BIOTECHNOLOGY PATENTS AND LEGAL POSITION IN INDIA

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Best Citation - M. NIKHILA & CH. SUSWANI, BIOTECHNOLOGY PATENTS AND LEGAL POSITION IN INDIA, 1 ILE IPCLR 6, 2022.

ABSTRACT

The pinnacle of human endeavour and the laws of nature is biotechnology. While biotechnology is not a recent development, it has existed for millennia and continues to evolve now. When we use the phrase "biotechnology," we're not just referring to conventional methods of fermented food production, but also to cutting-edge techniques like genetic engineering and recombinant DNA technology.

For a long time, fermentation technology was the go-to method for producing and preserving commodities. When biotechnology generated genetically modified or non-natural living beings, it revealed itself to be a field of marvels. For example, genetic engineering may be used to alter living creatures, allowing them to act and operate in a manner that is different from their natural state.

A genetically designed microorganism was given patent, and since then the area of biotechnology has acquired significant importance and patents have been issued on genetically altered plant and human genetic material. Law of patents in biotechnology had its origins in the seventh century, but it was in Venice in 1494 that the world's first patent law was adopted, which is considered the cornerstone for the world's present-day patent regime. The Venetian Statute's standards for usefulness, innovation, and non-obviousness still serve as the foundation for contemporary patent law worldwide.

Until recently, no one suspected that biotechnology might be used to control plants, animals, or even humans, therefore a complete legislation governing biotechnology was never really considered. The TRIPS agreement, however, offered protection and regulation for many biotechnology inventions as this sector evolved over time and required a thorough legal framework for effective regulation. However, because of the inherent difficulty of working with live organisms, patenting biotech innovations would necessitate extra care.

INTRODUCTION:

There is a lack of uniformity in Indian patent law and practice regarding the patenting of biological materials. The substantive legislation has a number of flaws that need to be addressed. Biotech goods face extra difficulties, including as obligatory disclosure of biological content, prior clearance from the Board of Biodiversity, and access & benefit concerns under the Indian Patent law, in addition to the restricted patentability criteria.

Patentability standards agreed upon by countries throughout the world are discussed in TRIPS Article 27. A product or procedure can be patented if it is unique, includes an innovative step, and has a commercial use. In all nations that have ratified the TRIPS Agreement, this standard applies. Article 27.2 states that innovations that violate public morals or public order, or that endanger the health and life of plants, animals, or humans, may be excluded from patentability if the exclusion is not based only on the fact that exploitation is illegal under the applicable legislation. Article 27.3 prohibits the patenting of anything other than microorganisms, plants, and animals for the purpose of treatment, diagnosis, or surgery.

Examples of criteria not present in TRIPS include, but are not limited to: For example, inventions based on agricultural and horticultural processes; methods of

business; methods of therapy for curative and preventive purposes; and traditional knowledge that is not patentable are examples of criteria that are inconsistent with TRIPS.

Non-patentable usage of a known substance: a new condition not specified in TRIPS. A substance's efficacy cannot be improved upon by any means other than by patenting the substance itself. This includes the following types of compounds: salts, ester-ethers, polymorphs, metabolites, and derivatives. All of these are not patentable unless they differ significantly from the substance itself in terms of efficacy.

For example, the usage of leguminous plants' root-nodule bacteria in combination does not enhance natural functioning; this new need is not included in TRIPS.

Sections 25 (j) and 64 (p) of the 1970 Act were further amended to require disclosure of biomaterial origin and source, broadening the breadth of reasons for opposition and revocation in the event that this information was not provided.

As an explanation for product patentability, biochemical, bio-technological and microbiological processes in chemical processes are included in the scope of patentability.

If an invention is patentable in India, it must meet all of the requirements of novelty, inventiveness, and industrial use. Section 3 and 4 of the Patents Act, 1970, mandate that it must not be eligible for a patent. The following innovations are ineligible for patent protection under biotech laws:

1. ***"An invention would not be patentable if it is immoral or against public order, harmful to human, animal or plant life or harmful to environment": Section 3(b)[15]***- It is illegal for a patent to be issued for inventions that are used for purposes that are detrimental to the health and well-being of human beings, animals, and/or plants, as well as to the environment. Examples include genetically altering animals that result in animal suffering without any major medicinal or other benefit, as well as technologies that have a negative environmental impact.
2. ***Living and Non-living substances discovery in nature- Section 3(c)[16]***-

   Living and non-living substances found in nature cannot be patented since they are not subject to patent protection. As a result, it is impossible to patent microorganisms, DNA, RNA, or proteins that have been extracted from live beings. In contrast to naturally occurring microorganisms, genetically engineered microorganisms and vaccines are patentable, subject to additional conditions. As a clarification, the statute was revised in 2002 to include "biochemical processes" in the description of potentially patentable chemical processes. According to Dimminaco (2012), it is not necessary to include living organisms in the final product for the technique to be patentable if the final product is commercially viable.

