

# **IPR STUDY MATERIAL (LAW 507)**

## **UNIT IV**

### **(PATENT)**

**BY**

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## INTRODUCTION

Generally speaking, patents are certificates given by the government which empowers the assignee or patent holder the right to exclude others (negative rights) from making, using, or selling the invention envisaged under such a certificate for a limited period of time. The first granted patent can be traced back to 1421 in Florence, Italy, where a three-year monopoly was granted to architect and engineer Filippo Brunelleschi for his industrial invention of a barge with hoisting gear for the purpose of transporting marbles.

According to the [World Intellectual Property Organization \(WIPO\)](#), a patent is an exclusive right granted for an invention (product/process) that is either a new way of doing something or provides a technical solution to a problem, and these exclusive rights are granted in lieu of disclosing to the public technical information (like best mode enablement, etc.) regarding the invention.

### *Different types of patent*

There are different types of patents that are granted across the world, and naturally, they vary across the world as patent rights are territorial rights (i.e., patent rights are enforceable only in the territory they are granted in). The different types of patents are discussed as follows:

- [Product patents](#)
- [Process patents](#)
- [Provisional patents](#)
- [Design patents](#)
- [Utility patents](#)
- [Plant patents](#)



## Product patents

Simply speaking, sometimes the inventors develop a product and/or method that provides a technical solution to a problem or is a new method of doing something. As mentioned before, it is the claims in a patent application (if deemed fit as per patent laws and rules) by the concerned patent office that gets patent protection. So, when in one or more claims a product is claimed to be protected and gets the said grant, such a patent is called a product patent. It is pertinent to note here that generally more than one invention cannot be claimed under one application and needs to be claimed by separate applications with some limited exceptions of interrelated products etc. Patent applications generally get rejected for a plurality of inventions if more than one product is claimed. To phrase it a little more technically, the independent claims of a (product) patent application cannot seek protection for more than one product or for a group of products linked so as to form a single inventive concept. But there can be more than one independent claim pertaining to the same product.

To sum up, in the wording of [Section 48\(a\)](#) of the Indian Patent Act, 1970, a patentee whose patent's subject matter is a product can enjoy the exclusive right to prevent third parties from making, using, offering for sale, selling, or importing such products in India without his consent. In other words, with respect to a product patent, the rights envisaged under the aforementioned Section 48(a) are available to the patentee. The corresponding provision in the US for rights related to product patents is [35 U.S.C 154 \(d\) \(1\) \(A\) \(i\)](#). The relevant EPC provision in this regard is [Article 64\(1\)](#).

## Process patents

As the name suggests, process patents are those patents where the claims envisage the process of making something. In other words, only the methods are protected under patent rights and not the end product. Again, some scholars prefer to use the term utility patents (discussed later) when only method claims are granted protection. But in India, since utility patents are not granted, the Indian Patent Act, 1970, has been long granting process patents. As a matter of fact, before India implemented the minimum requirements under [TRIPS](#) by the three amendments in 1999, 2002, and 2005, process patents were preferred more. This is because process patents provided less degree of protection as only the method was being protected and not the end product, and this was very beneficial for developing countries like India. It was only after the 2005 amendment to Indian patent laws, did product patents became mainstream in India.

Basically, with process patent protection, it becomes easier for the competitors to invent an alternative method to produce the same or minorly modified same end product. This was immensely beneficial for unpredictable arts like biotechnology and



developing and least developed countries preferred process patents over product patents for pharmaceutical inventions, etc. But this was against the interests of the big private players who wanted to enjoy a higher degree of patent rights, and thus product patents were made a minimum requirement under TRIPS that all countries needed to follow.

To sum up, in the wordings of Section 48(b) of the Indian Patent Act, 1970, a patentee, whose patent's subject matter is a process can enjoy the exclusive right to prevent third parties from the act of using that process and making, using, offering for sale, selling, or importing products made directly from such process in India without his consent. The corresponding provision in the US for rights related to product patents is 35 U.S.C. 154 (d) (1) (A) (ii). The relevant EPC provision in this regard is Article 64(2).

### Provisional patents

As the name suggests, provisional patents are temporary patents. In other words, the rights enjoyed by the patentee by virtue of a provisional patent are provisional in nature and can become mainstream upon fulfilling the territorial criteria of patentability within a prescribed time.

