HANDBOOK ON

INTELLECTUAL PROPERTY RIGHTS
&
TECHNOLOGY TRANSFER

Indian Council of Medical Research
2017

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Foreword by the Director-General

The Indian Council of Medical Research (ICMR) is one of the oldest science bodies in India with over a century of service to the nation. The broad mandate of the Council has been to conduct biomedical research towards improving the health of the Indian people. Over the last hundred years scientists of the Council have been carrying out research to find solutions to the health problems from malaria to malnutrition and from emerging infections to cancers through nation-wide institutional network. Most of the new knowledge in scientific journals for wide dissemination. The concept of protecting the new knowledge that has potential to create new products and processes not been widely known awareness of the concept of IPR protection. There have been exceptions where ICMR scientists have patented and then published.

This concept of patent-and-publish has assumed significance since 2005 when India became fully compliant with the global IPR regime viz., the Trade Related Intellectual Property Rights (TRIPS). The TRIPS mandates uniform patent protection systems across the globe and the earlier process patent regime in drugs and pharmaceuticals in India shielded our people from higher cost of medicines no longer exists. We therefore need to innovate and compete globally which is at once a challenge and an opportunity. Simply put the ICMR and India needs to create systems to both innovate and forge alliances to bring out affordable products of public health importance to Indian people. The council has been seized of this issue for long and has taken steps to promote creation, protection and exploitation of new IP. IPR Unit was set up in the ICMR headquarters in 1999 and the expanded Innovation and Translation Research (ITR) Division in 2013. Both IPR and technology commercialization policies that are inventor friendly are in place. The results are there to see; the Council filed more than a dozen patents in the first 80 years of its inception. Since 1999 over 140 patents have been filed. This clearly shows that a lot of innovative research work was being done in the nation-wide network of ICMR laboratories but a system of identification and protection of the new IPR was found wanting. The Council currently has a portfolio of over 50 technologies. Over a dozen technologies have been transferred to various industry partners commercialization. Recently, a new IPR and technology policy has been unveiled by the Government of India to promote a new thrust and focus towards creations of new innovations that would provide impetus to the 'Make in India' initiative.

The council has been continuing its efforts to create new IP by both intramural and extramural. As part of these ongoing initiatives, IPR Unit, ITR Division has brought out this booklet *FAQs on Intellectual*

Property Rights. This booklet gives a broad overview of all the important concepts of IPRs with essential information for a busy scientist as to how to file a patent. This document is based on relevant techno-legal information from various national and international sources. An expert committee under the chairmanship of Professor Seyed Hasnain has guided this effort. I would like to thank Prof Hasnain and other members of the committee for their help.

I am extremely hopeful that the *FAQs on Intellectual Property Rights* will be consulted by all biomedical scientists to increase their knowledge-base on IPRs to help them create even more new patentable knowledge and for translating them into new health products to achieve the overall national objective of affordable health care for all.

Dr Soumya Swaminathan
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Secretary, Department of Health Research,
New Delhi

A word from the Editor

Ever since its creation in 1999, the Intellectual Property Rights (IPR) Unit has been striving hard to promote innovation and research that would lead to patentable leads. The Unit has geared itself over to create a inventor-friendly system for scientists to consider protection of new knowledge created as new intellectual property before publication in peer reviewed journals. Several steps have been taken to that end which includes brining out the first IPR Policy in 2000. This was followed by the creation of Innovation and Translation Division in 2013. For the past hundred years, scientists working within and with support from the Indian Council of Medical Research have been carrying out high quality research to achieve its objectives. Any new information/data generated in the laboratory are immediately published for its widest dissemination and application for public good. Typically we have noticed over the years that scientists of the Council are keener to publish in the best possible journals as it would lead to peer recognition in a highly competitive world.

We have devised a system for ensuring that the new inventions/leads obtained in the laboratory are eligible for patent protection. For this purpose, a simple, structure new inventions reporting proforma has been devised to help researchers report their new inventions. In a short period, we inform the scientists whether the new inventions are eligible for patenting or not. If it does not fulfill the criteria, they are advised to publish. Those leads that are patentable, we advise researchers to simultaneously help us file prepare the patent application along with the preparation of the manuscript for publication. Once the patent is filed, they could mail the manuscript for publication. This system has worked reasonably well and many researchers (both intra and extramural) are becoming increasingly conscious of the need and importance of protecting such new knowledge generated through appropriate IPR systems before publication. The results of our efforts are visible: the Council filed only 15 patents for the first 80 years. Since 1999 over 140 patents have been filed. Two things standout- scientist with support from ICMR have been doing innovative work but the support systems have either unavailable or inadequate. Secondly, the recognition that patents lead to products for use in the Indian public health system that will help create especially diagnostics and vaccines for diseases exclusively prevalent in India and other poor countries that do not attract the interest of multinational pharma companies. We have been successful in transferring various technologies relevant to our needs to Indian companies. Some are in the pipeline.

In addition to these efforts, we also regularly conduct workshops on IP awareness in both ICMR and other institutes/Medical Colleges. The Unit has also started a Newsletter on IPR to make scientists (of

both ICMR and other institutes) aware of important national and international developments in the area of biomedical sciences. Despite these efforts, we still believe that the awareness of IPRs in the ICMR network of scientists and extramural researchers is still far from optimal. We believe that there is some innovative research done in the nation-wide network of ICMR laboratories that is still getting published before IP protection. The present *FAQs on Intellectual Property Rights* is another such effort in the direction to increase awareness of IP protection before publication. The booklet has been prepared by a group of experts under the chairmanship of Professor Seyed Hasnain. I am grateful to Professor Hasnain and members of the expert committee. I am grateful to Dr Soumya Swaminathan Director-General, Indian Council of Medical Research & Secretary, Department of Health Research, New Delhi for her guidance. I also would like to acknowledge the continued support and encouragement of Dr Chander Shekhar, Scientist G and Head, Division of Innovation & Translation Research. Finally, we are very hopeful that the present document on IPR will help increase awareness among ICMR scientists to help them protect all new knowledge before publication.

Dr. Sadhana Srivastava
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BASIC INFORMATION

ON

INTELLECTUAL PROPERTY

Q1. What is intellectual property?

The intellectual property (IP) can be described as novel or previously undescribed tangible output of any intangible intellectual activity. IP typically has an owner, can be bought, sold or licensed and must be adequately protected for exploitation. IP can include (patentable) inventions, industrial processes, software, data, written work, designs, images etc.

Q2. Why is the word 'Property' used in case of Intellectual Property?

Intellectual Property is like any tangible property like land, house, vehicle etc. that has commercial value. Only that IP is created through human intellect. Therefore, IP can be bought and sold just like conventional property e.g. a house or a car. Example: If a chemical entity has been invented by a scientist and institute/company wants to make drug for a specific treatment, the institute/company pays money to the scientist to get the rights of IP provided that IP (chemical entity) is adequately protected as IPR. In other words, the chemical entity becomes an "Intellectual Property" for the scientist. Similarly, if a biotechnologist has developed a new process for making an enzyme, which has commercial value for a company, it would buy the rights to use the IP from the inventor. Since, IPRs can be bought and sold just like property, we use the terms "Intellectual Property".

Q3. What are intellectual property rights?

Intellectual Property Rights are the legally-protected rights which enable owners of IP to exert monopoly control over the exploitation of these rights, usually for commercial gain. IPRs give the right to the inventor to stop others exploiting this property for a specified period of time that depends on the type of intellectual property.

Intellectual Property rights commonly encompass the following which are collectively called Industrial property:

1. Patents
2. Trademarks
3. Industrial Designs
4. Copyrights
5. Geographical Indication of Goods
6. Integrated Circuits
7. Protection of Undisclosed Information such as Trade Secrets

According to the World Intellectual Property Organization, intellectual property refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce. Intellectual property is divided into two categories:

Industrial property that includes i) patents for inventions; ii) trademarks; iii) industrial designs; and iv) geographical indications and *Copyrights* covers literary works (such as novels, poems and plays), films, music, artistic works (e.g., drawings, paintings, photographs and sculptures) and architectural design. Rights related to

copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs

Q4. What is the need for IPRs?

IPRs are needed to reward the original inventive efforts by innovators. The IPRs ensure that the person who has put in intellectual efforts has monopoly rights over his/her creation for a limited period of time and must be rewarded for his efforts. Example: as cited earlier, if a biotechnologist has developed a new process for making an enzyme that has commercial value for a company making that enzyme, he/she can get paid for his effort. With such an incentive system in place, inventors are stimulated to create more such inventions. If there are no IP rights, anyone can copy and the innovator does not get credit or due reward. For the society, IPRs lead to growth and development as the innovations so created are made into products and/or processes that can be marketed and sold. This creates job opportunities and helps economy.

Q5. How is an inventor rewarded?

Typically, after protecting the IP, inventors in the public or private sector, transfer their rights to their employers on certain terms and conditions through a licensing agreement. Like if an ICMR scientist assigns his rights to the Council which transfers the technology to the industry on societal /commercial terms. The revenue so generated from the selling/renting the IP is shared with the team of inventors. The bigger the invention more is the revenue generated which in turn benefits the inventor(s). *(For details on licensing and technology transfer, kindly refer chapter VI)*

Q6. Do IPRs create barriers for biomedical research and development?

IPRs do not create barriers for further carrying out further R&D. Researchers can use the information available in patents (in the public domain) for further research. As patent information is disclosed through public documents, researchers from any part of the world can access the patented information. However, if the new knowledge generated has to be patented, the new invention has to fulfill the criteria of patenting. Commercial exploitation is also subject to the rights already vested given to the original inventor. Thus there is no bar on carrying out R&D on a patented invention and the limitation is only on subsequent commercial exploitation as the scope for patenting is limited by the earlier patents granted.

Q7. What are the categories of intellectual property?

Intellectual Property rights commonly encompass Patent, Trademarks, Industrial Design, Copyright, Geographical Indication of Goods, Integrated Circuit and Protection of Undisclosed Information such as Trade Secrets.

Patent refers to inventions, each embodying a new idea capable of being made or used by industry and involving a non-obvious inventive step. (for details kindly refer chapter II).

Copyright refers Literary and artistic works, films, videos, records, broadcasts and typographical arrangements, including computer software.

Registered Design refers to designs and design drawings, mainly right of aesthetic objects, engineering components, architectural drawings, etc.

Trade Marks refers to product brand names, company logos, etc

Geographical indication refers to a name or sign used on a product which signifies the origin of the product and presence of features which are specific to that origin.

Layout design of integrated circuits refers to a layout of transistors and other circuitry elements, lead wires connecting such elements, expressed in any manner in semiconductor integrated circuits. In India, Semiconductor Integrated Circuits Layout-Design Registry (SICLDR) supervises examination and registration of Layout-Designs of integrated circuits. The Registry functions as per the guidelines laid down in the Semiconductor Integrated Circuits Layout Design (SICLD) Act 2000 and the Semiconductor Integrated Circuits Layout-Design (SICLD) Rules 2001.

Q8. What are other types of Intellectual Property Rights?

Besides the above major types of Intellectual property rights, Trade secrets and Protection of Plant Varieties and Farmers' Rights (PPVFR) Act are also forms of IP protection. The details of each of these rights are provided below.

Q9. What is a trade secret?

A trade secret refers to confidential information that is protected and utilized by a company to have competitive advantage. A trade secret broadly comprises of manufacturing secrets, composition secrets, commercial secrets etc.

Q10. How does a trade secret differ from a patent?

A patent is a techno-legal *document,* which has a prescribed format and is registered at the Indian Patent office and similarly in concerned authorities in other countries whereas a trade secret is not registered. The patented information is therefore disclosed and recorded in a public domain source while the trade secret are undisclosed and remains as a secret with its owners. There is therefore limited or no legal protection in case of leakage of such confidential information. The term of a patent of protection is fixed viz., 20 years from the time of filing, whereas life of a trade secret is indefinite as long as the owner of such information is able to keep confidential.

Q11. What are Farmers' rights?

Under the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001, a farmer who has bred or developed a new variety shall be entitled for registration and to save, use, sow, re-sow, exchange and share or sell

his farm produce including seed of a variety protected. Further, a farmer who is engaged in the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation shall be entitled in the prescribed manner for recognition and reward from the Gene Fund provided that material so selected and preserved has been used as donors of genes in varieties registered under this Act. (For more details of Farmer's rights, kindly refer chapter IV)

Q12. What are legislations covering different kinds of IPRs in India?

Different types of IPRs are governed by separate legislations as given below:

Patents: The Patents Act, 1970 as amended in 1999, 2002 and 2005.

Design: The Design Act 2000

Trade Mark: The Trade Marks Act, 1999

Copyright: The Copyright Act, 1957 as amended in 1983, 1984 and 1992, 1994, 1999, 2012 and the Copyright Rules, 1958.

Layout Design of Integrated Circuits: The Semiconductor Integrated Circuit Layout Design Act 2000.

Protection of Undisclosed Information: No exclusive legislation exists but the matter would be generally covered under the Contract Act, 1872, amended 1996

Geographical Indications: The Geographical Indication of Goods (Registration and Protection) Act 1999.

Plant Varieties: The Protection of New Plant Variety and Farmers Rights Act 2001.

Comparative details of various IPRs

Question ↓ / Type of IP →	Patent	Design	Trade Secret	Copyright	Trademark
What is protected?	Products, processes, compositions, functions	Cosmetic appearance	Knowhow	Original expression of an idea	Customer's idea about the source of the product or service.
What is forbidden to others?	Using the claimed invention.	Making something that looks the same.	Unauthorized use or dissemination by someone who has been let in on the secret.	Copying the expression	Confusing the customer.