   As a general rule, patents are not granted for plants or animals or their components (such as seeds, variations, or species). Plant and animal breeding techniques based on traditional procedures and tissue culture techniques, for example, are not patentable. In Monsanto (2013), the Intellectual Property Appellate Board (IPAB) gave some parameters on what constituted a "essentially biological process." To make a transgenic plant, the patent applicant stated in their application. However, the IPAB overturned the IPO's argument that it was a fundamentally biological process, even though the patent application had already been denied on other grounds According to Monsanto, the IPAB agreed that the plant cell in

[15] Section 3 (b) of the Patents Act, 1970.

[16] Section 3 (c) of the Patents Act, 1970.

the claimed procedure was altered as a result of human intervention in the way stated in the application and thus patent eligible. For example: Even though in India, genetically engineered plants and seeds have no patentability, genetically modified techniques are patentable. Furthermore, under the Protection of Plant Varieties and Farmers' Rights Act of 2001, a unique system of protection for plant varieties is provided.

3. ***New forms or uses of known substance: Section 3(d)[17]-***

Unpatentable are novel forms of recognized substances unless their attributes change greatly from their known effectiveness. As a result of this rule, patents may no longer be evergreened by minor adjustments or gradual improvements. However, legal experts, academics, non-governmental groups, and pharmaceutical businesses disagree on how to read it. According to the Supreme Court's Glivec decision (2013), there are several parameters for interpreting the scope of this clause. The clause, according to the court, raises the bar for medicines and medications, as well as other chemical compounds, when it comes to innovation. Nothing in the law defines the term "efficacy"- the power to generate a desired or intended outcome was defined by the court as "efficacy". The effectiveness test is dependent on the product's function, utility, or purpose. Consequently, the efficacy of a drug will be tested. An improvement in the effectiveness of a known drug cannot be achieved by simply altering its physical shape. Physical qualities such as greater flowability, processing, thermodynamic stability, and lesser hygroscopicity have nothing to do with medicinal effectiveness, yet they can be advantageous. However, Section 3(d) stipulates that any claim of improved therapeutic efficacy must be supported by research evidence, thus even an improvement in bioavailability may fall short of that standard. Any novel property or new application of a known material is also unpatentable under Section 3(d). As a result, a drug's second therapeutic effect cannot be protected by a patent. Section 3(d) of Monsanto (2013) rejected a claim for a method of creating heat, salt, and drought-resistant transgenic plants utilizing cold shock protein, because the cold-tolerant feature of cold shock protein was already recognized in the art.

4. ***Mere Admixture: Section 3(e)[18]-*** In order to patent a combination of two or more previously recognized chemicals, the combination must be more effective than the sum of its parts. In other words, a synergistic effect should arise from such a combination. It is imperative that the synergism is fully proved in the whole specification by giving suitable experimental evidence.
5. ***Methods of treatment and diagnosis: Section 3(i)[19]-*** Drug and medical device patents are not affected by the legislation. Stents, surgical sutures, and staplers are examples of medical devices that are eligible for patent protection.
6. Nevertheless, Section 3(i) prohibits the patentability of any process for the treatment of humans and animals in order to cure them of sickness or raise the economic worth of their products or any of the aforementioned categories.
7. ***Methods of agriculture or horticulture: Section 3(h)[20]-*** Agriculture and horticultural methods are exempt from patent protection. According to the dictionary definition of both terms, horticulture and agriculture are multi-step operations that include soil preparation, planting, adding manure and fertilizer, irrigation and pest and weed control. Harvesting and storing are also included in these processes. According to the claim, "An approach

[17] Section 3(d) of the Patents Act, 1970.

[18] Section 3(e) of the Patents Act, 1970.
[19] Section 3(i) of the Patents Act, 1970.
[20] Section 3(h) of the Patents Act, 1970.

to dealing with pests or phytopathogenic fungi that includes interacting with the pests or phytopathogenic microorganisms, their habitat, breeding grounds, food production, plants and seeds, soil, or other areas, materials, or environments where they are growing or may grow, or materials, plants and seeds, soil, substrates, or other areas that need to be protected from attack".