The US permits provisional patent applications where one can file the same without a formal patent claim, oath or declaration or fulfilling any information disclosure (prior art) requirements (since provisional applications are not examined). The objective behind this prima facie shortcut process is to provide inventors with the option of a lower-cost first patent filing in the US which helps to establish an early effective filing date. One can also use the term "patent pending" with regard to the invention of the provisional application. The same has been dealt with under [35 U.S.C. 111\(b\)](#).

There is a non-extendable 12-month window of time in the US (and in most countries of the world) in which the complete non-provisional patent application needs to be filed as per 35 U.S.C. 111(a). In the US, there is two months window time after the 12-month window to file the full non-provisional patent application where the benefits of provisional application may be restored if due fees are paid and it is shown in a statement that the delay was unintentional.

Although it is not mandatory, it is advised that the applicant submit a few drawings with the provisional application that help to understand the invention in compliance with [35 U.S.C. 113](#).

One pertinent thing that needs to be noted in this regard is that though requirements are relaxed in a provisional application as compared to a non-provisional application, the



following must be mentioned in a provisional application, viz:

- That the application is a provisional application.
- All the inventor name(s).
- All the residences of the inventor(s).
- Title of the invention.
- Name and registration number of agent or attorney and docket number (if applicable).
- Address of correspondence.
- Any government agency that has a property interest in the application.

In India too, the same benefit of filing a provisional application for a patent is available and gives the benefits of securing an early filing date (which becomes a priority date), a 12-month window to file the complete patent specifications, and is a low-cost affair. This is a very commercially viable plan, as with the “patent pending” status, negotiations for further business or investments with regard to the invention of the provisional application become easier and more reliable. [Section 9\(1\)](#) of the Patent Act, 1970, deals with the provisional application, and one can find how to file a provisional patent application in India [here](#).

The corresponding provision in the EPC to get provisional status is [Article 67\(1\)](#), which states that provisional status in the contracting states designated in the application can be obtained from the date of publication.

## Design patents

At the outset, it is pertinent to mention that the concept of design patents is a US concept and not permitted in India. Designs get protected in India under the [Designs Act, 2000](#), subject to fulfillment of related laws and rules, but the same is not patent protection but only design protection (proprietor gets copyright for design) for 10 years (extendable by 5 years upon fulfillment of certain conditions).

In the US, design patents have been defined under [35 U.S.C. 171](#). As stated in *In re Frick (1960)*, patents can be granted for designs vide 35 U.S.C. 171, subject to other provisions of Title 35. According to this provision, anyone who invents a new, original, and ornamental design for an article of manufacture may get a design patent for the same subject to fulfillment of related rules and conditions. It is clear from the statutory



definition that novelty, originality, and ornamentality are criteria for getting design patent protection besides passing subject matter eligibility. Thus, it can be stated that *“while a patentable design may contain old elements, the finished product must have an unobvious appearance and not merely be the result of an obvious combination of the old elements,”* as held in the [Paul W. Garbo \(1961\)](#) case.

Anyone versed with the basics of patent law can see that the criteria to get a product/process patent match more or less with that of a design patent except for the criteria of ornamentality which has replaced the ‘industrial applicability’ criteria for product/process patents.

Generally speaking ornamentality for an article of manufacture is the aesthetic features (shapes/configuration etc.) of such an article that has some functionality. It is very pertinent to note that the design needs to be unique and distinctive to the article and dictated by the function that it performs, but only the aesthetic aspects are protected and the functionality is not protected by design patents.

## Utility patents

Utility patents are another US concept and are not granted in India. Anyone who invents or discovers any new and useful process, machine, article of manufacture, composition of matter, or any new useful improvement thereof can get utility patent protection for 20 years just like regular patents (some countries like China give 10-year protection for utility model patents). Interestingly, more than regular patent applications, the USPTO gets utility patent applications. This is because of the lower degree of requirements of a utility patent application than a regular patent application. For example, lower levels of non-obviousness can be protected. In other words, marginal improvements can qualify for utility patents. Also, maintenance of utility patents is cheaper compared to regular patents and is subject to 37 CFR 1.20, and the amount of the current fee can be viewed in the USPTO Fee Schedule. Regarding when to pay and how often to pay the maintenance fees, the same can be obtained from the Patent Maintenance Fees Storefront. If the maintenance fees are not duly paid, just like regular patents, the utility patent protection lapses too, and the utility patent rights no longer remain enforceable. A business method patent is an example of utility patent in the US.

