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PROTECTING INDIGENOUS KNOWLEDGE THROUGH IPR: A CRITICAL STUDY

Punya Rai

Amity University Noida

Bhawna Batra

Associate Professor, Amity University Noida

INTRODUCTION

In the 1300s, the first person to uncover resources in the Alps created property rights for mining, logging, and water. This discovery was particularly significant. Throughout the course of the competition, distinctive advantages were bestowed onto those who produced anything of value. In the year 1409, a German was awarded the first patent for the construction of a model industrial mill. The British were told that they could not have a monopoly on the sale of playing cards since it was evident. The first English patent for the production of stained glass was granted to John of Utynam, and it was valid for a term of twenty years. It was around this period that the French made improvements to the system by registering and testing it. An invention known as a "hopper boy" for a grain elevator was granted a patent in the United States to Oliver Evans.

The United Kingdom Act of 1852 served as the basis for the first piece of patent-related law in India, which was enacted in 1856 and was known as Act VI. This piece of legislation was enacted with the intention of encouraging the invention of novel and practical items, as well as convincing inventors to reveal the trade secrets concealed within their creations. The Act was ultimately repealed by Act IX of 1857 due to the fact that it had been enacted without the approval of the British Crown. In the year 1859, a new piece of law known as Act XV of 1859

was presented to the public in order to give "exclusive privileges." The previous legislation was amended by this act, which expanded the priority period from six months to twelve months and restricted the issuance of exclusive privileges to inventions that were of significant value. In order to fulfil the requirements of this Act, importers were not regarded to be inventors.

THE PATTERNS AND DESIGNS PROTECTION ACT, 1872¹

The Act of 1859 was consolidated in 1872 to offer protection for designs. Act XIII of 1872 changed its name to "The Patterns and Designs Protection Act."

The Act of 1872 was further revised in 1883 (XVI of 1883) to provide a provision to protect the uniqueness of inventions that were previously disclosed in the Exhibition of India and before making an application for their protection. After the date of the inauguration of the Exhibition, a grace period of six months was given for submitting such applications.

This Act remained in effect for roughly 30 years without any changes, but in 1883, after changes were made to the patent law in the United Kingdom, it was decided that the Indian legislation should likewise incorporate those changes.

Therefore, in order to align the law of invention and designs with the changes made to the U.K. law, an Act was introduced in 1888.

THE INDIAN PATENTS AND DESIGNS ACT, 1911²

When the *Indian Patents and Designs Act, 1911 (Act II of 1911)* was passed into law, all of the acts that had come before it was ruled invalid and unenforceable. In 1920, an additional amendment was made to this Act in order to form reciprocal agreements with the United Kingdom and other nations for the purpose of assuring priority protection. This was done in order to ensure that priority protection was provided. During the year 1930, additional modifications were implemented. These modifications included, among other things, clauses that dealt with secret patent grants, additional patents, the government's use of inventions, and the ability of the Controller to repair errors in the patent register, and an increase in the length of the patent from 14 to 16 years. A modification was made in 1945 that required the

¹ *Patterns and Designs Protection Act, 1872*, Act 13 of 1872.

²The Patents and Designs Act, 1911 (Act No. II of 1911), available at:

<https://ecajmer.ac.in/facultylogin/announcements/upload/Indian%20Patent%20and%20Design%20Act,%201911.pdf>.

submission of the entire specification as well as the filing of the provisional specification within a period of nine months. This was a requirement that was necessitated by the revision.

After the country gained its independence, it was believed that the Indian Patents and Designs Act of 1911 was not fulfilling its intended purpose. It was determined that a comprehensive patent legislation would be desirable in light of the considerable changes that have occurred in the political and economic reality of the country. In 1949, the Government of India established a committee with Justice (Dr.) Bakshi Tek Chand, a former judge of the Lahore High Court, as its head. The purpose of this group was to guarantee that the patent system is beneficial to the interests of the country. The conditions of reference were:³

- “To conduct a survey and report on the functioning of the patent system in India; to investigate the existing patent legislation in India and to make suggestions for its improvement, particularly with regard to the provisions that are concerned with the prevention of abuse of patent rights;
- to consider whether any special restrictions should be imposed on patents pertaining to food and medicine; and to report on the findings of the survey and report.
- To make recommendations for the implementation of measures that will ensure effective publicity to the patent system and to patent literature, with a particular focus on patents obtained by Indian inventors;
- To investigate the necessity and practicability of establishing a National Patents Trust;
- To investigate whether or not it would be desirable to regulate the profession of patent agents.
- For the purpose of enabling the Indian Patent System to be more conducive to national interest by encouraging invention as well as the commercial development and use of inventions, the Committee will:
- To examine the functioning of the Patent Office and the services that it provides to the general public, and to make appropriate recommendations for improvement; and
- To report generally on any improvement that the Committee believes it is appropriate to recommend”.

The committee's interim report was released on August 4, 1949. It included ideas for changing *sections 22, 23, and 23A of the Patents and Designs Act, 1911*, in order to bring them in line

³ Office of the Controller General of Patents, Designs & Trade Marks, Government of India, History of Indian Patent System, available at: <https://ipindia.gov.in/history-of-indian-patent-system.htm>, last seen on 24/04/2025.

with the UK Acts of 1919 and 1949. Additionally, the committee made recommendations for preventing the misuse or abuse of patent rights in India. A further point that was brought up by the committee was that the Patents Act ought to make it abundantly apparent that things like food, medication, and surgical and curative devices ought to be made accessible to the general people at the most affordable prices feasible, while at the same time giving the patentee with sufficient compensation.

