Intellectual Property Rights Issues for Herbal Products

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Nidhi Sandal and Avinash Kumar

Abstract

The entire edifice of intellectual property rights system is based upon incentivising innovations by providing legally created private monopoly rights albeit for limited period and on certain conditions. Post TRIPS era, most of our Indian legal IP instruments have been amended, and even new legal instruments have been created in order to comply with provisions of the agreement. The present Indian law has adequate provisions for the protection of innovations in the area of herbals. During the past decade, there has been a spurt of herbal products which include health supplements and medicines for hypertension, obesity, arthritis, diabetes, neurological disorders, etc. (Liu et al. Life Sci 73:1543–1555, 2003; Modak et al. J Clin Biochem Nutr 40:163–173, 2007; Brown and Gerberg, J Sychiatr Pract 7:75–91, 2001). The bent of the global market towards herbal product is the driving force behind the R&D of big pharma companies towards the development of new herbal products. In coherence with the booming industry and extensive R&D work in the field of herbals, the role of intellectual property rights also becomes very important. Lots of innovation is taking place in R&D and all this needs to be properly protected through appropriate legal routes. Patents, copyrights, designs, trademarks and geographical indications are the types of IPRs that play an instrumental role in the legal protection of various aspects of herbal products and processes. Apart from these IP rights, the Protection of Plant Varieties and Farmers' Rights Act, 2001, was enacted to provide protection of plant varieties developed by plant breeders and farmers, so as to ultimately encourage development of new varieties of plants. It envisages facilitating the growth of seed industry ensuring high-quality seeds and planting material to the farmers. The Biodiversity Act 2002 provides

N. Sandal • A. Kumar (✉)
Defence Research and Development Organisation,
Rajaji Marg, New Delhi, 110 011, India
e-mail: avinash@hqr.drdo.in

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provisions for the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising art of the new use of biological resources and knowledge. For the effective implementation of the Act, National Biodiversity Authority (NBA) was established for the effective regulation of related activities. The Act makes specific provisions that no person can apply for intellectual property rights, in India or abroad, for any invention based upon research or information on a biological resource obtained from India without seeking prior approval from the National Biodiversity Authority. This chapter discusses in detail the intellectual property rights application for protection of innovations in herbals, special provisions and guidelines of the acts and also briefly describes related regulatory requirements.

12.1 Introduction

Recently, there has been a noticeable shift in the public perception and attention from synthetic to herbal medicine. Scarcity in the area of new molecular entities, public awareness about the side effects of synthetic drugs, abundance of medicinal plants in our country or the traditional method for the cure of diseases could be the plausible factors for the shift of this attention and consequent direction of research to the area of herbals. It has been estimated that total value of the world market for herbal products stands at around $83 billion, and Europe accounts for over 50 % of the total (Dennis 2013). Due to the emergence of herbal drug companies and growing market for the herbal products, a lot of research is going on for herbals/herbal formulations. A recent PubMed search (done in September 2013) using the keyword *herbal medicinal products* (HMPs) gave rise to 30,917 hits, with about 2700 of them published in 2013 (Pelkonen et al. 2014).

India is no exception to this trend, particularly because India is endowed with a variety of recognised indigenous system of medicine, viz. Ayurveda, Siddha, Unani, homeopathy, Yoga and naturopathy catering to the health requirements of people. Charaka Samhita is one of the most ancient, comprehensive and authoritative works of Ayurveda. It is considered the original reference book of holistic Ayurvedic medicine. India's traditional system of medicines has originated from the fact that India is a nation having megadiversity and exceptionally blessed with biological diversity due to its unique geographical location. Its natural ecosystems vary from colder Himalayan regions to the desserts in the northwest region as well as from sea coast to the green forests particularly in central and northeast India. Therefore, our traditional system of medicine provides herbal cure to both acute and chronic diseases of cardiovascular system, neurological disorders, endocrinological diseases and others.

It is interesting to note that cases related to legal protection of herbal-related innovations have successfully brought the public focus on the ill effect of wrong grant of legal protection on herbal-related innovations. In India, the post-2005 era has seen a heightened level of public debate and discourse about the very desirability of very strong patent rights particularly in the area of herbals. This debate was further fuelled when the USA granted patents on the uses of turmeric. A US patent No. 5, 401,504 was granted to two non-resident Indians Suman K. Das and Harihar P. Cohly on the use of turmeric for healing of wound. Subsequently, USPTO cancelled the patents when a re-examination was filed by the Council of Scientific and Industrial Research (CSIR), India, New Delhi, on the grounds of prior art (TKDL 2015). This particular case proved to be a historical one as for the first time any US patent claiming traditional knowledge originating from a developing was successfully challenged. A patent granted on fungicidal effect of extracts of neem seeds in Europe was also

revoked by the EPO in similar fashion. In the case of basmati rice, the applicant RiceTec had to amend the claims to exclude the well-known traditional Indian basmati rice lines. These cases of biopiracy triggered a heightened level of public interest as well as awareness about the pitfalls as well as opportunities related to legal protection of innovations in the area of herbal drug. The entire debate related to patent protection in the area of traditional knowledge has been catapulted to the centre stage with focus also shifted to the desirability of carving out appropriate procedures of the legal protection of innovations using traditional resources. Rising cases of misappropriation of traditional knowledge coupled with rapid erosion of biodiversity and a concern for right of local communities holding the traditional knowledge have also raised worldwide public concern.

A total of 557 published Indian applications and 210 PCT applications have been filed by Indians during 2001–2010 (Sahoo et al. 2011). Interestingly, most of the individual inventors for these applications are herbal practitioners (doctors, vaidyas or hakims). Sahoo et al. 2011 performed a study on the patent applications and grants by Indian applicants in herbal drugs during 2001–2010. Their analysis shows that CSIR has the maximum numbers of applications not only in India but also in the USA and EU. China has a heritage of about 2000 years in the area of herbal medicine. This is further supported by the abundance in traditional knowledge and biological resources available in their country. Like other streams of research, China is pursuing its research rigorously in the area of herbal. In China alone, approximately 100,000 herbal formulae and over 11,000 individual medicinal plants have been documented, which are generally hailed as rich natural resources for developing new drugs, including new lead compounds and new types of multicomponent drugs (Wang et al. 2008; Kuhn and Wang 2008 & http://www.who.int/mediacentre/factsheets/fs134/en/).

Herbal medicinal research offers a very high potential of innovations to the researchers which, in turn, provides opportunities for patenting as well. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations (Wang et al. 2008). The issues related to protection of knowledge, innovations and practices of traditional and indigenous medicine have also found echo at the forefront of international developments as well. India has played a major role in catapulting the entire issue of protection of traditional knowledge at the global stage resulting in WIPO setting up Intergovernmental Committee (IGC) as well as Doha Ministerial Declaration in 2001. Doha Declaration established a linkage between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) for fair and equitable sharing of the benefits arising from the use of genetic resources (Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material, Indian Patent Office, 2012).

As more and more interest is being generated for herbals among researchers, authorities at national and international level are taking serious note of all these developments and are making sincere efforts to make a proper equilibrium between the availability of monopoly right and the freedom for rest of public domain. IPR regime is an inseparable aspect of R&D, and in the case of herbals as well, it is very important to encourage R&D so that new products should reach market and benefit society. However, researchers or applicants need to be given due credit and incentives like commercialising their products and enjoying the monopoly rights provided by IPRs. At the same time, governments have made special provisions in the Patents Act 1970 for herbals so as to control the misappropriation of herbals/traditional knowledge like in the case of turmeric, neem and basmati. Patents are the strongest IP right giving monopoly rights to inventors/application for 20 years from the date of filing. Therefore, the Patents Act 1970 was amended to incorporate some provisions addressing the patentability of inventions using traditional knowledge. Further, Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material have been issues in 2012 by the Controller General of Indian Patent Office to provide

guidance to the examiners for examining a patent application related to herbals/traditional knowledge. Another important aspect associated with the patenting of herbals is the regulatory approval from the National Biodiversity Authority. However, other legal instruments of IPR regime including copyright, trademark and design do not have any special provision for herbal innovations, and the prerequisites for the registration of any one of these rights are unanimous for all application. This chapter is an attempt to highlight all the relevant aspects related to the legal protection of herbal innovation. The authors have oriented the chapter to give an overview of all the IP rights and how these rights can be attained and used for herbals.

12.2 Intellectual Property Rights

Intellectual property systems, world over are primarily concerned about motivating innovators by providing monopoly rights to them over their creations, albeit for limited duration, if their creations meet certain laid-down conditions. Intellectual property systems essentially provide legal mechanisms enabling innovators to stop third parties from unauthorised use of their innovations. The rationale of the intellectual property system is that the 'cost' of the monopoly rights conferred to the intellectual property holder is outweighed by the 'benefits' to the society. This is one reason that each type of intellectual property needs a specific legal instrument, which tries to strike a balance between the interest of the right holder and larger public interest. The entire edifice of the intellectual property regime is based upon the principle that innovators need to be motivated by conferring them monopoly rights for certain acts if their innovations meet laid-down criteria and conditions.

