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DECODING PATENTABILITY - HUMAN BODY-DERIVED BIO PRODUCTS IN IPR LAW

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Introduction

Bio goods are products made from the human body that include a wide range of materials and chemicals that are obtained from human tissues, cells, or genetic components. Cell lines, proteins, antibodies, and other physiologically active substances derived from diverse procedures using human biological material fall under this category, albeit they are not the only ones. These bioproducts' distinctive qualities provide a challenging junction between scientific advancement and morality, raising questions about their patentability.[1]

Patentability is very important in the field of biotechnology since the industry is so important to the advancement of medicine, agriculture, and many other areas. Because they provide inventors the only right to their inventions, patents are essential tools for encouraging innovation and continuing research and development. When it comes to bioproducts made from substances found in the human body, the need of patent protection is amplified. The capacity to get patents is essential for drawing in funding, motivating further research projects, and eventually making it easier to turn scientific discoveries into useful goods that benefit society as a whole.

The Patents Act of 1970, which is India's IPR legislation, sets up the rules for the domestic protection of ideas and inventions. In keeping with global norms, the Indian patent system aims to achieve a careful equilibrium between the rights of inventors and the general welfare. Patents are awarded for discoveries that advance technology without unreasonably limiting public access, according to the Patents Act, which lays out the requirements for patentability along with a number of limitations.[2] Understanding the context of Indian IPR law is crucial for assessing the patentability of bio goods produced from human body sources, given the intricate nature of these products and the legal and ethical constraints imposed by the nation.[3] In addition to offering a means of safeguarding novel discoveries, the Patents Act establishes limitations on the issuance of patents for goods or procedures that can give rise to moral questions or obstruct the general public's access to vital biotechnology breakthroughs.

Patentability Criteria in Indian IPR Law

A biotech innovation must not only meet the requirements of creative step, industrial application, and novelty for patentability, but also fit into the category of subject matter that is eligible for patents. Section 3 of the Patents Act 1970 excludes some innovations from patentability. Sections 3(b), (c), (d), I, (h), (i), (j), and (p) are especially pertinent to biotech patents.[4]

According to Section 3(b), if an innovation is used or exploited for profit in a way that is against public policy, morality, or causes grave harm to people, animals, plants, or the environment, it is not protected. For instance, only genetically altered biological materials that have no effect on the environment or other living things are eligible for patent protection.
Another crucial provision, Section 3(c), specifies that the discovery of any living entity or non-living material existing in nature is not permissible subject matter for a patent. Biological materials that are extracted and isolated are usually regarded as naturally occurring compounds, thus they are not eligible for patent protection. According to the recently released IPO Guidelines, only materials produced via significant human intervention are deemed patentable; sequences derived straight from nature are not.

In the Patent Law, Section 3(d) is controversial, especially for biotech patents, which are frequently referenced when referring to changes made to already-

[1] Jones, Phillip B. C. (1991). Patentability of the products and processes of biotechnology. *Journal of the Patent and Trademark Office Society, 73(5),* 372-398.
[2] Rathee, Himangshu. (2016). Patentability of human genes: scaling an indian perspective. *Indian Journal of Law & Public Policy, 2(2),* 24-42.
[3] *Id.*
[4] *Biotechnological inventions in India: law, practice and challenges*. (2015, October 23). Lexology. Retrieved January 2, 2024, from https://www.lexology.com/library/detail.aspx?g=8405b078-b301-4672-8850-84f74ea23aa7.

existing substances. This provision rejects claims if a change does not result in a new form of a known substance displaying enhancement of the known efficacy. It restricts patentability rather than setting an absolute threshold. Uncertainty surrounds the parameters of improved efficacy in the context of biotech innovations.

Section 3(e), which disqualifies a material derived by simple mixing and any method of preparation from patentability, poses another common issue. Combination vaccines are often rejected because to this clause, which stipulates that a mixture including known components is patentable only if it exhibits synergism. However, because statutes do not clearly define synergism, the IPO must decide whether an invention is patentable on a case-by-case basis.
Additional difficulties for applicants arise from Section 3(h), which designates a technique of agriculture or horticulture as unpatentable subject matter. When it was made apparent in subsequent recommendations that Section 3(h) only applied to traditional methods used on wide fields, some relief was given.