Based on the above recommendation of the Committee, the 1911 Act was amended in 1950 (Act XXXII of 1950) regarding the working of inventions and forced licensing/revocation based on the Committee's advice. Other clauses connected to the patent's endorsement with the phrase "licence of right" on a government application so that the Controller might issue licences, with the following amendments in 1952 and a measure was proposed in the Parliament in 1953 based on the Committee's recommendations (Bill No.59 of 1953). However, because the government did not push for the bill's consideration, it was allowed to expire.

The Government of India established the Justice N. Rajagopala Ayyangar Committee in 1957 to investigate the possibility of revising the Patent Law and provide recommendations. Two parts made up the Committee's report, which was delivered in September 1959⁴. The first section addressed general issues of the Patent Law, and the second section included in-depth notes on several provisions of the 1953 failed measures. The first section also discussed the drawbacks of the patent system and offered suggestions for improvement in terms of the law. Despite its flaws, the committee advised keeping the Patent System in place. This report called for significant legal reforms, which served as the inspiration for the Patents Bill of 1965. On September 21, 1965, this measure was introduced in the Lok Sabha, but it was never passed⁵.

THE PATENTS ACT, 1970⁵

Following the presentation of a revised draught in 1967, the Joint Parliamentary Committee's final proposal was the impetus for the passage of the Patents Act of 1970 when it was presented. Specifically, this Act repealed and replaced the 1911 Act, which was a statute pertaining to patents. On the other hand, the 1911 Act continued to consider designs. The majority of the

⁴ **Rajagopal Ayyangar Committee**, *Report on the Revision of the Patent Law*, Government of India, September 1959.

⁵ The Patents Act, 1970, Act 39 of 1970, available at:

<https://legislative.gov.in/actsofparliamentfromtheyear/patents-act-1970> (Visited on April 24, 2025).

provisions of the 1970 Act became operational on April 20, 1972, when the Patent Rules, 1972 were made available to the public.

This Act remained in operation for more than twenty-four years, until December 1994, without any modifications being made to it. With the adoption of an ordinance on December 31, 1994, several changes were made to the Act; however, the ordinance was only in effect for a period of six months. Additionally, in the year 1999, a new ordinance was published. This ordinance was eventually superseded by the Patents (Amendment) Act, 1999, which went into effect retrospectively on January 1, 1995. In spite of the fact that such patents were not allowed, the updated Act made it possible for applications to be submitted for product patents in the areas of pharmaceuticals, agrochemicals, and medications. However, following the 31st of December in 2004, these applications were nothing more than going to be evaluated.

THE PATENTS (AMENDMENT) ACT, 2002⁶

“The Patents (Revision) Act of 2002 made the second amendment to the 1970 Act (Act 38 of 2002). The older Patents Rules, 1972 were replaced by the new Patent Rules, 2003, which went into effect on May 20, 2003”.

THE PATENTS (AMENDMENT) ACT, 2005

“The Patents (Amendment) Ordinance, 2004 went into effect on January 1, 2005, and it introduced the third amendment to the Patents Act 1970. The Patents (Amendment) Act 2005 (Act 15 of 2005), which went into effect on January 1, 2005, later took the place of this Ordinance. It was passed on April 4, 2005”.

TRIPS COMPLIANCE AND AMENDMENTS

The Uruguay Round of GATT trade negotiations ended on December 15, 1993. “Marrakech enforced the World Trade Organization (“WTO Agreement”) on April 15, 1994. For the first time, GATT negotiations covered international trade intellectual property rights. An Annexure of the WTO Agreement contained the Trade-Related Aspects of Intellectual Property Rights Agreement” (the “TRIPS Agreement”).

⁶ The Patents Act, 1970 (Act 39 of 1970).

On January 1, 1995, the “WTO Agreement went into effect, together with the TRIPS Agreement (which is binding on all WTO Members).⁷ The prior accord, the World Trade Organization, which went into effect on January 1, 1995, created a new organization. Prior to being required to implement the TRIPS Agreement, Member States of the WTO were given a predetermined amount of time following the enforcement of the agreement establishing the WTO. The most comprehensive and significant international agreement on intellectual property rights is known as Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreement is automatically enforceable against all WTO members. The agreement consists of most of the forms of intellectual property like patents, copyright, trademarks, trade secrets, geographical indications, industrial designs, and exclusionary rights over new plant varieties”.

One of the key agreements for advancing intellectual property on a global scale has proven to be TRIPS. TRIPS provided a global minimum standard for the enforcement and protection of all types of IP, however it omitted to include a global minimum standard for patents. The major goal of intellectual property's trade-related element is to encourage effective and adequate protection of intellectual property rights and to ensure that the policies and practices used to uphold such rights do not inadvertently obstruct lawful trade.