Intellectual property rights is an umbrella term comprising a variety of legal rights to protect legal human creativity which includes inventions, literary and artistic works, symbols, names, images and designs. The system grants legal rights based on certain criterion making a balance between the monopoly right and larger public interest. For example, in the case of patents, monopoly rights are granted if the invention meets the criteria of novelty, nonobviousness and industrial applicability. These rights could be to make use of the inventions and right to transfer among other rights. Each type of intellectual property right demands its own set of operating rules.

In 1994, when negotiations on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS') were concluded, governments of all WTO member countries (151 countries as of August 2007) had agreed to set certain basic standards for the protection of all form of intellectual property rights in all member countries. The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) recognises the following rights:

- Copyright and related rights
- Trademarks
- Geographical indications
- Industrial designs
- Patents
- Layout designs (topographies) of integrated circuits
- Protection of undisclosed information

All these intellectual property rights protect legally the creations of mind including inventions, literary and artistic works and symbols, names, images and designs used in commerce. Figure 12.1 provides an overview of the IPRs and the form of IP protected therein.

A patent is a legally created monopoly right for an invention granted for to the applicant for 20 years, in exchange for disclosure of his invention. This legal right enables the applicant to exclude others from making, using, selling and importing the patented product or processing for producing that product for those purposes without his consent (Controller General of Patents Designs and Trademarks 2015). It is a territorial right and therefore it is effective only within the specific territory where it is granted. A patent is granted when three criteria of novelty, inventive step and industrial applicability are satisfied. This is the worldwide applicable criteria to grant

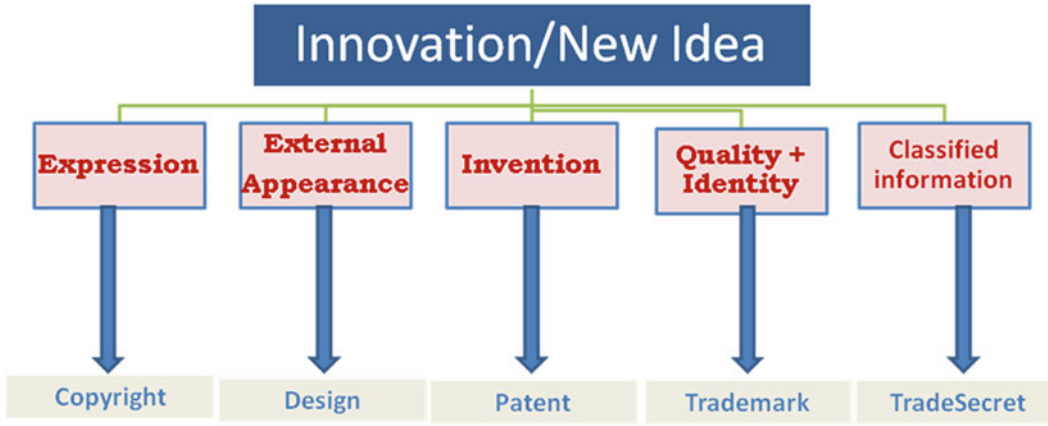

Fig. 12.1 Protecting innovations under IPR regime

a patent. However, each nation has its own legislation, and the patent is granted by their national/regional patent offices. In India, the Patents Act 1970, Section 2 (1) (i) and Section 2 (1) (j), sets out the legal requirements to obtain a patent in India. Once a patent is granted, the owner of the patent has legal rights to exclude others from making, using, selling or importing the invention in a country in which the patent has been granted for a period of 20 years from the date of filing.

For obtaining patents in several countries, the applicant has to apply in each county of interest, and the application undergoes examination as per the laws and rule of that country. Prior to 1883, the applicants had to file patent in each country of interest on the same day so as to maintain the priority of their invention. This was very difficult and cumbersome process. After a diplomatic conference in Paris in 1880, a convention called 'Paris Convention for the Protection of Industrial Property' was signed in 1883 by 11 countries. As per this convention, the applicant of the member country can file a subsequent application within 6 months (for industrial designs and trademarks) or 12 months (for patents and utility models) from the first filing in any of the member country. This convention provides 12 months time to the applicants so that they may choose the country and complete the process of filing their application in different countries. At present, there are 173 member countries of the Paris Convention.

There is another route to file a patent application in several countries, i.e. under Patent Cooperation Treaty (PCT). In the year 1970, the World Intellectual Property Organisation implemented this treaty. An applicant by filing a single international patent application through Patent Cooperation Treaty effectively can ensure priority in each of its contracting states. At present, there are 147 members of this treaty. India became its member in the year 1998. This route provides several advantages of the Paris Convention. A PCT application can be filed within 12 months from the date of filing a patent application in any one of the member country. Under PCT, there are several examining/search authorities which provide a preliminary examination within 16 months of the priority date of an application. This examination provides useful information to the applicants for deciding the countries for national phase entry. Figure 12.2 shows the flow chart for filing a patent application in several countries through PCT route.

Copyright protects the expression of ideas. It provides legal protection to the creators under the Copyright Act 1957, for original literary and artistic works, which include computer programs, multimedia and electronic databases apart from literary works, illustrations, photographic works, musical works, drawings, paintings, cinematographic works, sculpture, etc. The owners of the copyrighted works can stop others from using

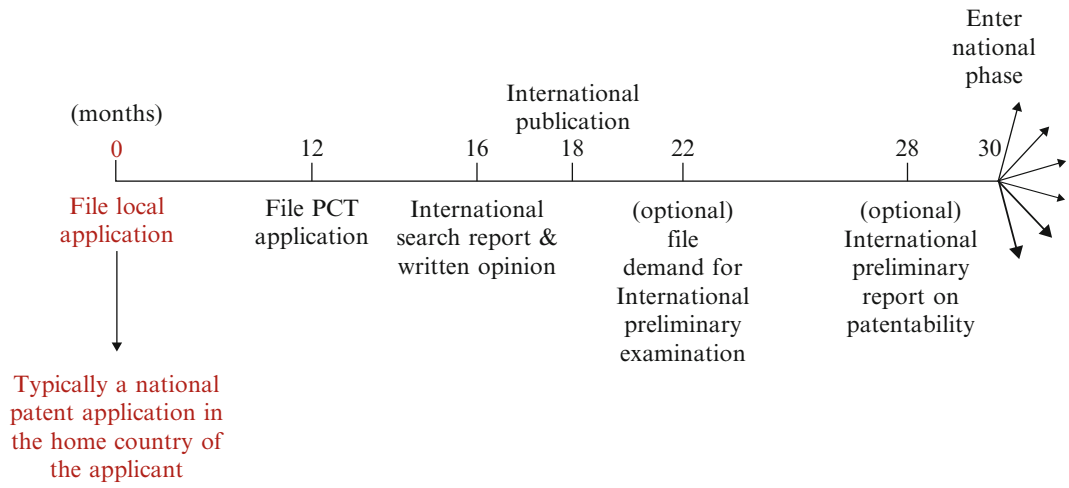

Fig. 12.2 The PCT system

such copyrighted works without their authorisation thus providing them incentives and motivation. Some of the rights, enjoyed by the owners of copyrighted works, include right to reproduction, right to communicate to the public, right to public performance, right to translation, right to adaptation, etc.

According to the definition provided in the Intellectual Property Office, India, 'A Design refers to the features of shape, configuration, pattern, ornamentation or composition of lines or colours applied to any article, whether in two or three dimensional (or both) forms. This may be applied by any industrial process or means (manual, mechanical or chemical) separately or by a combined process, which in the finished article appeals to and judged solely by the eye. Design does not include any mode or principle of construction or anything which is mere mechanical device' (Information Booklet for applicants for Registration of Design, *The Patent Office, Intellectual Property Office, Kolkata* 2010). In India, design protection is provided under the new Designs Act 2000.

According to the definition provided in the Intellectual Property Office, India, 'A trade mark (popularly known as brand name) is essentially a visual symbol which may be a word signature, name, device, label, numerals or combination of colours used by one undertaking on goods or services or other articles of commerce to distinguish it from other similar goods or services originating from a different undertaking'. It is provided under the Trade Marks Act 1999 that goods and services are classified according to the International Classification of Goods and Services.