The exclusion of procedures pertaining to the treatment of people or animals from patentability under Section 3(i) is another common cause of objections in the prosecution of biotech innovations. While in vitro diagnostic techniques using extracted tissues or fluids have been awarded patents by the IPO, new rules place these techniques under Section 3(i) and indicate that they may be rejected in the future.
Based on Article 27.3(b) of the TRIPS Agreement, Section 3(j) severely restricts the patentability of biotech innovations. Under this clause, patents cannot be obtained for plants, animals, seeds, variants, species, or vital biological processes unless there is a substantial human component. The Plant Varieties Protection and Farmers' Rights Act of 2001 provides an alternative means of safeguarding such discoveries in the case of transgenic plant varieties, through sui generis protection.

Apart from the difficulties mentioned in Section 3 of the Patents Act and the scant corpus of case law, there are other particular criteria in India that discourage prospective applicants from submitting biotech discoveries. One significant financial burden, for example, falls on patent applicants, who must pay a filing fee of around $13 for each page of the sequence listing. Given the intricacy of biotech inventions, which can entail lengthy sequence lists spanning hundreds of pages, this financial burden is especially noteworthy.

Furthermore, where biological material's source and place of origin are included in a patent specification but are not adequately explained or made public, the Patents Act's Section 10(4)(ii)(D) mandates such information be revealed. Declarations that the invention incorporates biological material from India as specified in the specification and that the required permission from pertinent authorities will be filed prior to the patent being awarded are additional requirements in the patent application form. The NBA authorization requirement for Section 10(4)(ii)(D) was adopted in 2005 in order to align with the Biological Diversity Act, 2002, which safeguards sovereign rights over genetic resources. Still, its execution was a bit slow at first. However, new regulations have emphasized how important NBA approval is to accelerate biological material patent applications.[5]

While getting NBA clearance is a complex and time-consuming process in terms of itself, adding it as a requirement for patent award is likely to cause delays. Notably, the recommendations extend beyond the Patents Act's statutory requirement, which limits disclosure to situations in which biological material is either not publicly available or is not sufficiently disclosed in the specification. Applicants looking to patent biotech innovations are unfairly burdened by the extra need of disclosing the source and origin, regardless of whether the biological material is sourced from India or another country.

Bio Products from Human Body Source
Bioproducts that originate from the human body represent a unique domain within the field of biotechnological advancements. This specialized field includes complex procedures including biological material extraction, manipulation, and synthesis that are uniquely derived from human bodies. These bio products cover a broad range of topics, including tissues, cells, proteins, and genetic materials, illustrating the diverse character of this discipline. These bioproducts are unique due to their innate complexity, which is closely related to the complexities of human biology. These goods, in

[5] *Id.*

contrast to other biotechnological innovations, explore the fundamentals of human life and present particular ethical, scientific, and legal issues.

These bioproducts are essential to many fields, including genetics, regenerative medicine, and medicine. For example, they might completely change how we diagnose and treat patients in the medical industry. Human body genetic contents provide information about illness susceptibility and tailored therapy, opening the door to more focused and efficient medical treatments. Furthermore, bioproducts have applications in the field of genetics that include genomic research and gene therapy. Through the synthesis and manipulation of genetic materials, scientists may explore the complexities of human DNA, leading to a better understanding of genetic illnesses and possibly opening up new treatment opportunities.[6]

Bio products obtained from human body sources have potential use in tissue engineering and organ transplantation within the field of regenerative medicine. The capacity to separate and work with cells and tissues creates opportunities for the development of specialized solutions to deal with the lack of available organs and improve transplant outcomes. Bioproducts and biotechnology have a lot to offer in terms of expanding the boundaries of biotechnology and healthcare. It also emphasizes how crucial it is to manage the difficulties involved in using materials that are directly derived from human bodies by taking ethical issues, legal frameworks, and responsible research procedures into account.

The legal classification of bio goods derived from the human body poses a complex difficulty in the field of IP Law. It takes legal navigation to determine if these goods are eligible for patent protection. Potential problems with Section 3 of the Indian Patents Act, which lists exclusions from patentability, provide as an example of this intricacy. Examining in this context becomes essential, taking into account provisions pertaining to biological processes, innovations that violate public order or morals, and the full or partial patenting of plants and animals. Furthermore, there is an extra level of complexity involved in making sure that international accords and conventions are followed.[7]

The difficulties with legal categorization also arise in interpreting patent claims, which leads to discussions about the acceptable bounds of protection and possible infringement issues. This categorization is dynamic in nature due to recent legal precedents and ongoing jurisprudential changes. Addressing these legal issues is crucial as the limits of patentability in the biotechnological setting are still being defined. This is not just to support innovation but also to make sure that moral standards and community values are strongly maintained in the quickly developing field of biotechnology.