Issues covered by the TRIPS⁸

- The manner in which the fundamental laws of the trading system and other international agreements pertaining to intellectual property ought to be applied.
- What are the most effective ways to defend intellectual property rights?
- How governments should properly execute those rights on their own turf.
- How to handle member-to-member intellectual property problems.
- In the period that the new system is being deployed, there should be specific transitional measures in place.

Features of the TRIPS⁹

⁷ **WIPO Copyright Treaty, 1996**, adopted by the Diplomatic Conference on 20 December 1996, World Intellectual Property Organization (WIPO), available at: <https://www.jus.uio.no/english/services/library/treaties/14/14-01/wipo.xml> (last visited Apr. 24, 2025).

⁸ Supra note 24

⁹ Supra note 24

The TRIPS agreement encompasses three primary features, which are as follows:

1. The standard- The primary objective of the trade-related part of intellectual property is to safeguard the subject content.
2. Implementation and compliance- The second element pertains to the enforcement of domestic procedures and remedies, particularly in relation to provisional measures and border measures.
3. Resolution of disputes- The agreement stipulates that any disputes between members of the World Trade Organisation over trade-related aspects of intellectual property obligations will be subject to the dispute settlement mechanism of the World Trade Organisation.

Obligations under TRIPS Agreement¹⁰

The TRIPS agreement outlines several important intellectual property principles that are relevant to business. Member States are required to adhere to the Paris Agreement, the Berne Convention, and other WTO agreements, as well as their own criteria for awarding temporary monopolies on intellectual property. The regulations encompass the essential prerequisites for bestowing monopolies on all forms of intellectual property (IP), together with limitations on duration, provisions for enforcement, and protocols for resolving disputes related to IP. Upon the implementation of the TRIPS agreement on January 1st, 1995, all developed countries were granted a one-year period to comply with its provisions. Until the year 2000, developing nations and changing economies were granted a five-year prolongation. As of 2006, the Least Developed Countries (LDCs) were given a period of 11 years to fulfil their obligations. Some nations believe that the long-term goal should be accomplished. The deadline for pharmaceutical patents in some Least Developed Countries (LDCs) has been extended until 2016.

At present, there are 30 Least Developed Countries (LDCs) that are under the governance of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and are also members of the World Trade Organisation (WTO). Additionally, another 10 LDCs are now in

¹⁰ Supra note 24

the process of becoming members. The principle of Most Favoured Nation (MFN) is now incorporated into the TRIPS Agreement, marking its inclusion in the global discourse on intellectual property rights. According to this ideology, any advantage, kindness, special right, or exemption granted to inhabitants of any other nation must be immediately and unconditionally offered to all other individuals (regardless of membership status), with one specified exclusion. The procedures described in the multilateral agreements signed under the auspices of WIPO regarding the obtaining or preservation of intellectual property rights are exempt from this regulation, similar to how they are for domestic remedies.

These agreements fulfilled both the purpose of the IPR and the goal of setting a minimum standard for its safeguarding. These agreements define a minimum threshold for enforcing intellectual property rights (IPR), allowing right holders to protect their legitimate interests through legal proceedings in civil court or administrative procedures.

New Dimensions and Issues for Resolution¹¹

In the upcoming decades, as technology continues to advance and explore new possibilities, intellectual property rights (IPR) will take on favorable forms to promote innovation and the exchange of knowledge in a highly competitive network. The complex matters in intellectual property rights (IPR), such as

- The first topic concerns the legal ownership of internet domain names and trademarks, particularly in relation to copyright laws in the online environment.
- The second topic relates to the legal rights connected with traditional knowledge, previous art, material transfer agreements, and bio-prospecting.
- Software applications and patents.
- The convergence of biotechnological progress, ethical dilemmas, and patent issues.
- Compulsory licensing options, border limitations, parallel imports, and erosion of intellectual property rights.
- Regulation of technology exports by the government

PATENT LAW IN INDIA

¹¹ Ganguli P., *Intellectual Property Rights: Imperatives for the Knowledge Industry*, 22 **World Patent Information** 167 (2000).

Liberalization and globalization are characteristics of the modern world. As a result, several nations, including India, which must compete with other nations on the global market, have enacted economic reforms. A nation's development is greatly influenced by patent legislation. More so now that India must compete with wealthy nations like the United States in the World Trade Organization.

A patent is a legally binding document granted by the government to the inventor, granting them the sole authority to sell, produce, utilize, and import the invention for a specified duration after the concept is published. Patents are legally mandated to protect innovators by imposing restrictions on the individuals authorized to market their products on their behalf. The origins of the term "patent" can be traced back to ancient French, Latin, and English. The term "patentem" and "patente" originated in the late 13th century, denoting the concept of an open letter. The phrase acquired its present connotation during the 1580s when it was elucidated as a governmental authorization for the production and commercialization of a certain commodity.

In business, a patent is used to create, market, and sell a product. Patents are used for many of the things that consumers buy. A patent is typically valid for 20 years from the application date once it has been granted by the government. The document that grants a person or company the exclusive right to sell a product is an official government letter patent. Once the patent application has been filed and approved, the patent applicant or vendor may begin collecting royalties for their products.

A royalty is a sum of money given to a product's creator in exchange for the right to use it; it is intended to pay them for their labour.¹² A producer of a television advertisement might do this by paying a songwriter royalty for the use of their music in the ad. Patents and royalties are often kept private by businesses using strong agreements and trade secrets, at least until the product is introduced to the market.