In addition to the above-mentioned forms of intellectual property rights, i.e. patents, designs, trademark and copyrights, there are three more IPRs which provide monopoly rights to creators in the different field. These rights, although may not be of direct relevance to the innovations in herbals, cover the Plant Variety Protection and Farmers' Rights, geographical indications and the layout designs (topographies) of integrated circuits. The Plant Variety Protection and Farmers' Rights Act provides legal protection to new plant varieties including seed after fulfilment of certain conditions. A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities, a reputation or characteristics that are essentially attributable to that place of origin. Layout designs (topographies) of integrated circuits are a field in the protection of intellectual property which provides legal protection to two- or three-dimensional layout or topography of an integrated circuit (IC or 'chip'), i.e. the arrangement on a chip of semiconductor devices such as transistors and passive electronic components such as resistors and interconnections. The entire gamete of IP protec-

tion has been designed to provide legal protection to all possible creation of humans; therefore, it covers different types of rights providing protection to different types of innovations after fulfilling the requisite criteria for the grant. However, for the purposes of this paper, only those IPRs and their provisions relevant for the herbals have been discussed in detail.

12.3 Patent Protection for Herbals

A patent is a set of exclusive rights granted by a government to an inventor or applicant for a limited amount of time (normally 20 years from the filing date) at the cost of making a complete disclosure of the details of his invention. It is essentially a negative right, which exclude others from using the patented invention. A patent must disclose the details of the invention so that a person skilled in the art must be able to reproduce the patented invention without undue experimentation (Section 64 (1) (h), Indian Patent Act 1970). It should clearly address the following questions:

- What was the problem?
- What was the available solution(s)?
- Why available solution(s) did not solve your problem?
- What was your idea/approach?
- How did you design and carry out experimental work?
- What were your results and data?
- How did it solve your problem?
- What other possible problems can it solve in related area?

A patent document is a technolegal document drafted to address the above aspect of the invention, but any innovation must meet the three criteria of the patentability which includes novelty, inventiveness and industrial applicability (Fig. 12.3). These criteria are universally accepted for the grant of patent in any country. Apart from these criteria, each country has their own laid-down laws which define the patentable invention, and the patents are examined according to these laws. Like in India, the Patents Act do not grant patents for the method of use, method of treatment or new use of a known substance, but in the USA or Europe, the new use of known substance is a patentable subject matter. The patent system of each country is guided by the patent law of their country. In India, a patent is granted after a thorough examination for ascertaining the novelty, inventiveness and industrial applicability of each patent application. Apart from this, there are some sections of the Act which categorise some inventions as not patentable inventions, and for herbals or inventions related to traditional knowledge, the Patents Act 1970 has some special provisions.

12.3.1 The Patents Act 1970

Indian law has adequate provisions for the protection of inventions related to herbals. Any patent application relating to herbals having novelty, inventive step and industrial applicability under Section 2 (1) (i) and Section 2 (1) (j) is patentable as per the Patents Act 1970.

> Section 2 (1) (j) : "invention" means a new product or process involving and inventive step and capable of industrial application. (Section 2 (1) (i), Indian Patent Act 1970)
> Section 2 (1) (ja): "inventive step" means a feature of invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art. (Section 2 (1) (j), Indian Patent Act 1970)

12.3.1.1 Novelty

> An "invention" means a **new** product or process involving and **inventive step** and capable of **industrial application** (Section 2 (1) (i), Indian Patent Act 1970)

An invention is new (novel) if it has not been anticipated by publication in any document anywhere in the world or used in the country or prior claimed in an application for patent in India or form part of the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere before the date of filing of patent application or date of priority, that is,

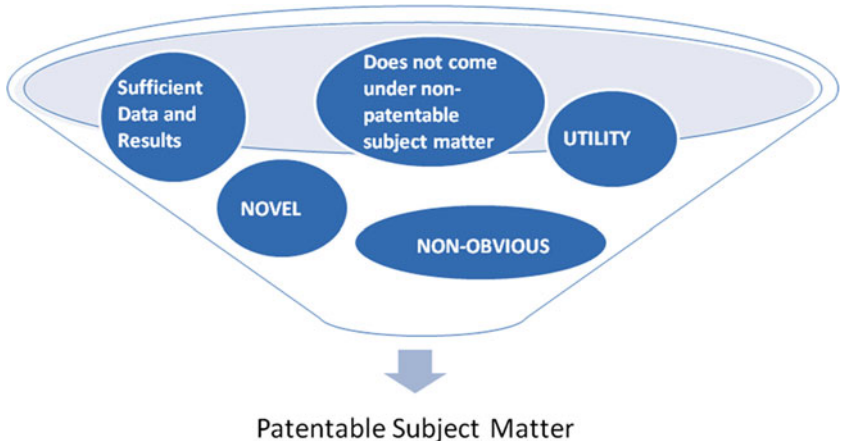

Fig. 12.3 Criteria to patentability

the subject matter has not fallen in the public domain or that it does not form part of the state of the art. As per the Patents Act 1970, novelty is

> any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art. (Section 2(1)(l)of the Act)

Before we proceed, it would be better to acquaint with the concept of prior art. "Prior art" is the information that was known before the date of filing a patent application. If it is public **anywhere** in the world, it is prior art (Fig. 12.4). It includes patent literature and non-patent literature comprising

- Books
- Journal/related magazines
- Abstract books
- Indexes
- Proceedings of conferences
- Catalogues
- News (printed, telecasted on TV or radio)
- Conferences, seminars, workshops
- Public prior use

It is evident to ascertain that the patentability of an invention, novelty and inventiveness of an invention is examined over the existing prior art

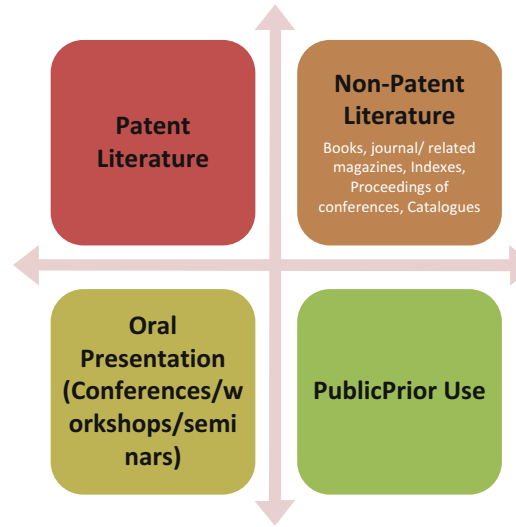

Fig. 12.4 Prior art documents

documents. Prior art search should also be conducted by the inventors or applicants before filing a patent application. However, during the examination of a patent application, the examiners carry out extensive prior art search to check the novelty and inventiveness. Let us understand the concept of novelty with an example of a patent application disclosing a process for extracting the aqueous extract of leaves of *Gomphostemma niveum* which has at least 30 % alkaloids. In this invention, the essential features of the patent include

- Process for extraction
- Aqueous extract
- Leaves
- *Gomphostemma niveum*
- At least 30 % alkaloids

During prior art search, if a prior art comprising the above-listed five features of the invention is found in **one** single prior art document, then only the novelty of the above invention is destroyed, and the document is referred as 'novelty destroying document' (Fig. 12.5). Thus, to destroy novelty,

- *The prior art should disclose the invention either in explicit or implicit manner.*
- *Mosaicing of prior art documents is not followed in the determination of novelty.*
- *A generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure. For instance, a metal spring may not take away the novelty of a copper spring.*
- *A specific disclosure in the prior art takes away the novelty of a generic disclosure. For instance, a copper spring takes away the novelty of a metal spring* (MPEP, Novelty, 08.03.02).

12.3.1.2 Inventive Step

An 'inventive step' is one which makes the invention 'nonobvious to a person skilled in the art'. In other words, if the invention is obvious to the person skilled in the art, it cannot be said to involve an inventive step. As per the Patents Act 1970 and the Patents Amendment Act 2005 (which came into effect retrospectively, January 1, 2005), the definition of Inventive step was further revised to read as

> "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art. (Section 2(1)(ja) of the Act)

Thus, the standard of inventive step has evolved to include economic significance of the invention apart from already existing criteria for determining inventive step.

Manual of Patent Office Practice and Procedure Published by the Indian Patent office provides detailed examination guidelines on inventive step. Although it must be understood that the manual has no legal binding on the examination of any patent application in case of conflict between manual and patent laws and rules, the patent laws and rules would prevail. However, the manual does provide an indication about the manner in which the examination of any patent application shall be carried out in the entire branch of patent offices. General principle of MPEP states that an invention is patentable only if it involves one or more inventive steps. In relation to the determination of patentability, an examiner first conducts an enquiry as to the novelty of the claimed invention and then proceeds to conduct an enquiry on whether the claimed invention involves one or more inventive steps (MPEP General Principle (08.03.03.01)). Then the guidelines suggest the steps to determine inventive step (MPEP Determination of Inventive step (08.03.03.02)).

