

## **A Review on India's biotechnology patenting regulations and challenges**

<sup>[1]</sup>Adv. Meghna Tribhuwan, <sup>[2]</sup>Dr. Shaikh Anisur Rahaman, <sup>[3]</sup>Nikhil Vilas Tribhuwan

<sup>[1]</sup> PhD Researcher, Dept of PG studies in Law, Dr. Babasaheb Ambedkar Marathwada University.

<sup>[2]</sup>Assistant Professor, SSRA Law College, Beed

<sup>[3]</sup>Assistant Manager, research and development Matrix life science PVT LTD

### **Abstract**

An inventor who obtains a patent is given the sole authority to commercialise their idea for a 20-year term and to safeguard it openly and without restriction. With its significant economic worth, a patent may be regarded as one of the most significant forms of IP rights. The rules governing patents have a long history and have changed throughout time in response to societal needs, the rate of invention, and the intricacy of such advances. The Patent Act, 1970 and its 2005 and 2006 amendments, known collectively as the Patents (Amendment) Act, govern patent law in India. For many academics, biotechnology has grown to be an essential tool, and the innovations it has inspired. In addition to inspiring the development of several innovators and playing a significant part in enhancing the country's health, biotechnology has emerged as a valuable instrument for many researchers. The preservation of these inventors' rights becomes inappropriate, therefore several biotechnological innovations including drugs, microbes, and transgenic animals have been awarded patent protection globally. This essay seeks to evaluate Indian patent law with a particular emphasis on how it affects biotechnological inventions. It sheds light on the patent rights of transgenic animals, microorganisms, and pharmaceuticals, as well as how compulsory licensing prevents the misuse of patent law.

**Keywords:** Patent, Biotechnological Inventions, Pharmaceutical Industry, Micro Organisms, Transgenic Animals, Compulsory Licensing.

### **Introduction**

A patent is a legal document that the government issues to an inventor in exchange for their creation of a new item or technique that offers a fresh approach to a problem or new way of doing something. In exchange for a thorough public disclosure of the specific idea, it grants the inventor the exclusive right to use their innovation for a set period of time, often for twenty years. To grant the creator unique rights to profit from their inventions is the objective. It provides innovation protection without the requirement for secrecy.

Until the patent expires, imitators and even independent creators of the same concept are prohibited from using or commercialising the innovation. A patent is a cartel right because it gives the patentee an exclusive monopoly for 20 years before it enters the public domain and is used by others for economic gain. To utilise their innovations, however, third parties may be granted permission or licences by the patent owner under mutually agreed-upon conditions. The owner can potentially transfer ownership of

the patent to another person by selling them the rights to the innovation. In line with the development of technology and societal demands, patents have a very long history, and the legislation governing them has also changed through time. In line with the development of technology and societal demands, patents have a very long history, and the legislation governing them has also changed through time.

### **Related Work**

The first statute on the protection of innovations in India, Act VI of 1856, was based on the British patent law of 1852 since the history of patents in India dates back to the time when India was still a province of the British empire. Later, in 1859, it was changed to give the inventors some exclusive rights. Subsequently, the Protection of Inventions Act of 1883 and the Patterns and Designs Protection Act of 1872 were approved, and they were eventually combined into the Inventions and Designs Act of 1888.

All prior legislation pertaining to patent law were repealed by the Indian Patents and Design Act, 1911, which also placed control of patent administration in the hands of the Controller of Patents. Once the country gained its independence, it was discovered that this act had fallen short of its goal and it was determined that a more comprehensive patent legislation was necessary given the country's significant changes in the political and economic landscape.

To evaluate Indian patent law and make sure the patent system serves the interests of the country, a committee was established in 1949 under the chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired judge of the Lahore High Court. The Act of 1911 was revised in 1950 based on this committee's recommendations. A committee headed by Judge N. Rajagopala Ayyangar was established in 1957 to investigate and provide recommendations to the government about the possibility of revising the Patent Law.