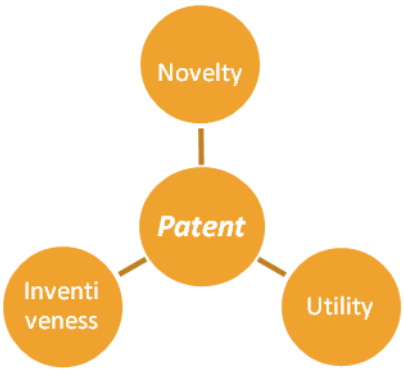
How is the right established?	Examination	Examination	Use in trade	Origination	Use in trade
What is needed to get protection?	Invention must be novel, useful, and not obvious to a skilled person. It must be disclosed in detail	Cosmetic appearance must be new and not obvious.	Know how must be well defined, not generally known, and must be safeguarded.	Concrete realization of the expression.	Mark must be distinctive rather than descriptive
How long does protection last?	Upto 20 years.	10 years (India) with possibility of renewal for 5 years. 14 years (US)	Until the information is not disclosed	Lifetime + 60 years after the death of Author	As long as it is used.

Q13. Which are the administrative bodies for protection of different IPRs in the country?

Patent, designs, trademarks, copyrights and geographical indications are administered by the Controller General of Patents, Designs and Trademarks under the control of the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry. The Act on Layout Design of Integrated Circuits and Information Technology Act 2000 is administered by the Ministry of Telecommunication and Information Technology. The Act on New Plant Variety is administered by the Ministry of Agriculture.

Q14. How is the term 'a new product or a process' defined?

For patent protection a product is considered as *new product* as such invention - a composition, formulation, device, drugs or vaccine or some other useful outcome is not known to the public through publication or prior use anywhere in the world. That is it must not have been disclosed anywhere in the public domain. The invention should not therefore be a part of the existing global state of the art viz. information publicly available in magazines, technical journals, books; newspapers, published patents etc.



Q15. Which inventions are patentable under the Indian Patents Act?

Inventions relating to product, process, formulation, drugs/vaccine, compound etc. are patentable as per the Indian Patent Act. (For details refer to Chapter II)

Q16. Which inventions are not patentable in India?

An invention must satisfy the three criteria for patentability and should not be against national and other public interests. The Indian Patent act identifies such non-patentable inventions (for details refer Chapter III).

Q17. What are the three criteria of patentability?

In accordance with the Indian patent Act, 1970, an invention must possess the following:

i. Novelty

ii. Inventiveness

iii. Industrial applicability

* (for details on the three criteria, kindly refer to Chapter III)

Q18. What kinds of products can be protected through IPR?

A patentable product may be a drug, pharmaceutical, agrochemical and other chemical like isomer, polymorph, pro-drugs, active metabolites, hydrates and other chemical substances which differ significantly in properties with regards to efficacy, in accordance with product patent regime in India. Specifically, IP such a product must fulfill the three prescribed criteria and must not pertain to the list of *inventions not patentable* under the Indian Patent Act.

Q19. Is traditional knowledge patent protectable?

Indian Patent Act, 1970 permits IP protection of traditional knowledge with certain conditions. It prohibits the protection of traditional knowledge in its crude form, but if it has been utilized to produce formulations, drugs or product with substantial inventive inputs and meets the criteria of patentability then it may be protected. (For details, kindly refer chapter

Q20. What is a copyright?

Copyright is a right given to creators of literary, dramatic, musical and artistic works and producers of cinematograph films and sound recordings etc.

Courtesy: USPTO/Intellectual-property-symbols

Q21. Which aspects of the creative work are protected under the copyright?

Copyright provides the following rights to the creator:

1. Right of reproduction
2. Adaptation of work
3. Translation of work
4. Communication of work to the public.

Q22. What is the term of protection of copyright?

A copyright lasts for the lifetime of the author (creator) and 60 years after death of the creator. The period of 60-year is counted from the year following the death of the author. But 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.

Q23. Can a copyright protected work be legally used without permission of the owner?

For purposes pertaining to research, study, criticism, review and news reporting, as well as use of works in library and schools and in the legislatures, the use of a copyright protected work is permitted under specific conditions without specific permission of the copyright owners. The following works are allowed under the copyright law without necessitating permission from copyright owner:

i. For the purpose of research or private study,
ii. For criticism or review,
iii. For reporting current events,
iv. In connection with judicial proceeding,
v. Performance by an amateur club or society if the performance is given to a non-paying audience, and
vi. Making of sound recordings of literary, dramatic or musical works under certain conditions.

Q24. What is plagiarism?

Plagiarism is the act of copying someone else's writing viz. academic, creative, blogs etc. and claiming it as one's own work. This also includes improper citation of the sources in compiled works.

Q25. What is copyright infringement?

A copyright protected work is considered to be infringed when a 'substantial' part of the protected work is used unauthorized. The 'substantial' herein is defined qualitatively rather than quantitatively, but this definition may vary from case to case.

Q26. What is the difference between plagiarism and copyright infringement?

Plagiarism and Copyright infringement overlap but also have some differences as plagiarism can also occur for works that cannot be protected via copyrights, such as ideas, facts and other intangible creative works. Further a creative work, such as a book or a song which has lived full term of its copyright protection and has entered 'public domain' may be copied.

Also, plagiarism is theft and typically pertains to not giving due credit vide citations, references etc. to the creator; unauthorized use of copyright protected work even with proper citations without permissions from the creator,

Q27. What is the significance of IPRs for a researcher?

IPRs are of different categories based on variety of intellectual inputs. Patents are most important form of IPRs for researchers. Knowledge of IPRs is important for researchers in several ways like:

- Help researchers to create and protect innovative knowledge to create products and processes that can be commercialized. In addition, inventors can also focus on doing socially and commercially relevant research:
- Prevent duplication of work: Search of patent databases shows what has already been done before and what is the scope of improvement, thus saving precious time and money on duplicating of R&D. Some research may never get published and will remain in patent documents. Patents form an important source of technical information: In some cases, patents may be the only source of detailed technical information/data unlikely to be available anywhere else. Also, unlike publications, the source of patents is usually a single database.
- Patents enable researchers to have 'legal rights' over their work that could lead to some financial rewards.
- Patents help in revenue generation: Licensing of patents will lead to financial benefit to researchers and their institute.
- Patent filing may prevent infringement as the researchers will know patents as to how much of the knowledge is already protected. Basic knowledge of IPRs helps researchers respect others rights and decides whether their work is infringing or not, especially for commercialization.
- Patenting stimulates creativity, especially if the new IP leads to successful products and processes.

courtesy: www.thinglink.com

Q28. Do patents impact access to affordable health?

Patenting of pharmaceutical products creates a monopoly status to the new drugs as long as there is IP protection. The owners of the IP may price the products as per their desire, often as a price beyond the reach of many who require. Such a pricing may make these medicines beyond the reach of the poor. Due to this profit-oriented system, most pharma R&D is called as market driven as the R&D is supported only for such drugs which lead to revenue generation. Thus, there is very little R&D on the so called neglected diseases for which have limited market. Therefore, for many diseases of the poor there are few drugs and other remedies available in the market as the pharma industry does not invest in R&D due to poor returns on the investment.

Q29. What is the scope of patentability of biological inventions?

Some biological inventions are based on research conducted using living entities of natural origin viz. animal, plant, human beings including parts thereof. Living entities other than natural origin, such as micro-organism, vaccines, transgenic animals and plants etc., biological materials such as genes, DNA, replicons, plasmids,

vector, tissues, cells etc., process relating to living entities, process relating to biological material, methods of treatment of human or animal body etc. There are restrictions on patenting of inventions using biological material as given below.

The following inventions are not patentable in India:

- Living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organism and any process of manufacture or production relating to such living entities.
- Any method of treatment such as medicinal, surgical, curative, prophylactic, diagnostic and therapeutic of human beings or animals or other treatments of similar nature.
- Any living entity of other than natural origin such as transgenic animals and plants, any part thereof.
- The biological materials such as organs, tissues, cells, viruses etc. and process of preparing thereof.
- Biological processes for the production of plants and animals such as method of crossing or breeding etc.
- Any biological material and method of making the same which is capable of causing serious prejudice to human, animal or plant lives or health or to the environment including the use of those would be contrary to public order and morality are not patentable such as terminator gene technology, germ line modification, alteration of human or animal genetic makeup, studies on human or animal embryos while the living entity of artificial origin such as micro-organism and processes relating to micro-organisms or producing chemical substances using such micro-organisms, vaccines are considered patentable but the biological material such as recombinant DNA, plasmids and processes of manufacturing thereof are considered patentable if they are produced by substantive human intervention. Gene sequences, DNA sequences without having disclosed their functions are not patentable as they lack inventive step and industrial application.

Also, in case of use of biological inventions it is often mandatory to mention the source or geographical origin of used material and must be mentioned in the specification of the patent application.

Q30. If there is new IP involving new biological material, how can it be protected?

If an invention has been made using a new biological material and patent protection is sought for the same, then such materials are required to be deposited in any of the International Depositary Authorities (IDA) recognized under the Budapest Treaty on or before filing of the application. In addition, reference of such deposit is to be made in the patent specification for supplementing the description for sufficiency of disclosure of the invention.

Q31. What is the state of patenting of higher life forms?

Higher life forms are not patentable anywhere in the world. Only lower life forms like transgenic, recombinants are patentable in some western countries, but not in India. Sections of the Indian Patent Act, 1970 restricts the patenting of life forms under sections such as Section 3(j) of the Act specifies that 'plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals'. 'Method of agriculture or horticulture' is not patentable under Section 3(h). Section 3(i) restricts patenting of 'any process for medical, surgical, curative, prophylactic, diagnostic or other treatment of human beings, animals etc. Section 3(j) prohibits patenting of conventional techniques/processes such as plant breeding methods such as tissue culture techniques etc. But life forms with appropriate human intervention may be patentable in India under proper intimation to the Indian patent office about the source and geographical origin of the microorganism, whereas for protection of plant varieties a sui generis system is to be followed.

Q32. How is human intervention defined?

The era of patenting of life forms started with the landmark case Diamond *vs. Chakraborty*; where Dr. Ananda Chakrabarty, USA developed a method for directed evolution of Pseudomonas bacteria, also known as oil eating bacteria, at General Electric Company's facility. The US patent office refused the patent but on appeal to higher court, the patent was eventually granted. Further, human intervention typically includes R& D activities such as, identification of a mutant, isolation and purification of a strain, any such modification etc.

Q33. Can pharmaceutical compositions be patented in India?

The patent law of India has been amended defining scope of patenting of pharmaceutical compositions. Accordingly, pharmaceutical compositions other than mere admixtures resulting in the aggregation of properties of the ingredients, but having synergistic affect may normally be patentable. But known pharmaceutical compositions in different new dosages and different delivery system such as capsules, tablets, syrups, suspensions etc, are not patentable. New use of known substance or its new use in a pharmaceutical composition is not normally patentable. Any method of using known pharmaceutical composition is also not patentable.

Q34. What is evergreening of patent?

A patent confers protects to an invention for a definite period of time typically 20 years. In some sectors like pharma, companies tend to extend the patent monopoly beyond 20 years through small, incremental innovation to prevent entry of generics into the market. This process of attempting to extend the life of a patent beyond 20 years through small, incremental innovation etc. is called "Evergreening". (For more details, kindly refer chapter II).

Q35. What are biosilimars?

A biosimilar refers to a biological product which is highly similar to a pre-existing and approved biological product (reference product), and does not clinically differ in terms of safety and effectiveness from the reference product. A biosimilar may also additionally meet standards for interchangeability with reference product.

Q36. What is the criterion for a composition to be adjudged as a biosimilar?

A biosimilar needs to have the same mechanism of action as its reference product i.e. it must work in the same way as the reference product. For regulatory purposes a biosimilar should posses same mechanism of action, route of administration, dosage form, and strength as the reference product. Additionally, a biosimilar may also be prescribed for the indications and conditions of use that have been previously approved for the reference product.

Q37. What is the difference between a generic biological product and a biosimilar?

Generic (chemical) drugs have the same active ingredient, safety and efficacy and they are used in the same dosage form, strength, and route of administration as the innovator drug. Therefore technically brand-name and generic drugs are considered *same* as the innovator product. Biosimilars, on the other hand, are considered to be *highly similar* (not same) to the reference (innovator) product but has allowable differences in the composition etc. The biosimilars, however, do not have clinically significant differences in terms of safety, and potency from the reference product. This is because unlike chemical generics, biosimilars are structurally more complex and 200 to 1,000 times the size of a generic drug. Further, in terms of manufacturing, biosimilars are manufactured in living cells, then extracted and purified, whereas generics are manufactured purely through chemical synthesis.

Q38. What are the advantages of using a biosimilar?

Just like generics, biosimilars provide a huge cost advantage over the reference drug while serving the same purpose. They often cost a fraction of the innovator product.

Q39. What is the need to have IPR policy for R&D organizations?

The IP policy articulates the agency's /country's desire to support creative activity, to encourage open dissemination of ideas, and to recognize and reward the inventors. IP policy provides clarity on the overall focus of the objectives of the R&D of the organization, helps innovators file patents and the industry to approach the agency for commercialization of the inventions.

Q40. Does the ICMR have an IP policy?

The ICMR IPR Policy released in 2000 and revised in 2013 aims to make scientists aware of their needs and responsibilities to protect new knowledge generated using ICMR funds and facilities. The IP policy provides for techno-legal and other professional help and support to ICMR scientists to file patents in India and abroad. The IP thus created is exploited for bringing out products and processes for public health with focus on promoting R&D as well as affordable health care.