(a) For determination of inventive step, all or any of the prior art(s) revealed during the search process to perform an enquiry as to whether such prior art(s) discloses the claimed invention is relied upon.
(b) Publications existing on the date of filing of complete specification would be considered as a prior art.

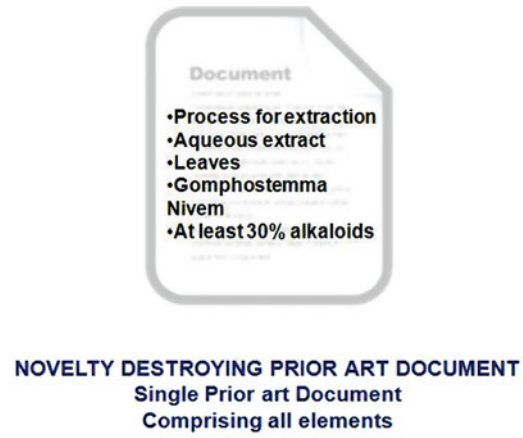

Fig. 12.5 Novelty destroying document

(c) However, Indian applications filed before but published on or after the date of filing of complete specification of the instant application are considered as a prior claiming.
(d) Invention as a whole shall be considered. In other words, it is not sufficient to draw the conclusion that a claimed invention is obvious merely because individual parts of the claim taken separately are known or might be found to be obvious.
(e) If an invention lies merely in verifying the previous predictions, without substantially adding anything for technical advancement or economic significance in the art, the inventive step is lacking.
(f) For the purpose of establishing obviousness of the invention, citing a mosaic of prior arts is permissible, provided such prior art is enabling.
(g) If the invention is predictable based on the available prior art, merely requiring workshop improvement by a person skilled in the art, the inventive step is lacking.

With respect to the previous example of *Gomphostemma niveum* which describes a process for extracting the aqueous extract of leaves of *Gomphostemma niveum* which has at least 30 % alkaloids, the inventive step over the prior art will be established if one of the elements of the invention is not available anywhere in a prior art. Let us consider a hypothetical prior art document, D1, which discloses the process for extracting an aqueous extract of leaves of *Gomphostemma niveum*. It does not mention about the alkaloidal content of the final extract. There is another prior art document D2 which discloses the aqueous extract of leaves of *Gomphostemma niveum* having 10 % alkaloids. When these two documents are read subsequently, it appears that the D1 discloses the subject matter of invention, and in view of D2, it can be deduced that the extract of D1 and D2 anticipates the presence of alkaloids in any aqueous extract of leaves of *G. niveum*. In such case, the inventive step has to be highlighted which may include the duration of extraction process or the temperature or pH of the extraction process which is yielding at least 30 % alkaloids in the final extract because 10 % alkaloids are already reported. In such a case, the exact process parameter resulting in substantial increase of alkaloids is the inventive step of the invention.

12.3.1.3 Industrial Applicability

In order for an invention to be patentable, an invention must be capable of industrial application. Industrial application in relation to patentability means that the invention is capable of being made or used in an industry. The specification explains the industrial applicability of the disclosed invention in a self-evident manner. Usually industrial applicability is self-evident. A specific utility should be indicated in the specification supported by the disclosure.

Thus, novelty, nonobviousness, industrial applicability and utility form the essential requirements of patentability. These conditions have been universally accepted as the essential prerequisites of patentability. Apart from this, Section 3 of the Patents Act 1970 elaborates on what are not inventions as per law. For the purpose of this chapter, it is important to discuss what are not inventions as per the Patents Act 1970.

12.3.2 Inventions Not Patentable

The Indian Patent Law excludes certain categories of invention from patent rights. It can be inferred that monopoly rights in these very categories are not considered to be in wider public interest. Under the Patents Act 1970, the inventions listed from Section 3 (a) to 3 (p) are not inventions and hence are not considered to be patentable. Specifically, *Section 3* (b), (c), (d), (e), (h), (i), (j) and (p) are of relevance with respect to the patent applications related to herbals (*Section 3*, Indian Patent Act 1970).

> 3 (b) An invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment is not an invention.
>
> 3 (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

3 (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

3 (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

3 (h) a method of agriculture or horticulture;

3 (i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

3 (j) plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and spices and essentially biological process for production or propagation of plants and animals;

3 (p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

For example, an invention: a method of adulteration of food. The intended use or commercial exploitation of which is found to be injurious to public, animal or plant life or health, such as a method of adulteration of food.

Among others, Section 3 (d) was introduced in the Patents Act 1970, in the year 2005, in order to comply with the requirements of TRIPS. However, this has become an extremely powerful tool for the examiners to reject the patent applications filed on the trivial improvements. The main objective of this section is to prevent applicants from obtaining patents on already known medicines which are just a mere increment or trivial improvement of the known substances and also a refusal to the patent on discovery of new form or new use of known drugs. This particular section prevents applicants indulging in evergreening of their patent rights. This section shot into prominence when a patent application filed by Novartis before the Chennai Patent Office related to drug name GLIVEC which was slightly a different version of their 1993 patent for anti-leukaemia drug was rejected under Section 3 (d). Subsequently, the applicant challenged the constitutionality of Section 3 (d) before the High Court at Madras. The case went up to the Supreme Court of India, and in 2013, the Supreme Court of India upheld the constitutionality of Section 3 (d) and the patent remained rejected (Kant 2009). This section is also very important for the inventions related to herbals or traditional knowledge as the researchers use known herbs or other biological resources; therefore, a patent application related to herbals must not fall under this section. To summarise, the non-patentable inventions of herbals under this section, the following inventions are not considered patentable:

- Extracts per se
- New property or use of a known herb or herbal extract
- Extracts of different parts of herbs
- Mere method of extraction for a known herb
- Combination of herbal extract without significant property
- Formulations of extracts/herbs without a substantial improvement

Other than Section 3 (d), the Patents Act 1970 also has a unique provisions, like Section 3 (p) incorporated in 2002 with the implementation of the Patents (Amendment) Act 2002. Section 3 (p) states that an invention is not patentable where 'an invention is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components'. Traditional knowledge, being knowledge already existing, is not patentable, for example, the antiseptic properties of turmeric for wound healing or the pesticidal and insecticidal properties of *neem*. The examiner conducts an investigation by using various resources like Traditional Knowledge Digital Library (TKDL) and other references to decide as to whether the claimed subject matter falls within the purview of this provision.

Section 3 (b), (c), (e), (h), (i) and (j) also debar certain inventions from patentability criteria. Section 3 (b) states that an invention causing serious prejudice to human, animal or plant life or health or to the environment is not an invention,

like a combination of herbs/herbal extract imparting properties that may cause serious health diseases or a herb that may destroy the crops or a method of extraction that makes the extract poisonous, etc. Section 3 (c) describes non-patentable inventions which fall under the category of discovery/abstract theory/scientific principle. For example, finding of a new herb occurring freely in nature is a discovery and not an invention.

Section 3 (e) is also an important section of the Patents Act 1970, which describes that mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance is not an invention. An admixture resulting in synergistic properties is not considered as mere admixture, e.g. a soap, detergent, lubricant and polymer composition, etc., and hence may be considered to be patentable. A mere aggregation of known herbs/herbal extracts which does not result in any improvement and serves as comprising the properties of the constituents separately is considered a non-patentable invention. For patentability, the final product which is produced by admixing two or more ingredients or a process of producing such substances should satisfy the requirement of add-on feature which may include

- Synergistic effect: for example, combination of senna leaf extract with isabgol for enhanced laxative effect
- Improved stability: addition of a buffer in an extract to maintain the pH of the extract stable for a month or addition of a chemical to prevent sedimentation
- Decrease in side effects: combination of fennel seed extract with antihistamines (Allegra and Benadryl) so as to overcome the side effect of increased acid reflux

Section 3 (h) states that a method of agriculture or horticulture is not an invention. For example, a method of producing a plant, even if it involved a modification of the conditions or a method of producing mushrooms or a method for cultivation of algae, etc., is not patentable. Likewise, the method of improving the cultivation of herb is also not patentable. For the benefit of the society, such inventions are categorised as non-patentable inventions. Section 3 of the Patents Act 1970 has been drafted very meticulously so as to keep a balance between the interest of inventors and the public. Section 3 (i) and 3 (j) are also relevant for understanding the patentability of herbal inventions as Section 3 (i) excludes process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products as an invention. For example, a medicinal method is not patentable under this section. A process of administering medicines orally, or through injectables, or topically or through a dermal patch or the order of administering two drugs or herbal extract(s) to obviate side effects or a method of treatment using herbal formulation, etc. is not patentable. Further, Section 3 (j) excludes (a) plants in whole or in part, (b) animals in whole or in part, (c) seeds, (d) varieties and species of plants and animals and (e) essentially biological process(es) for production or propagation of plants and animals, are not patentable. Section 3 clearly demarcates the inventions that cannot be considered patentable under the Patents Act 1970. This helps the researchers to understand the concept and purpose of granting a patent especially in the case of herbals as herbal medicines are considered as household items in India, for example, using fennel seeds as carminative agents and stem of *Glycyrrhiza glabra* or tulsi leaves for cough. Patent applications related to herbals must be examined with a special consideration, notably keeping in view the vast traditional knowledge that is getting transferred from one generation to another in India. Also, patenting is important for herbals; therefore it's an additional responsibility of the patent offices to grant a patent for herbal inventions considering all these above-mentioned aspects of herbals.