Judicial Pronouncements

The case of *Monsanto Technology LLC vs. Controller of Patents and Designs*,[8] decided by the Intellectual Property Appellate Board (IPAB), is a compelling one when it comes to Section 3(j). A patent application was filed by Monsanto Technology LLC for a process that creates transgenic plants that can endure harsh environmental conditions. The assertion was made that a significant portion of the manufacturing process, specifically, the insertion of the rDNA molecule into the plant cell to confer temperature resistance, was carried out by humans. But the IPO was unmoved, maintaining that the invention in question was a primarily biological process and was therefore ineligible for patent protection under Section 3(j) of the relevant patent laws. The rejection further said that there was no inventive step and that the subject matter was invalid under Section 3 (d). Regarding the application of Section 3(j) in the appeal, the IPAB concurred with the IPO; nevertheless, it disapproved of the conclusions made on the inventive step and Section 3(d). As the IPAB made clear, the procedure in question includes human intervention on a plant cell and results in a modification to that plant cell, which puts it beyond the purview of Section 3(j).

The Calcutta High Court's 2002 ruling represents a turning point in the development of biotech patent law. Dimminaco AG filed a patent application in

[6] Mueller, J. M. (2007). Biotechnology patenting in India: will bio-generics lead sunrise industry to bio-innovation. *UMKC Law Review, 76(2),* 437-490.

[7] Puranikmath. (2021, June 29). *Patenting Life Forms In India - Challenges And Scope*. Retrieved January 2, 2024, from https://www.mondaq.com/india/patent/1085388/patenting-life-forms-in-india--challenges-and-scope.

[8] OA 02 of 2012/PT/DEL & M.P. Nos. 35 & 36 of 2013.

Dimminaco AG v. Controller of Patents, Designs and Trademarks to protect poultry from infectious bursa infection.[9] The patent application concerned a method of preparing an infectious bursitis vaccine. A virus-like live entity was present in the finished product. The IPO argued that an invention cannot be patentable unless it pertains to a novel and practical technique of production, citing the present patent rules in support of its position. It further underlined that a procedure cannot be considered a manner of manufacture if it results in the production of a living virus since it must create an object or substance. As a result, Dimminaco's application was denied.

The 'vendibility' test was employed by the court in the appeal procedure to ascertain whether the method in question qualified as a manufacturing process. This test states that an innovation must either create a vendible good, improve or return a vendible good to its original state, or maintain and shield a vendible good from degradation. The court came to the conclusion that, after passing through a manufacturing process, the method did in fact comprise a substance because it produced a sellable product.

In terms of living things and patentability, certain clauses expressly state that sequences that are extracted straight from nature cannot be patentable; nevertheless, biological materials that are acquired by significant human intervention may be an exception. Notably, the US Supreme Court ruled in *Association of Molecular Pathology v. Myriad Genetics, Inc.* that naturally occurring, fully separated DNA molecules or gene fragments cannot be patented as they are considered products of nature.[10] On the other hand, as cDNAs are artificially created and do not arise spontaneously, they were considered eligible for patent protection even if they lack naturally existing non-coding sections. Given that the guidelines explicitly state that sequences isolated directly from nature are not patentable, it will be interesting to see if the IPO and legal authorities follow Myriad's lead and permit applicants to seek protection for cDNA or other recombinant DNA sequences that are blatantly distinguishable from naturally occurring DNA. This is due to the fact that the recommendations don't outline the minimal levels of human intervention that are necessary.

Moreover, in the matter of *Diamond v. Chakrabarty*, the decision made it possible for microbes to be patented in the US.[11] The Court of Customs and Patent Appeals maintained the ruling made by the US Supreme Court on March 17, 1980, to award a patent for a bacteria called Pseudomonas putida that could break down crude oil. As a result, the Supreme Court upheld the idea that an invention's eligibility for patent protection is independent of its living nature.

