Indic Legal Law Journal

ISSN: 2583 - 6385

Volume No. 2
Issue No. 5
Feb 2024 - March 2024
Pages: 13 - 17
Author Name: Nikhil Harikumar P, RGSOIPL, IIT Kharagpur

DEPOSITORY REQUIREMENT OF PATENTS: A CROSS COUNTRY COMPARISON BETWEEN INDIA AND THE US

1. Introduction

All patent applications are required to be accompanied by a set of documents known as patent documents. They include pertinent scientific and other information on the specification of the product or process that is being patented, as discussed in the patent application. The nature of patent documents is such that they are extremely confidential because they deal with the inventor's claims regarding their novel invention. It is important that the information that is disclosed in the patent application be presented in such a way that any individual who is typically skilled in the art or profession will be able to carry out the invention.

In the case of biological inventions that involve microorganisms like bacteria, fungi, yeast, tissue cells, protozoa, and so on, it is possible that it will be necessary to submit the biological material in order to provide evidence in support of the claim. What is known as "Depository Requirements of Patents" is the name given to this requirement, which is mandated by various jurisdictions in light of international obligations. The purpose of this article is to provide a better understanding of this essential criterion by comparing and contrasting the depository requirements of patents in India and the United States.

2. Budapest Treaty

With regard to this matter, the most important international treaty is the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure," which was ratified in the year 1977. One of the most important landmarks in the history of patent agreements is this treaty, which mandated the guidelines and procedures for the signatories to

adopt adequate depository facilities for the storage of microorganisms prior to the granting of patents. This treaty is a significant milestone in the history of patent agreements. The material that was deposited in any one of the depositories was recognized by all of the signatories to the Budapest Treaty, which meant that this treaty was also beneficial to the inventors. The signing of this treaty was a part of the implementation of Article 27(3)(b) of the TRIPS Agreement, which acknowledged microorganisms as subject matter that could be patented.

Additionally, the treaty provided for the establishment of independent International Depository Authorities (IDAs), the primary purpose of which is to collect and store biological material, including microorganisms, prior to taking into consideration the possibility of granting patents on them. There are currently 47 established IDAs that are recognized by the World Intellectual Property Organization (WIPO). These IDAs are located all over the world.

Both India and the United States were parties to the Budapest Treaty, and as a result, they were obligated to ratify and draft domestic legislation for depository requirements in accordance with their respective patent regimes. In accordance with Chapter 2400, Section 2402 of the Manual of the Patent Examining Procedure, the United States of America incorporated the treaty obligations, and India did the same under Section 10 of The Indian Patent Act, 1970, which addresses the Contents of Specification in a patent application. There are a number of significant differences between the requirements for providing a depository in India and the United States, despite the fact that the essence and spirit of both pieces of legislation are identical. In this article, an attempt is made to establish a comparative analysis in the Depository Requirement under patent regime in both of these countries. This is carried out by drawing the similarities and differences in the legislations of each of these countries independently.

3. United States of America

Let us begin our analysis with the US, which possesses a patent legal framework that is more comprehensive. A comprehensive explanation of the rules and procedures relating to the deposit requirement in the case of biological patents can be found in Sections 2401 to 2435 of the United States Patent Law. As patentable subject matter, it acknowledges the existence of bacteria, fungi, including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. The law goes on to specify the requirements for depository institutions, including the time at which an initial deposit must be made, the description of the

depository in the application specification, the acceptable depository, the term of the deposit, the viability of the deposit, and other details.

With regard to the submission of a patent application for biological material in the United States, a written description is not sufficient on its own. In the majority of cases, the submission of a written description as well as a deposit is required in order to be granted a biological patent. This requirement is mandated by the legislature.

For the purpose of granting patents, the United States Patent and Trademark Office (USPTO) is the responsible body that has been entrusted with the task of regulating biological material, which includes the collection and storage of any such material. It is also interesting to note that, according to Section 2403 of the legislation, there is a list of biological materials that are patentable in the United States. This list is not exhaustive.

On the other hand, the deposit requirement might be loosened in the case of biological materials that are well-known and easily accessible in the public domain. The aforementioned two conditions must be satisfied in order for this exception to be applicable; it is not applicable in the absence of either of the conditions. The patent legislation in the United States also includes special provisions for the biological material that can be manufactured with or without undue experimentation, etc., which results in an expansion of the scope of their invention protection system.