There are usually two types of utility patents, viz- provisional and non-provisional. As discussed before, under the heading of provisional patents, the term ‘provisional’ refers to temporary protection with the privilege of ‘patent pending’ status. Whereas the non-provisional utility patent application is the one where the applicant files with complete specifications. The provisional route is the quick and inexpensive way to establish a filing date in the US, and this filing date can be claimed within the twelve-month window frame by submitting the non-provisional or complete application. It is pertinent to note



that if this twelve-month window is crossed, the provisional application will not be examined and will get abandoned status. After the non-provisional application is submitted, the examiner examines the same for patentability, and if all the requirements are met, a non-provisional utility patent application is granted. Statistically speaking, every year the USPTO receives approximately half a million patent applications, and the majority of these are non-provisional utility patent applications.

## Plant patents

Plant patents are granted in the US, but not in India. In India, there is the [Protection of Plant Varieties and Farmers Rights Act, 2001](#), with equivalent purposes and adjusted to serve India.

In the US, [35 U.S.C 161](#) deals with plant patents. According to this provision, anyone who invents or discovers and asexually reproduces any distinct and new variety of plant other than a tuber propagated plant or a plant found in an uncultivated state can get a plant patent subject to the conditions and requirements of the [35 U.S.C Title](#).

The grant of protection is for 20 years from the date of filing the application, just like regular patents. Regular patenting requirements apply herein too, like novelty, non-obviousness, industrial applicability, and subject matter restrictions.

It is pertinent to note here that for plant patents, plants in their ordinary meaning are considered. Algae and macro-fungi are also considered as plants, but bacteria will not be considered here.

Some of the accepted modes of asexual reproduction in plants include:

- Rooting Cuttings
- Grafting and Budding
- Apomictic Seeds
- Bulbs
- Division
- Slips
- Layering



- Rhizomes
- Runners
- Corms
- Tissue Culture etc.

The reason only asexual reproduction is considered in this regard is because asexual reproduction leads to uniformity and stability in the plant.

## HISTORY OF PATENT

The first step of the patent in India was Act VI of 1856. The main objective of the legislation was to encourage the respective inventions of new and useful manufactures and to induce inventors to reveal their inventions and make available for public. The Act was repealed by Act IX of 1857 as it had been enacted without the approval of the British Crown. Fresh legislation was enacted for granting 'exclusive privileges' was introduced in 1859 as Act XV of 1859. This legislation undergoes specific modifications of the previous legislation, namely, grant of exclusive privileges to useful inventions only, an extension of priority period from 6 months to 12 months. The Act excluded importers from the definition of an inventor. The Act was then amended in 1872, 1883 and 1888.

The Indian Patent and Design Act, 1911 repealed all previous acts. The Patents Act 1970, along with the Patent Rules 1972, came into force on 20 April 1972, replacing the Indian Patent and Design Act 1911. The Patent Act is basically based on the recommendations of the report Justice Ann. The Ayyangar Committee headed by Rajagopala Iyengar. One of the recommendations was the allowance of process patents in relation to inventions related to drugs, drugs, food and chemicals. Again The Patents Act, 1970 was amended by the Patents (Amendment) Act, 2005 regarding extending product patents in all areas of technology including food, medicine, chemicals and microorganisms. Following the amendment, provisions relating to exclusive marketing rights (EMR) have been repealed, and a provision has been introduced to enable the grant of compulsory licenses. Provisions related to pre-grant and anti-post protests have also been introduced.

## SCOPE OF PATENT (What can be patented?)

[Sections 3 and 4 of the Indian Patents Act, 1970](#) clearly mentioned the exclusions regarding what can be patented in India. There are certain criteria which have to be fulfilled to obtain a patent in India. They are:



- Patent subject:

The most important consideration is to determine whether the Invention relates to a patent subject matter. Sections 3 and 4 of the Patents Act list non-patentable subject matter. Unless the Invention comes under any provision of Section 3 or 4, it means that it consists of a subject for a patent.

- Novelty:

Innovation is an important criterion in determining the patent potential of an invention. Under [Section 2\(l\) of the Patent Act](#), a novelty or new Invention is defined as “no invention or technology published in any document before the date of filing of a patent application, anywhere in the country or the world”. The complete specification, that is, the subject matter has not fallen into the public domain or is not part of state of the art”.

Simply, the novelty requirement basically states that an invention that should never have been published in the public domain. It must be the newest which have no same or similar prior arts.

- Inventive steps or non-clarity:

Under [Section 2\(ja\) of the Patents Act](#), an inventive step is defined as “the characteristic of an invention that involves technological advancement or is of economic importance or both, as compared to existing knowledge, and invention not obvious to a person skilled in the art.” This means that the invention should not be obvious to a person skilled in the same field where the invention is concerned. It should not be inventive and obvious for a person skilled in the same field.

