NATIONAL FRAMEWORK WITH REGARDS TO PATENTING IN BIOTECHNOLOGY FIELD

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ABSTRACT

Patents in biotechnology encompass technological advancements, such as how something works, how it is constructed, and how it is utilized. They grant the owner the only right to restrict anybody from making, using, selling, offering for sale, or importing an invention in a certain region without his authorization for a specified amount of time. This paper describes the legislative framework in our nation for biotechnology patenting. This paper will focus on Indian laws regulating biotechnology protection and patenting.

Keywords: Patent, Biotechnology, Legislative Framework, Protection of biotechnology, Strategies for protection.

INTRODUCTION

Biotechnology has grown inside the overdue twentieth and early 21st centuries to incorporate contemporary and diverse sciences like genomics, recombinant gene strategies, implemented immunology, and consequently the evolution of pharmaceutical cures and diagnostic checks. The phrase "biotechnology" become first used by "Karl Ereky" in 1919, which means the processing of staple items with the help of dwelling organisms. Biotechnology currently acts as a crucial role in almost all fields of pharmaceutical science, genetics, molecular biology, biochemistry, immunology, embryology, and cell biology-based stem cell research, bioremediation, and biodegradation. Biodiversity genetic resource creation is acknowledged as biotechnology. Biotechnology, generally, involves any methodology that utilizes the living organisms or some parts of organisms to create or alter goods, enhance plants or animals, or grow microorganisms for specific acts. Humanity has been using the different arrangements of biotechnology since the beginning of humanity. However, the latest emergences of present day biological techniques (e.g., recombinant DNA, cell fusion etc) has posed prime social and ethical concerns and have produced problems with intellectual property rights. In addition to

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the pharmaceutical industry, biotechnological advances and research are instrumental in the health care systems, the food sector, the polymers and materials industries, etc. A significant risk commitment is part of the outcome of research and development in this field. Much more importance is attached to promoting such findings with regard to the patenting of innovations in that department and allowing the expanding research zone to support itself on a monetary basis. Patents in biotechnology encompass technological advancements, such as how something works, how it is constructed, and how it is utilized. To protect the invention from being made, used, sold, offered for sale, or imported by anyone else, ensure that the owner has the exclusive right to do so in a certain region without his authorization for a specified amount of time. This paper describes the legislative framework in our nation for biotechnology patenting. This paper will focus on Indian laws regulating biotechnology protection and patenting. Out of a total of 50659 applications filed, the number of applications filed by Indian applicants was 17,005, which shows about a 9% increase over the previous year, wherein the corresponding number was 15,550. Inconsistent with the growth in past years, this year too, applications filed by Indian applicants have shown an increasing trend in the domestic filing, which was 33.6 % of the total applications filed[1].

PATENT LAW RELATING TO BIOTECHNOLOGY IN INDIA

Under the Patent Act 1970, Patentable inventions must pass a 2-step test:-

A patent application must not fall under any of the categorization expressly excluded under Section 3 of the Patent Act, and it must also pass the well-known three-pronged test of novelty, inventive stage, and industrial applicability. The following are the excluded biotechnology-related inventions:-

Section 3 (b) stipulates that an invention is ineligible for cover if its use or commercial exploitation is “contrary to public order or morality” or “causes serious prejudice to human, animal or flowers or health or to the environment” [2]. Patents for biotechnology are limited to genetically modify biological materials that do not harm humans, animals, plants, or the environment.

[1] Intellectual Property India. < "IP_India_Annual_Report_2019_Eng.pdf”>

[2] Debashish Banerjee and Pankaj Musyuni ‘Biotechnological inventions in India: law, practice and challenges’, Lexology <https://www.lexology.com/library/detail.aspx?g=8405b078-b301-4672-8850-84f74ea23aa7>

Section 3 (c) directs that the “discovery of any animate factor or nonliving materials taking place in nature” doesn`t represent the material that is eligible for patent. For instance, the extraction and isolation of organic substances are normally taken into consideration the mere discovery of a already existing substance and are consequently barred beneath this provision. The lately posted IPO Guidelines for reviewing of biotechnology applications for Patents mainly tells that sequences remoted immediately from nature aren't patentable. In fact, current case law holds that only biological materials created with substantial human involvement are considered to be patentable.