Section 3(h) was determined to apply to the claim, and it was denied. Treatment of seeds with chemicals before or during planting in the field for plant culture was deemed unpatentable in 9827/DELNP/2007 for decreasing mycotoxin contamination of a plant or harvested plant material.

8. ***Traditional knowledge: Section 3(p)[21]-*** Patentability is particularly denied to an innovation that is only a combination or replication of previously known qualities of a conventionally recognized component or components. Ayurveda, unani, siddha, and yoga are all part of India's Traditional Knowledge Digital Library (TKDL), which has been created to house the country's traditional knowledge. Prior art searches will be made easier thanks to the database, which is available to major patent offices across the world. Five languages are provided for the information (English, German, French, Japanese and Spanish). If you have any patent applications that pertain to traditional knowledge in India, you may use the TKDL to get them withdrawn or cancelled quickly.
9. Plants and animals in whole or any parts thereof other than micro-organisms but including seeds, varieties and species.[22]
10. Essentially biological processes for the production or propagation of plants and animals.[23]

[21] Section 3(p) of the Patents Act, 1970.
[22] Section 3 (j) of the Patents Act, 1970.
[23] Section 3 (j) of the Patents Act, 1970.

Gene ownership, human cloning, genetically modified humans, animal suffering, environmental threats due to genetic manipulation, and ecological balance are only few of the severe difficulties that arise while patenting biotech technologies. Even though biotechnology is important to scientists, obtaining a patent in India might be difficult at times.

BIOTECHNOLOGY PATENT APPLICATIONS AND ITS FORMAL REQUIREMENTS:

1) Deposition of biological material-

Because it's not widely available and can't be accurately described, an applicant is required to deposit any biological material stated in their specification as per Patent Act 10(4). According to the Budapest Treaty, the data must be sent to an international depository body. The Microbial Type Culture Collection and Gene Bank in Chandigarh and the Microbial Culture Collection in Pune are India's international depository authority.

Patent applications in India must be filed no later than the date of the deposit. The deposit must be mentioned in the specification within the allotted time frame (i.e., three months from the filing date). Before a patent may be issued in India, a request for clearance from the relevant body must be made. All of the biological material's features must be included in the specification in order for it to be correctly identified. These contain the institution's name and location, as well as the deposit date and number. Applicant must also explain where the biological material came from. It is mandatory that the applicant declare both the source of the gene sequence and the source of the plant material that is being converted if a gene sequence from a plant is claimed and utilized in this manner.

2) Sequence listing:

Sequence listings for genes, nucleotides, and polypeptide sequences are required in the whole standard. Electronic

submission is required for the sequence list. There must be a reference to the gene's accession number. According to the number of pages, the charge for filing a comprehensive specification is calculated. Because of the large page count that comes with sequence listing, the filing price can sometimes be increased significantly. is supplied. An amendment to the Patent Rule 2003 has been proposed by the GOI that would limit the highest amount that may be paid in the case of sequence listing.

PATENTING OF BIOTECHNOLOGY:

TRIPs specify the minimal requirements for patent protection and use that must be met by all member nations of the international intellectual property rights framework. Many nations in the WTO have made changes to their patent laws in order to adhere to the TRIPS agreement. The Indian Patent Act 1970 is one of these countries.

There are specifics for biotechnology patentable subject matter under the TRIPS agreement, which is significant to the field of innovation. In all sectors of technology, if the product or technique is fresh, imaginative and can be used in industry, it is considered a patentable invention. Microorganisms, microbiological processes, and nonbiological processes used in the production of agriculture are all subject to patent protection under TRIPS Article 27(3). There are several uses for microorganisms that can be patented under this clause, such as agricultural and environmental applications. Biotechnology may be used to a wide range of processes and product creation.[24] Because of this, member countries must guarantee protection for microorganisms as required by the TRIPS Agreement.[25]

a) Various Issues:

Economic and Social Implications: Since the invention of monoclonal antibody technology, molecular biology methods, and recombinant DNA, the commercial interest in biotechnology has expanded dramatically since contemporary biotechnology first appeared, even though fermentation has been used to manufacture beer and bread for centuries. Resistance to development in plants and animals can be achieved by the use of biotechnology-based medications such as recombinant erythropoietin and growth hormone.[26]

There are several agricultural and industrial applications for medicinal plants. Some regulations still apply to the growing and gathering of cannabis. Higher yield and content can be protected, but it's an open question. Recombinant DNA technology allows for the selective modification of higher species' genetic material. In fact, genes may be passed from one species of creature to another, even if those animals are not closely related. It is possible to create novel gene combinations by splicing and cutting existing genes.