- Capable of industrial application:

Industrial applicability is defined in [Section 2 \(ac\) of the Patents Act](#) as “the invention is capable of being made or used in an industry”. This basically means that the Invention cannot exist in the abstract. It must be capable of being applied in any industry, which means that it must have practical utility in respect of patent.

These are statutory criteria for the patent of an invention. In addition, other important criteria for obtaining a patent is the disclosure of a competent patent. A competent patent disclosure means a patent draft specification must adequately disclose the Invention, so as to enable a person skilled in the same field related to carrying out the Invention with undue efforts.

## **INTERNATIONAL PROTECTION OF PATENTS**

The Patent Cooperation Treaty (PCT) is an international agreement that allows inventors to seek patent protection for their inventions in many countries at once:



- **How it works**

Applicants can file a single "international" patent application with the national patent office of their country or with the International Bureau of WIPO in Geneva. The PCT application undergoes preliminary processing and examination, but it doesn't become a patent.

- **National stage**

Within 30 months of the PCT application's priority date, applicants must "nationalize" their application in each country where they want a patent. The national patent office in each country will then examine the application independently.

- **Benefits**

The PCT helps patent offices make decisions about granting patents, and it gives the public access to technical information about inventions.

While international patent protection can be an option, it may not be the best strategy for all inventors and businesses. The cost of acquiring multiple patents, hiring local counsel, and suing for damages can be high. It may be better for some to focus on protecting their invention in their primary market and spend money on marketing, research, and development

### [PARIS CONVENTION, 1883](#)

The Paris Convention covers all forms of industrial property, such as patents, trademarks, industrial designs, utility models, geographical indications, service marks, trade names, and the prevention of unfair competition.

The Paris Convention was created with two goals, which are-

- first, to prevent the unforeseen loss of patent protection eligibility by publishing 81 patent applications and taking part in international exhibitions before submitting national patent applications; and
- second, to some extent, harmonise the various patent laws of the various countries.

The substantive provisions of the Paris Convention can be divided into three main categories-



1. **National treatment**– As per the terms and conditions of the convention, every secretary state must ensure that the citizens of their nation and the citizens of other contracting states have an equivalent degree of protection regarding industrial property. Citizens of non-contracting states shall be entitled to national treatment under the convention in the same manner as in their own state if they reside in the contracting state or have a lawful and functioning industrial or commercial presence there.
2. **Priority rights**– It covers within its ambit industrial designs, trademarks, and utility models. This right gives the holder the ability to file an application for protection in any other contracting state within a certain amount of time, that is, 6 months for industrial designs and trademarks and 12 months for patents and utility models, based on a standard initial application that was filed in one of the contracting states. It would be assumed that these additional applications were filed on the same day as the first application. To state it otherwise, it means that they will supersede any application filed by third parties for the same invention, utility model, trademark or industrial design during the previously indicated term.

The subsequent applications would not be influenced by any subsequent event, including the publication of an invention or the sale of items bearing an industrial design or mark, because they have their foundation in the original application.

1. **Common rules** – They are as under:
  - **Patents**– Patents issued for the same invention in different Contracting States are independent of one another. A patent cannot be refused, cancelled, or terminated in any Contracting State on the grounds that it has already been so in another Contracting State, and the granting of a patent in one Contracting State does not obligate other Contracting States to do the same. The refusal to award a patent or the invalidation of a patent on the grounds that the sale of the product or of a product made using the patented technique is subject to domestic legal restrictions or limitations is not permitted.
  - **Marks**– The filing and registration requirements for marks are governed by local law in each Contracting State and are not governed by the Paris Convention. As a result, neither a registration nor a request for registration of a mark that is put forward by a citizen of any Contracting State may be denied or invalidated on the grounds that the application, registration, or renewal was unaffected in the country of origin.
  - **Registration**– A trademark’s registration in one Contracting State is unrelated to any potential registrations in other nations, including the place of origin.
  - **Industrial Designs**– Each Contracting State is required to preserve industrial designs, and protection cannot be revoked because products containing the



design were not produced there.

- **Trade Names**– Trade names must be protected in every Contracting State without being required to file or register the names.
- **An indication of Source**– Each Contracting State is required to take action to prevent the direct or indirect use of misrepresentations regarding the origin of commodities or the identity of their producer, maker, or trader.
- **Unfair competition**– Each Contracting State shall offer adequate safeguards against unfair competition.