Regardless of whether a provisional or complete specification is included in the patent application, the term of all Indian patents is twenty years, beginning on the date of filing. This means that the term begins on the date of filing. On the other hand, the twenty-year period

¹² Daisy Jain, "What is a patent", iPleaders Blog, Aug. 16, 2022, available at <https://blog.ipleaders.in/patent-law-2/> (last visited Apr. 24, 2025).

commences on the date of the international filing (PCT) for applications that are submitted in accordance with the Patent Cooperation Treaty.

In principle, the owner of the patent has the sole right to prevent or hinder others from commercially exploiting the invention that has been patented. In other words, the protection afforded by a patent ensures that the invention cannot be manufactured, utilized, disseminated, imported, or sold by third parties without the permission of the registered owner of the patent. By giving innovators exclusive rights to profit from their ideas, the patent system hopes to inspire them to progress technology. Books, films, and works of art cannot be patented, but copyright law offers protection for these types of works.

Novelty and inventive step are fundamental concepts in patent law (or lack of obviousness). They grant the right to forbid anyone from using the innovation for the life of the patent from doing so, including independent creators of the same concept as well as copycats¹³. Therefore, a patent has the unique ability to be utilized to forbid others from using any kind of invention in their goods and services. Thus, a patent creates significant challenges for its rivals. This is why only industrial advances that are deemed to qualify as patentable inventions are granted patents, rather than all industrial improvements.

There were several obstacles that the general population of India had to overcome in order to obtain the necessary drugs for human treatment. In the majority of cases, these pharmaceuticals were brought in from other countries. In light of the fact that there is a lack of natural drugs and a significant demand for them, prices are fairly high. External laws had an effect on the local laws that were in place. Some of the most expensive pharmaceuticals in the world were sold in India.

The law governing patents is essential because it fosters the development of new technologies. It does this by protecting the rights of those who introduce new ideas, which in turn encourages scientific research and advancement. Patent law is responsible for providing regularization as well as assistance with all aspects of patent registration. Patent law was developed with the primary purpose of ensuring that creativity is unlimited and encouraging people to continue innovating by providing protection for their works. This was the major driver behind the

¹³ **World Intellectual Property Organization (WIPO)** (n.d.), *Patents*, available at: <https://www.wipo.int/patents/en/> (accessed on: 24 April 2025).

formation of patent law. As a consequence of this, patent law is essential since it functions to protect the rights of innovators. There is widespread recognition of the importance of patents on a global scale.

One of the primary objectives of patents was to encourage the development of new technologies, breakthrough scientific discoveries, and industrial advancements. The law about patents grants the inventor a monopoly on the use of their patented products, but it also allows others to use such products with the inventor's permission and for a price.

In the past, the purpose of patent protection was to encourage creative endeavors and the free disclosure of the particulars of ideas that were novel. A temporary monopoly on the use of an invention is granted by patent protection, which provides an incentive for the sharing of ideas. However, inventors may be reluctant to share their ideas because they are afraid that someone else will imitate their creation. Detailed information regarding the invention is included in the application that is available to the general public:

- By enforcing the patent to exclude competitors, monopolizing the market, and setting a high price, the inventor can recover the cost of inventing the idea during the period of time that the patent is for protection.
- In exchange for royalties, granting the invention to other individuals under the terms of a licence.
- If a person or company breaches the patent, you have the option of filing a lawsuit to seek damages.
- Making the offer to sell the invention to a third party

The patent protection system is significantly more robust than other kinds of intellectual property protection, such as copyright. It is only the manner in which an idea is communicated that is protected by copyright; it does not prevent other people from expressing the same thought in different ways.

As an additional point of interest, patents are an efficient method of negotiation. It is possible for a Cooperation to negotiate a zero-sum contract or a lesser license payment if it wishes to make use of a patent that is owned by another company but also possesses patents that the other company may utilize.

The findings made by one scientist have an impact on and provide information to the discoveries made by other scientists. If discoveries were kept a secret, industries would come to a halt; hence, fostering distribution is beneficial for society as a whole as well as for business.

A patent grants the person who invented the invention the right to manufacture, use, market, sell, and import the innovation for a period of time that has been established in advance. To put it another way, the person who has the patent has the exclusive ability to prohibit or prevent anyone from making use of the innovation that is protected for commercial purposes. In the absence of authorization from the patent holder, the innovation cannot be manufactured, utilized, distributed, imported, or sold for a profit. It provides protection against patent infringement, which means that the original creator has the ability to pursue legal action against any items that attempt to imitate their innovation or infringe on a patent that has already been issued.

If every single person kept their findings a secret, there is no question that scientific progress would be sluggish. Therefore, it would appear that encouraging people to publish their discoveries is a successful strategy for advancing scientific research and the arts that are beneficial. On the other hand, one of the most effective ways to accomplish this is to share your finding with other people so that they can profit from it.

PATENTABILITY AND NON-PATENTABILITY ¹⁴

The Indian Patent Act stipulates that in order for an invention to be patented, it must possess all of the necessary characteristics that are necessary for patentability.