From the standpoint of an inventor, Section 3 (d) is one of the most divisive clauses in Indian law. This is frequently due to its widespread application throughout the majority of technological sectors and, consequently, the generous latitude given to officials in its interpretations, the hazards of which a number of recent legal disputes involving pharmaceuticals have highlighted. This part is typically cited in biotech patents when a material has been modified. It is a restricted exception since it does not establish an absolute standard.

Section 3 (d), excludes a change of an existing drug from patentability if it doesn't produce a "new type of a known substance" that shows "improvement of the known effectiveness." Court rulings have provided some guidelines for improved pharmaceutical efficacy, but the specifics of this expression in relation to biotech discoveries are not yet understood.

Section 3 (e), This disallows the patentability of any process used to create "material acquired by simple mixing" Under this clause, combination vaccines will always need a prescription. A compound made up of well-known components is now thought to be patented as long as it shows synergism. However, the synergy with regard to biotech patent claims lacks a clear statutory definition, much as the confusion surrounding enhanced efficacy under Section 3(d), allowing the IPO to handle patentability concerns on a case-by-case scenario.

Section 3 (h), which declares "a technique of agriculture or horticulture" to be an ineligible subject matter, the IPO automatically objects to biotech ideas pertaining to these industries. A modest amount of assistance has been provided by recent guidance that makes it clear that Section 3(h) only pertains to "conventional procedures" used in open fields.

Section 3 (i) It prohibits "any method for the medical, surgical, curative, preventive, diagnostic, therapeutic or some other kind of treatment of citizens" from being patented, as well as "any procedure for the similar treatment of animals to liberate them from sickness or to raise their

worth or that of their products." However, it is noteworthy that the IPO occasionally granted patents for in vitro diagnostic procedures carried out on tissues or fluids that were completely removed from the body. However, because in vitro diagnostic procedures now fall under Section 3(i), it is doubtful that the IPO would ever award such patents.

The regulations are susceptible to revision-supported judgments by higher legal officers and do not have the legal power of law. In vitro diagnostic techniques are frequently thought to be outside the purview of Section 3, although the courts have not yet made a decision on this (i). However, it is hoped that when the time comes, the courts would adopt a liberal view. Additionally, Section 3(p) is frequently used. According to this provision, an invention that "is lore or is an aggregation or duplicate of known qualities of a traditional component or component" is categorically excluded from patentability.

Claims are evaluated via searches of various databases, including the common Knowledge Digital Library, to see if they meet the qualifying standard stated by this clause. Extracts, alkaloids, and other naturally occurring active ingredients found in many plants, combinations of plants with known therapeutic effects, combination products of recognised active ingredients, and discoveries of an ideal or workable variety of historically known ingredients through routine experiments are inventions that typically fall within the parameters of the ineligibility scanner.

Section 3 (j) which is broadly modelled on Article 27.3(b) of the Agreement on Trade-Related Aspects of IP Rights[3]. Plants and animals, in whole or in part, seeds, variations, and species, as well as "basically biological techniques for production or propagation of plants and animals" are all not patentable according to Section 3(j). As a result, since crossing and breeding are basically biological processes, they cannot be patented. Like Section 3 (b), the restriction is eliminated in the event of processes that include a significant amount of human involvement. The Plant Varieties Protection and Farmers' Rights Act of 2001, on the other hand, grants transgenic plant varieties a single layer of protection.