Recombinant DNA technology, as compared to traditional techniques of selective breeding, provides a faster and more reliable means of creating new creatures with the required features. To increase the nutritional value, reproductive efficiency and growth rate and illness resistance of farm animals using "transgenic" animals, the animals are utilized in medical research as well as pharming. The application of transgenic technology for conservation of animal species is also conceivable.[27]

Since it is now possible to create and patent transgenic animals, many have questioned whether it is ethical to be able to create and patent living inventions. For the first time in history, modern biotechnology presents an unprecedented challenge to patent law since it relies on the discovery and

[24] J H Reichman, "The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries (2000) 32 Case W. Res. J. Int'l L. 441.

[25] Y Ko, "An Economic Analysis of Biotechnology Patent Protection" (1992) 102 Yale L. J 777.

[26] Gould, M. David and C Gruben William, "The Role of Intellectual Property Rights in Economic Growth," Journal of Development Economics, 1996, 48, 323-350.

[27] Mansfield, Edwin, 1994, Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer, International Finance Corporation, Discussion Paper 19.

utilization of natural and living components, as well as their change.

An ongoing debate is taking place over the patenting of biotechnological inventions. The contentious new biotechnology patents can be attributed to a variety of causes. Some of the most pressing difficulties and challenges facing the patenting system in the biotechnology industry must be addressed as soon as possible. The following are some of the actions to take.

Criteria of Patentability: Patentability standards for issuing patents in biotechnology have been presenting new hurdles in the form of detecting the uniqueness in living matter, which is a challenging undertaking, if not impossible. The reason for this is that living objects, such as animals and gene sequences, are not unique since they occur naturally.

Non-obviousness: Biotechnology has been plagued by the question of obviousness since scientists often utilize the same procedures to identify different gene sequences, even though the gene sequences may be completely different. A patent cannot be granted if the innovation would have been evident to someone of ordinary competence in the field had the preceding technology 'prior art' been available.[28]

Patenting of Human Genome: The patenting of the human genome is fraught with peril. As a result, the most prevalent argument to this patent type is that human genes exist in nature and are not artificially created. The issue of gene patenting brings up two conflicting concerns,[29] Ethically, can we patent parts of the human genome that are part of our 'natural' or universal heritage? In light of the enormous financial resources and human labor expended to discover the human genome, is it moral to reject patenting it?

Conflict/Challenges over Patenting Issues in Biological Materials:

Patent law may be challenged by the unique properties of emerging technology, which might lead to difficult challenges of explanation. In today's biotechnology, it's getting harder and harder to tell the difference between a finding and an innovation. In addition, GMOs are unique in that they are products of human ingenuity. Several of them are not only still breathing, but they may also reproduce on their own and are inconsistent, difficult to explain, etc. They will interact with the surroundings in unexpected ways if they are allowed to roam freely.[30]

It's important to remember that genetic resources are abundant in the world's least developed countries, and many of these countries object to intellectual property laws and claims of 'biopiracy,' citing moral and social justice concerns. TRIPS does not define microorganisms and microbiological processes. This raises the question of whether human intervention is required to demonstrate a level of innovation in the found microorganism or if naturally occurring microorganisms are patentable in their pure state. It also raises the question of whether a product made using a well-known microorganism may be patentable, as well as whether the technique itself can be. If microorganisms and microbiological processes are not defined clearly in the TRIPS agreement, then the country must distinguish between products resulting from human intervention and those occurring naturally.[31]

The right to patent live beings, in particular assets and seeds that have been generated or acknowledged as customary and common knowledge, is a topic of extra arguments and difficulties in the area of biotechnologies. As a result, indigenous knowledge and the rights of indigenous people, as well as the long-term health of local ecosystems, are often jeopardized, as is our ability to safeguard the global

[28] Chapman Audrey, A human rights perspective on intellectual property, scientific Progress, and access to the benefits of science, Science and Human Rights, American Association for the Advancement of Science (Washington, D.C., United States of America), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_5.pdf.

[29] Article 15.1 (b), International Covenant on Economic, Social and Cultural Rights, henceforth ICESCR, adopted 16 December 1966, 21 U.N. GAOR Supp. (No. 16), p. 49, U.N. Doc. A/6316 (1966).

[30] Mcinrey, Biotechnology: Biogen v. Medeva in the House of Lords, [1998] EIPR 14 and Ko Yusing, An Economic Analysis of Biotechnology Patent Protection, 102 The Yale L. J., 777 (1992).