According to the conditions for patent eligibility, "Novelty," "Inventive step," and "Industrial Application" are the prerequisites. In addition to satisfying the standards established above, the

¹⁴ Effectual Services, 'Section 3 of Indian Patent Act: Importance and Interpretation' [https://www.effectualservices.com/section-3-of-indian-patent-act-importance-and-interpretation/#:~:text=Invention\(s\)%20not%20Patentable&text=The%20patentable%20criteria%20are%20E2%80%9CNovelty,4%20related%20to%20atomic%20energy](https://www.effectualservices.com/section-3-of-indian-patent-act-importance-and-interpretation/#:~:text=Invention(s)%20not%20Patentable&text=The%20patentable%20criteria%20are%20E2%80%9CNovelty,4%20related%20to%20atomic%20energy) accessed 24 April 2025.

invention should not fall under Section 3 (which deals with non-patentable subject matter) or Section 4 (which deals with atomic energy).

The Indian Patent Act's Sections 3 and 4 provide definitions for innovations and discoveries that are not eligible for patent protection. A comprehensive comprehension of the extensive range of exclusions from patentability has significant importance for inventors and enterprises endeavouring to obtain intellectual property rights in India. The present study investigates the principal categories of innovations that have been identified as ineligible for patent protection in accordance with the stipulations outlined in the Indian Patent Act.

The focus is on the omissions of mathematical methodologies, computer algorithms, gradual medical progress, and traditional knowledge. This study examines pertinent legal precedents that have raised inquiries regarding the interpretation and limitations of these legislative exclusions. This study aims to elucidate the non-patentable subject matter in relation to the balanced objectives outlined in the Indian Patent Act.

One perspective suggests that the legislation aims to promote genuine innovation. Simultaneously, it endeavours to mitigate the occurrence of monopolies and instances of patent exploitation within domains such as computational methodologies, traditional wisdom, and minor cosmetic modifications. Section 4 is labelled as 'Excluded inventions as defined by this Act,' accordingly¹⁵. The purpose of these regulations is to prevent monopolies in areas that are considered non-patentable according to India's policy objectives by specifying the subject matter that is not eligible for patents.

Section 3 explicitly defines "What are not inventions" and clearly specifies that if something does not qualify as an invention, it is considered a non-patentable notion and fails to meet the criteria for patentability. Hence, if a patent application pertains to any of the subsections or groups mentioned in this section, it is not eligible for submission. From Section 3(a) to 3(p), there are a total of 15 subsections.

¹⁵ **Prashant Reddy.** "Non-Patentable Inventions under the Indian Patent Act," *Mondaq*, (April 19, 2025) <https://www.mondaq.com/india/patent/1403916/non-patentable-inventions-under-the-indian-patent-act>.

According to Section 3 of the Patents Act, “plants and animals, excluding microorganisms, along with their parts, seeds, variations, and species, as well as essentially biological methods for their production or propagation, are not considered inventions”.¹⁶

The portions that are listed below do not qualify as innovations according to the definitions provided by this Act, and as a result, they are not eligible for patent protection under the Indian Patent Act of 1970. However, the examples are provided solely for the purpose of illustration, and it is not appropriate to draw any inferences from them. Subjective evaluations might be made depending on the circumstances of a particular situation.¹⁷

PROTOCOLS FOR THE EVALUATION OF PATENT APPLICATIONS CONCERNING TRADITIONAL KNOWLEDGE AND BIOLOGICAL RESOURCES

“Patent applications involving traditional knowledge and/or biological material that violate legal provisions may be denied under Section 15 or through pre-grant opposition as per clauses (d), (f), and (k) of Section 25 (1). Additionally, granted patents may be annulled in post-grant opposition under clauses (d), (f), and (k) of Section 25 (2) of the Patents Act, 1970. The failure to disclose or the incorrect identification of the source or geographical origin of biological material utilized in an invention within the whole specification constitutes a basis for both pre- and post-grant opposition under clause (j) of Sections 25 (1) and 25 (2) of the Patents Act, 1970.”

Given the aforementioned facts and the significance of the issue, it is essential to exhibit appropriate care and diligence in the processing of patent applications concerning traditional knowledge and/or biological materials, as well as in subsequent post-grant actions. Consequently, the subsequent directives are promulgated for rigorous adherence by all Examiners and Controllers:

1. Evaluation:

¹⁶ G. Krishna Tulasi & B. Subba Rao, “A Detailed Study of Patent System for Protection of Inventions,” *Indian Journal of Pharmaceutical Sciences* 547–554 (2008).

¹⁷ **Manual for Patent Office Practice and Procedure** (2016), http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure.pdf (accessed April 24, 2025).

All patent applications pertaining to Traditional Knowledge (TK) must be accurately identified, screened, and classified as "Traditional Knowledge" by the RECS Section. The RECS supervisor must ensure that no case pertaining to TK is inaccurately screened or categorized. The individual responsible for screening must assign the appropriate IPC classification to such TK applications to ensure they are correctly directed for examination to the relevant groups, including Chemistry, Pharmaceuticals, Agrochemicals, Biotechnology, Microbiology, Biochemistry, Food, and Mechanical, among others. For instance, classifications include C07D, C07G5/00 for Chemistry; A61K, A61L for Pharmaceuticals; A01N for Agrochemicals; C12S, C12N, C07K4/00, 14/00 for Biotechnology; C12N, C12P, C12Q for Microbiology; C12F, C12G for Biochemistry; A23C, A23L for Food; and B25F for Mechanical. The classification of an application as "Traditional Knowledge" is an administrative procedure designed to streamline the evaluation and signify that the application pertains to significant subject matter relevant to traditionally recognized substances, articles, or methods of their preparation or utilization.