12.3.3 Other Relevant Provisions of the Patents Act 1970 for Herbal Patent Applications

The Patents Act 1970 has been essentially designed to ensure that only patents with technical advance are granted in the hands of applicants for asserting monopoly. Various provisions under the Act have been placed at different levels to ascertain the technical advancement of the patents. Right from the filing to prosecution and then grant, a patent application is examined thoroughly in view of the patent act and the guidelines as discussed above. There is another provision in the Act that empowers any person to challenge the validity of a patent. The pre-grant opposition (under Section 25 (1)) and post-grant opposition (under Section 25 (2)) are designed to ensure that only valid and enforceable patents are granted. Pre-grant opposition under Section 25 (1) can be filed by any person after the pre-grant publication of the patent application by way of lodging an opposition to the controller based on specific grounds (the Patents Act 1970). Post-grant opposition under Section 25 (2) can be filed by any interested person before the expiry of a period of one year from the date of publication of grant of a patent again based on specific grounds. These provisions together enable any person/interested person to file opposition against the applied patent/granted patent to stop the grant or invalidate a wrongly granted patent, respectively.

It may be mentioned that among other grounds of opposition, Section 25 (1)(j) and Section 25 (1)(k), quoted below, are extremely relevant for getting patent rights in the area of herbals.

> Section 25: (1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground—
>
> (j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
>
> (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,

Even after the grant of patent, any interested person can file opposition within a year of notification of grant of a patent on some of the specific grounds under Section 25 (2) which also include grounds mentioned above.

> Section 25 (2): At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:—
>
> (j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention;
>
> (k) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,

Another relevant section under the Patents Act 1970 is Section 64 – revocation of patents. As per this section, any person interested or the Central Government may make a petition on any of the grounds, specified for revocation of patent under Section 64 of the Patents Act, before the Appellate Board. A patent may also be revoked by the High Court on a counterclaim in a suit for infringement of patent. There are various grounds for revocation before the elaborated in Section 64 that may be used to revoke a granted patent. Section 64 (p) and (q) incorporated via the Patents Amendments Act 2002 are related to herbal invention.

> (p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
>
> (q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

All the sections of the Indian Patents Act 1970, presented at the time of formation of the

Act or incorporated during the amendments, are in coherence with each other and substantiate the fact that patenting an invention using traditional knowledge of herbals of India should be protected under the Act, but under no circumstances, any invention should be protected which violates these section. The spirit of the patent system in India is to benefit the society from the research and development in herbals and also granting monopoly rights to researches for a limited period of time (Table 12.1).

Indian Patent Office has also issued guidelines for the examiner and the controllers to examine the inventions related to the herbals/traditional knowledge. The guiding principles of this document not only help the examiners but also inventors to understand the importance of patenting activity in herbal thereby guiding inventors to draft their applications in such a way that the grant of their application should not become an impediment for public interest.

12.3.4 Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material

It is important that the innovation related to herbals should be provided legal protection under the law, but it is also the prerogative of the government to protect the biological diversity of India. Keeping in view importance of patenting in traditional knowledge, Guidelines for all Examiners and Controllers to be followed, while examining any patent application related to traditional knowledge, were issued in the year 2012. For the patent applications relating to traditional knowledge (TK), these guidelines very explicitly describe how to judge novelty and inventive step. These guidelines focus on the circumstances under which an invention should be considered patentable. The threshold for patentability has been clearly described in these guidelines with the help of six guiding principle.

Table 12.1 Patentable herbal invention in India

Patentable inventions in India
Novel formulation
Novel combinations involving selection of specific items/ingredients, specific proportions
Novel combinations that show synergy/antagonisms, better stability, better absorption/bioavailability
Novel combinations with explicit inventive steps like the addition of a chemical stabilising the formulation or enhancing penetration through the skin or increasing the rheological properties, etc.
Uniquely standardised to provide specific quality which is responsible for activity, e.g. ratios of components, etc.
Unique delivery devices like inhalation delivery devices
Combination of processes and compositions

> **Guiding Principle 1:** If the subject-matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge.
>
> **Guiding Principle 2:** Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.
>
> **Guiding Principle 3:** In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.
>
> **Guiding Principle 4:** Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.
>
> **Guiding Principle 5:** In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive.
>
> **Guiding Principle 6:** In case individual ingredients are already known for the treatment of a disease as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).

(Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material, 2012, Indian Patent Office)

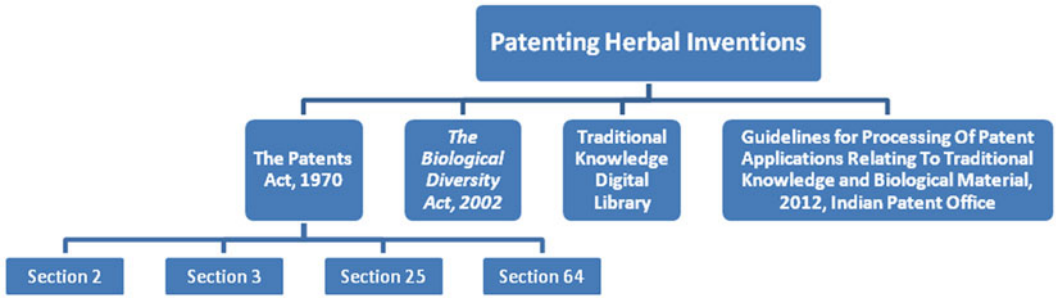

Fig. 12.6 Considerations for patenting herbal inventions

All these guiding principles very explicitly describe the inventions which are not patentable. The guiding principles are in coherence with the Patents Act 1970, and they just provide guidance to the examiners as well as patent applicants (Annexure I). Apart from these guiding principles, the guidelines also highlight that it is imperative to obtain NBA permission under the Biological Diversity Act 2002, for filing any patent application-related TK. The Biological Diversity Act 2002 provides very clearly that

> no person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of National Biodiversity Authority before making such application;
>
> if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned;

The National Biodiversity Authority shall dispose of the application for permission made to it within a period of 90 days from the date of receipt thereof. All the relevant sections of the Patents Act 1970 have been crafted to take care of biological resources of India, and few provisions are inspired by the Biodiversity Act 2002. The Indian Patent Law complements Section 6 (1) of the Biological Diversity Act 2002 by making it mandatory for the applicant of a patent to submit a declaration under Form I (Application for Grant of Patent) of the Patents Rules 2003 to the effect that 'the invention as disclosed in the specification uses the biological material from India and the necessary permission from the Competent Authority shall be submitted by me/us before the grant of patent to me/us'. This is one of the most important aspects of filing and prosecution of patents covering herbal inventions, and it would be a good idea to discuss this in detail for thorough understanding of the readers/researchers (Fig. 12.6).

12.3.5 National Biodiversity Authority

Patents together with access and benefit sharing are a critical component of conserving biodiversity. This was acknowledged in the objectives of the United Nations Convention on Biodiversity (CBD) to conserve biodiversity (Art 1) together with the recognition that patents and other forms of intellectual property should support the CBD's objectives. The access and benefit-sharing objectives of the CBD have now been implemented in India, and the National Biodiversity Authority constituted under Biodiversity Act 2002 is the nodal centre to obtain permissions related to IPRs in the area of traditional knowledge.

12.3.5.1 The Biological Diversity Act 2002

India is one of the 12 mega biodiversity countries of the world and accounts for 7–8 % of the recorded species. The biodiversity legislation regulates access to biological resources. As mentioned in the introduction, the Act provides for conservation of biological diversity, sustainable

use of its components and fair and equitable sharing of benefits arising art of the new use of biological resources and knowledge. The Act established National Biodiversity Authority for the regulation of related activities. It also established State Biodiversity Boards and contains important provisions so as to stop indiscriminate use, misappropriation as well as granting of monopoly rights on biological resources (NBA 2015). The following three-tier structures at the national, state and local level have been created:

- National Biodiversity Authority (NBA)
- State Biodiversity Boards (SBB)
- Biodiversity Management Committees (BMCs)

It provides that any foreign national or corporation can obtain any biological resources occurring in India or knowledge associated thereto for research or commercial purposes only after taking the approval of the National Biodiversity Authority. Not only that, it also provides according to the province of Section 4 that even the result of research related to biological resources of India cannot be transferred to any foreign individual or corporate without the approval of National Biodiversity Authority. However, it does make exception for publication of research papers as well as for certain collaborative research projects.