[31] Barton, Research-tool patents: issues for health in the developing world. Bulletin of the World Health Organization, 2004, 80, 121-125.

environment. Biotechnological inventions may not be adequately protected under the present patent system.

Biotechnological patents have the potential to benefit an ineligible patentee since the parties involved in this field often award patents on gene fragments, genetic testing, and proteins whose true functions are not completely understood.[32] Biotech goods are shrouded in controversy not because of the actual product itself, but rather because of the new IPR framework in place, and the MNCs' increasing hold on intellectual property.

ROLE OF BIOLOGICAL DIVERSITY ACT[33]:

Pre-informed consent, transparency and access, and benefit sharing were all addressed in India's Biological Diversity Act. The primary goal of this legislation is to guarantee an equal distribution of the benefits resulting from the use of biological resources and associated traditional knowledge through the regulation of such access. Biological Resources or knowledge associated with them must be obtained with the approval of NBA under Section 3, and Section 4 requires Indian individuals/entities to seek approval before transferring knowledge/research and material about any biological resources (occurring in or obtained from India) to foreign individuals, institutions, or companies (whether non-resident Indians or companies incorporated in India) (that are not incorporated or registered in India; or incorporated or registered in India with foreign participation in its share capital or management). An expert body, like the Biodiversity Management Committees (BMC), may be consulted by the NBA before it grants clearance under Section 19 of the Natural Resources Conservation Act (NRCA). Biological Diversity Act Section 5 (Collaborative Initiatives) does not require further NBA permission for projects that have been approved by the Government or are in accordance with the Government's policy guidelines.

The Indian Forest Act of 1927 and the Wildlife Protection Act of 1972 govern flora such as bacterial and fungal strains that live in reserved and protected forests. There are two laws in India that govern forest management and forest conservation, respectively. The Wildlife (Protection) Act strives to save wild animals, birds, and plants via the establishment of national parks, wildlife sanctuaries, and other protected areas. Additionally, the law stipulates that some plants may not be picked, uprooted, or otherwise disturbed.

Plants, animals, and microorganisms, as well as the genetic material and byproducts they produce, are all considered "biological resources" under the Biological Diversity Act. The use of genetic material from living humans is prohibited. However, the NBA does not have to approve the extraction of bacterial and fungal strains, as well as any value-added products, because they are not considered 'biological resources'. Obtaining such material for commercial reasons is only needed of the Indian partnering firm of a foreign corporation if they notify the State Biodiversity Board in advance. It is the responsibility of EXIM policy to set the costs associated with export licenses. In order to import and export particular biological material, the Director General of Foreign Trade requires further approval.

Biological Diversity Act prohibits any application for any intellectual property rights (IPR) in or outside India without prior approval from the NBA. Several steps of gatekeeping are contemplated for this:

Before filing for any sort of IPRs (in India or elsewhere) based on research or knowledge about a biological resource derived from India, applicants must get NBA's prior consent (section 6(1)). IPR rights linked to the preservation of plant varieties, however, do not need this authorisation. For this reason, it is the Plant Varieties and Farmers' Rights Authority, formed under the Protection of Plant Varieties and Farmers' Rights Act of 2001 (PPVFRA), which distributes rights and assesses benefits in such

[32] Richard Dahl, Pending resolution: the question of who owns DNA. Environmental Health Perspectives, 109 (1), 2007, A31-A33.
[33] Conservation of Bio-diversity Act 2002 and Biological Diversity Rules, 2004.

circumstances. As a result, this Authority approves the transfer of the right to the NBA;

It's possible to get this permission after the patent application is published and before the patent is granted. IP rights can be transferred to other parties only if the individual provided access to biological resources and related knowledge by the NBA has obtained permission to do so.

The NBA is most likely to apply benefit sharing requirements, such as royalty payments, joint ventures, and the transfer of technology, while approving such authorization. There are a number of considerations that must be taken into account when determining the amount of compensation that should be paid. International Regime on Access and Benefit Sharing; Evolving sui generis system for Traditional Knowledge preservation; Amendments to the Biological Diversity Act, 2002 and Biological Diversity Rules, 2004 were all opened for public hearing by the National Biodiversity Authority (NBA). We haven't seen the final product. Pre-informed consent, transparency and access, and benefit sharing were all addressed in India's Biological Diversity Act. The primary goal of this legislation is to guarantee an equal distribution of the benefits resulting from the use of biological resources and associated traditional knowledge through the regulation of such access.