## RIO CONVENTION ON BIO-DIVERSITY AND TRIPS AGREEMENT

### Relationship between Intellectual Property Rights (IPR) and biodiversity

Biodiversity conservation and Intellectual Property Rights, share an intricate relationship due to the effect they have on each other. Researchers utilise bio-resources and natural resources to derive their benefits and create products for pharma, cosmetics, agriculture and other industries that may require patenting or any other form of legal protection or sharing the knowledge through technology transfer, which are all facets of Intellectual Property Law. Still, over-exploitation of these resources and utilising resources that have community rights attached to them or are prevented from being used for human exploitation pose a threat to local and global biodiversity coverage. This must be tackled by both biodiversity conservation law and intellectual property law. Both of these legal disciplines need to incorporate commonalities of effect and cause to prevent each from overlapping with the other to a significant extent, with a detrimental effect. There are many ways in which these effects can be felt. Some of them are:

### Biopiracy

Biopiracy is one of the most inevitable concerns in the spheres of IPR and Biodiversity. It refers to the utilisation or exploitation of bio and natural resources for capital gains without providing any credit to the local community that preserves the biodiversity resources or has preserved the traditional knowledge attached to them. They are not compensated adequately or at all for their contribution, and neither is their consent obtained before venturing into the territory and researching their local biodiversity. This leads to conflict between industry and indigenous people, who have been protecting the resources for many generations. Due to the overarching effects that biopiracy has on



local communities, many international frameworks, like the [Nagoya Protocol](#), have attempted to deal effectively with the problem by trying to establish an equitable access and benefit sharing mechanism that intends to create a positive involvement of local communities in the process of utilizing the biodiversity that they are associated with. This will create a balance between protecting indigenous knowledge and innovation in the field of research while ensuring that local communities are fairly compensated and their consent remains vital.

## Bioprospecting

Unlike biopiracy, bioprospecting implies a more positive approach. It is the process of incentivising academia and research institutions to conduct more research on biological and natural resources to create innovative solutions for human problems. This helps in understanding or analysing ways of utilising certain bioresources for the benefit of mankind. It also promotes conducting research towards the discovery of new and unknown species, which can help in the creation of innovation. These innovations can have many tangible benefits for pharma companies and the agricultural sector. Further, they contribute largely to the growth of the economy. While innovation is beneficial, some entities would seek to over-exploit the resources, leading to their exhaustion or extinction, which needs to be prevented by intellectual property law as most of these innovations are patented for commercial use and monopolized under the particular legal system. There need to be limitations in place to conserve the resources from over-exploitation. There also needs to be provision for the promotion of the growth of such resources due to their demonstrated economic value and contribution to society.

## Traditional knowledge

Traditional knowledge refers to knowledge about the correct ways of using certain biological resources like plants, forest produce, herbs, and shrubs for deriving medicinal properties or other beneficial uses. This traditional knowledge is preserved by local indigenous communities and passed down through generations to keep it alive. Appropriating this traditional knowledge can have an adverse effect on the local communities, as they are largely dependent on it. Therefore, while appropriation of this knowledge is done for the greater good of mankind and economic valuation, the local communities that pass on this traditional knowledge through their generations must be fairly compensated and must receive credit or benefits arising out of it. One such example of traditional knowledge is using haldi/ turmeric for its antiseptic and anti-bacterial properties for healing wounds. This was also appropriated by a big pharma and we shall discuss the case in detail later. India has a repository of its traditional knowledge in the form of [TKDL, i.e., the Traditional Knowledge Digital Library](#), which enlists the traditional knowledge, its usage and the communities associated with it so as to prevent misappropriation of the same by global industries.



## International frameworks – TRIPS and CBD

The [Agreement on Trade Related Aspects of Intellectual Property Rights](#), or TRIPS, is a central part of the WTO (World Trade Organisation) regime and is one of the primary pieces of legislation and the international framework on IPR on a global level. It primarily deals with the commercial nature of intellectual property. Considering how commerce can adversely affect biodiversity, it also has provisions that deal with the interplay of biodiversity conservation and intellectual property rights.

The TRIPS agreement describes the minimum standard of protection that every member nation that is a part of the WTO needs to abide by for patents, especially those dealing with genetic resources. They have to follow certain guidelines when an entity tries to get patent protection for an invention that utilises genetic resources from plants, animals and microbes. In terms of provisions, [Article 27.3\(b\)](#) of TRIPS allows for the registration of patents that involve plants and animals but specifically excludes microorganisms. It also allows for the registration of patents involving “essential biological processes” for the production of plants and animals, but it also enables member nations to restrict the usage of certain microorganisms in terms of inventions and their patenting. One of the criticisms that TRIPS faces is that it does not directly mention anything regarding “access and benefit sharing” mechanisms, which has left a huge loophole for entities to exploit biological resources without bearing any compensation to the nations of origin or the local communities dealing with those resources.