Challenges and Controversies

Creating patent claims for bio goods made from materials found in the human body is a complex process that mostly involves finely delineating limits. The intricacy of biological materials poses significant concerns regarding the degree to which patent claims may be made without violating naturally occurring occurrences. Reaching the necessary delicate balance necessitates a subtle strategy that takes into account the intrinsic diversity of biological systems. This difficulty is increased by the dynamic nature of bioproducts, where it can be difficult to distinguish between components that are found naturally and innovations that have been created by humans. As a result, careful consideration of creative processes and the claimed subject matter's industrial applicability are required.

The problem becomes much more difficult when taking into account the possibility of overlap with findings made in nature. It becomes difficult to determine whether bio products are innovative since some ingredients may naturally present before the creative process. The difficult task of differentiating between naturally occurring substances and those that have been altered or isolated by humans falls on patent offices. As a result, legislative frameworks need to change to give precise instructions on whether bioproducts can be patentable. To properly address these issues, a balance that respects the integrity of naturally occurring ingredients while promoting innovation is necessary.

In order to navigate these complications, it becomes critical to thoroughly examine creative actions. Because bio products are always changing, patent offices must carefully examine the creative processes that go into making them in order to make sure they satisfy the requirements of originality, non-

[9] AID NO. 1 OF 2001.
[10] 133 S. Ct. 2107; 186 L. Ed. 2d 124.
[11] 447 U.S. 303 (1980).

obviousness, and industrial application. Furthermore, a thorough assessment of the claimed subject matter's industrial application is necessary to ascertain its commercial viability and likelihood of being put to practical use.

Moreover, the dynamic terrain of biotechnological breakthroughs demands constant revisions to the legal frameworks controlling patent claims. In light of the swift advancements in the biotechnology industry, regulations have to provide unambiguous and adaptable standards that take into account the complexities of bioproducts. This flexibility is essential to creating an atmosphere that supports new bioproduct development and research while protecting naturally existing materials from unjustified infringement.

Beyond the legal and technological spheres, public perception and acceptance of bio goods made from human bodies present significant obstacles. It need a multidimensional strategy that includes open communication, ethical considerations, and a sophisticated grasp of society values to address concerns and doubts. Fears of exploitation, unethical behaviour, or the commercialization of human biological resources are common causes of scepticism. The goal, advantages, and safety measures related to the patented bio goods must be made clear in transparent and open communication between patent applicants and holders in order to allay these worries.

The Way Forward

To address the evolving landscape of biotechnology and the unique challenges posed by bio products derived from human sources, potential reforms in Indian Patent Law are crucial. Considering the advent of artificial intelligence (AI) in developing 3D models of organs, some of which are constructed using bio products derived from the human body, there is a need to reevaluate the criteria for patentability. These models, often incorporating bio products derived from human sources, have the potential to redefine healthcare and research methodologies. The law should explicitly recognize the intersection of AI and biotechnology, ensuring that inventions arising from these synergies are adequately protected. However, In contemplating the patentability of 3D organ models developed with AI and bio products, it is essential to consider the ethical implications and societal benefits. Striking a balance between fostering innovation and safeguarding human dignity is paramount.

Additionally, there should be a concerted effort to streamline and expedite the patent examination process for biotechnological inventions. Establishing a specialized division within the patent office to handle biotechnology-related applications could ensure that examiners possess the necessary expertise to assess the unique aspects of these inventions. Furthermore, introducing provisions for expedited examination of applications related to critical health issues could facilitate quicker access to innovative solutions.

Conclusion

Getting a patent is the strongest kind of intellectual property protection since it gives the owner of the rights the greatest control over how the material is used. Because biotechnology deals with living things, including products derived from the human body, patenting takes on special importance in this field. Modern biotechnology has great potential for discovering and using biological resources in a variety of industries, including medicines, ecology, and agriculture. Because biotechnology focuses on patenting living things, it has brought complex issues that have greatly impacted the development of patent laws. Indian patent laws traverse this territory in resolving patentability issues in biotechnology while adhering to the TRIPS Agreement. The United States and other developed nations see the TRIPS Agreement favourably for developing countries, seeing it as a means of promoting technology, innovation, and commerce as well as drawing investments. Subject to specified requirements, the United States may, within its authority, provide permits for plants that have undergone certain quality upgrades using biotechnology procedures. In the modern world, biotechnology plays a crucial role in healthcare and agriculture, providing ways to lower healthcare costs and increase global food security.

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