Q41. How can inventors exploit the benefits of Intellectual Property?

Exploitation of Intellectual Property is an important challenge. The conversion of intangible form of IP into tangible forms such as formulations, drugs, processes, biosimilars etc. are few examples of benefits creation of new IP as it can be sold to an industry. Commercialization of such tangible products leads to rewards to inventor/ creators through royalty sharing of revenue generated and the organization. It can also lead to the creation of affordable health products for the public health system.

Q42. When does someone enforce its IP rights?

As mentioned an innovation is protected with the purpose of commercial exploitation by the innovator and the organization which has funded the invention. If somebody infringes the protected IP and/or seeks to obtain rights that belong to IP right holder, or in situations of breach of confidentiality, the IP rights holder may enforce his/ her rights through legal means.

Q43. How much information needs to be included in the patent application?

A patent application must have enough information to enable a person “skilled in the art” to practice the invention. Therefore, all important aspects of the invention must be present or the patent could be later declared invalid. However, one should avoid too much disclosure of information/material in the patent application. Besides the basic information about invention, the "preferred embodiment", which is what the inventor believes, is the best way to practice the invention can also be disclosed.

Q44. When does a patent start to confer protection to my invention?

A patent application affords protection to the invention from the date of its filing. The date of filing generally renders a right of priority to the applicant. (For further details, refer chapter II)

Q45. Can I protect my invention in more than one country?

Patent is a territorial right and must be filed in various geographical territories for protection. Thus if one wants IP protection in more than one country, they can apply for a patent in various countries of their interest

directly. Or they can choose the Patent Co-operation Treaty (PCT) route or conventional applications. (For details of these routes, refer Chapter V)

Q46. What is the Convention on Biological Diversity?

The Convention on Biological Diversity (CBD) is a legally binding multilateral environmental agreement that recognizes the sovereign rights of states to use their own Biological Resources has 194 contracting Parties (Countries) including India as its members, CBD came into effect on 29th December 1993.

Q47. What are the objectives of CBD?

CBD was enforced with three major objectives:

1. Conservation of biological diversity
2. Sustainable use of the diversity
3. Ensuring fair and equitable sharing of benefits of such use.

Q48. What is Biodiversity Act, 2002 and how is it related to CBD?

India is party to the Convention on Biological Diversity (CBD) and has enacted an umbrella legislation called the biological Diversity Act 2002. The Act mandates implementation of the CBD and it's objectives through decentralized system with the NBA. Additionally, the act, advises the state Governments in the selection of areas of biodiversity importance to be notified as heritage sites and measures for the management of such heritage sites.

Q49. What is NBA?

Ministry of Environment and Forests, Government of India has established a National Biodiversity Authority (NBA) in 2003 to ensure regulation of the Biological Diversity Act. NBA is a Statutory, Autonomous Body and performs facilitative, regulatory and advisory function for the Government of India. The NBA advises the Government on conservation of biodiversity and selection of biological heritage sites commences appropriate action to oppose grant of intellectual property rights in foreign countries arising from the use of Indian biological resources or associated traditional knowledge. Further, for state wise regulation, State Biodiversity Boards (SBB) has been created in along with approximately 31,574 Biological management committees across India.

Q50. How NBA regulates the Intellectual property?

The NBA mandates the application for IP rights for inventions based on any research or information on a biological resource obtained from India vide its form III, this has to be submitted at NBA with required fees by Indian or NRI applicants.

Under the Biological Diversity Act, 2002, Section 6(1) provides that prior approval of NBA before applying for any kind of IPRs in India or outside based on any research or information on a biological resource obtained from India. However, in case of patents, permission of the NBA may be obtained after application is made but before sealing of the patent.

What is Patent?

Q1. What is a patent?

Patent is a techno-legal document granted by the government that provides legal protection to an invention. Patents are territorial in nature and granted in return of the full disclosure of the invention by the inventor. Upon the expiry of the term of the patent, the information given in the patent document becomes public to enable other users to benefit typically carrying out R&D. A patent confers limited monopoly to the inventor which ensures that the invention is not used, sold, and/ or otherwise commercialized by anyone without consent of the owner of the patent.


GOVERNMENT OF INDIA
THE PATENT OFFICE
Patent Certificate

Patent No. : 230753
Application No. : 838/DEL/2003
Date of Filing : 25/06/2003
Patentee : INDIAN COUNCIL OF MEDICAL RESEARCH

It is hereby certified that a patent has been granted to the patentee for its invention entitled "A HERBAL HYPOGLYCEMIC COMPOUND FOR CONTROLING DIABETES MELLITUS" as disclosed in the above mentioned application for the term of 20 years from the 25 day of JUNE 2003, in accordance with the provisions of the Patents Act,1970.

Date of Grant: 27/02/2009

Controller of Patents

Note.- The fees for renewal of this patent,if it is to be maintained , will fall / has fallen due on 25 day of JUNE 2005 and on the same day in every year thereafter.

Indian Patent Certificate
Courtesy: Indian Patent Office

Q2. What is the distinction between patented inventions and know how?

Often, information/data disclosed in the patent application that is made public as patent specification may not be sufficient for 'working the invention' or commercial exploit of the invention to make a product or use as a process to make a product. Typically, in the patent document, inventors disclose only the most relevant/minimal data/information for substantiating the claims mentioned in the patent. In otherwords, the patent granting authority only needs to be satisfied that the claims made in the patent application are substantiated by the data provided. Knowhow, on the other hand, covers all the critical data/information necessary to execute the implement to commercialize the invention such as; exact operating conditions, details of the production methods, setting up a production plant, plant layout designs and drawings etc. This knowhow that is available only with the inventor(s) as only they are familiar with the invention. Know-how is critical for making a product or using a process and is critical in the licensing of technology to a commercial entity. Know how is usually kept as a trade secret and is neither shared with public (disclosure in the patent application) nor protected through patents as it means disclosure of critical data/knowledge available only with the inventor(s). Knowhow developed around an existing patent is made available to the licensee while the process of up scaling and manufacturing of a product during the commercialization of an invention. Knowhow is therefore required to successfully work the invention to bring out a product or use the new process by a company.

Q3. Who is an inventor for a Patent?

All the people who have significantly contributed for achieving the result(s) reported in the invention are eligible to be called as the inventor(s) of a patent. They could be scientists or technical personnel who have contributed to the development of the patent. The sequence of inventors is decided collectively or as per the institutional IP policy. Typically, those who have contributed significantly feature in the beginning as primary inventors. Their role as inventors will decide their share of the royalty received by the selling/renting of the invention.

Q4. Is a patent granted in one country automatically enforceable in other countries?

Patent rights are essentially territorial in nature and are granted only for a country (or countries), where it has been applied for and granted. There is nothing like a global patent or a world patent. For obtaining patent rights in several countries, the applicant has to file patent application in each of the country of interest for grant of a patent separately. This would entail payment of official fees and all associated expenses, like the attorney fees, essential for obtaining patent in each country.

Q5. Does grant of a patent in one country affect its grant or refusal in another country?

Each country has its own patent system and law accordingly each country is free to grant or refuse a patent on the basis of scrutiny by its patent office as each country has clear-cut legal provisions under its patent law. Thus, granting of a patent in one country does not necessarily mean that other countries have to grant the patent for the same invention. Similarly, the refusal of the patent in one country does not mean that granting of patent will be denied by other countries.

Q6. What is expected from patentee as an obligation to the State?

Patents are granted by the Government, for a limited period for potential commercial exploitation of an invention in consideration of the disclosure of the invention. A patentee must disclose the invention in enough detail in the patent document for person skilled in the art can practice it after the expiry of the term of the patent or after the patent has lapsed due to nonpayment of maintenance fee or practice it with the consent of the patent holder during the life of the patent. Disclosure of an invention is a legal requirement for obtaining patent. As the right is conferred by the State, it can be revoked by the State under very special circumstances in public interest even if the said patent has been sold, licensed, manufactured, or marketed in the meantime.

Q7. Where to submit patent application?

Application for the patent has to be filed in the respective patent office of a country from where the applicants belong. The territorial jurisdiction of the applicant is decided based on whether any of the following occurrences falls within the territory

a) Place of residence, domicile or business of the applicant (first mentioned applicant in the case of joint applicants).

b) Place from where the invention actually originated.

c) Address for service in India given by the applicant when he has no place of business or domicile in India. A foreign applicant should give an address for service in India and the jurisdiction will be decided upon that. An applicant (Indian or foreigner) also can give his Patent Agent's address as address for serving documents if he/she wishes.

Q8. How are the jurisdictions divided territorially in India?

The Indian patent office operates from four regional offices situated at Mumbai, Kolkata, Delhi and Chennai with its headquarters at Kolkata. Each patent office manages its separate territorial jurisdiction as follows:

Mumbai: Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhattisgarh, the Union Territories of Daman & Diu and Dadra & Nagar Haveli.

Delhi: Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttarakhand, National Capital Territory of Delhi and the Union Territory of Chandigarh.

Chennai: Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and the Union Territories of Puducherry and Lakshadweep.

Kolkata: States of Bihar, Orissa, West Bengal, Sikkim, Assam, Meghalaya, Manipur, Tripura, Nagaland, Arunachal Pradesh and Union Territory of Andaman and Nicobar Islands

Q9. When should an application for a patent be filed?

A patent application should be filed as soon as possible after the completion of the invention without any public disclosure. Applications can also be filed with provisional specification disclosing the essence of the nature of the invention without detailed claims of a patent. This will help in claiming of priority of an invention.

Q10. Can a published or disclosed invention be patented?

Publication or any other public disclosure of an invention anywhere or in any form by the inventor before filing of a patent application would disqualify the invention to be patentable. It is therefore very important to file a patent application before publicly disclosing the details of the invention. In general, any invention which is made public before an application is filed would be considered 'prior art' (generally disclosure made available to the public anywhere in the world by written or oral disclosure). Hence, inventors should not disclose their inventions in any form before filing of a patent application in India.

Q11. Is there a possibility to file a patent after publication of an invention?

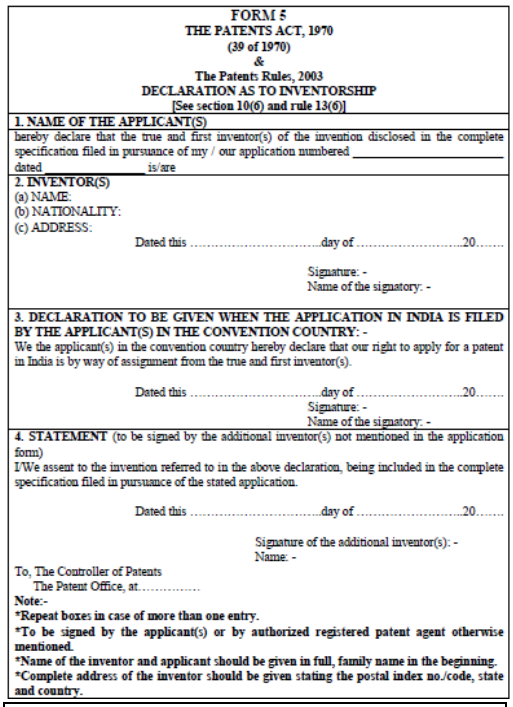
Indian Patent Act under sections 29, 30, 31 & 32 gives provisions under which patent application can be filed despite public disclosure, and such public disclosure will not be considered to have been anticipated. Indian patent act, section 29 entitled ‘Anticipation by previous publication’ provides filing for a disclosed invention if applicant or the patentee proves that matter published was obtained from him or any person from whom he derives title without his consent or the consent of any such person. Section 30 entitled ‘Anticipation by previous communication to the government’ gives provision for patent filing if invention has been communicated to the government or any person authorized by the government for the purpose of investigation of the invention. Under section 31, entitled ‘Anticipation by public display’ a complete specification shall not be deemed to have been anticipated if, invention has been displayed in an exhibition to which the provisions of the instant section has been extended by the Central Government; or invention is described in a publication in consequence of display of the invention in such an exhibition; or invention has been used by any person without the consent of the true and

first inventor or a person deriving title from him after it has been displayed in such an exhibition; or disclosing the invention before a learned society or publishing the invention in the transaction of such society; provided the application is filed within 12 months from aforementioned public display. Under section 32 entitled Anticipation by public working, a complete specification shall not be deemed to have been anticipated if the invention has been filed within 12 months after the invention has been publicly worked for the purpose of reasonable trial considering the nature of the invention.

However, in some countries like the USA allow for a grace period of one year which permits patenting of an invention within a year after disclosure of the invention.

Q12. What are the responsibilities of a patentee?

A patentee must disclose the invention in patent document for anyone to practice it after the expiry of the patent or practice it with the consent of the patent holder during the life of the patent. The Complete Specification describing the invention is a techno-legal document. It should disclose the invention adequately/ completely to meet the requirement of the Indian Patents Act (for patent applications filed in India) and should also enable a person possess average skill in the art to work the invention without assistance of the patentee. This is possible only when the complete specification describes the invention fully particularly its operation and/or method by which it is to be performed. It is also essential that the best method for performing the invention, which is known to the applicant, is disclosed in the Complete Specification.



FORM 5
THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003
DECLARATION AS TO INVENTORSHIP
[See section 10(6) and rule 13(6)]

1. NAME OF THE APPLICANT(S)
hereby declare that the true and first inventor(s) of the invention disclosed in the complete specification filed in pursuance of my / our application numbered _____ dated _____ is/are

2. INVENTOR(S)
(a) NAME:
(b) NATIONALITY:
(c) ADDRESS:

Dated this .....day of .....20.....