The Patents Act of 1970, which went into effect on April 20, 1972 with the publication of the patent regulations, was created as a result of the contributions and suggestions made by both of these committees. Further revisions were adopted in 1992, 2002, and 2005 to make minor changes and put the Act in accordance with international agreements including the TRIPS agreement. The Indian Patent Act covers both the method and the product.

According to section 159 of the Patents Act of 1970, which gives the Central Government the authority to create regulations for the Act's implementation and controlling patent administration, the Patent Regulations of 1972 were announced and came into effect on April 20, 1972. After afterwards, these regulations were sometimes changed until they were replaced by the 2003 Patent Regulations on May 20. The Patents (Amendment) Regulations of 2005 and the Patents (Amendment) Rules of 2006 further altered them.

Inventions that pass the three precondition conditions are given a patent under the Patent Act of 1970. The innovation must be original and must not have existed before in order to pass the test. Second, the innovation must significantly advance technology; as a result, it must be novel and not just a straightforward modification of already existing equipment. The last requirement is that the innovation must be beneficial, which can be taken to mean that no patent can be issued for a creation that can only

be utilised for immoral or unlawful activities. The Indian Patent Act does not specifically say what types of innovations are eligible for patents; instead, it defines eligibility for a patent in a negative sense, defining a class of inventions that are not eligible for patents under clauses (a) to (p) of section 3 of the act.

One of the most contentious, debatable, and challenging topics a patent attorney must frequently address in practically every meeting with an ardent Entrepreneur is whether or not an invention is patentable. Unfortunately, there is no definitive answer to this problem because there are several possible solutions. An idea's patentability is not addressed in the Patent Act of 1970. A discovery needs to be new, useful in industry, and obscure to someone skilled in the field in order to qualify for a patent. An idea can satisfy all three of these criteria.

A patent application may be filed as a provisional or a full specification, according to Section 10 of The Patents Act of 1970, which also lists the requirements for filing one. Ideas may be patented under this provision if they satisfy certain requirements. A provisional application cannot be submitted without the concept being feasible and having the potential to evolve into a full-scale invention. After a year of submitting the provisional application, one can devise a method for carrying out the concept and then submit the complete application after explaining the idea and submitting a patent application.

### **Procedure to apply Patent**

1. Disclosure of the innovation: The initial step is to inform a professional about your idea. By signing a non-disclosure agreement, this is accomplished. Every information regarding an innovation that is known must be included, without being overlooked.
2. Do a search for patentability. A specialist typically charges between INR 10,000 and INR 20,000 for this phase. The expert will now carry out a comprehensive study to find any past evidence in any available databases. A patentability report based on the invention will also be created by them.
3. Choosing whether to proceed with a patent application: This decision can be made after a thorough analysis of the (potentially) prior history of the invention. It should be emphasised that for an innovation to qualify for a patent, it must be compared to already-existing prior artworks. In order to qualify, it must be "technically sophisticated," "economically important," or both on an existing piece of art.
4. Patent Drafting: The inventor or a professional can draught the application. A professional should receive between 20,000 and 30,000 Indian rupees in payment. One of the most crucial elements in the entire procedure, it calls for expertise in both law and technology.
5. Filing the patent application:

One can submit the patent application in the prescribed manner using the appropriate forms, subject to a fee of INR 1,600 or INR 4,000 or 8,000 depending on the type of application. These are payable for filing the patent application with the Patent Office. If a request is not submitted for an early publication, the patent application will be published within 18 months.

#### 5. Submitting a patent application:

Depending on the kind of application, a cost of INR 1,600, INR 4,000, or INR 8,000 must be paid in order to submit a patent application in the way specified using the proper forms. Fees must be paid in order to submit your patent application to the Patent Office. The patent application will be published in 18 months if no request for early publication is made.

#### 6. Request for examination:

In step six, known as "Request for Examination," the applicant must ask the Indian Patent Office to evaluate the patent application within 48 hours. The charge for this step ranges from INR 4,000 to INR 20,000.