In the uncommon event that the RECS Section's screening and/or classification of applications pertaining to TK during allotment/examination is deemed inappropriate, the relevant Examiner/Controller must promptly inform the Group Leader, who shall then undertake re-screening and/or re-classification without delay.

In the event that an application is inaccurately screened and categorized as "Traditional Knowledge," only the Technical Head should possess the authority to re-screen and/or re-classify it to an alternative screening category upon the proposal of the relevant Group Leader¹⁸.

The System Administrator must establish distinct screening areas within the Module, specifically TK-Chemical, TK-Biotechnology, and TK-Mechanical.

2. Allocation:

¹⁸ Lakshmikumaran, Malathi. "A Rising Need for a Modern Understanding of 'Traditional Knowledge' under Indian Patent Law." Lakshmikumaran & Sridharan Attorneys, 17 June 2024. <https://www.lakshmisri.com/insights/articles/a-rising-need-for-a-modern-understanding-of-traditional-knowledge-under-indian-patent-law/>.

In the relevant Group, the Group Leader shall serve as the Controller for all applications pertaining to TK. The Group Leader/Controller must guarantee full compliance with the provisions concerning the safeguarding of traditional knowledge and/or biological material.¹⁹ The designated Group Leader shall appoint an appropriate Examiner from within their Group to handle all applications pertaining to TK. The relevant Group Leader/Controller and Examiner should strive to perpetually enhance their understanding of Traditional Knowledge and/or Biological Resources.

All applications or cases currently in progress, including pre-grant opposition concerning TK, shall be reassigned to the designated pair within the appropriate Group. Whenever an Examiner or Controller encounters a case pertaining to TK, he or she shall notify GL for reallocation.

3. Assessment:

In all instances concerning TK and/or biological material, the Examiner must conduct a comprehensive search for anticipation in TKDL and/or other databases. Should any citation be derived from the TKDL database, a copy of the citation (translated into English) must accompany the examination report.

4. Evaluation of Novelty and Inventive Step

The Patents Act stipulates that the subject matter asserted in a patent application must be novel. The innovative step constitutes a fundamental principle of patentability. It is frequently referred to as the ultimate gatekeeper of the patent system. In evaluating the uniqueness and innovative step of traditional knowledge-based inventions, the following guiding principles must be adhered to²⁰:

- a. Guiding Principle 1: "Claims pertaining to extracts, alkaloids, and/or the isolation of active plant ingredients that are naturally present in plants cannot be deemed novel or inventive if the utilization of such plants is already established within the framework of Traditional Knowledge.

¹⁹ **Office of the Controller General of Patents, Designs & Trademarks**, *Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material (2012)* https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf.

²⁰ Office of the Controller General of Patents, Designs & Trade Marks, Government of India, "Guidelines for Patents," available at: <https://ipindia.gov.in/guidelines-patents.htm> (last visited on 24 April 2025).

- b. Guiding Principle 2: "The amalgamation of plants possessing established therapeutic effects with additional plants containing identical therapeutic agents, all of which are recognized for treating the same ailment, is deemed an evident combination."
- c. Guiding Principle 3: "If an ingredient is already recognized for treating a disease, it establishes a presumption of obviousness that a combination product containing this known active ingredient would be effective for the treatment of the same disease."
- d. Guiding Principle 4: "Identifying the optimal or feasible ranges of conventionally recognized ingredients through systematic experimentation lacks inventiveness."
- e. Guiding Principle 5: "If several ingredients are recognized to possess identical therapeutic properties according to traditional knowledge, isolating a single component from them cannot be deemed inventive."
- f. Guiding Principle 6: "If individual ingredients are already recognized for treating a disease within Traditional Knowledge, it follows that a combination product containing these established ingredients along with additional plants exhibiting the same therapeutic effects would be more efficacious than the individual medicinal plants used in isolation (additive effect)."

5. Publication of a list of patent applications relating to traditional knowledge

The System Administrator is responsible for publishing a separate link on the official website of CGPDTM that contains a list of all pending patent applications linked to TK. These patent applications are disclosed in accordance with section 11 (A) of the Patents Act legislation. It is recommended that this list be automatically updated on the website in accordance with the screening field in the module on a real-time basis. At the very least, the following fields ought to be displayed on the list: the application number, the date of filing, the title of the invention, and the name of the applicant (indexed in the order of the date of invention filing)²¹.

²¹ **Office of the Controller General of Patents, Designs and Trade Marks.** *Trade Marks Manual* (Government of India, 2021) https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf accessed on 24 April 2025.

In addition, a list of patents that have been issued on applications that are linked to TK ought to be provided on the website for all patents of this kind that have been granted since July 1, 2012. Additionally, this list ought to be automatically updated on the website in accordance with the screening field implemented in the module on a real-time basis. At the very least, the following fields ought to be displayed on the list: the application number, the patent number, the date of filing, the date of grant, the title of the invention, and the name of the patentee (indexed in the order of date of grant).