[3] Debashish Banerjee and Pankaj Musyuni 'Biotechnological inventions in India: law, practice and challenges'.< https://www.iam-media.com/global-guide/iam-yearbook/2016/article/biotechnological-inventions-in-india-law-practice-and-challenges >

LEGISLATIVE FRAMEWORK AND POLICIES FOR THE PROTECTION OF BIOTECHNOLOGY

EXIM Policy	Under the Bio-Technology Park (BTP) programme, units that promise to export all of their produced goods and services may be established.
Recombinant DNA safety guidelines laid down by the Department of Biotechnology	The Guidelines include topics related to genetically modified organisms in research. It also covers the genetic modification of green plants, the use of r DNA technology in the development of vaccines, the large-scale processing and intentional or unintentional release of species, plants, animals, and goods developed from r DNA technology into the environment. The Guidelines do not apply to matters involving human embryo genetic manipulation, the use of foetuses and embryos in scientific research, or human germ line gene therapy.
National Seed Policy, 2002	This approach targets and aims because biotechnology will be a crucial component in agricultural progress in the future decades. Genetic engineering/modification methods hold great promise for the production of crop varieties that are more resistant to biotic and abiotic stressors. There is an urgent need for an enabling environment for the application of frontier sciences to agricultural growth, as well as more investment in research and development. Simultaneously, concerns regarding possible harm to human and animal health, bio security, and farmer interests must be addressed.

Environment Protection Act, 1986 .	The Environment (Protection) Act of 1986 is where the Regulations for the Manufacture, Use, Import, Export, and Storage of Dangerous Microorganisms/Genetically Modified Organisms or Cells 1989 (Rules, 1989) were initially published.
Drugs & Cosmetics Act 1940	An Act to regulate the production, distribution, and sale of drugs and cosmetics.
Seeds Act, 1966	This Act provides for the compulsory registration of seed on the basis of its results, the deregulation/deregulation of seed industry/processing units, and the imposition of harsher penalties for the control of the sale of spurious seeds. [4]
The Biological Diversity Act, 2005	It addresses matters such as the preservation of biological variety, the equitable distribution of the advantages brought about by the exploitation of biological resources, knowledge, and related matters.
The Indo-Australian Biotechnology Fund	To organise and fund collaborative research seminars.
National Guidelines of Stem Cell Research and Therapy 2007 were established by Department of Biotechnology and Indian Council of Medical research.	These recommendations contain a framework to guarantee that human stem cell research is carried out responsibly, with ethical consideration, and that it complies with the legal requirements for biomedical research in the area and stem cell research in particular.
Guidelines for Study in Transgenic Plants & Guidelines for Toxicity and	Were adopted by the Department of Biotechnology, Ministry of Science and Technology- The existing guidelines cover

4 Priyanka Rastogi, 'Protection of Biotechnology Under Indian Laws'. July 04, 2016 < Protection Of Biotechnology Under Indian Laws - Patent - India (mondaq.com)>

Allergenicity Assessment of Transgenic Crops, Plants and Plant Sections, 1998	areas of recombinant DNA research in plants, including the production of transgenic plants and their soil growth for molecular and field evaluation. The Guidelines also cover the import and shipping of genetically modified plants for research purposes only.[5]

STRATEGIES FOR BIOTECHNOLOGY POLICY DEVELOPEMENT IN INDIA

In 2007, the Government of India's DBT released the "National Biotechnology Development Strategy." The execution of the Biotechnology Strategy (2007) has shown significant potential. The current 'National Biotechnology Development Strategy: 2015-2020' of India intends to establish India into a world-class bio-product manufacturing centre[6]. It plans to begin a serious mission, supported by large investments, to develop cutting-edge biotech goods; provide a solid framework for R&D commercialization, and give India's human resources more access to science and technology. The new strategy would expand on the former strategy, which was implemented in 2007, to speed up the sector's growth to keep up with demand worldwide. The DBT would provide funding for research using modern biotechnology in all fields of basic and interdisciplinary sciences. The emphasis would get on the generation of biotech products, processes, and technologies to reinforce efficiency, productivity, safety, and cost-effectiveness of agriculture, food, and nutritional security; affordable health and wellness; environmental safety; clean energy and biofuel; and bio-manufacturing[7].