#### 7. Reacting to Objections:

At this phase, the draught and report that will be sent to the authorities of the Patent Office are carefully examined. The inventor now has the chance to include their originality or innovative element into any more works of art discovered throughout the assessment.

#### 8. Granting of the patent:

If the application satisfies all of the standards, it will be released for grant and advertised by a publication that is in print.

#### 9. Patent renewal:

A patent is typically good for 20 years. The owner is required to renew the patent for a modest cost after 20 years.

### **PATENT IN BIOTECHNOLOGY**

The term "biotechnological innovation" refers to a process that employs live creatures, or any portion of them/components, etc., to build microorganisms and organisms that are designed for certain applications, or to construct or refine goods or to make them better. Agriculture, agro-industry, fertilisers, the food business, diagnostics, zoo methods, semiconductors, pharmaceuticals, the trash industry, fuel, chemistry, etc. are just a few of the many industries that utilise biotechnological inventions. The rules pertaining to the patenting of innovations are applied for biotechnological inventions, despite everything else being put aside and what has previously been established. Moreover, the pharmaceutical industry and the life sciences have had a significant impact on life expectancy and quality of life. Nowadays, biotechnology is the foundation of most contemporary medications.

Nowadays, biotechnology is the foundation of most contemporary medications. The use of biotechnology and/or microbiotechnology has made it possible for inventions relating to processes or methods of producing tangible and intangible substances (such as enzymes, antibiotics, insulin, interferon, alcohols, vaccines, etc.) by using such microorganisms or by utilising the aforementioned

biologically referred chemical substances produced by using genetically engineered organisms and substances more economically.

The Patent Office also gives patents on procedures and techniques for producing things, in addition to items like pharmaceuticals, DNA, and antibodies. The actions that need to be done in the invention's technique or process will be reflected in the claims of these patents. Genes, proteins, and organisms may now be used for exploitation thanks to biotechnological innovations. It has the ability to alter how illnesses are identified and treated, how food is grown, how energy is created, and how trash is disposed of. Similar to other innovations, the validity of biotechnological inventions is determined by their novelty, originality, and viability for commercial use.

Along with things like drugs, DNA, and antibodies, the Patent Office also grants patents on manufacturing processes and techniques. The claims of these patents will outline the steps that must be taken in order to implement the invention's technique or procedure. Thanks to advances in biotechnology, it is now possible to exploit genes, proteins, and organisms. It has the power to change how diseases are detected and treated, how food is grown, how energy is produced, and how rubbish is thrown away. Similar to other breakthroughs, the novelty, creativity, and commercial feasibility of biotechnological inventions determine their validity.

Any technological advancement that uses biological material to create or enhance products or procedures is referred to as "biotechnology". The pharmaceutical sector is a subset of the economy that revolves around the development, manufacture, and marketing of pharmaceuticals. In addition to all of this, genes are identified as separate components of a DNA segment that encode the whole individual body, making DNA a key biotechnological component that cannot be copyrighted. The information recorded in a person's genetic code is probably their future diary since it depicts a private future.

DNA sample collection infringes on three different types of privacy: bodily, genetic, and behavioural. Bodily privacy is when a sample is taken from a person's body; genetic privacy is when a person's DNA sample is used to predict future health and other information; and behavioural privacy is when the information is used to determine where a person has been and what he has done. Gene sequencing and gene patenting may violate private rights since they limit a segment of the body. Genes are the basis of human existence and a part of every cell in the body. The right to privacy may be violated if gene patent rights are allowed.

The inherent privacy infringement in providing ownership rights in which every individual is a part-owner solely for the dignity of a human being is highlighted by opponents of gene patenting. Gene patenting could go against the basic tenets of personal and social privacy.

## **PATENT IN PHARMACEUTICAL INDUSTRY**

India has one of the major pharmaceutical industries in the developing world, ranking fourth in terms of output and thirteenth in terms of domestic consumption value. Over the past 30 years, it has evolved from being essentially nonexistent to a world leader in the production of generic medications. Indian pharmaceutical businesses increased the accessibility of less expensive versions of the most widely used patent-protected medications worldwide by becoming experts in reverse engineering. The 1970 Indian Patent Act made this feasible.