According to the United States Patent and Trademark Act, Section 2405 contains the provisions that pertain to acceptable depository service. Additionally, clause (2) of this section recognizes any other depository that is recognized as being suitable for the purpose, provided that the conditions are satisfied. This is in addition to the fact that IDAs are recognized as depositories. Among these are impartiality, objectivity, independence, and the infrastructure that is required, among other things. There are additional sections in the United States patent legislation that discuss the time at which an initial deposit must be made, the replacement of a deposit, the term of a deposit, the viability of a deposit, and other related topics.

4. India

India, which is a signatory to the Budapest Treaty in 1977, has also made the necessary modifications to its domestic legislation in order to comply with the obligations that were stipulated in the treaty. The submission of documents that describe the nature and characteristics

of biological material is made mandatory in India, just like it is in the United States that this requirement is imposed. For this reason, a descriptive notice of this kind ought to be included with the deposits when biological patent claims are being submitted.

India has established two international depositories for microorganisms in accordance with the Budapest Treaty. These depositories are located at the Institute of Microbial Technology (IMTECH) in Chandigarh and the Microbial Culture Collection (MCC) in Pune. When it comes to biological material that is not accessible to the general public, access to the material that is stored in the depository is only granted after the patent application has been submitted.

When it comes to the deposit requirements of patents in India, the most important provision is section 10(4)(d)(ii) of Indian Patent Act, 1970. In the context of the filing of biological patents, this section makes it obligatory to adhere to the Budapest Treaty in conjunction with the conditions that are listed in Section 10(4)(d). The contents of this section deal with provisions that pertain to the time of deposit of the material, the characteristics of the material that is required, the indication and numbering of materials, the identification of the material, and access to the material.

Another provision in Indian law that is pertinent in this regard is Section 3(j) of the Indian Patent Act, which was passed in 1970. The patenting of microorganisms was not recognized in India prior to the amendment of the Patents Act in the year 2002. In light of Article 27.3(b) of the TRIPS agreement, which mandated that countries that signed the agreement acknowledge microorganisms as subject matter that is eligible for patent protection, this new section was added to the patent law.. In the context of the filing of biological patents, this section makes it obligatory to adhere to the Budapest Treaty in conjunction with the conditions that are listed in Section 10(4)(d). The contents of this section deal with provisions that pertain to the time of deposit of the material, the characteristics of the material that is required, the indication and numbering of materials, the identification of the material, and access to the material.

A further provision in Indian law that is pertinent in this regard is Section 3(j) of the Indian Patent Act, which was passed in 1970. The patenting of microorganisms was not recognized in India prior to the amendment of the Patents Act in the year 2002. In light of Article 27.3(b) of the TRIPS agreement, which mandated that countries that signed the agreement acknowledge microorganisms as subject matter that is eligible for patent protection, this new section was added to the patent law.

5. Conclusion

Despite the fact that both India and the United States have formulated deposit requirements in accordance with the Budapest treaty, there is a significance in the way that their respective legislations have been drafted. This is an interesting point to take into consideration. The United States of America takes a more comprehensive approach, incorporating the majority of the potential scenarios associated with biological material in an elaborate manner. On the other hand, Indian legislation makes an effort to adhere to the conventional method of incorporating the treaty obligation into law.

Due to the fact that the statutory provisions are limited to one or two sections, the depository requirement in the Indian Patent Act is more susceptible to interpretation by the judiciary and various academic institutions. In contrast, the Deposit Rules in the United States are meticulously codified across more than thirty-five sections, ranging from Section 2401 to Section 2435, and include a large number of subsections and references. It is the rules of the United States Patent and Trademark Office (USPTO) on deposit requirements that serve as a research material for academicians and industry experts in the field of biological patents.

6. References

1. Udapudi, S. V., & Singh, V. (2020). Juxtaposition Of Patent And Biotech Inventions: Awaits Answer On New Trends.
2. Barfield, C., & Calfee, J. E. (2007). Biotechnology and the patent system. *American Enterprise Institute: Washington, DC*.
3. Sahoo, N., Manchikanti, P., & Dey, S. H. (2011). Herbal drug patenting in India: IP potential. *Journal of Ethnopharmacology*, *137*(1), 289-297.
4. Harney, D. J., & McBride, T. B. (2007). Deposit of biological materials in support of a US patent application. *Intellectual property management in health and agricultural innovation: a handbook of best practices, Volumes 1 and 2*, 973-980.