The updated mission is to:

1. Promote the use of information and expertise for the benefit of humanity;
2. Launch a important , skilfully directed mission supported by substantial investment for the development and generation of the newest biotech products;
3. Empower India's unparalleled human resources in science and technology;

[5] Priyanka Rastogi, 'Protection of Biotechnology Under Indian Laws'. July 04, 2016 < Protection Of Biotechnology Under Indian Laws - Patent - India (mondaq.com)>

[6] Press Information Bureau, Government of India, Ministry of Science & Technology 'National Biotechnology Development Strategy 2015-2020, 30-December-2015 15:32 IST.

[7] Renu Swarup & A. Vamsi Krishna, *'DBT: Building a Strong Biotechnology Research & Translation Ecosystem'*, Science Reporter.< http://sciencereporter.niscair.res.in/home/article/511 >

4. Build a solid facility for R&D and commercialization; and
5. Transform India into a bio manufacturing powerhouse of the highest calibre.

The ten guiding principles of the National Biotechnology Development Strategy: 2015–2020' are as follows[8]:

1. Building a skilled workforce and leadership,
2. Revitalizing the knowledge environment at par with the growing bio-economy,
3. Enhancing research opportunities in basic, disciplinary, and interdisciplinary sciences,
4. Encouraging use-inspired discovery research,
5. That specializes in biotechnology tools for inclusive development,
6. Nurturing innovation, translational capacity, and entrepreneurship.
7. Ensuring a transparent, efficient and globally best regulatory system and communication strategy,
8. Biotechnology cooperation by fostering global and national alliances,
9. Strengthening institutional capacity with redesigned governance models, and
10. Creating a matrix of measurement of processes also as the outcome.

NATIONAL BIOTECHNOLOGY POLICY OF INDIA

In the 1980s, India started to develop a legislative and regulatory framework for the agricultural biotechnology sector. The nation is currently witnessing significant developments across all biotechnology industries. Enactment of the principles for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989 under the Environment Protection Act, 1986 (EPA) was the pioneer legislation associated with agricultural biotechnology in India[9]. The Biotech Regulatory Agency of India (BRAI), the Indian Biotech Policy, and the regulatory framework are still considered as being

[8] Department of Biotechnology, Ministry of Science & Technology, Government of India <https://dbtindia.gov.in/about-us/strategy-nbds>

[9] Alok Chandra Samal and Piyal Bhattacharya, Biotechnology Policy in India, Department Of Environmental Science, University Of Kalyani, West Bengal-741 235, India. <13-Biotechnologypolicyinindia.pdf>

managed by the EPA (1986) and, consequently, the Rules (1989). The Ministry of Science and Technology, the Ministry of Environment, Forestry and Global Climate Change, and the Ministry of Agriculture are in charge of India's relatively independent biotechnology regulatory oversight. The globe is regulated by some risk-management organisations that are either inside or outside of those ministries. Additionally, there are several organisations that oversee the biotechnology industry in various Indian states. While certain Indian governments are open to embracing the benefits of biotechnological applications, others are still wary of this cutting-edge technology. As a result, each state has a different biotechnology policy and set of restrictions.

CONCLUSION

The rules and organisations governing the use and ownership of biotechnology in India are numerous and complicated. Furthermore, as previously stated these laws and institutions remain in their infancy and are vulnerable to attack. The process of constructing jurisprudence, without a doubt, modifies the aim and meaning of many of its rules. Nonetheless, patterns in the numerous laws impacting biotechnology usage and ownership in India may be seen in terms of public interest protection. Similarly, in India, access to biological resources is regulated to avoid bio piracy while also preserving the rights of resource holders. India has diverse bio diversity. The Human Resource existing in India is one of the country's key and biggest potentials. The human gene pools in India, as well as the country's varied plant, animal, and microbial diversity, present an interesting potential for genomic study. As a result of tremendous developments in scientific knowledge, the biotech sector is currently flourishing at a rapid rate. However, because their nature differs from the typical subject matter of patents, certain scientific innovations have yet to be accepted for patenting. India has experienced quite a favourable consequence in the growth of the biotechnology area, but understanding that India may still accomplish more development if the regulation structure is made more defined and a bit more flexible would assist India in the long run.