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LEGAL FRAMEWORK IN INDIA:

As a result of TRIPS, all innovative items and processes with an incentive step and the potential for industrial use must be granted patent protection. It is permissible for governments to restrict plant life, animal life, and basically any biological process used in their creation from patentability.

Patenting 'an effective sui generis system' or any combination thereof is required by governments to safeguard plant types. The patentability of microorganisms and microbiological processes is specifically prohibited. However, the lack of definitions in this article leaves the meaning of terminology used in this article to the interpretation of national legislation.[34]

***TRIPS Controlling Patent Regime of Member Countries*:**

Domestic legislation in the member nations of TRIPS are greatly legalized. However, there are two caveats set forth in the provision's second and third clauses that require nations to establish a patent system that is both efficient and comprehensive.

According to article 27(2), members may exclude innovations from patentability if doing so is required to maintain public order or morals, including the health or well-being of human beings as well as animals and plants, or if doing so would result in substantial environmental harm.

Members may also exclude diagnostic, therapeutic, and surgical methodologies for the treatment of humans or animals, as well as plants or animals besides microorganisms, and essentially biochemical characteristics for the production of animals or plants other than non-biological and microbiological processes, from Article 27(3). However, plant variations must be protected either through patents or the sui generis system.

Article 30 of TRIPS provides that the execution of such exceptions does not interfere with the regular exploitation of the patent and the legitimate interests of the patent holder, which is noteworthy.

***Indian Patent Law: Perspective for Grant of Patents*:**

'Invention' is defined in the Indian Patent Act, 1970, which is regarded a model statute in the history of Patent regimes, and it provides the ground for deciding the stages for patents. "Invention" is defined as follows in Section 2(1) (j) of the Act: "A novel product or technique involving an innovative step that is capable of industrial application."

According to the aforementioned definition, a patentable invention must meet the following criteria: novelty, non-obviousness, and industrial use or utility.

In order to meet the primary requirement of novelty, an invention must be fresh and distinct from prior art. An invention is referred to as a 'prior art' if it has not been previously published in any form or in the public domain anywhere in the globe.

If an invention has an innovative step, or non-obviousness, it should not be obvious to an expert in the field. If you're a scientist, you don't need to be an inventor; you don't need to go against accepted scientific ideas; you don't need to take unimaginable risks. Assuming the same or comparable challenges happen in other disciplines, a knowledgeable individual will hunt for alternatives by transferring technology from one of those fields to the one in which they are interested, assuming the transfer requires normal experimental effort.

As a result, in order for an invention to be patentable in India, it must be innovative, non-obvious, and industrially

[34] Pankaj Musyuni, Patenting of Biotechnological Products Issues Perspective to US, Europe and India, International Journal of Pharmaceutical Sciences and Research, pp 1403-1411, https://ijpsr.com/bft-article/patenting-of-biotechnological-products-issues-perspective-to-us-europe-and-india/?view=fulltext.

relevant (utility). It is also important that the innovation is re-usable. To answer the question of whether biological materials, such as microbes, may be considered novel, the aforementioned criteria must be used. One of the most difficult issues in biotechnology is the definition of inventiveness. The provision of specifics about the innovation to be protected is a requirement of the patent law.

'Sufficiency of disclosure' is a typical term for this. Due to the fact that biotechnology innovations include living creatures, meeting the criteria of appropriate disclosure presents particular challenges (biological material). Words fail me when it comes to describing such things. As far as biological innovations are concerned, a practice has arisen wherein the inventor is required to deposit a sample of the live creature involved in the invention with an approved depository authority in order to demonstrate sufficient disclosure.

For innovations incorporating biological materials, the Act does not specify how to fulfill Section 10(4)'s criterion of adequacy of description. The Indian Patent Act prohibits the patenting of some biotechnological innovations, such as living and nonliving substances found in nature. However, this does not include microorganisms that have been altered, or those that have been isolated. Any time an organism's characteristics have been altered and the ensuing product or process is in conflict with public policy or morals, harming people, animals, plants, or the environment as a whole is the outcome.

Some examples of what is prohibited from being patented under the Act include any process for treating humans or animals for the aim of making them disease-free, increasing their product value, or improving their economic worth.. Prohibition of the Act's restrictions on patenting plants and animals in whole or in part also prohibits patenting of seeds, variations and species, as well as fundamentally biological processes for producing or multiplying plants and animals[35].

In spite of these restrictions on patentable innovations, biotechnology inventions have grown, notably from the traditional biotechnology such as fermentation, east, etc., despite these restrictions.