Signature: -
Name of the signatory: -

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY THE APPLICANT(S) IN THE CONVENTION COUNTRY: -
We the applicant(s) in the convention country hereby declare that our right to apply for a patent in India is by way of assignment from the true and first inventor(s).

Dated this .....day of .....20.....

Signature: -
Name of the signatory: -

4. STATEMENT (to be signed by the additional inventor(s) not mentioned in the application form)
I/We assent to the invention referred to in the above declaration, being included in the complete specification filed in pursuance of the stated application.

Dated this .....day of .....20.....

Signature of the additional inventor(s): -
Name: -

To, The Controller of Patents
The Patent Office, at.....

Note:-
***Repeat boxes in case of more than one entry.**
***To be signed by the applicant(s) or by authorized registered patent agent otherwise mentioned.**
***Name of the inventor and applicant should be given in full, family name in the beginning.**
***Complete address of the inventor should be given stating the postal index no./code, state and country.**

Form -5, Indian Patent Act
Courtesy: Indian Patent Office

Q13. What are the documents to be filed with the patent application?

Application for patent (Form 1) in duplicate should be accompanied with the -

i. Prescribed fee (need to be paid within one month)
ii. Provisional or complete specification in Form 2 and drawings (if any) in duplicate. If provisional specification is filed it must be followed by complete specification within 12 months.
iii. Statement and undertakings regarding foreign filing details in respect of the same invention in Form 3.
iv. Declaration as to inventorship in Form 5 (In the case of a convention application and PCT national phase application and filing complete after provisional); and abstract of invention in duplicate.

v. Priority document (if it is a convention application)

vi. Power of attorney (Authorization of patent agent or any other person) in Form 26 and

vii. Proof of right if the application is made by the assignee.

viii. If the Application pertains to a biological material obtained from India, the applicant is required to submit the permission from the National Biodiversity Authority any time before the grant of the patent indicating clearly the source of geographical origin of the biological material used in the Specification, wherever applicable.

Q14. What is the term of a patent?

The term of the patent in India is 20 years from the date of filing for all types of inventions.

Q15. How does one keep a patent enforced to full patent term?

To keep a patent live, it has to be renewed regularly by paying the prescribed renewal (maintenance) fees as prescribed under the Indian patent office. If the patent is not renewed, it will cease to remain in force and the invention becomes open to public. Anyone can then utilize the patent without the danger of infringing the patent.

Q16. How is evergreening achieved?

Evergreening is a strategy through which a patent owner tries to seek patent protection beyond the stipulated period of 20 years. This is attempted through seeking ownership through filing of another patent based on trivial or minor modifications on the original patent. Examples could be minor variations like new dosages, new combinations, new forms of release, or new forms for patenting of drugs. These variations however must satisfy the essential criteria of patentability for the independent patent filed.

Q17. What is the working of a Patent?

Under Section 146 of the Indian Patents Act 1970, the Controller of Patents requires patentees to submit annual "Statements of Working" vide 'Form 27'. The Controller would like to ensure that a patent filed/granted is being used / commercialized in India. It is to be submitted at the Indian Patent office within three months of the end of each year (i.e. 31st March of each year). This is essentially to ensure that someone buys/rents a patent and does not exploit the same with a clear motive to kill the invention from being exploited. This is often part of a strategy of some companies to minimize competition.

Q18. What is the purpose of seeking working of a patent?

Working of a patent vide form 27 is published annually along with list of granted patents. This system facilitates the dissemination of information on patented inventions for promoting research and competition. Such information is used by competing companies to apply for a compulsory license of the invention.

Q19. How is a patent disclosed in a patent application?

The disclosure of an invention is done in the form of a write-up (Specification) in a prescribed format in such a way that a person skilled in the art may be able to work the invention. The specification as given earlier is a techno-legal document containing full scientific details of the invention and claims to the patent rights. The specification, thus, forms a crucial part of the Patent Application. The specification may be filed either as a Provisional or as a complete specification.

The specification (provisional or complete) is to be submitted in Form-2 along with the Application in Form-1 and other documents, in duplicate, along with the prescribed fee. The first page of the Form 2 contains:

a) Title of the invention
b) Name, address and nationality of each of the applicants for the Patent
c) Preamble to the description
d) Description (from 2nd page)
e) Claims (On a separate page; for complete specification only).
f) Abstract of the invention

Q20. What is a Provisional Specification (PS)?

A patent application with Provisional Specification is usually filed to establish priority of the invention in case the disclosed invention is only at an early stage and a delay is expected in giving final shape to the invention. A patent application with provisional specification does not however confer any legal patent rights to the applicants. Filing of a Provisional patent application is, however, a very important strategy to establish the earliest ownership of an invention as ensure priority of an invention through blocking priority date. No patent is granted on the basis of a provisional specification. Under the Indian Patent Act it has to be followed by a complete specification within 12 months (extendable by 3 months) for obtaining a patent for the said invention. However, one can also directly file a complete specification without filing a Provisional Specification application.

Q21. What is Complete Specification (CS)?

The Complete Specification is a techno-legal document which fully and completely describes the invention and discloses the best method of performing the invention. Submission of complete specification is essential to obtain a patent. Every complete specification shall:

a) Fully and particularly describe the invention and its operation or use and the method by which it is performed;

b) Disclose the best method of performing the invention which is known to the applicant for which he is entitled to claim protection;

c) End with a claim or set of claims defining the scope of the invention for which the protection is claimed;

d) Make reference to deposit of the biological material in the international depository authority, if applicable; and

e) Be accompanied by an abstract.

Q22. What are the criteria to be used for naming inventors in an application for patent?

The naming of inventors is normally decided on the basis of the following criteria:

(i) All persons who have contributed towards development of patentable features of an invention.

(ii) Persons who have made intellectual contribution in achieving the final results of the research work leading to a grant of patent.

(iii) Persons who have helped in conducting the experiments, constructing apparatus or making the drawings or models without providing any intellectual inputs are generally not entitled to be named as inventors.

(iv) Form 5 is required for Declaration of inventorship

To avoid difficulties in deciding the names of inventors it is essential that all scientists/other personnel engaged in research should keep factual, clear and accurate record of daily work done by them.

Typically, most R&D institutions and companies have a clear policy on inventorship and their rights and responsibilities.

Q23. What is the cost of filing a patent application in India?

Some important fees* required for filing a patent are given below:

No.	Action	Natural person		Small entity		Large entity	
		E-filing	Physical filing	E-filing	Physical filing	E-filing	Physical filing
1.	Filing of patent application along with complete/ provisional specification	1,600/-	1,760/-	4,000/-	4,400/-	8,000/-	8,800/-
1.a	Each sheet of specification in addition to 30	160/-	176/-	400/-	440/-	800/-	880/-
1.b	Each claim in addition to 10	320/-	352/-	800/-	880/-	1,600/-	1760/-
2.	Request for publication of a patent	2,500/-	2,750/-	6,250/-	6,875/-	12,500/-	13,750/-

3.	Request for examination of patent u/s 11B	4,000/-	4,400/-	10,000/-	11,000/-	20,000/-	22,000/-
4.	Renewal fee (every year)						
	2^{nd} year to 6^{th} year	800/-	880/-	2,000/-	2,200/-	4,000/-	4,400/-
	7^{th} year to10^{th} year	2,400/-	2,640/-	6,000/-	6,600/-	12,000/-	13,200/-
	11^{th} year to15^{th} year	4,800/-	5,280/-	12,000/-	13,200/-	24,000/-	26,400/-
	16^{th} year to20^{th} year	8,000/-	8,800/-	20,000/-	22,000/-	40,000/-	44,000/-
5.	Application for restoration of a patent	2,400/-	2,640/-	6,000/-	6,600/-	12,000/-	13,200/-

*Note: As per **the Indian Patent Act, 1970** and may subject to change**.** Additionally, there are several other fee requirements depending on the requisite of Inventor.

Q24. What is the difference between an Indian Patent and a US patent?

A patent granted by a patent office is applicable within the geographical boundaries of that country only. A US patent is granted by the United State Patent Office to an inventor, who has filed his application within the USA, whereas an Indian Patent is granted by the Indian Patent Office to an inventor, who has filed his application with Indian Patent office. A US Patent is applicable within the geographical limits of USA only and enjoys no IP protection in India, if the same US patent has not been filed in India for the grant of a patent.

Q25. When does a patent expire?

A patent can expire in the following ways:

1. The patent has lived its full term i.e. the term specified by the patent act of the country typically 20 years from the date of filing.
2. The patentee has failed to pay the renewal fee. A patent once granted by the Government has to be maintained by paying annual renewal fee.
3. The validity of the patent has been successfully challenged by an opponent by filing an opposition either with the patent office or with the courts.

Q26. What are patentable inventions under the Patents Act, 1970 (as amended in 2005)?

Invention means any new and useful

i. Art, process, method or manner of manufacture.
ii. Machine, apparatus or other article.

iii. Substances produced by manufacturing, and include any new and useful improvements of any of them and an alleged invention.

iv. New compounds, new compositions

v. Synergistic composition

vi. Medical device (improved/new)

vii. Improvement of an existing process for the production of known compound, known material, known composition.

Q27. What is the patenting process in India?

Patenting in India comprises of filing of the provisional or complete application, or complete specification. If a provisional patent application is filed then complete application needs to be filed within 12 months from date of filing. The patent application (with complete specification) is published after 18 months from date of filing. Subsequently a Request for Examination (RFE) is to be filed within 48 months of the date of filing. The application is then examined which leads to issuance of Examination Reports, and, if the patenting authority is satisfied, grant of a patent. The Patent Examiner issues a First Examination report for the filed applications and seeks response from the applicant and inventor on clarifications as per the Indian Patents act. This response has to be furnished within 6 months of the issuance of FER. A second examination report may also be published on a case to case basis. The Grant of patent is subjected to the response to queries raised in examination reports and only if the patent granting authority if satisfied with the responses for the clarification sought. The timeline for the process is given as below:

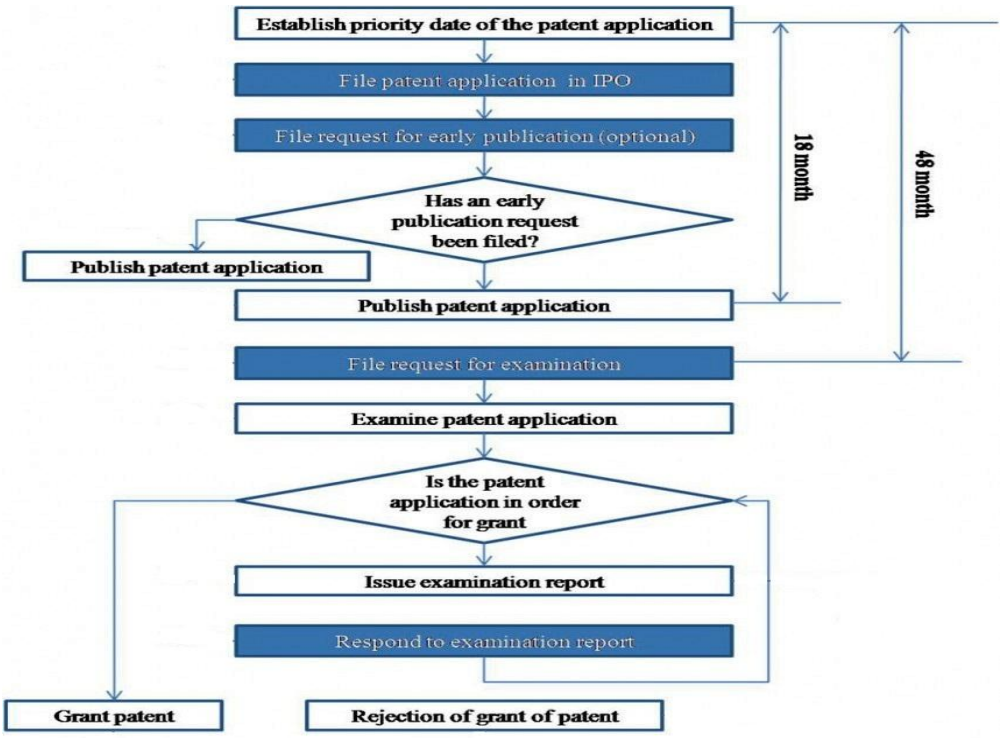


Fig: The flowchart illustrates the timelines involved in patenting process. The steps in blue blocks are actions that have to be taken by an applicant and the steps in white block are actions that are taken by the patent Office. *(Courtesy: invntree*)

Q28. Who grants Patents?

A national patent office of a particular country grants the patent, for example, in India the patent is granted by the Office of the Controller General of Patents, Designs & Trade Marks.

Q29. How long does it take for a patent to be granted?

The grant of a patent in India currently takes about 3 to 5 years. This does not depend on the complexity of the patent, but more on the field of an invention and how many clarifications have been sought by the examiner.

Q30. How soon does a patent give protection?

In a sense, some protection is granted to the inventors as soon an application is filed, since it allows calling the invention as "patent pending". However, if there is an infringement, the inventor cannot bring action against an infringer until the patent is actually issued. But the fact that a patent is pending on an invention may keep a potential infringers at bay as they may have to incur financial loss if the original patent applicant manages to prove there has been an infringement of patent rights.

Q31. Is renewal of a patent possible after it expires?

If a patent has expired it means that the invention is now "In the Public Domain," and anyone can use, make it, produce it, etc. without any risk of infringement. A lapsed patent application cannot be renewed or patented again. There is a possibility of getting extension, for medical related patents with the government approval. In case of drug patents, the testing and approval required by FDA may sometimes take almost all of patent term. In Korea and Japan, extension is possible only due to delay of examination in the patent office.