TRIPS acknowledges the significance that traditional knowledge holds and recognises the role that indigenous communities play in protecting and preserving it. Yet, at the same time, it does not create any strict protection norm for traditional knowledge except for [Article 8\(j\)](#). The provision simply calls for “mutually supportive” actions for the cross sections of IPR and Traditional knowledge. This lacuna or ambiguity needs to be addressed to effectively deal with concerns regarding the misappropriation of traditional knowledge without equitable monetary benefits for the local communities.

TRIPS vitally deals with patent protection and rights, but it also sheds light on the protection of plant varieties and, by doing so, tries to acknowledge the role that plant variety protection could have on biodiversity conservation. [Article 27.3\(b\)](#) of the TRIPS enables its member nations to create a “*sui generis*” (nation’s own domestic system of laws) system for the protection of plant variety with the goal of securing various approaches towards the promotion of biodiversity conservation and the ethical use of genetic materials extracted from plant species.

The public health enabling provision of the TRIPS agreement has raised the most crucial contentions about the conservation of biodiversity. This provision, which is essentially a part of the [Doha Declaration](#), allows member nations to take actions



suitable for the protection of public health and to increase accessibility to crucial medicines. This is contentious, as this provision is often used by pharmaceutical companies to get unfair access to bio-resources and allows them to exploit biodiversity under the guise of public necessity. There needs to be a balance between public necessity and biological conservation in the sense that both are achieved without hampering the other.

The [Convention on Biological Diversity, 2003](#) or the CBD, is an international framework of legislation that was adopted by nations on the occasion of the Earth Summit of Rio 2000 with the objective of protecting biological and natural resources for future generations. It rests on three main pillars: protection of biological diversity, sustainable use of biological resources, and equitable benefit sharing models. Having recognised the interplay between IPR and biological diversity, CBD enlists certain provisions to manifest this relationship positively.

It enlists the concept of “prior informed consent” in terms of accessibility towards the biological resources of a particular nation. It mandates corporations to acquire prior informed consent from the member nations and the local indigenous communities before granting access to any traditional knowledge or biological material associated with the country or originating from the country. This provision tries to ensure that every nation has the utmost sovereignty over its natural resources and can enact provisions to prevent registration of any form of IPR that could potentially have an adverse effect on the biological diversity and the local communities of the nation. This has caused many nations to modify their patent laws in such a way that they incorporate provisions highlighting the requirements and the process to gain prior informed consent from the local communities and biodiversity boards for gaining access to research and inventing innovations using the genetic resources of plants and animal species.

The most significant effect of CBD has been the creation of a robust “Access and Benefit Sharing Model,” which mandates entities to share equitably any benefit arising from an invention or innovation utilising natural resources of a particular community with the particular indigenous or local community of a member nation. It recognises the interdependence that local communities and biological resources have with each other and therefore requires the entities to fairly and equitably compensate the communities for gaining access to and commercialising the flora and fauna or the traditional knowledge of the community. It mandates disclosure of the origin of the natural resources so as to ensure that the patent applicants have an access and benefit sharing agreement with the local community and are abiding by the provisions secured by CBD.

In terms of provisions, [Article 8\(j\)](#) of the CBD recognises the significance of traditional knowledge and requires member nations to create a repository for the same so as to ensure strict protection of the same and consequently achieve implementation of the ABS (Access and Benefit Sharing Model) for the local communities. [Article 15\(7\)](#) lays out the ABS model in intricate detail as a mandate for member nations to include in



their domestic legislation.

The Nagoya Protocol also complements CBD by dealing with prior informed consent and the Access and Benefit Sharing Model. Except for those, it also talks about “mutually agreed terms,” which is a concept that requires thorough negotiation between the inventor and the community that provides the biological material, consequently leading up to an agreement that highlights all the conditions regarding the extent of access, the amount of compensation, etc. This helps empower local communities by giving them the authority to set the terms for the commercialization of their resources. It also requires the creation of an Access and Benefit Sharing Clearing House (ABSCH), which would be a digital documentation of all sorts of information relating to the ABS mechanism and enable access to information on biological material, associated traditional knowledge and IPR norms for researchers and innovators interested in the same.