Process or method for producing tangible and non-living things by bioconversion or by using such microorganisms or by using the above-mentioned biologically active substances was assessed and found patented. The spirit of patent law was to prohibit living things like bacteria, gene-cell lines, and the like from patentability, even though the Act of 1970 made no express mention of patentability.

Patentable subject matter: To be eligible for a patent, an invention must meet the definition of patentable subject matter set out in the Patent Act. As far as patentable subject matter goes, the United States has a wide range of options to choose from. Only laws of nature, substantive facts, and intellectual and abstract concepts are not patentable subject matter in the United States

An innovation or discovery must be useful in order to be eligible for a patent under Section 101 of the United States Patent Act. The USPTO does not strictly examine usefulness when dealing with biotech innovations, thus an invention must have some practical use in the form of an instant benefit to the public to meet this condition. If a biotech innovation can be proved to have substantial and credible use to a person of ordinary skill in the field, it will be eligible for patent protection.

The term "novelty" refers to something that is unique or innovative. In order to be considered patentable, an invention must be brand new when compared to prior art (existing data and knowledge at the time of conception of the invention in the public domain). Section 102's

[35] Gupta, S. (2002), The Problems Raised by Biotechnological Inventions for Patent Scope Interpretation (http://www.inter-lawyer.com/articles/patent-scope.html)

uniqueness does not differ from Section 101's newness. When compared to other types of innovations, the bar for uniqueness that needs to be crossed in the biotechnology industry is rather low.

To be patentable, an invention must be non-obvious in the context of the prior art. To be patentable, a new invention must have substantial differences from the previous art that are not evident to a person of ordinary ability in that field at the time of the invention.

As a composition of matter, DNA sequences are patentable as a chemical compound under US patent law. All plants of a certain species that have a specific new gene added to them by biotechnological techniques are granted patents in the United States. Using this method, a gene can be patented in addition to legal rights over the isolated gene and DNA sequences, the genetic engineering tools that employ the sequences, and the plants developed from these tools.

For Patents in Europe, the following scenario is the most likely:

The Convention's Implementing Regulations were also amended to reflect the Directive. Biotechnological inventions may, in theory, be eligible for patent protection under the EPC. The relevant provisions of the Convention are to be treated and construed in line with Rules 23b-e for European patent applications and patents for biotechnological innovations. In addition to the Directive 98/44/EC, it can be utilized as a way of interpreting.[36]

BIOTECH PATENT JURISPRUDENCE IN INDIA:

1) **Dimminaco A.G. v. Controller[37]:**

India's biotechnology sector is still at a very early stage of growth, and so there has been no significant case law creation in this area. The A.G. v. Controller of Patents, Designs & Trade Marks (in 2002) case is a landmark in Indian biotechnology patent law since it established the first time that the practicality of a biotech innovation could be proven. An infectious bursitis vaccine preparation technique was the subject of the innovation. However, the invention's usefulness was not in question. It's not clear how long ago this decision was made, but Indian commentators see it as epoch-making because it overturned a long-standing policy of the Indian Patent Office to reject such process claims, opening up biotechnology patenting in India much like the Chakrabarty decision did in the United States.

In India, "no patent has yet been awarded for any technique of preparing a live creature," according to the Assistant Patent Controller. This might lead to more issues in India, where imported advanced inventions would have to be patented, according to the Controller of Patents.

He also said the 1970 Patents Act based on a 1959 government-commissioned Iyengar Committee advice that "innovation" should be defined more narrowly. According to Appellant Dimminaco, no previous art was provided by the Patent Office to oppose the claimed procedure, nor did it doubt the vaccine's usefulness in the final product. To be eligible for patent protection, the "manner of manufacturing" must fall inside the Patent Act's specified innovations. Calcutta High Court re-examined the Patents Act, 1970's definition of "manner of manufacture" after summing the views of the parties and noting that the word "manufacturing" was not defined. The dictionary definition of "manufacturing" or its "use in the specific trade or business" must be acknowledged in such instances, according to the court. The vendibility test is one of the most prevalent ways to determine if a manufacturing method "deserves to be patented or not." When the Patents Act, 1970, provides no definition of "manufacturing," "the dictionary must be accepted," as in this case. Because the final product contains living virus, the Assistant Controller made an illegal legal error by saying that the process of making the final product is not an innovation because it involves a live virus.

[36] Derek Wood, European Patents for Biotechnological Inventions- Past, Present and Future, World Patent Information 23 (2001) 339-348.
[37] (2002) I.P.L.R 255 (Cal).