Section 4 of the Act makes specific provisions that no person can apply for intellectual property rights, in India or abroad, for any invention based upon research or information on a biological resource obtained from India without seeking prior approval from the National Biodiversity Authority. In the following situations, NBA's permission is required:

- For commercialization of research results when the source material used for research belongs to countries biodiversity
- When research results have to be shared with foreigners
- When a foreigner/institution wants access to the country's biodiversity for undertaking research

However, the following are exempted from above:

- Local people and community of the area for free access to use biological resources within India
- Growers and cultivators
- Vaidyas and hakims
- Normally traded commodities
- Collaborative research with approval of the Central Govt.

The National Biodiversity Authority, an autonomous body created in 2003, performs the role of regulatory as well as advisory body on the matters related to biological resources. The entire set of responsibilities, mandated under the Biological Diversity Act (2002), is performed in a decentralised manner with NBA advising the Central Government on matters related to conservation, sustainable use and benefit sharing.

The State Biodiversity Boards advise the concerned state governments on issues related to biodiversity. The local-level Biodiversity Management Committees (BMCs) are responsible for documentation of biological diversity, preservation of habitats, conservation of domesticated stocks, breeds of animals and microorganisms, etc. The National Biodiversity Authority has been able to create State Biodiversity Boards in a number of states apart from creating about 30,000 BMCs.

Section 6 (1) makes it mandatory to seek prior approval from NBA for filing any IPR application, whether in India or abroad on a biological resource obtained from India. The applicant has to fill Form III required to obtain an application for intellectual property right and submit at NBA for approval. This is a detailed form which requires information about the biological material used for the invention (Annexure I). Effective January 1, 2005, it has become mandatory for a patent applicant to furnish a declaration in Form I, to be submitted to the patent office along with patent specifications for seeking patent rights, to the effect that the applicant would be submitting the necessary permission from the competent authority before grant of patent, in case the specification uses the biological material from India.

12.3.6 Traditional Knowledge Digital Library

As the purpose of this chapter is to provide a holistic view about the patenting in herbals/traditional knowledge, it is important to update the readers about Traditional Knowledge Digital Library (TKDL). The genesis of TKDL can be traced to the legal battle fought by CSIR in US Patent Office for re-examination of US Patent Number US 5401504, granted to two US-based Indians for wound healing properties of turmeric. This was a joint project initiated by the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) (erstwhile Department of Indian Systems of Medicine and Homoeopathy, ISM&H) and National Institute of Science Communication and Information Resources (NISCAIR) (erstwhile National Institute of Science Communication, NISCOM) in order to prevent misappropriation of disclosed traditional knowledge (TK). It serves as a more easily accessible non-patent literature database that deals with traditional knowledge subject matter (Gupta, 2005). It integrates multidisciplinary skills in traditional knowledge, classification expertise, International Patent Classification, information technology and language expertise in French, German, Spanish and Japanese. Therefore, project team represents above skill set.

At present, apart from the Indian Patent Office, the following seven patent offices are using TKDL, and negotiations are underway with the New Zealand IP Office for signing the access agreement.

(i) Japan Patent Office (Apr 2011)
(ii) United Kingdom Patent & Trademark Office (Feb 2010)
(iii) Canadian Intellectual Property Office (Sep 2010)
(iv) German Patent and Trade Mark Office (Oct 2009)
(v) United States Patent and Trademark Office (Nov 2009)
(vi) Intellectual Property, Australia (Jan 2011)
(vii) European Patent Office (Feb 2009)

12.3.6.1 TKRC and IPC Concordance

One of the major factors for the success of TKDL is the unique classification system called the Traditional Knowledge Resource Classification (TKRC) on which TKDL is based and which makes the use of TKDL easy and effective in carrying out prior art searches. Traditional knowledge documentation lacked a classification system. Therefore, a modern classification based on the structure of International Patent Classification (IPC) was evolved. This has been attempted for Ayurveda and has been named as Traditional Knowledge Resource Classification (TKRC). The TKRC like the IPC has a system of classification based on hierarchical system of language-independent symbols for retrieving non-patent literature on Indian systems of medicine. TKDL concentrates only on the aspect of defensive protection which just prevents others from claiming any form of intellectual property protection over traditional knowledge and does not recognise or confer any rights on the knowledge holders.

12.3.6.2 TKDL Database

TKDL database is essentially a dynamic database covering more than two lakh formulations collected from Ayurveda, Unani, Siddha and Yoga texts, continuously updated. The entire information is provided in a standard format. It also provides modern names to the plants, diseases and processes and establishes linkage between traditional and modern knowledge. Over the years, TKDL has been successfully used for the cancellation/withdrawal of a number of patent applications filed in the USA, European Patent Office, etc. For example, formulations on Indian Systems of Medicine appear in the form of a text, which comprises the following main components:

- Name of the drug
- Origin of the knowledge
- Constituents of the drug with their parts used and their quantity
- Method of preparation of the drug and usage of the drugs
- Bibliographic details

TKDL gives modern names to plants (e.g. *Curcuma longa* for turmeric), diseases (e.g. fever for jwar) or processes, mentioned in the literature related to Indian Systems of Medicine, and establishes relationship between traditional knowledge and modern knowledge. The change that TKDL has brought in has been quite impressive. As of August 2011, 53 patent applications of the pharma companies of the USA, Great Britain, Spain, China, etc. had been either set aside or withdrawn or cancelled or declared as dead patent applications on the basis of third-party observations submitted by the TKDL team based on the information present in the TKDL database.

12.4 Copyright

Indian state provides the strongest possible protection to the creators of copyrightable works through the Indian Copyright Act amended from time to time. Works protected under Copyright Act are as follows:

(i) Literary, dramatic and musical work. Computer programs
(ii) Artistic work
(iii) Cinematographic films including soundtrack and video films
(iv) Record on any disc, tape, perforated roll or other device

The general rule is that copyright lasts for 60 years. In the case of original literary, dramatic, musical and artistic works, the 60-year period is counted from the year following the death of the author. In the case of cinematograph films, sound recordings, photographs, posthumous publications, anonymous and pseudonymous publications, works of government and works of international organisations, the 60-year period is counted from the date of publication.

India has a very strong and comprehensive copyright law based on Indian Copyright Act 1957 that was amended in 1981, 1984, 1992, 1994 and 1999. The amendment in 1994 was a response to technological changes in the means of communications like broadcasting and telecasting and the emergence of new technology like computer software. The 1999 amendments have made the Copyright Act fully compatible with Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. With these amendments, the Indian copyright law has become one of the most modern copyright laws in the world.

Herbal innovations falling under any one of the categories defined above can be protected through copyright. It may include labels, monographs, pamphlets, papers, product information leaflets of herbal products, etc. Unlike patents, there are no special guidelines or provisions in the Act for the innovations related to herbals. The copyright protects the form of expression rather than the subject matter of the writing. However, it is equally important to take copyright protection wherever applicable as it involves commercial interests of the stakeholders.

International Scenario The 1886 Berne Convention first established recognition of copyrights among sovereign nations, rather than merely bilaterally. Under the Berne Convention, copyrights for creative works do not have to be asserted or declared, as they are automatically in force at creation: an author need not 'register' or 'apply for' a copyright in countries adhering to the Berne Convention. The regulations of the Berne Convention are incorporated into the World Trade Organization's TRIPS Agreement (1995), thus giving the Berne Convention effectively near-global application.

12.5 Design

Industrial design right is intellectual property right that protects the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or composition of pattern or colour or combination of pattern and colour in three-dimensional form containing aesthetic value. An industrial design can be a two- or three-dimensional pattern used to produce a product, industrial commodity

or handicraft. An industrial design is registrable under the Designs Act 2000, if it meets the following prerequisites:

The design should be new or original, not previously published or used in any country before the date of application for registration. The novelty may reside in the application of a known shape or pattern to new subject matter.

The design should relate to features of shape, configuration, pattern or ornamentation applied or applicable to an article.

The design should be applied or applicable to any article by any industrial process.

The features of the designs in the finished article should appeal to, and are judged solely by, the eye. This implies that the design must appear and should be visible on the finished article, for which it is meant.

Significantly distinguishable from known design or a combination of known designs.

Not comprise or contain scandalous or obscene matter.