Q32. When should one access the patent literature?

All inventors should continuously access patent literature - before the start of the research and development project or when they are stuck with some technical problem.

Q33. Which are the main sources for patent information?

National patent offices, International information vendors like Dialog, Orbit, Questel STN, free or charge based patent websites, free databases such as INPASS, patentscope (WIPO), USPTO, Expacenet, free patents online, google patents etc..

Q34. Who should draft the patent application?

Though the inventor himself can draft the application, it is desirable to use a person skilled in legal drafting like a patent attorney/agent.

Q35. Who is entitled to file a patent application?

Application for patent can be made individually or jointly by the true and first inventor (who has made intellectual contribution in development and achieving the final results of the research work leading to a patent) or by his assignee or legal representative of the deceased person entitled to make such an application. Whether the invention made by an employer belongs to the employee depends on the terms and conditions of the employment contract. Therefore, it is necessary for the employer to take enough care in drafting the terms of the service contract, in order to ensure that he has a right over any inventions made by the employee

Q36. Who owns the invention?

The ownership of an invention depends upon the terms and conditions of the employment contract. Typically, all inventions made by research and development staff usually belong to the employer.

Q37. When is patent application published?

Patent application is published after 18 months from date of filing or priority date. There is provision of early publication on filing a request on form 9 and payment of prescribed fees and patent application is published by the patent office within a prescribed period of one month after receiving such request.

Q38. What is a Request for Examination (RFE)?

Examination for examination of an application is done only upon a request made by the applicant or interested person within forty-eight months from the date of application in India. If the request is not made within forty-eight months, the application of patent is deemed to be withdrawn by the applicant. Once a request for examination is made, the Controller of patents assigns the application to a patent examiner to examine the specification given in the patent and other related documents submitted along with the patent application. Report by the patent examiner is to be submitted within such period as may be prescribed from the date of reference.

Q39. What is revocation of a patent?

Revocation of patents as defined in Section 64 of the Indian Patents Act, 1970 (as amended by the Patents (Amendment) Act 2005) is to claim invalidity of existing patents on pre-defined grounds vide petition by any person or Central Government or on a counter-claim in a suit for infringement of the patent by the High Court.

Q40. What are the grounds for Patent revocation?

As per the Section 64 of the Indian Patents Act, 1970 (as amended by the Patents (Amendment) Act 2005), following are the major grounds for patent revocation:

1. Invention as claimed in any claim of the complete specification was claimed in patent granted with an earlier priority date in India.

2. Subject of any claim of the complete specification is not an invention
3. invention so far as claimed in any claim of the complete specification lacks novelty and/ or inventiveness, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents.
4. Invention, so far as claimed in any claim of the complete specification, is not useful.
5. The complete specification does not sufficiently and fairly describe the invention and/or the method by which it is to be performed, and/ or the source or geographical origin of biological materials and/ or the any of the claims is not sufficiently and clearly defined or based on the matter disclosed in the specification.
6. Applicant for the patent has failed to disclose any required information to the Controller or has furnished information which in any material particular was false to his knowledge.
7. The claimed invention was known as a traditional knowledge.
8. By the government (including a person authorized by the Government or a Government undertaking) as a consequence when the invention has been communicated or disclosed directly or indirectly to the Government or is considered mischievous to the State or generally prejudicial to the public.
9. By the High Court on the petition of the Central Government or any person, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of Government.
10. By Controller for non-working**;** when a compulsory license has been granted, the Central Government or any person interested may, apply to the Controller for an order revoking the patent, if the patented invention has not been worked in the territory of India, or the reasonable requirements of the public have not been satisfied, or if the patented invention is not available to the public at a reasonably affordable price.

Q41. What are the recent amendments in Indian Patent Rules?

Indian Patent rules were amended w.e.f 16th May, 2016. These rules now incorporate the definition of 'start up' and procedural changes in examination of applications, Sequence listing, deposition of biological material, hearing etc. A start up means any entity which works towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property and does not have a turnover of more than INR 25 crore, a startup will also be eligible for a provision called 'expedited examination' which would mandate the Controller to issue First Examination Report (FER) within 115 days from the acceptance of request for expedited examination. The response to such FER also is to be filed within 6 months wherein extension of 3 months may be available on request.

For more details, kindly refer the amendments published by Indian Patent office at http://www.ipindia.nic.in/IPActs_Rules/Patent_(Amendment)Rules_2016_16May2016.pdf)

Q27. What is right of priority of an invention and its significance in PCT??

If an inventor files a patent application in one country, he can file applications in other countries of interest within one year from the date of first filing. Those other applications are then treated as if they were filed on the date of the first application. This is called the "right of priority" and was introduced by the Paris Convention. The period of priority is usually 6 months for industrial designs and trademarks and 12 months for patents and utility models. The basic purpose of the right of priority is to safeguard, for a limited period, the interests of a patent applicant in his endeavour to obtain complete and/or international protection for his invention, thereby removing the negative consequences of the principle of territoriality in patent law.

Q42. Can it be exemplified?

Suppose Mr. A has invented an improved tyre and has filed a patent application on it in the USA on April 15, 2003. Starting from April 16, 2003, Mr. A has then one year to file patent applications in other countries. If Mr. A files a patent application on April 15, 2004 in India for his tyre, and if he claims the priority of the earliest patent application filed one year before, then the date for examining the novelty and inventive step requirements in India will be April 15, 2003, not April 15, 2004. However, the actual date of filing in the selected country remains April 15, 2004, and this is the date from which the 20-year duration of any ensuing patent is calculated. The example applies to all countries which are parties to the Paris Convention.

From the desk of Inventor

Q1. What is Invention?

An invention means a new or unique product, device, method, composition or process which involves an inventive step and has industrial applicability.

Q2. What is Innovation?

Innovation is the successful exploitation of new ideas in the form of conversion into a useful machinery or process, by any person, using own intellect.

Q3. What is difference between an invention & innovation?

In its purest sense, "invention" can be defined as the creation of a product or introduction of a process for the first time. "Innovation," on the other hand, occurs if someone improves on or makes a significant contribution to an existing product, process or service. Every innovation may not be a patentable invention but almost every invention is an innovation and patentable.

Q4. How is 'novelty' component established in an invention for patenting?

Novelty is a feature which did not exist previously and which has not been disclosed in the *prior art* of a patent application. For an invention to be judged as novel, the disclosed information in a patent should not be available in the 'prior art'. This means that there should not be any prior disclosure of any information contained in the patent application anywhere in the public domain, either in a written or in any other form, or in any language, before the date on which the application has been first filed i.e. the 'priority date'.

Q5. How is 'inventiveness' element established in an invention?

According to the Indian patent law, inventiveness is the second major criteria in establishing the patentability of an invention. It is defined as a feature that involves technical advancement as compared to the existing knowledge and having social or economic significance or both and ultimately which controls the invention as not obvious to a person who is specialized in particular subject matter or is skilled in the art. The complexity or the simplicity of an inventive step does not have any barring on the grant of a patent. In other words a very simple invention can qualify for a patent. A mere part of invention is sufficient to establish a valid patent. In other words, even a simplest invention, if it qualifies the patent criteria (novelty, non-obviousness and utility) can be patented.

Q6. How is 'utility' defined in an invention?

Usefulness is one of the major criteria in patent to establish patentability. In fact, a patent can be obtained only for an invention that has usefulness and applicability. Usefulness should not be limited to commercial gain, but it must be ultimately beneficial for the society.

Q7. How are biological inventions different from other biomedical inventions?

Inventions pertaining to a material containing biological material , capable of reproducing itself or being reproduced in a biological system product consisting or a process by which such materials are produced, processed or used are known as Biological inventions

Biomedical inventions, on the other hand, employ principles of natural science to develop knowledge, interventions, or technology of use in healthcare or public health.

Q8. What are the necessary components contained in a patent document?

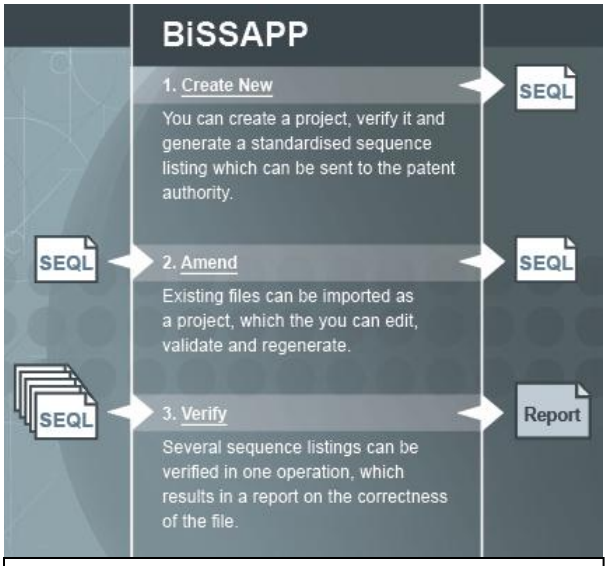
A patent application must have the following information:

Bibliographic: Title of the invention, date of filing, country of filing, inventor's name, assignee name and reference of cited documents etc in a structured format.

Background of the invention or State of the art: Information on the state of art available on the date of filing his invention. It must also include shortcomings/drawbacks of the state of the art and the problems faced by the inventor.

Summary of the Invention: A brief summary of the invention indicating the nature and substance of the object of the invention. The summary will indicate the advantages of the invention. This section should present the general idea of the claimed invention in summarized form.

Description of the invention: Detailed description of the invention, duly supported by a series of workable examples. The invention has to be described in complete detail, so that any person, who is skilled in the art, can work out the invention.



BISSAP for Sequence listing;
Courtesy: European patent Office

Courtesy: http://www.nickykriel.com

Drawings: The drawings of a patent application describe the invention visually, using a chemical or mechanical structure, charts and graphs, and detailed relationships of features.

Claims: This is the most important component of the patent establishing inventor's rights over the state of the art. It is for this portion protection is granted. This has to be carefully drafted.

Also, Biotechnology inventions must have sequence listing if the application includes nucleic acid or amino acid sequences. If sequences are disclosed, every nucleic acid molecule that is at least ten nucleotides, and every protein that is at least four amino acids, must be included in the list. Sequence listing is required to be filled in a specific text format.

Q9. How can one define the claims?

Claims are the most important part of the patent specification. Patent claims are the part of a patent or patent application that defines the scope/boundaries of protection/ownership granted by the patent. The claims are brief descriptions of the subject matter of the invention, eliminating unnecessary details and distinguishing the invention from what is old. The claims are the operative part of the patent. Novelty and patentability are judged by the claims, when patent is granted.

The major function of the claim or claims is to clearly define the scope of protection granted. The claims must be clear and concise and also be supported by and agree with the invention/innovation disclosed in the descriptive part of the patent specification.

Q10. How can one define Unity of Invention?

All the claims in the application for a patent must refer to the same inventive idea, i.e. they must all share one inventive concept. This is called as "Unity of invention".

Q11. What are the different categories of independent claims stating unity of invention?

If the invention relates with the product, the independent claim is called a product claim. The different categories depend on the Product, Process for its manufacture and use of the Product, Process and Apparatus for carrying out the process etc.

E.g. if somebody has developed a Single nucleotide polymorphism (SNP), claims may be drafted for-

- A novel SNP
- A method of expressing SNP
- A kit utilizing the SNP

All of these claims are linked by the inventive concept that sequence A is new and inventive. Therefore, anything based on sequence A must share this property too. Similarly, for biopolymer produced from a Genetically Modified Organism, the claims may be like- Biopolymer per se, Process for manufacture of biopolymer, and use of the Biopolymer, process for biopolymer manufacturing and its use or application. These things constitute unity of invention.

Q12. What is sufficiency of disclosure?

It means that the complete specification (techno-legal document describing the invention) should disclose the invention completely, so that a person skilled in the art can work on the invention. Following things need to be examined to check this aspect, like whether:

a. The specification is properly titled.

b. The subject matter is fully and particularly described in the specification.
c. The claims define the scope of the invention properly.
d. The Specification describes the best method of performing the invention or not.
e. The source and geographical origin, in case of inventions related to biological materials, has been disclosed.
f. Approval obtained from Biodiversity Authority, wherever applicable.

Accession number and other details of the depository are given, if applicable.

Q13. Is there any difference in the filing of patent application in respect of microbiological and other inventions?

A microbial invention may be described as an invention wherein microbes constitute the basic ingredient in the invention. To obtain legal protection in terms of a patent, a complete disclosure is required in the form of complete specification but sufficient disclosure may not be always possible in the microbial invention. The inventor is therefore required to deposit the strain of a microorganism in a recognized International depository authority (IDA) before filing a patent application. The IDA assigns a registration number to the deposited microorganism. This number needs to be quoted in the patent application. Further, samples of strains can be obtained from the depository for further working on the patent. There are many international depositories in different countries, which are recognized under the Budapest Treaty. This is a specific requirement only for microbial inventions.

Q14. What is an International Depository Authority (IDA)?

An International Depository authority is essentially a culture collection facility, recognized by the World Intellectual Property Organization (WIPO), Geneva in accordance with the Budapest Treaty for the deposition of microbial strain for patents filed based on microbial inventions. As of now, the WIPO has recognized 46 facilities as IDA in various countries. An applicant needs to deposit the strain in only a single IDA.

Q15. Is there an International Depository Authority (IDA) in India?

