent approach to the issue of life patents in spite of the liberal leaning among the common European patent instruments, particularly the EPC and the Biotechnology Directive.' This is mostly due to the fact that both of the aforementioned documents are in compliance with local laws.

Despite the liberal tendencies of common 'European patent instruments' such as the 'EPC' and the 'Biotechnology Directive,' the 'national IP laws' of most European countries remain more stringent and severe regarding life patents. This is largely because these documents adhere to local laws.[14]

IV. STATUS OF PATENTABILITY IN INDIA

In order to understand the status of patentability in India we need understand the laws relating to and processes for patenting microorganisms in India.

Patents Act, 1970 [15]

'Article 27(3)(b) of the TRIPS Agreement' permits member states to exclude patents for **"plants and animals, other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."** As a signatory to the Agreement, India has adhered to this provision. In June 2002, India amended its patent laws by revising the definition of **'invention'**. Previously, section 2(j)[16] included additional requirements such as 'being an art, product, or process, method or manner of manufacture; machine, apparatus, or other article; or a substance produced by manufacture, including any useful improvements on these.' These additional requirements have been removed, and now the definition has been simplified. The '**only requirements for patentability are that a product or process must be new, non-obvious, and useful**.'

In compliance with TRIPS, the '**Patents Act of 1970'**, as amended in June 2002, grants 'patent rights for new microorganisms.' Section 3(j) of the Act **excludes from patentability "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**

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27(1), Marrakesh Agreement Establishing the World Trade Organization, 1994 (WTO).
[14] Ameen Jauhar and Swati Narnaulia, Patenting Life the American, European and Indian Way, 15, Journal of Intellectual Property Rights, 55-65, (2010).
[15] Patents Act, 39 of 1970, Acts of Parliament, 1970 (India).
[16] Inserted by Patents (Amendment) Act, Section 2(j), 38 of 2002, Acts of Parliament, 1970 (India).

propagation of plants and animals."[17]

Subsequently, 'The Patents Act, 1970' was once again '**amended in the year 2005**, so as to establish congruence with TRIPS. The amendment **deleted Section 5**[18] of the Act, which provided for only process patents. The provision included inventions where only methods or processes of manufacture were patentable. Therefore, the deletion of this section paves way for product patents, which is in stark opposition to US approach that argues patenting of life forms has tremendous advantages.'

Dimminaco A G v. Controller of Patents and Designs[19]

Facts of the case-

The appellant applied for a patent for a process he invented to create a "**Bursitis vaccine**" aimed at protecting poultry from Bursitis infection. The process involved **using a live virus both during the creation of the vaccine and in the final product.**

The Patent Office Examiner reviewed the application under Section 12 of the Patents Act, 1970 (hereinafter referred to as the Act) and rejected it, finding that the claim did not meet the requirements of an "invention" under Section 2(j)(i) of the Act and that the application fell under Section 5(a) or 5(b) of the Act, as the product of the process was a food or drug. The appellant then appealed to the Controller of Patents and Designs, who delegated authority to the Assistant Controller of Patents and Designs (hereinafter referred to as the Assistant Controller) under Section 73(3) of the Act. The Assistant Controller upheld the Examiner's decision, rejecting the application. Consequently, the appellant approached the Calcutta High Court under Section 116 of the Act.

Issues-

The issues that the learned bench took into considerations were:

1. 'Whether there is a bar to the patentability of a process of manufacturing when the process and/or the product involves/contains a living organism.'
2. 'Whether such a process of manufacture qualifies under Section 5 of the Act.'
3. 'Whether such a process qualifies as an invention under Section 2 (j) (i) of the Act.'

[17] Inserted by Patents (Amendment) Act, Section 3(j), 38 of 2002, Acts of Parliament, 1970 (India).
[18] Omitted by Patents (Amendment) Act, Section 4, 15 of 2005, Acts of Parliament, 1970 (India).
[19] Dimminaco AG v Controller of Patents and Designs, (2002) IPLR 255 (Cal)

Ratio Decidendi-

The Calcutta High Court diverged from the previous stance. It rejected the Controller's argument that a 'patent is granted only for a process resulting in an article, substance, or manufacture, and that a vaccine containing a living organism does not qualify as an article, substance, or manufacture.' The Controller had argued that the dictionary definition of an article is a 'material thing, item, or thing of a particular class or kind as distinguished from a thing of any class or kind,' which does not include living things. The Court, however, stated that the "***law does not bar processes where the end product is living, noting that there is no statutory bar in the Act against accepting a manner of manufacture as patentable, even if the end product contains a living organism."***

Through 'creative judicial interpretation,' the Court held that: **'The Indian statute on patents does not restrict the patentability of microorganisms developed in a controlled laboratory environment.'**

Referring the usual dictionary definition of 'manufacture,' the court held that manufacture occurs when **'the material in question, after going through the process of manufacture, has undergone any change by the inventive process and becomes a material different from the starting material.'** The court held that this definition of manufacture does not exclude the process of preparing a product containing a living substance from being patentable.

The court also held that the process for creating a vaccine results in a vendible product, even if the end product contains living material. The court stated that if an invention produces vendible items, improves or restores the condition of a vendible item, or enhances its preservation and prevents deterioration, then the invention meets the **vendibility test.** Therefore, since the claimed process for the patent results in a vendible product, it qualifies as a substance after undergoing the manufacturing process. The court concluded that a new and useful art or process is an invention, and when the end product is a new article, the process leading to its manufacture is an invention.