Despite the fact that section 5 of the act of 1970 provided an exemption by allowing process patents for foods, medicines, or drug ingredients while expressly excluding product patents for the same, all of this was only possible because there was no products patent system for pharmaceuticals and medicines. India was able to copy patented drugs without having to pay a licencing fee as a consequence, enabling the businesses to distribute the drugs to the general people at reasonable prices. This scenario changed after the implementation of the 2005 revision to conform with Trade Related Aspects of Intellectual Property Subjects.

As a result, this amendment increased patent protection for pharmaceutical products and broadened TRIPS' application to cover all foods, drugs, and medicines. Furthermore, it extended the length of patent protection from the 1970s' legislation's 7 years to 20 years. The creation of product patents wasn't done to stop the cheap mass production of generic pharmaceuticals; rather, it was done to encourage the development of new, more effective therapies in India and provide an alternative strategy for the problem of medication availability.

As a result, this amendment provided patent protection for pharmaceutical products and increased TRIPS' overall scope to cover foods, medicines, and other therapeutics. In addition, it extended the length of patent protection from the 1970s' 7-year law to 20 years. Not to stop the cheap mass production of generic pharmaceuticals, the introduction of product patents was intended to encourage the development of new, more effective therapies in India and provide an alternative strategy for the problem of medication availability.

However, the product patent raises issues regarding increased drug costs for the general public and patent holders abusing their rights by failing to commercialise or produce their innovation in developed nations in order to increase profits. In order to prevent such patent rights abuses and to stop the use of the innovation due to concerns about public morals, the TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) provides for the issue of a compulsory licence.

## SCOPE AND CHALLENGES

Given that Indian patent law and practise are still developing, they are not yet completely established and/or standardised with regard to the patenting of biological materials. The substantive legislation still has a number of issues that need to be resolved. Biotech goods must disclose biological content, receive prior clearance from the Biodiversity Board, and deal with access and benefit concerns within the Indian Patent system in addition to the strict rules for patentability.

While TRIPS prohibits the exclusion of inventions that are novel, non-obvious, and broadly applicable to industry, Indian law has a long list of exceptions to the patentability requirement, including the following:

- a. TRIPS consistent - living or inanimate naturally occurring components derived from biological material or their portions; procedure to produce such components; separation of living organisms, genetically altered or transgenic organisms, and cell components; separation and modification processes; use of biological material;
- b. Consistent with TRIPS, plants and animals as a whole or in part; different species of plants and animals; seeds; basically biological means of propagation;
- c. Criteria not contained in TRIPS, such as frivolous or a straightforward arrangement of well-known components;
- d. Criteria that are inconsistent with TRIPS, including as inventions based on business techniques, curative and preventative treatment procedures, or traditional knowledge that are not deemed patentable.
- e. New requirement: absent from TRIPS - new uses of well-known substances are not thought to be patentable. Salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, compositions, and derivatives are also not considered patentable unless they "do not result in the enhancement of known efficacy of the substance" or "differ significantly in properties with regard to efficacy."
- f. New requirement: simple admixture, such as the bacteria present in the root-nodules of leguminous plants, is not found in TRIPS and does not improve natural functioning;
- g. Additional disclosure of source and origin biological materials for patent grant is now required and is not covered by TRIPS (further amendments to Sections 25 (j) and 64 (p) of the 1970 Act expand grounds for opposition and revocation to include nondisclosure of source and origin of biomaterials).
- h. Limitations on Patentability - Including biochemical, biotechnological, and microbiological processes in chemical processes as an explanation for the purpose of product patent.