The Assistant Controller's judgment was overturned because the court found that the Indian Patent Office had already issued a few biotechnology method patents that resulted in a live end product. By denying Dimminaco's application on the grounds that it could not be classified as a "method of manufacture," the Assistant Controller had "not acted on sound considerations." When it comes to artificial life forms, the MPPP says that "living entities of artificial origin such as microorganisms or vaccines are deemed patentable, but higher life forms like as plants and multicellular creatures of natural or artificial origin are not". Aside from the fact that biological material, such as recombinant DNA (rDNA), Plasmids, and procedures for making them are patentable, they must be generated by human involvement. In addition, micro-organism procedures and chemical compounds produced utilizing micro-organisms are eligible for patent protection.

2) Speaking Roses International Inc. vs. Controller-General of Patents and Anr.[38]

"Providing an image on an Organic Product, being flowers" was the patent application filed by the Petitioners, namely Speaking Roses worldwide Inc., on September 19, 2002. Later, they received their responses and compliance to the First Examination Report (FER) and the Second Examination Report (SER). It had been denied by an order on the following five key reasons, however. Section 3(j) of the Patents Act, 1970 was cited as the initial reason for the application's denial. Plants and animals in whole or in part, save for micro-organisms but includes seeds and species and fundamentally biological processes for the production or multiplication of plants and animals," according to sub-clause (j), are exempt from this prohibition. In this sub-clause, a patent cannot be granted for plants or any biological processes used to produce or propagate plants. There were no flowers or organic items to be protected by the patent, but rather an image on an organic product. That's why they were attempting to patent something else. A mechanical method rather than a biological one was to be used to make such a picture. That's why it wasn't covered by aforementioned Section3 (j).

In light of this, the Petitioners' claim lacked the requisite creative step to be eligible for a patent, as three other inventors had previously been granted patents for a similar purpose. A pad/roller was used as a transfer medium by the Petitioners, who claimed that their product was significantly different from that of the patentees. Another innovator employed a computer-controlled laser beam to cut and modify the picture on the flower's surface, resulting in changes to the organic product's substance and rapid degradation. Although the Petitioners' pad printing procedure did not affect anything, Patentability requirements of inventive step and originality are met since the Petitioners were the first to file an application for the process they are claiming a patent for.

According to the other three grounds of objection, Petitioners' claim does not adequately specify the invention, the title of patented product lacks clarity, and the Petitioners' claims are inconsistent with each other. It was the Court's conclusion that the Petitioner's intent was clear, succinct, and distinct in their application's title, "Providing an Organic Product with a Mechanical Process for Imprinting a Message," and therefore their application's title was appropriate. Because of their pictorial explanation of the technique, the court concluded that Petitioners' claim for a method patent was in perfect accordance with their illustration. It was also found that the Petitioners' summary of their invention, which was included in the application, provided a clear definition of their invention's methods, such as the images that should be imprinted on the specifically illustrated organic products, as well as a clear objective of their exercise.

Aside from concluding that there was no need for the Petitioners to alter their claims in light of these new facts, the Court refused to accept any additional arguments from the Respondent about whether it was possible to broaden the scope of their claim. A patent application cannot be dismissed because just one of the patent's assignees

[38] 2007 (109) Bom L R 630.

submitted the application, a judge said in the conclusion. Last but not least, the Court overturned the Respondent's decision to reject the patent.

CONCLUSION:

As was already said, the patenting of biological materials is a relatively new issue in India. It has not yet become commonplace to either patent or not patent biological innovations. As long as it is identified by its protein or amino acid sequences at least in both the invention's description and claims, the Patent Office frequently grants patent protection for inventions that relate to novel, inventive, and altered genetic material. As a result, a variety of criteria must be satisfied by the innovations. It is noteworthy that India still routinely judges the patentability of biological material on a case-by-case basis.

The post-TRIPS patent laws in India support the patenting of biotechnology as a way to achieve a competitive advantage in a number of ways. The Dimminaco decision also shows that the government and courts have a better awareness of the importance of biotechnology patenting. If the description/enablement requirements are satisfied and the prosecution is well-defined, as is evident from the previously disclosed permitted claims, a variety of biotech patents can be obtained. Given that India is one of the most biodiverse nations in the world, it makes sense to protect biotechnological concepts so that Indian biotechnology research can compete internationally. India can benefit from its plentiful bioresources thanks to a provision that grants patent protection for biotechnological concepts and creations.

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