There are two WIPO recognized IDAs in India,:

1. Microbial Culture Collection (MCC)
   National Centre for Cell Science (NCCS),
   University of Pune Campus, Ganeshkhind
   Pune-411007, Maharashtra, India
   http://www.nccs.res.in

2. Microbial Type Culture Collection and Gene Bank (MTCC)

Institute of Microbial Technology (IMTECH),
Council of Scientific and Industrial Research (CSIR)
Sector 39-A, Chandigarh - 160 036, India
http://mtcc.imtech.res.in

Q16. What are the different kinds of inventions which are not patentable in India?

An invention may satisfy the condition of novelty, inventiveness and usefulness but it may not qualify for a patent under the following situations, as referred in India Patent Act 1970, Section 3:

i. An invention which is frivolous or which claims anything obviously contrary to well established natural laws. e.g. A machine allegedly giving 100% efficiency.

ii. An invention for which the primary or intended use or commercial exploitation could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment. E e.g. Any machine or method for counterfeiting of currency notes

iii. The mere discovery of scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature .E e.g. $E = mc^2$

iv. The mere discovery of a new form of a known substance which does not result in 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.

Explanation: For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regards to efficacy.

v. A substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance. E e.g. Mixture of sugar and colorants in water, which only produces aggregation of properties and synergistic properties

vi. The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way. e.g. A known type of torch connected to a known type of pen. Note, both the pen and torch work independently of each other

vii. A method of agriculture or horticulture. eg- a method of growing plants

viii. Any process for 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.

ix. Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants or animals. e.g. Cloning of animals

x. A mathematical or business method or a computer program per se or algorithms.

xi. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions. E.g. movies, poems etc.

xii. A mere scheme or rule or methods of performing mental act or method of playing game. E.g. Method of playing chess

xiii. A presentation of information. E.g. Presenting information in the form of a graph

xiv. Topography of integrated circuits since protection of Layout Designs of Integrated Circuits is governed separately under the Semiconductor Integrated Circuit Lay-out Designs Act, 2000

xv. An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components. E.g. Usage of Nilgiri oil for reducing aches

xvi. Inventions relating to atomic energy.

Q17. What is the patenting process of an invention?

A patent application is processed at the relevant patent office. Following steps need to be taken while proceeding with a patent application and thereby converting an invention into a patent application:

Firstly, a patentability search is conducted for establishment of patentability in terms of fulfilling the criteria of a patent. Then, the patent applications are drafted generally in consultation with a patent attorney or a patent agent.

Filing of the application is accompanied with the execution of Declaration of invention and an Assignment under which the inventor(s) assigns his / her rights in the patent to the ICMR (in case of ICMR funded research). A request for examination is is to be filed within a period of 48 months from filing date of complete specification. The patent application is published 18 months after initial filing and then examined by the Indian Patent Office, following the examination, the patent office may grant the patent or reject or seek changes through the issue of a so called First Examination Report (FER) or action required by the applicant in the application submitted. This letter sent by the Indian Patent Office is referred to as an Office Action or Official Action. The applicant or his legal nominee must file a written response, usually within three to six months. The patent attorney (legal representative of the applicant) responds to the FER through appropriate response which may include amending the claims and/or make changes to satisfy the queries raised in FER. This procedure is generally referred to as patent prosecution. During the prosecution process, inputs from the inventor(s) are often needed to enable the patent attorney understand the technical aspects of the invention and/or the prior art cited against the application to enable submission of a satisfactory response to the FER. Often two there could be two Official Actions and two responses that are legally permissible.

Q18. What is the next step for a patent application filed provisionally?

After filing a provisional application, the inventor(s) has to file a complete specification, with full patent claims, within one year from the filing date (priority date) and decisions also may be taken on foreign filings. The inventor may add further findings or modification in his/her invention within this one year window period.

Q19. What are different kinds of patent applications?

The following types of applications for patent can be filed:

1. Ordinary Application
2. Convention Application
3. PCT International Application
4. PCT National Phase Application
5. Application for Patent of Addition
6. Divisional Application
7. Start Up application

Q20. What is an Ordinary Application?

A patent application filed for the first time in the patent office without claiming any priority from application made in convention country or without any reference to other application under process is known as an ordinary application.

Q21. What is a Convention Application?

An application for a patent filed in respect of an invention, claiming a priority date based on the same or substantially similar application filed in one or more of the convention countries are called as a Convention Application. A convention application should be filed within **12 months** from the date of earliest priority application. It should be noted that a provisional specification cannot used to file a Convention Application.

Q22. What is a PCT International application?

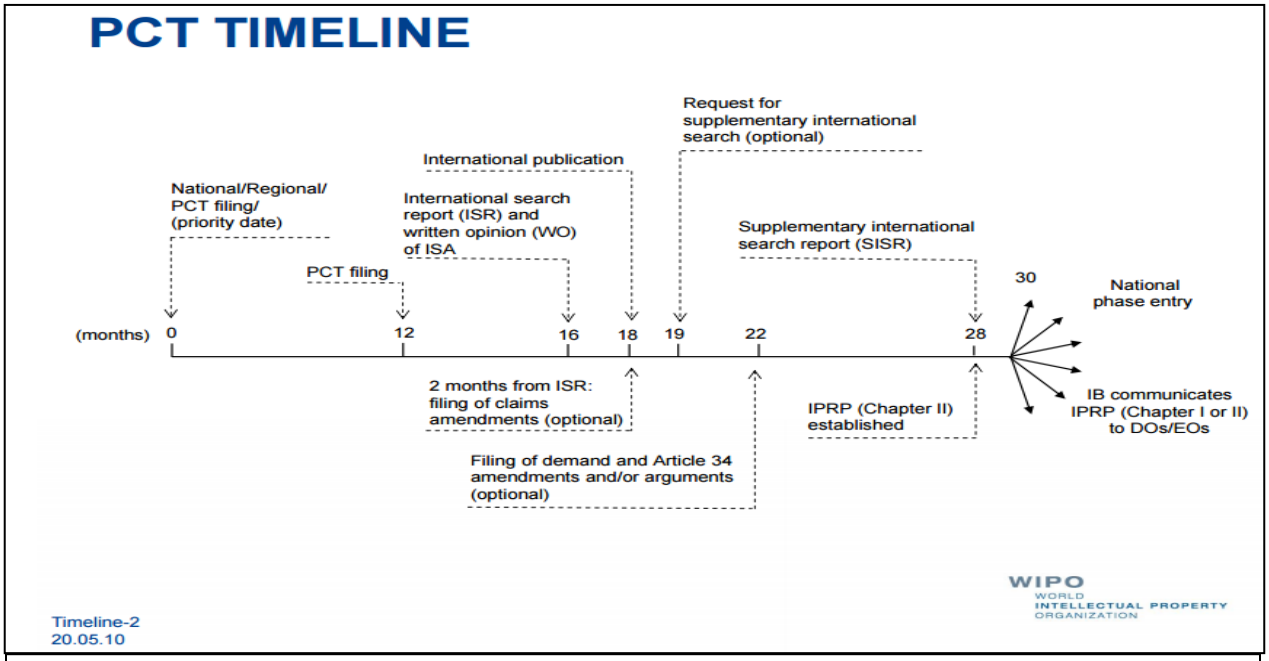
A Patent Cooperation Treaty (PCT) application is an international application governed by World Intellectual Property Organization (WIPO), Geneva, and can be validated in 148 countries as member states. The PCT is an international filing system for patents in which the applicant files in the receiving office in a country and gains an early priority date in all the designated countries without affecting the priority date. This is a simple and economical procedure which enables patent protection for the inventions corresponding to a single priority date in many countries. Indian Patent office is a receiving office for international applications by nationals or residents of India. A PCT application shall be filed with the appropriate designated office in triplicate for applications filed in the head office (WIPO, Geneva and quadruplicate for branch offices, either in English or in Hindi language

Q23. What is the significance of priority in a PCT application?

A patent starts conferring the associated rights from the date of filing of the patent application. After filing a PCT application when a national phase patent application is filed, the priority date shall be the date of filing of the foreign or PCT application. Similarly, if an application is divided into two applications, the priority date shall be date of filing of the parent application.

Q24. What is a PCT-National Phase Application?

According to the Patent Cooperation Treaty, an international application enters national phase, in the designated countries within 31 months (30 months for some members) from the priority date. The designated countries then prosecute the applications in accordance with the relevant laws. Indian Patent office prefers signed Form 1A with the national phase application. It is not mandatory for the applicant to submit the documents while entering the national phase for filing the application in the designated or elected member countries, as it is obligatory on the part of WIPO to send those things to the designated offices. However, submission of all necessary documents is preferred for convenience and faster processing of the application, as the designated office may ask for other documents if necessary.



PCT Timeline

Courtesy: www.wipo.int

Q25. Which is the appropriate office in India for submission of PCT applications?

PCT application can be filed in any of the Indian Patent Office located at New Delhi, Chennai, Mumbai and Kolkata (Head Office).

Q26. What is the cost of filing a PCT application?

The cost of filing a PCT application by an Indian Applicant is as follows:

Table: The cost of filing a PCT application by an Indian Applicant

1.	Transmittal Fees	17, 600/- for large entity 8,800/- for small entity and 3,250/- for individuals (All figures in INR)
2.	International Filing Fee	USD($) 1,384 as on Jan 01, 2016
3.	Fee per sheet over 30 sheets	USD ($) 16
4.	Search Fee	depends on the International Searching Authority (ISA) selected by the applicant as on Jan 01, 2016: AT: USD 2,084 AU: USD 1,560 CN: USD 330 EP: USD 2097 US: USD 2080

* Where; AT = Austria; AU= Australia; CN= China; EP= Europe; SE= Sweden; US= United States of America.

Q27. What is an application for Patent of Addition?

An application for patent of addition shall be made at the Indian Patent office if an inventor comes up with an improvement or modification of the invention described or disclosed in main application which should have been already filed or granted in India.

A patent of addition allows an applicant to protect that modification or advancement in an invention but the Complete Specification of that application shall include specific reference to the number of main patent or the application for the main patent as the case maybe, and a definite statement that the invention comprises an improvement in, or a modification of the invention claimed in the specification of the main patent granted or applied for. A Patent of Addition shall be granted only after the grant of the main patent. However, a Patent of Addition application gets the same priority date as the main patent application as also date of the Patent of addition as the main patent unless it is filed as a independent application.

Q28. What is a Divisional application?

In cases where the Controller of Patents identifies an application as lacking the 'Unity of Invention' i.e. the claims of a complete specification relate to more than one invention, an applicant at any time before the grant of a patent may be asked to divide the application and file further application(s) in respect of invention(s) disclosed in the provisional or complete specification already filed. This type of application divided out of the parent one is called divisional application.

Examination of a divisional application and the original parent application are always done simultaneously. The priority date for all the divisional application will be same as that claimed by the parent application. It is to be emphasized that the complete specification of the divisional application should not include any matter not in substance disclosed in the complete specification of the first application and the reference of parent application should be made in the body of the specification.

Q29. What is a Start Up application?

In accordance with the patent rules Amended in 2016**,** a "startup" is defined as a new company/LLP/a registered Partnership firm which has been found not more than 5 years ago, does not have a turnover of more than INR 25 crores in any financial year, in the last 5 years' time, and is working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property. A patent application generated through a Start up is called a Start Up application. Flexible Patent rules for have been amended to facilitate start ups for IP protection by giving various benefits.

Q30. What is opposition under the Indian Patents Act 1970?

The Indian Patents Act, 1970 provides for pre grant and post grant opposition. Pre-grant opposition can be filed after the publication of patent application and before the grant of patent by any person with a statement and evidence in support of the opposition. On the other hand, post-grant opposition can be filed within one year of the grant of the patent.

There is a set legal procedure for the hearing of both pre and post grant oppositions laid down under the Indian Patent Act 1970 and rules. An opposition board is constituted for each of the opposition notification accepted by the Controller for the post grant opposition proceedings. Opposition in both cases will be allowed on the grounds specified in the Indian Patent Act.

Q31. What are the grounds for opposition?

According to the Indian Patent Act 1970 and rules, pre-grant and post-grant opposition can be filed only on the following grounds:

(i) Claimed invention or its part wrongfully obtained.

(ii) Claimed invention is published in any patent or any other document before the priority date.

(iii) Claimed invention was publicly known or publicly used before the priority date.

(iv) Claimed invention is obvious and clearly does not involve any inventive step, having regards to the matter published or used (in India) before the priority date.

(v) Claimed invention is not the invention within the meanings of the Patent Act or is not patentable under the Patent Act.

(vi) The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed.

(vii) The applicant has failed to disclose to the Controller the information regarding foreign applications filed for the same invention by him or has furnished the information which in any material particular was false to his knowledge.

(viii) In case of a Convention application, if the application is not filed before the expiry of 12 months from the date first application for the protection for the invention made in convention country.

(ix) The complete specification does not disclose or wrongly mentioned the source and geographical origin of biological material used in the invention.

(x) Claimed invention was anticipated having regard to the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere.

Q32. What is the publication and examination of patent application?

Publication: The publication of a patent application is different from the publication in a learned journal printed or web-based. In context of patent application, –the patent office published the applications after 18 months of filing of the patent application or from the date of priority (whichever is earlier) in the official gazette of the Indian Patent office for inspection by public and checking for objections. All the patent applications except the applications prejudicial to the defense of India or abandoned due to non-filing of complete specification within the prescribed time-limit after provisional or withdrawal of the application are published in the official Gazette. The publication will include the particulars of the date of the application, application number, name and address of the applicant along with the abstract. No application for patent shall be opened for public inspection before publication. After the date of publication of the application, as stated above, the complete specification along with provisional and drawing, if any, and abstract may be inspected at the appropriate office by making a written request to the Controller in the prescribed manner.