## Conclusion

As previously said, India is still learning about the challenges surrounding the patenting of biological material. Regarding the patenting or non-patenting of biological innovations, standardised practise has not yet been adequately established. However, the Patent Office typically accepts such inventions as patentable if a claim of an invention relates to a novel, inventive, and modified genetic material, wherein such genetic material is identified by its protein or amino acid sequences at least in the description and in the claims, and such genetic material is capable of industrial application. As a result,

the innovations must meet a variety of quite wide requirements. It is important to highlight that biological material patenting in India is still frequently decided on a case-by-case basis.

A number of elements in India's post-TRIPS patent rules make biotechnology patenting more desirable as a foundation for competitive advantage. The *Diminaco* ruling also represents a rise in judicial and administrative understanding of the significance of biotechnology patenting. It is clear from the permitted claims previously revealed that biotech patents can be obtained in a variety of fields so long as the description/enablement conditions are met and the prosecution is conducted clearly.

Additionally, since India is one of the nations with a high level of biological diversity, it would be wise to protect biotechnological inventions as this would enable Indian biotechnology research to compete internationally. With an enabling mechanism for patent protection in biotechnological advances and inventions, India can better capitalise on its abundant bioresources.

## References

- [1] The Patents Act, 1970 as amended by The Patents (Amendment) Act, 2005 along with The Patents Rules, 2003 as amended by The Patent (Amendment ) Rules, 2006
- [2] Biotechnology and Patent Law-patenting living beings-Dr. Sreenivasulu, N.S., Dr. Raju, C.B.(2008)
- [3] The Patents Act 1970, 1999 & 2002, along with The Patent Rules, 2003
- [4] Manual of Patent Practice & Procedure-published by office of the Controller General of Patents, Designs & Trademarks
- [5] "Patentability of Biological Material(s) - Essentially, Therapeutic Antibodies - in India", (2008)
- [6] Universal Guide to Patents Law, Manish Arora
- [7] Patent Law by P Narayanan-fourth edition
- [8] Biotechnology Patenting in India: Will Bio-Generics Lead a "Sunrise Industry" to Bio-Innovation? (January 2008) by Janice M. Mueller
- [9] [www.patentoffice.nic.in/ipr/patentjournal/](http://www.patentoffice.nic.in/ipr/patentjournal/) Annual Report
- [10] *Diminaco Ag v Controller of Patents & Designs and Others*, [2001] AID No.1.
- [11] Judgement of *Speaking Roses International Inc. vs Controller-General of Patents and Anr.* citations: 2007 (109) Bom LR 630, MIPR 2007 (2) 75;
- [12] Report of Mashelkar committee "whether it would be TRIPS compatible to exclude micro-organisms for patenting
- [13] R.A. Mashelkar et al., Report of the Technical Expert Group on Patent Law Issues, Dec. 2006
- [14] Corporate Law Group's database of biotechnological patent/patent applications, prosecution history file and research papers
- [15] Bio Patent-Japan Patent Office, Asia-Pacific Industrial Property Center, JIII, 1999
- [16] Conservation of Bio-diversity Act 2002 and Biological Diversity Rules, 2004. National Biodiversity Authority website. [www.nbaindia.org](http://www.nbaindia.org)
- [17] Sharing with the Kanis-A case study from Kerala, India- R.V. Anuradha
- [18] Access and Benefit Sharing Systems: An Overview of the Issues and the Regulation- Janak Rana Ghose, (March 2003)
- [19] Examination Guidelines for Patent Applications relating to Inventions in the field of Chemicals, Pharmaceuticals and Biotechnology.
- [20] Protection of Traditional Knowledge in Indian Patent Act-Dinesh Dayma
- [21] The protection, conservation and effective management of traditional knowledge relating to biological diversity rules, 2009



[22] Indian Patent Law, Office Procedures and Examination Practice for Biotechnology Patent Applications Dr. K.S. KARDAM Deputy Controller of Patents & Designs Indian Patent Office.

**Authors Profile:**



Ms. Meghna Tribhuwan is a PhD Researcher working under Dept of PG studies in Law, Dr. Babasaheb Ambedkar Marathwada University, Aurangbad