This decision by the Calcutta High Court aligned with the positions in the United States, most European countries, and Japan, where many biotechnology processes are patentable, regardless of whether the resultant product is living or non-living. Following the Dimminaco decision, Indian law has kept pace with the needs of the thriving biotechnology industry.

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V. BIO-PATENTS: A CRITICAL UNDERSTANDING OF THE MORAL AND ETHICAL DILEMMAS

The matter of patentability of living entities, such as cells and tissues, extends beyond the scope of simply creating laws and regulations. Fundamentally, it is a clash of various interests, concepts, beliefs, and frameworks. This issue prompts a debate that is rooted more in ethical concerns than in straightforward legal or technical issues. The ensuing discourse delves into the moral and legal debates, emphasizing the key points of disagreement within bio-patent systems.

(A) The 'Invention versus Discovery' argument-

A major point of contention for ‘anti-bio patent’ proponents is ‘whether an organism or living product created using a naturally occurring substance’ can be considered more than just a ‘discovery’ and be granted patent protection as a "novel invention." This is crucial question because, traditionally, mere discoveries are not protected under patent law. The key issue is whether there has been enough human intervention to produce an organism that is distinct and independent from its naturally occurring counterpart.

In most patent systems, especially those influenced by the TRIPS Agreement, bio patents are allowed. The argument that these are simply "products of nature" is considered outdated and invalid. However, caution is necessary when navigating this aspect of patent law. Granting too many "utility patents" to “living organisms and related structures” can raise significant ethical concerns.

(B) The Environmental Ethics-

Environmental ethics is defined as the relationship between humans and their environment, emphasizing a fundamental respect for the land rather than viewing it solely as a resource to exploit. This ethical framework seeks to promote a harmonious coexistence between humans and other living beings, ensuring that the latter are not merely subjected to exploitation.

The "fruits for labour" argument, which advocates for adequate rewards for human creators, appears fundamentally opposed to the principles of “environmental ethics.’ The prior emphasizes rewarding human effort in creating a product, the latter argues that the intrinsic value of the naturally occurring organism used in the product means that the organism's interests should be the primary ethical concern.

As highlighted by the ‘US Supreme Court’ in “*Diamond v. Chakrabarty*,” human intervention can create a novel organism, something previously unknown to mankind. Similarly, Indian

jurisprudence emphasizes the importance of inventive steps that transform an original substance into something significantly different from its initial state.

The author firmly believes that presuming ‘ownership in favour of the research subject, or the person from whom the research material is sourced, over the end product that results from human ingenuity, is flawed.’ This is true even if the material originally belonged to the person, unless the criteria for patentability are met. Such a presumption could discourage further research and development.

(C) The Questions of Order Public and Morality-

‘Article 27(2) of the TRIPS Agreement’ allows signatory nations to not include certain inventions from patentability to ‘enforce public order or morality.’ Similar provisions are found in the ‘European Patent Convention.’ The challenge arises from the ambiguity in these texts regarding the core meaning of such provisions. For example, the TRIPS provision solely restricts the commercial use of inventions based on public order or morality grounds. This leads to a considerable gap, as the exception does not apply to unethical inventions that are not intended for commercial exploitation.

There is ongoing debate on whether these provisions prohibit research in specific fields or merely restrict the issuance of patents. This conflict indicates that patent law may be overreaching, infringing upon the territory of regulatory law. It becomes problematic when patent law extends protection to fundamental research that is considered unethical.

VI. CONCLUSION

Comparing nascent patent regimes like India's with those of developed regions such as Europe and the USA reveals differing stances on the patentability of microorganisms and other life forms. While India is generally against the corporatization of patents, it has proactively addressed the patenting of microorganisms and life forms by efficiently implementing the changes suggested by TRIPS. This indicates India's desire to promote research and development in biotechnology and related fields.

It's crucial to examine these arguments and understand their implications for the ethical and successful implementation of any intellectual property rights (IPR) regime. The questions raised throughout the project are not merely academic but highlight legitimate concerns about growing ‘patent regime.’ Conversely, an excessively cautious statutory approach could result in numerous legal challenges. Thus, a balanced system, especially in emerging patent regimes like India, must find equilibrium, allowing for situational exceptions.

A significant push and a successful movement toward more robust IP regimes for 'biotech inventions, including living organisms' have been observed. As the developing in the preceding years in the have become more TRIPS compliant, the processes have accelerated. But, despite such compliancy, there remains a 'question of whether protection equivalent to that in the developed world can be achieved,' given the potential trade and foreign direct investment benefits and ethical considerations on both sides.

In light of this conflicting position, the authors argue for balancing the commercial interests of individuals with those of the public. They believe that while the direct and effective implementation of TRIPS is crucial, there remains room for incorporating flexibilities tailored to the specific conditions of the IP regime of India. It is vital to remain sensitive to public interests, especially concerning public health and ethical issues. However, to foster scientific knowledge and temperament, which is also a constitutional duty for every citizen, it is essential to avoid unwarranted suspicion and distrust of commercial entities and their actions.

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