Examination: A request for examination (RFE) in form - 19 is to be filed simultaneously with the patent filing or within 48 months from the date of filing or earliest priority date; in case the RFE is not filed the corresponding application will not be examined and will be deemed as withdrawn. A request for examination may be normal or express.

After the examination, a patent may proceed for grant or a First Examination Report (FER). In the FER, objections/requirements may be communicated to the applicant or his agent according to the address for service.

Reply to the FER is to be submitted with needed amendments in complete specification within a period of 06 months from the date of First Examination Report (FER). No further extension of time is available in this regard.

If all the objections are not complied within the period of six months, the application will be deemed to have been abandoned. When the application is in order for acceptance, it is notified in the Gazette of India.

Q33. Can a patent application be withdrawn?

The applicant may, at any time after filing the application but before the grant of a patent, withdraw the application by making a request in writing and by paying the prescribed fee. However, if the applicant makes a request for withdrawal within 15 months from the date of filing or priority of the application, whichever is earlier, the application will not be published. The application withdrawn after the date of publication cannot be re-filed as it is already laid open for public inspection. However, application withdrawn before the publication can be re-filed provided it is not disclosed otherwise.

Q34. How is a patent granted?

If the application is not opposed or the opposition is decided in favor of the applicant or is not refused, and if the application satisfies all the requirements of the patent act, the patent is granted or sealed on making a request in Form 9 along with sealing fee within 6 months from the date of notification of acceptance of the complete specification in the Gazette of India at the appropriate office where the application was filed. However, it is extendable by three months. If the sealing fee is not paid within the prescribed period, it will be treated as "NO PATENT". There is no provision in the Indian Patent Act to revive the said patent.

Protection of Traditional Knowledge

Q1. What is Traditional Knowledge?

Traditional Knowledge (TK) is defined as the knowledge continually developed, acquired, used, practiced, transmitted and sustained by the communities/individuals through generations. TK is a collectively owned asset and indicates the cultural or spiritual identity of the social group in which it operates and is preserved. In other words, TK is an open-ended way to refer to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs and handicrafts marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity.

Traditional Knowledge
Courtesy: www. Lexorbis.org

In India, Traditional knowledge refers to the knowledge, innovations and practices of indigenous communities which they have developed over many generations with traditional utilization of natural resources including environment, flora, land etc. TK is mostly undocumented and typically inherited via word of mouth from generation to generation**.** The World Intellectual Property Office (WIPO) defines TK as indigenous knowledge relating to categories such as agricultural knowledge, medicinal knowledge, biodiversity related knowledge, and expressions of folklore in the form of music, dance, song, handicraft, designs, stories and artwork. Examples are as follows:

- Use of turmeric (*Curcuma longa*) for medicinal purposes.
- Use of ashwagandha (*Withania sominifera*) to treat heart related ailments.
- Traditional healing practices such as Yoga.

Q2. What are the important features of TK?

Traditional knowledge is sustained through generations. TK therefore is holistic, qualitative, moral, spiritual, intuitive, etc.

Q3. What is the patentability status of Traditional Knowledge?

Indian patent laws do not permit protection of TK Under section 3 (p) of the Indian Patent Act, 1970. , An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components is not an invention and cannot be patented.

However, if there is a substantial improvement in the existing TK to enable the invention fulfill the criteria under the Indian IP law, IP protection can be sought.

Courtesy: USPTO; Intellectual property symbols

Q4. How does Indigenous Traditional Knowledge differ from western science?

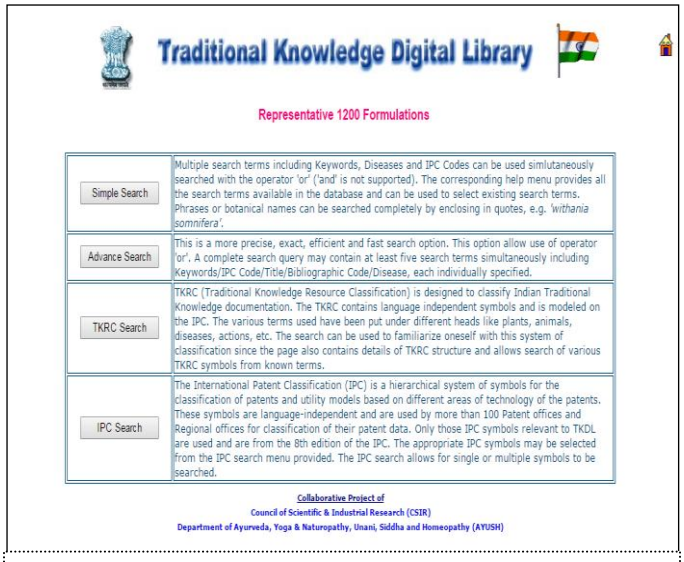
In our country, TK systems exist principally in the form of songs, proverbs, stories, folklore, community laws, common or collective property and inventions, practices, rituals etc. Unlike the western custom of disseminating knowledge through publication, academic and literary modes, the TK is transmitted from forefathers to next generation primarily through verbal transmission. The knowledge is considered collective to the community, not private to one individual or small group, whereas western science possesses a systemic, analytical and compartmentalized approach.

Q5. What are the key issues for IP protection of TK?

The key issue for protecting TK is prior disclosure of the innovation as much of TK is already in public domain being passed on orally or through documentation through generations. This makes most TK ineligible for IP protection as most information is already part of 'prior art' and therefore there is very little in terms of novelty that needs to be established for patent protection.

Q6. How important is Traditional Knowledge?

TK is an integral part of strength of local community knowledge. Attempts to exploit TK owned by local communities for industrial or commercial benefit is a major issue as it is unfair exploitation of knowledge owned by local communities as IP protection creates monopoly of patent owners. Governments the world-over including India have enacted laws to prevent such unfair exploitation of TK.



Courtesy: www.tkdl.res.in

Q7. What is TKDL?

TKDL stand for Traditional Knowledge Digital Library and it is collaborative project of the Government of India through the Council of Scientific and Industrial Research (CSIR) and the Ministry of AYUSH. to provide information on traditional knowledge existing in India, in various languages and format as a single repository. TKDL serves as a reference of prior arts for patent examiners at International Patent Offices (IPOs).

Q8. What are the features of TKDL?

The two main features of TKDL are '*Accessibility'* and '*Availability'*. TKDL provides accessibility in terms of '*Language, format and Classification'.* The Indian traditional knowledge exists in local languages such as Sanskrit, Urdu, Arabic, Persian, Tamil, etc," and TKDL translates this traditional knowledge into the native languages of the patent examiners, including the five languages of "English, French, Spanish, German and Japanese."

The *format* of TKDL is also unique and laid down in a format similar to the "patent application format, which is easily understandable by patent examiners." The full listing for each TK entity contains a bibliography of traditional Indian documents, and the bibliography contains links to scanned images of these documents in the original language.

Other feature is the *classification.* TKDL has created a new classification system for the traditional knowledge, known as the "Traditional Knowledge Resource Classification (TKRC)" and is "based on the structure of International Patent Classification (IPC)." Each listing in the TKDL includes both TKRC codes and IPC codes.

Another main feature is the availability of TKDL. TKDL in complete form is available only to certain national patent offices for use by patent examiners. However, a "representative" version of the database is available at the TKDL website. This database has 1,200 representative listings.

Q9. What is TKRC?

TKRC stands for Traditional Knowledge Resource Classification (TKRC) is an innovative classification system of TKDL. TKRC has structured and classified the Indian Traditional Medicine System in approximately 25,000 subgroups for Ayurveda, Unani, Siddha and Yoga. TKRC has enabled incorporation of about 200 sub-groups under A61K 36/00 as defined in the International Patent Classification instead of few sub-groups earlier available on medicinal plants under A61K 35/00 thus enhancing the quality of search and examination of prior-art with respect to patent applications field in the area of traditional knowledge.

Q10. What are the legal aspects for the utilization of TK?

For IP protection and utilization of TK following issues needs to be considered:

i. **Prior Informed Consent**: A prior consultation or documented consent from traditional knowledge holders must be acquired by third parties before using their knowledge.
ii. **Equitable Benefit Sharing**: This balances the interests of the right holders and the general public. i.e the knowledge holders must be appreciated with compensatory payments or other non-monetary benefits for using their traditional knowledge for commercial or public health purposes.

iii. **Unfair Competition**: The TK and its practitioners must be protected against any unfair practices such as false claims, illegal use of knowledge, etc. The unfair completion law has been extensively used for protection of integrated circuits, layout designs, geographical indications, undisclosed information and test data and this could be extrapolated for the protection of TK.

iv. **Distinctive signs:** Traditional signs, symbols and terms associated with TK may be protected as distinctive marks. Such signs may be exploited as trademarks, collective marks, certification marks and geographical indications.

v. **Customary laws**: These laws define how traditional communities develop, hold and transmit TK.

vi. **Contracts**: Legally binding documents between parties to outline and **e**nforce access and benefit sharing agreements as well as trade secrets. For example: Confidentiality/non-disclosure agreements, Exclusive licenses etc. Contracts relating to TK.

Q11. Are there other mechanisms for the protection of traditional knowledge?

As per the Indian Patent system, it is not possible to protect Indian TK. However, there are some non-IP based mechanisms for protecting TK which are covered by International conventions such as i) '*UN Convention to Combat Desertification'* for protection of traditional knowledge in the ecological environments and sharing of benefits arising from commercial utilization of such TK; ii) '*Primary Health Care Declaration' by WHO* recognized the relevance of traditional knowledge in the field of medicine; iii) the '*Doha Declaration'* by World Trade Organization which has , instructed the TRIPS Council to examine issues regarding the protection of traditional knowledge emerging from the trade and development; and iv) '*International Treaty on Plant Genetic Resources* for Food and Agriculture' which recognizes farmers rights and the protects traditional knowledge pertaining to plant based food and agriculture.

Q12. What are Access and Benefit Sharing (ABS) regimes?

Access and Benefit Sharing (ABS) refers to granting permission to enter an area for the purpose of sampling, collecting, and removing genetic or other resources. Benefit sharing refers to all forms of compensation for the use of genetic resources, whether monetary or non-monetary. This might also include participation in scientific research and development of genetic resources, and sharing the findings of any potential benefits resulting from this work. In other words 'ABS' regimes are set of rules and regulations at national level implementing one of the objectives from the UN Convention on Biological Diversity (CBD), which seeks to compensate the country of origin of the genetic resources, should the materials be commercialized.

Following questions moved to the end from Question no 6, 7 and 8

Q13. How are plant varieties protected in India?

The plant varieties are protected through methods such as Sui generis system, or plant breeding or The International Union for the Protection of New Varieties of Plants (UPOV) In principle, patenting of higher life

forms such as plants or animals are not patentable subject matter under section 3 (j) and 3 (h) of the Indian Patents act, wherein section 3 (j) states that 'plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals' are considered non patentable matter and section 3 (h) states that 'a method of agriculture or horticulture' is not patentable.

Q14. What is UPOV?

UPOV was established by the International Convention for the Protection of New Varieties of Plants, in synchrony with WIPO's objective to protect plant varieties. UPOV's mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants.

Q15. What is sui generis system for protection of plant varieties?

Sui generis is a system of protection for plant varieties as an alternative or addition to a patent system for protecting plants. Accordingly in India plant protection came into being for new plant varieties as Protection of Plant Varieties and Farmers' Rights (PPVFR) Act in 2001.

International Scenario of IP

Q1. What is World Trade Organization (WTO)?

World Trade Organization (WTO) is an international organization which administers the rules of trade globally for liberalization and expansion of international trade by developing agreements, frameworks and dispute resolution processes. The WTO came into effect on January 1, 1995 under the Marrakech Agreement which replaced the General Agreement on Tariffs and Trade (GATT) of 1948. Majority of WTO's current work comes from the 1986–94 negotiations called the Uruguay Round and earlier negotiations under GATT. World Trade Organization has 162 members as on November 2015. It is headquartered in Geneva, Switzerland.

Q2. What is the mandate of WTO?

The WTO's main functions are to regulate trade negotiations and enforcement of negotiated multilateral trade rules. These two functions are performed with mandates such as: Assisting in developing and transition of economies, specialized help for export; including establishment of International Trade Centre, global economic policy-making, establishing a transparent system between WTO and Public worldwide**.**

Q3. What is GATT?

GATT stands for General Agreement on Tariffs and Trade (GATT), which came into effect on January 1, 1948. GATT is a multilateral agreement for regulating international trade. As per its preamble, the purpose was "substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis." It lasted with 123 countries as members till Uruguay Round of Agreements dated April 14, 1994, and then the World Trade Organization (WTO) were established on January 1, 1995.

Q4. What is WIPO?

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations set up in 1974. The WIPO administers 26 international treaties in the area of intellectual property. WIPO has 148 member states and was established by a convention on 14 July 1967, entering into force in 1970. It is headquartered in Geneva, Switzerland.

Q5. What are the main objectives of WIPO?

Following are the main objectives of WIPO:

- Intellectual property protection globally through cooperation among member states and, where appropriate, in collaboration with any other international organization.
- Ensuring administrative cooperation among the intellectual property unions created by the Paris and Berne Conventions and sub-treaties concluded by the members of the Paris Union.

Q6. What is International Bureau?

The International Bureau is the secretariat of the WIPO, which centralizes the administration of the unions created under the various conventions. International Patent applications may be filed directly with the International Bureau as Receiving Office to WIPO's headquarters as an alternative to filing with the competent national or regional Office.

Q7. What are the linkages between WIPO and WTO?