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)

The Council of Scientific and Industrial Research (CSIR) and the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy (AYUSH) have joined forces to create the Traditional Knowledge Digital Library (TKDL) in 2001, which is a pioneering initiative of India. The goal of this initiative is to prevent the exploitation of Indian traditional knowledge and to protect it at Patent Offices around the world. Those indigenous and local groups that rely on traditional knowledge (TK) for their means of subsistence are in possession of an asset that is both valuable and vulnerable. For clarification, traditional medicine is responsible for meeting the medical requirements of more than 70 percent of the population in India and providing a means of subsistence for millions of individuals²². Additionally, there has been a resurgence of interest and attention in the utilization of traditional medicine on a global scale, which has increased its susceptibility to being exploited. The recent granting of a patent in the United States for the wound healing capabilities of turmeric brought to light the risk of complacency in the process of proactively protecting traditional knowledge. The amount of time, effort, and money that was spent on the revocation of the patent for turmeric at the United States Patent and Trademark Office (USPTO) brought to light the necessity of putting in place a proactive mechanism for the protection of traditional knowledge. The problem that is associated with Indian traditional knowledge is further complicated by the fact that India's traditional medicinal knowledge is written in languages such as Sanskrit, Hindi, Arabic, Urdu, Tamil, and a number of other languages, and frequently in ancient local dialects that are no

²² **CSIR.** *Traditional Knowledge Digital Library (TKDL)*. Available at: <https://www.csir.res.in/documents/tkdl>. (Accessed: 24 April 2025).

longer used²³. Therefore, even when it is documented, the Indian traditional knowledge is not accessible to patent examiners at patent offices around the world, nor is it understood by them.

By systematically and scientifically converting and structuring the available contents of the ancient texts – which are currently focused on Indian Systems of Medicines *such as Ayurveda, Siddha, Unani, and Sowa Rigpa as well as Yoga practices* – into five international languages, namely English, Japanese, French, German, and Spanish, with the assistance of information technology tools and an innovative classification system known as TKRC, the Traditional Knowledge Digital Library was originally conceived with the intention of overcoming the language and format barrier. Within the TKDL database, there are currently around 4.54 lakh formulations and practices that have been transcribed as of this moment²⁴.

The TKRC has organized and categorized the Indian Traditional Knowledge (TK) into several thousand subgroups for Ayurveda, Unani, Siddha, and Yoga-related terminology, aligning these divisions with contemporary terminology. Incorporating approximately 200 sub-groups under A61K 36/00 in the International Patent Classification, as opposed to the few sub-groups that were previously available on medicinal plants under A61K 35/00, consequently improved the quality of search and examination of prior art with regard to patent applications field in the area of traditional knowledge. This was made possible by the recognition of this one-of-a-kind classification, which is known as TKRC.

Additionally, TKDL has established international guidelines and norms when it comes to the establishment of TK databases that are based on TKDL requirements. As part of the fifth session of the Intergovernmental Committee (IGC) of the World Intellectual Property Organization (WIPO) on Intellectual Property and Genetic Resources, Traditional Knowledge, and Expression of Folklore, this was approved by the Committee in the year 2003.

Through the use of TKDL technology, several fields of study, including Ayurveda, Unani, Siddha, Sowa Rigpa, and Yoga, as well as languages, including Sanskrit, Arabic, Urdu, Persian,

²³ World Intellectual Property Organization (WIPO), "About the Traditional Knowledge Digital Library (TKDL)," WIPO, 2011, available at https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html (last visited on April 24, 2025).

²⁴ India, Ministry of Electronics and Information Technology, "Information on Traditional Knowledge Digital Library," Government of India, accessed April 24, 2025, <https://services.india.gov.in/service/detail/information-on-traditional-knowledge-digital-library>.

Tamil, English, Japanese, Spanish, French, and German, as well as traditional knowledge, are brought together with contemporary science and contemporary medicine systems²⁵. The information that is currently contained in TKDL comes from books that are part of the Indian Systems of Medicine. These publications are in the public domain, which means that any individual or organization, whether on a national or international level, is entitled to access them. The TKDL is a cutting-edge instrument that fills the role of a bridge between patent examiners and the publications that are considered to constitute prior art.

In addition, pre-grant oppositions and third party observations are sent to a variety of patent offices around the world, in addition to prior-art evidences from TKDL. The influence has already been realized to a significant degree. As of this moment, 324 patent applications have been either rejected, withdrawn, or changed on the basis of the prior art evidences that are available in the TKDL database²⁶. This has been accomplished with low expenses and without the expenditure of an excessive amount of time and effort. Taking into consideration that APEDA had to spend almost seven crores on legal fees in order to get a few claims of Basmati rice patent invalidated, this is an important development.

As the world's first prior-art database of traditional knowledge, the TKDL has shown to be an effective deterrent against the illegal acquisition of biological materials. TKDL has established a new standard for the protection of traditional knowledge (TK) all over the world. This is accomplished by proving the benefits of proactive action and the strength of strong deterrence, which has earned it international recognition as a singular endeavor. The emphasis is placed on deterrence and the prevention of the incorrect grant of patents. This is accomplished by ensuring that patent examiners have access to prior art that is connected to traditional knowledge (TK) without restricting the use of traditional knowledge.²⁷

CHALLENGES IN PROTECTION OF TK AND INITIATIVES TO OVERCOME

²⁵ Press Information Bureau, *India's 75th Independence Day Celebrations*, PIB, (2022), <https://static.pib.gov.in/WriteReadData/specificdocs/documents/2022/sep/doc20229199001.pdf> (accessed April 24, 2025).