Not be contrary to public order or morality.

The Locarno Agreement provides an internationally agreed classification system based upon the functionality of the goods under the design registration. Overall there are 32 classes which are further divided into subclasses. The assigned classification must correspond to the functionality of the item under consideration for design registration. Normally, the name of the article should be such that it is common/familiar in the trade or Industries. The name of the article as mentioned in the application form should correspond with the representation of the article as filed.

The design right is initially granted for 10 years which could be further extended by another 5 years by paying a one-time extension fee of Rs 2000. Industrial design protection is largely associated with the external appearance influencing commercial value of the products like in the case of formulations, shape of tablets, bottles used for dispensing medicines and shape of outer packaging box. There are no special provisions for herbals for design registration, and the herbal innovations under this IPR regime are examined and registered like any other design from any field.

International Protection The Hague Agreement facilitates filing of design application in several countries. An applicant file a single international application with national office, a party to the Hague Agreement governed by World Intellectual Property Office, and can seek protection in all the member countries of the agreement. The design rights historically originated in the United Kingdom in 1787 with the Designing and Printing of Linen Act and have expanded from there (Table 12.2).

12.6 Trademark

A **trademark** or **trade mark** (represented by the symbol ™) or **mark** is a distinctive sign or indicator of some kind which is used by an individual, business organisation or other legal entity to identify uniquely the source of its products and/or services to consumers and to distinguish its products or services from those of other entities. A trademark could be typically a name, word, phrase, logo, symbol, design, image or a combination of these elements. There are a lot of trade-

Table 12.2 What herbal innovations can be protected under the IPRs

Herbal innovations	
Copyright	Labels, monographs, pamphlets, papers, product information leaflets of herbal products, etc.
Design	Shape of tablets, bottles used for dispensing medicines, shape of outer packaging box, etc.
Trademark	Logo, symbol, design, image or a combination of these elements
Geographical indications of goods	Goods from a specific part of the country having distinctiveness and quality
Protection of Plant Varieties and Farmers' Rights	New plant varieties
Trade secret (No registration possible)	Process, formula, business information, design, instrument, pattern, compilation of information, etc.

marks related to herbals products, like GANDHAM, a herbal bath soap; Nature's gold crème, Nature's Fruit Bleach by Nature's Essence Private Limited; NIKHAR soap; etc. Trademark protection adds value to the product by providing it a desired identity through name, logo, etc. It is equally important for herbal products as there is a boom in the herbal market, and trademark facilitates trading of products.

The owner of a registered trademark may commence legal proceedings for trademark infringement to prevent unauthorised use of that trademark. The owner of a common law trademark may also file suit, but an unregistered mark may be protectable only within the geographical area within which it has been used or in geographical areas into which it may be reasonably expected to expand.

The Trade Marks Registry was established in India in 1940 and presently it administers the Trade Marks Act 1999 and the rules thereunder. It acts as a resource and information centre and is a facilitator in matters relating to trademarks in the country. The main function of the Registry is to register trademarks, which qualify for registration under the act and rules.

The duration of protection afforded to a 'mark' varies from country to country and registrations are issued for finite periods of time. However, because of the fundamental purposes of marks – namely, avoiding public confusion, encouraging competition and protecting the owners' goodwill – registrations may be renewed and thus extend indefinitely as long as the marks are used.

The initial registration of a trademark in India is for a period of ten years but may be renewed from time to time for an unlimited period by payment of the renewal fees.

International Protection It is important to note that although there are systems which facilitate the filing, registration or enforcement of trademark rights in more than one jurisdiction on a regional or global basis (e.g. the Madrid and CTM systems), it is currently not possible to file and obtain a single trademark registration which will automatically apply around the world. Like any national law, trademark laws apply only in their applicable country or jurisdiction, a quality which is sometimes known as 'territoriality'.

The major international system for facilitating the registration of trademarks in multiple jurisdictions is commonly known as the 'Madrid System'. Madrid System provides a centrally administered system for securing trademark registrations in member jurisdictions by extending the protection of an 'international registration' obtained through the World Intellectual Property Organization. This international registration is in turn based upon an application or registration obtained by a trademark applicant in its home jurisdiction.

The primary advantage of the Madrid System is that it allows a trademark owner to obtain trademark protection in many jurisdictions by filing one application in one jurisdiction with one set of fees and make any changes (e.g. changes of name or address) and renew registration across all applicable jurisdictions through a single administrative process. Furthermore, the 'coverage' of the international registration may be extended to additional member jurisdictions at any time.

12.7 The Geographical indications (GI) of Goods (Regulation and Protection) Act

A geographical indication (GI) is a name or sign used on certain products which corresponds to a specific geographical location or origin (e.g. a town, region or country). The use of a GI may act as a certification that the product possesses certain qualities or enjoys a certain reputation, due to its geographical origin.

In December 1999, the parliament passed the Geographical Indications of Goods (Registration and Protection) Act 1999. This Act seeks to provide for the registration and better protection of geographical indications relating to goods in India. India, as a member of the World Trade

Organization (WTO), enacted the Geographical Indications of Goods (Registration and Protection) Act 1999 which has come into force with effect from September 15, 2003.

Under Section 1 (e) of Act, GI is defined as:

> 'Geographic Indication' in relation to goods, means an indication which identifies such goods as agricultural goods natural goods or manufactured goods as originating or manufactured in the territory of a country or a region or locality in that territory, where a given quality reputation or other characteristic of such good is essentially attributed to its geographical origin and in case where such goods are manufactured goods, one of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality as the case may be.

A few of the agricultural goods registered as GI are provided in the following:

1. Navara rice: Certificate No.40 dated November 20, 2007
   Registered proprietor: Navara Rice Farmer's Society, Karukamanikalam, near Chittur, Kerala
   Medicinal rice used in Ayurveda treatment
   Varieties covered: Two black glumed and golden yellow glumed varieties of Navara rice
2. Palakkadan matta: a popular rice variety
   Bold red rice with a unique taste because of its special geographical area and peculiar weather of Eastern wind
   Registered proprietor: Palakkad Matta Farmers Producer Company Ltd.
   Varieties covered: 10 – Aryan, Aruvakkari, Chitteni, Chenkazhama, Chettadi, Thavalakanna, Eruppu, Poochamban, Vattan Jyothy and Kunjukunj. However, more rice varieties with matta properties cultivated in Palakkad can be added to this list after detailed examinations.

Any association of persons or producers or any organisation or authority established by or under any law for the time being in force representing the interest of the producers of the concerned goods, who are desirous of registering geographical indication in relation to such goods, can apply in writing to the Registrar.

The application for registering geographical indication should include the various requirements and criteria as specified in Rule 32 (1) which are:

(i) The reason to designate the good as a geographical indication
(ii) The class of goods
(iii) The territory
(iv) The particulars of appearance
(v) Particulars of producers
(vi) An affidavit of how the applicant claims to represent the interest
(vii) The standard benchmark or other characteristics of the geographical indication
(viii) The particulars of special characteristics
(ix) Textual description of the proposed boundary
(x) The growth attributes in relation to the GI pertinent to the application
(xi) Certified copies of the map of the territory
(xii) Special human skill involved, if any
(xiii) Number of producers
(xiv) Particulars of inspection structures, if any, to regulate the use of geographical indication

Registration of a GI enables producers to stop unauthorised use by others thereby boosting exports and their economic prosperity. Currently, there are 235 registered GI in India out of which 50 belongs to agricultural category including Malabar pepper from Kerala, Coorg Green Cardamom from Karnataka, Naga Mirchi from Nagaland, Guntur Sannam Chilli from Andhra Pradesh, etc. (Geographical Indications Registry India, 2015).

International Protection The TRIPS Agreement essentially stipulates the following obligations on the part of member countries in relation to the protection of GIs. There are, in effect, two basic obligations on WTO member governments relating to GIs in the TRIPS Agreement:

1. **Article 22 of the TRIPS Agreement** says that all governments must provide legal opportunities in their own laws for the owner

of a GI registered in that country to prevent the use of marks that mislead the public as to the geographical origin of the good. This includes prevention of use of a geographical name which although literally true 'falsely represents' that the product comes from somewhere else.

2. **Article 23 of the TRIPS Agreement** says that all governments must provide the owners of GI the right, under their laws, to prevent the use of a geographical indication identifying wines not originating in the place indicated by the geographical indication. This applies *even where the public is not being misled*, where there is no unfair competition and where the true origin of the good is indicated or the geographical indication is accompanied by expressions such as 'kind', 'type', 'style', 'imitation' or the like. Similar protection must be given to geographical indications identifying spirits.

12.8 The Plant Variety Protection and Farmers' Rights

The purpose of providing legal protection to new plant varieties is to encourage the plant breeders for their innovation. The rights provided to the plant breeders over their new plant varieties, for a limited period of time, motivate them to invent new plant varieties in the larger public interest. The Plant Variety Protection and Farmers' Rights Act 2001 was enacted in India to protect the new plant variety. Rules for the same were notified in 2003.

12.8.1 Objectives of Plant Variety Protection and Farmers' Rights Act

(i) To stimulate investments for research and development both in the public and the private sectors for the development of new plant varieties by ensuring appropriate returns on such investments

(ii) To facilitate the growth of the seed industry in the country through domestic and foreign investment which will ensure the availability of high-quality seeds and planting material to Indian farmers.

(iii) To recognise the role of farmers as cultivators and conservers and the contribution of traditional, rural and tribal communities to the country's agro biodiversity, by rewarding them for their contribution through benefit sharing and protecting the traditional right of the farmers.

(iv) More importantly this act provides safeguards to farmers by giving farmers rights while providing for an effective system of protection of plant breeders' rights. The Act seeks to safeguard researchers' rights as well. It also contains provisions for safeguarding the larger public interest. The farmer's rights include his traditional rights to save, use, share or sell his farm products of a variety protected under this Act, provided the sale is not for the purpose of reproduction under a commercial marketing arrangement.

12.8.2 Varieties Registrable under the Plant Variety Act

1. A new variety if it conforms to the criteria of novelty, distinctiveness, uniformity and stability
2. An extant variety if it conforms to criteria of distinctiveness, uniformity and stability

12.8.3 Definition of Novelty, Distinctiveness, Uniformity and Stability

Novelty Plant variety is novel if on the date of filing of the application for registration for protection, the propagating or harvested material of such variety has not been sold or otherwise disposed of, by or with the consent of breeder or his

successor, for the purpose of exploitation of such variety.

In India earlier than one year, or outside India, in the case of tree or vines, earlier than six years, or in any other case, earlier than four years, before the date of filing such application, provided that a trial of a new variety which has not been sold otherwise disposed of shall not affect the right to protection.

Distinctiveness New plant variety will be considered distinct if it is clearly distinguishable by at least one essential characteristic from any other variety whose existence is a matter of common knowledge in any country at the time of filing of the application.

Uniformity New plant variety will pass uniformity test if subject to the variation that may be expected from the particular features of its propagation it is sufficiently uniform in its essential characteristics.

Stability New plant variety will be considered stable if its essential characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

Compulsory Plant Variety Denomination After satisfying the above four essential criteria, every applicant shall assign a single and distinct denomination to a variety with respect to which he is seeking registration: in the case of trees and vines, eighteen years from the date of registration of the variety and, in the case of extant varieties, fifteen years from the date of the notification of that variety by the Central Government under Section 5 of the Seeds Act 1966. In other cases, it is fifteen years from the date of registration of the variety.

Initially the certificate of registration shall be valid for nine years in the case of trees and vines and six years in the case of other crops and may be revived and renewed for the remaining period on payment of fees as may be fixed by the rules.

At present, the Protection of Plant Varieties and Farmers' Rights Authority, India, has issued a list of 88 crops/species for which seeds can be submitted to the authority for testing (Protection Of Plant Varieties And Farmers' Rights Authority, India 2015). These crops/species include isabgol, menthol mint, brahmi, coriander, almond, walnut, grapes, etc.

International Protection Under the TRIPS Agreement, it is obligatory on part of a member to provide protection to new plant variety either through patent or an effective sui generis system or a combination of these two systems. India was therefore under an obligation to introduce a system for protecting new plant variety. India opted for sui generis system and enacted the New Plant Variety Protection and Farmers' Rights Act. However, in many countries such plants can be protected through patent and UPOV Convention.

UPOV is an abbreviation of Union pour la Protection des Obtentious Vegetals (Union for protection of new varieties of plant). It is an international convention which provides a common basis for the examination of plant varieties in different member states of UPOV for determining whether a plant variety merits protection under UPOV or not.

12.9 Trade Secret

Trade secret can also be a useful legal vehicle for protecting innovations related to herbals, when dealing with outsiders' improper acquisition, disclosure and use of relatively secret information. Trade secret is unique among all the other legal instruments of legal protection as it is limited and fragile. It does not apply to publicly available, reverse-engineered or independently developed information. Broadly, a **trade secret** can be a formula, practice, process, design, instrument, pattern or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors or customers. In some jurisdictions, such secrets are referred to as 'confidential information' or 'classified information' (WIPO 2015).

The precise language by which a trade secret is defined varies by jurisdiction (as do the particular types of information that are subject to trade secret protection). However, there are three factors that, although subject to differing interpretations, are common to all such definitions. A trade secret is information that:

- Is not generally known to the public
- Confers some sort of economic benefit on its holder (where this benefit must derive *specifically* from its not being generally known, not just from the value of the information itself)
- Is the subject of reasonable efforts to maintain its secrecy

A company can protect its confidential information through non-compete and non-disclosure contracts with its employees (within the constraints of employment law, including only restraint that is reasonable in geographic and time scope). The law of protection of confidential information effectively allows a perpetual monopoly in secret information unlike patent which has only 20-year term. The lack of formal protection, however, means that a third party is not prevented from independently duplicating and using the secret information once it is discovered.

Trade secrets are by definition *not* disclosed to the world at large. Instead, owners of trade secrets seek to keep their special knowledge out of the hands of competitors through a variety of civil and commercial means, not the least of which is the use of non-disclosure agreements (NDA) and non-compete clauses. An employee may be required to sign an agreement for not revealing his or her prospective employer's proprietary information, in exchange for the opportunity to be employed by the holder of secrets. Often, the employee will also sign over rights to the ownership of own intellectual works produced during the course (or as a condition) of their employment. Similar agreements are often signed by other companies with whom the trade secret holder is engaged, e.g. with the trade secret holder's vendors, or third parties in licensing talks or involved in other business negotiations. Trade secret protection *can*, in principle, extend indefinitely, and this may offer an advantage over patent protection, which lasts only for a specifically limited period of time. Coca-Cola, the most famous trade secret example, has no patent for its formula and has been very effective in protecting it for many more years than the twenty years of protection that a patent would have provided. The relationship between intellectual property law, secrecy and disclosure with respect to herbals has important consequences. In the case of herbals, it is all the more important that society as a whole should be benefited from the disclosure of commercially valuable information. If any property of a part of tree has been found, then society has an interest in encouraging the disclosure of this knowledge to other entities that can improve upon it and bring it to the larger public. Trade secret should be used as an effective mechanism for protection of herbal innovations.

12.10 Conclusion

Herbal innovations are important for the society, and to encourage research in the area of herbals, it is imperative that the IPR regime should provide adequate protection to the innovations made by inventors. Herbals have a huge potential to fill the gap arising due to the lack of new molecular entities. Researchers have been looking at the herbals and their activities for clues for development of new molecular entities. IPR regime had been instrumental in promoting research and motivating researchers for their innovations, and there is no reason that herbals should be an exception for the same. However, any IPR regime must make a proper equilibrium between the availability of monopoly right and the freedom for rest of public domain. In the case of herbals, some of the provisions of IPR regimes, particularly patent regime, have been designed to do the same. It must be understood thoroughly that herbal innovations are treated on equal footing with other innovations for granting any IPR. Herbal innovations can be protected but one needs to find the right combination of IPRs and the IPR tools and use them. Patents provide the strongest monopoly right to the herbal inventions. It will be instructive to highlight grant of a

patent on an invention related to the processing, extraction, composition and use of extracts of a plant *Plectranthus amboinicus* filed by a Taiwanese Company, the Development Center for Biotechnology (patent application number 1556/KOL/2007). The Indian Patent Office upheld during a pre-grant opposition proceeding, where some of the claims were objected by the opponent (CSIR). Obviously, the doors of even the strongest possible monopoly right for herbals are not totally closed in India or elsewhere. To summarise, patents are granted for herbal innovations in case:

- The formulation is novel.
- Novel combinations involve selection of specific items/ingredients and specific proportions.
- Novel combinations show synergy/antagonisms, better stability and better absorption/bioavailability.
- Novel combinations have explicit inventive steps like the addition of a chemical stabilising the formulation or enhancing penetration through skin or increasing the rheological properties, etc.
- Uniquely standardised to provide specific quality those are responsible for activity, e.g. ratios of components, etc.
- Uniquely delivered like inhalation delivery devices.
- Patents are grantable for combination of processes and compositions.

However, unlike patents, innovations related to herbal products protected under trademark laws, copyrights law, design act, GI, plant varieties, etc. are treated equally with other innovations. There are no special provisions or guidelines under any of these above-mentioned IPRs for herbals thereby strengthening the researchers to protect their innovations.

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