²⁶ Traditional Knowledge Digital Library (TKDL), 'About TKDL,' <https://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdl.asp?GL=Eng> (last visited April 24, 2025).

²⁷ Forum on Indian Traditional Medicine, *Protection of Traditional Knowledge in India: Scoping Paper No. 2* (RIS, New Delhi, September 2018).

Given that the majority of laws are changed or created as a result of evolution and necessity, it is not surprising that the requirement to safeguard traditional knowledge has grown in tandem with the progression of time. In particular, there is a need to put an end to the commercial misuse of such knowledge that often follows unauthorized access, as well as the unauthorized use of traditional knowledge.

In addition to assisting them in the preservation of such historical practices, it is of the utmost importance to safeguard the indigenous people against the eventual loss of their knowledge. Additionally, the protection of TK will encourage its extensive and effective utilization.

It has been established that there have been multiple instances in the past where intellectual property was inappropriately used to steal Indian traditional knowledge. As an illustration of this argument, it cites patents that have been obtained on the fungicidal characteristics of neem and the wound healing capabilities of turmeric.

In point of fact, there have been reports of recent attempts to try to attach a trademark to yoga as well as to claim copyright over yoga postures. In light of this, it may be deduced that the misuse of TK will persist in the absence of an international law applicable to it. Traditional communities have additional challenges as a result of the incorporation of traditional knowledge (TK) into business models, such as the Yoga model, as well as the utilization of intellectual property rights and commercialization opportunities. The safeguarding of traditional knowledge faces obstacles on both the domestic and international levels.

Unlike other types of intellectual property rights, India does not have any laws or acts that specifically safeguard traditional knowledge. On the other hand, several intellectual property acts include provisions that pertain to traditional knowledge. The Patents Act of 1970 has sections 25 and 64, which are included in this category. Traditional knowledge is one of the grounds that can be used to revoke a patent application, and these laws provide one of those grounds.

In a similar vein, the Copyright Act of 1957 does not specifically address the protection of traditional cultural, literary, or artistic works, nor does it include the protection of folklore. Nevertheless, provisions for the protection of unpublished Indian works are included in Section

31A. Copyright protection, on the other hand, is only in effect for a short amount of time, and it also requires that specific criteria be satisfied.²⁸ Because of this, the preservation of traditional knowledge does not have a lot of scope under this intellectual property law at the moment.

Over the course of the past few years, India has been an active participant in TK conventions and has made serious attempts to protect its large Traditional Knowledge base on an international basis. In addition to the United States Patent and Trademark Office and the European Patent Office, the Council of Scientific and Industrial Research (CSIR) is continuously working to improve the effectiveness of the TK database. Access to Indian traditional knowledge is also available at these offices. There are three specific reasons why the existing intellectual property rights system is unable to protect traditional knowledge, as was indicated earlier.

To begin, the current system exists with the intention of privatizing ownership and is intended to be retained by people or businesses, but traditional knowledge is owned collectively by the entirety of the population. Secondly, this protection is limited in time, whereas traditional knowledge is passed down from one generation to the next without interruption. Thirdly, it holds a limited interpretation of invention, which is that it must fulfill the requirements of novelty and be capable of being applied in industrial settings. This is in contrast to the traditional definition of innovation, which is incremental, informal, and takes place over a period of time. For this reason, it is essential to have a special type of protection, often known as a Sui Generis protection regime, in order to safeguard traditional knowledge.

Initiated activities

There are a number of international groups, instruments, and projects that are particularly relevant to traditional knowledge. These include the Convention as well as other international organization. The following are some examples of them, but the list is not exhaustive:

- i. *Principle 22 of Agenda 21, which was the primary document that emerged from the Earth Summit that took place in Rio de Janeiro in 1992, acknowledges that indigenous*

²⁸ IPR Studio, *India's Efforts to Protect Traditional Knowledge*, IPR Studio (last visited Apr. 24, 2025), <http://iprstudio.com/indias-efforts-to-protect-traditional-knowledge/>.

peoples have a significant part to play in environmental management and development due to the fact that they have established their own traditional methods and expertise;

- ii. The International Labor Organization's Convention 169 on Indigenous and Tribal Peoples: This Convention calls for action to protect the rights of indigenous peoples;*
- iii. The Declaration on the Rights of Indigenous Peoples (UNDRIP);*
- iv. The United Nations Permanent Forum on Indigenous Issues (UNPFII);*
- v. The World Intellectual Property Organisation (WIPO);*
- vi. The United Nations Education, Scientific, and Cultural Organisation (UNESCO);*
- vii. The European Bank for Reconstruction and Development, the Asian Development Bank, and the African Development Bank.*

These are the organisations that have taken action to protect the rights of indigenous population. The World Bank and the United Nations Development Programme (UNDP) are two of the financial institutions that have made it their mission to ensure that the development process encourages the participation of indigenous peoples.