There is an agreement of cooperation between WIPO and the WTO that came into force on 1 January 1996. The agreement provides cooperation in three main areas:

- National laws and regulations: Their access, translation and notification.
- Protection of national emblems by implementation of appropriate procedures.
- Technical cooperation.

Q8. What is GATS?

The World Trade Organization introduced a treaty known as "General Agreement on Trade and Tariff in Services (GATS)" in January 1995 as a result of the Uruguay Round of negotiations. The major objectives of GATS are: forming a reliable system of international trade rules; equal and fair treatment of participants, stimulating economic activity through guaranteed policy bindings; and liberalization in trade and its development.

Q9. What is Paris Convention?

Paris Convention is an international convention for promoting trade by encouraging protection of industrial property among member countries. All the member countries provide national treatment to all the applications from the other member countries for protection of industrial property rights.

The Convention was first signed in Paris, France, on March 20, 1883. Since then, the Convention has been revised several times latest being in 1979. India became a member of the Paris Convention on December 7, 1998. The convention currently has 176 members.

Q10. What are the principal features of the Paris Convention?

The fundamental extracts of the Paris Convention are listed below:

- National treatment,
- Right of priority,
- Independence of patents,
- Parallel importation,

- Protection against false indications and unfair competition.

Q11. What is the meaning of national treatment under the Paris Convention?

Paris convention ensures that national of a member country is given equal treatment when he/she protects the invention in other member country as his own national.

For example; if an Indian Pharmaceutical company applies for the grant of a patent for a novel drug compound in USA, as per the Paris Convention, the US Patent Office shall apply the same norms and rules to the applicant from India, as applicable to a US citizen for granting a patent. Therefore, there no requirement for domicile or establishment in the country where protection is sought. .

Q12. Is there a provision for compulsory license in the Paris Convention?

Under the Paris convention, each member country has a right to advocate for the grant of compulsory licenses to prevent the abuses resulting from the exclusive rights offered by a patent. Compulsory licenses for failure to work or insufficient working of the invention may be requested after four years from the date of filing of patent application or three years from the date of the grant. Such licenses are non-exclusive and non-transferable.

Q13. What is PCT?

PCT or Patent Cooperation Treaty is administered by the WIPO. It was adopted in 1970 and became operational in 1978. It is an international treaty which facilitates the blocking of priority date with simultaneously designating the country where the invention is intended to be protected. Currently PCT has 148 Contracting States including India.

Q14. What are the advantages of filing PCT application?

The PCT simplifies the process of obtaining patents in a number of countries by filing of a single application. It greatly benefits the applicants, Patent Offices of the designated countries and the general public as well. The advantages of filing patent application through the PCT process are indicated below.

Advantages for the applicant:-

i. PCT saves time, work and money, for any applicant seeking protection for an invention in a number of countries. Under the PCT, the applicant needs to file single application (international application) in one country, in one language and in one format and pay one initial set of fees in one currency as stipulated. The applicant is accorded a date of filing, which will be effective in all the designated countries.

ii. By designating any or all of the PCT countries, the applicant can simultaneously seek patent protection for an invention in each of a large number of countries.

iii. Applicant gets 18 months or more to decide if he/she actually wants to proceed ahead with his / her application. Due to this extra time (more than what is available under the traditional patent system) gained by the applicant through filing of PCT application. The inventor can keep all the options open for protecting his / her invention while still investigating its commercial possibilities abroad until 18 the month window period.

iv. Through international search report, the applicant can evaluate the possibilities of his / her invention being patented before incurring major costs in foreign countries. Further the PCT provides an option for international preliminary examination utilizing which an applicant can be doubly sure before entering national phase.

v. If the applicant files his/her international application in the form prescribed by the PCT, he / she is reasonably assured that it cannot be rejected on formal grounds by any Designated Office during the national phase of processing the application.

Advantages for Patent Office of Designated Country:

i. The National Patent Office of designated countries can have the advantage in handling more patent applications because the verification and other formal requirements would have generally been checked during the international phase.

ii. The search and examination is done by WIPO, therefore the need for search and examination by the national patent office can be considerably reduced or virtually eliminated. In most cases, the examining Patent Office benefit from these two kinds of special reports generated in the international phase. In case of non-examining Patent Offices, they are in a much better position to complete the process faster if they receive an application already examined in the international phase.

iii. The Patent Office's can also save publishing costs. If the international application is published in the official language of the country, the National Patent Office can forego the publishing altogether.

The general public is also benefitted by PCT as technical information in patent documentation is disseminated globally and can lead to worldwide information exchange.

Q15. Where can International patent applications be filed?

The international applications can be filed:

i. At the National Office of or acting for the contracting state of which the applicant is a resident.

ii. International Bureau (IB) of World Intellectual Property Organization (WIPO).

Indian inventors desiring to file an International application must file with any of the receiving offices at Kolkata, New Delhi, Mumbai & Chennai or the International Bureau of WIPO, Geneva.

Q16. What is an international search authority (ISA)?

The designated International search authority examines the PCT application for patentability and provides the international search and written opinion. The application is examined on the criteria of patentability and queries on the same are raised. In accordance with Article 19 of the PCT, a period of 2 months is provided to answer the objections with necessary changes in the application; this improves the chances of patent acquiring in national phase.

Q17. Which are the International Search authorities (ISA) for Indian applicants?

An applicant from India can choose any one of the following ISA/ International Preliminary Examination Authority (IPEA) for international search and preliminary examination:

- Indian Patent Office
- Australian Patent Office
- Austrian Patent Office
- European Patent Office
- State Intellectual Property Office of the People's Republic of China
- Swedish Patent and Registration Office
- United States Patent and Trademark Office

Q18. What is the fee structure for search by ISA?

The search fees is different for each ISA and may be revised from time to time, For Indian patent office as the ISA, search fees is INR 10,000 ($154) for large entity whereas INR 2500 ($ 38) for a natural person, whereas if the designated office is any International Patent office then the fees ranges from 330 $ for State Intellectual Property Office of the People's Republic of China to 2097 $ for European Patent Office. Some International Search Authorities such as European patent office and Austrian Patent Office also provide 75% reduction for natural persons. For the supplementary searches, only Austrian, Swedish and European patent office are available for an Indian applicant and the fees ranges from CHF 928 to CHF 2046, along with CHF 200 as handling fees which is same for all the International Search authorities.

Q19. What are the essential elements to be included in an International application?

The International application must contain a request, a description, one or more claims, one or more drawings (where required) and an abstract. It must comply with the prescribed physical requirements and should be in one of the prescribed languages added with payment of the required fees. In case of biological inventions, the microbial strain must be deposited in an International Depository Authority (IDA) under the Budapest treaty.

Q20. Can an International application be withdrawn?

Yes, an International application can be withdrawn by a notice at any time before technical preparations for International publication have been completed i.e. not later than 15 days before the date of publication.

Q21. What is the Budapest Treaty?

When a biological invention involves the use of a microorganism, the specification describing the invention cannot efficiently enable third parties to carry out the invention in the absence of biological material. Therefore, for all such inventions, deposition of biological material is imperative. For this purpose, the Budapest treaty was signed in Budapest on April 28, 1977 and later on amended in September 26, 1980. The Budapest treaty has recognized institutes in all its member countries and mandates the deposition of the microbial strain in the International Depository Authority (IDA) and its disclosure in the patent application. India became a member of this Treaty, with effect from December 17, 2001.

Licensing

&

Technology Transfer

Licensing

Courtesy: www.cipartlibrary.com

Q1. What is licensing?

A license is a legal agreement by which the owner of an invention (licensor) grants rights to the licensee to make, use, and/or sell the invention within the framework of license agreement. Any entity that aims to manufacture and market a patented product needs a license from the licensor.

Q2. How do you license an invention?

Licensing, in simple terms, is the buying or renting of the rights to intellectual property (the invention) with the intent to produce and market, typically on commercial terms. . The inventor who licenses his or her invention receives a fee for the invention being licensed. Such a payment could be a one-time payment (lumpsum payment) and/or percentage of revenue generated as royalty. The Licensing Agreement therefore paves the way for an invention into a marketable product. The process of licensing of invention varies from organization to organization but is typically negotiated between teams from licensor and the licensee. The major parameters in licensing include:

- Exclusivity of the licence
- Lumpsum upfront payment
- Rate and mode of payment of royalty.
- Territory for the licensing agreement
- Liability issues

Q3. What issues are to be considered before collaborating with a company?

The inventor must enter into a properly drafted Non Disclosure Agreement (NDA) with the company before initiating discussions to ensure that the invention is protected from unfair exploitation. If the collaborator and/or the company seek material for testing and evaluation, a properly drafted Material Transfer Agreement (MTA) must be signed or a commercial evaluation license or an internal commercial use license may be signed.

Q4. What is a Material Transfer Agreement?

Tangible research materials created by researchers must be protected through a specific legal agreement. Such agreements are called Material Transfer Agreements and are useful for commercial development or even for

further R&D. It is important to contact the IPR or Technology Transfer Units prior to receiving or sending out any research materials to enable protection of IPR from unfair exploitation.

Q5. What is a *Confidential Disclosure Agreement*?

The transfer of proprietary information, even in a casual conversation, could legally be considered a public disclosure and hence loses protection. In the worst case scenario, such a disclosure could allow the individual or a company, to whom this information was disclosed to use or transmit to others your confidential information, thus placing it in the public domain. Further, this would preclude the possibility of obtaining intellectual property protection and therefore may lose commercial value of the invention. Therefore a legal agreement between the transferor of proprietary information (such as a researcher) to another entity (such as a corporate representative of a researcher) is necessary. Such a legal document for the protection of proprietary information is called a Confidential Disclosure Agreement or Non-Disclosure Agreement.

Q6. What is a C*ommercial Evaluation license*?

Commercial Evaluation License typically grants a non-exclusive right of limited duration to make and use an invention for the purpose of evaluating its commercial potential. The license does not grant the right to sell or otherwise distribute the invention. Companies are required to obtain a commercial patent license for further use and/or development of the invention.

Q7. What is an *Internal Commercial Use license*?

Internal Commercial Use License, grants the non-exclusive right to the licensee to make and use the invention as a tool in the Research &Development and/ or production activities. These licenses do not grant the right to sell or otherwise distribute the invention, but allow the licensee to use the invention.

Q8. What is non-exclusive and exclusive patent license?

Both non-exclusive and exclusive Patent Licenses allow a company to commercialize the invention as per the licensing agreement. An exclusive license limits the use of the invention to a single entity barring others from use. Non-exclusive license, on the other hand, is given to multiple licensees to different entities for commercial exploitation.

Q9. What are the advantages of licensing a technology?

Licensing an intellectual property will help:

- Ensuring commercialization of an invention
- Bring the product to market for public use.
- Generates revenue to the inventor(s) and the agency.
- Enhances the image of the organization as the product carries the details of the licensor.

- Helps the economy of the country.

Q10. What is compulsory licensing?

Compulsory licensing is a system when a government allows a company to produce a patented product or utilize a patented process without the consent of the patent owner. It is well defined under the patent act of a country.

Q11. Does the Indian Law provide for compulsory licensing?

As per the Indian Law, a compulsory license can be sought after 3 years from the date of the grant of the patent on the following grounds:

a. If the reasonable requirement of the public (domestic and foreign) need for the product have not been satisfied

b. If the Patented Invention is not available to public at a reasonable price;

c. If the Patented invention has not been worked in India.

Additionally, in the case of a national emergency and/or for preventing major disease epidemics, the Controller can permit compulsory licensing irrespective of the above three conditions. (For compulsory licensing under Paris convention, refer chapter VI; 'International Scenario of IP)

Q12. What are the different types of Compulsory licenses?

Compulsory licensing can be categorized based on the conditions required for its application. It is also defined in the Indian Patents Act, 1970 (amended in 2005) under sections 84 for patent misuse, under section 92 for compulsory licensing in Public interest, under section 92 (A) for exports of pharmaceutical products and under section 91 for compulsory licensing for related patents.

Technology Transfer

Technology Transfer: From labs to Homes;
courtesy: blog.ourcrowd.com

Q1. What is technology transfer?

Technology transfer is the formal transfer of IP or other rights to any entity to use and commercialize new invention. Typically, transfer technology is done after protecting the IPR (viz., patents and copyrights) after a process of due diligence about the company and with some terms and conditions for licensing.

Q2. Why is technology transfer required?

An invention would be beneficial for the public if transferred successfully through technology transfer and marketed. In the health sector, tech transfer ensures availability of new and better products for public use. Technology transfer and commercialization of inventions provides monetary benefits to the inventors, agency supporting the inventionns, the company and also the country.

Q3. What is the process of 'technology transfer'?

Technology transfer is a process that recognizes the practical and commercial aspects of basic science research and discoveries and increases its outreach for the benefit of public and also encourages further innovation.

Technology Transfer/management also comprises evaluation and management of invention portfolios, patent prosecution, demonstration of knowhow, negotiating licensing agreements and periodic review of cooperative research agreements already in place. Part of the technology transfer process involves the prosecution of patents

which is overseen by the National Patent and Trademark Office. Individuals with advanced degrees in the subject are needed to review and process patents in the relevant field such as a biomedical expert is needed to review and process patent of biotechnology.

Q4. What is the purpose of technology transfer?

Coordination, nurturing, and linkages are the basic function of technology transfer process. The coordination between technology users and developers as well as between researchers and manufacturers is an important element of technology transfer. During the coordination process access to relevant internal and external resources to individual projects and enterprises has to be enabled by participating parties.

The main ingredient for moving technology from a research laboratory to a company for manufacture and marketing is an environment that is supportive of entrepreneurship. This needs to be encouraged by providing guidance, counseling and resources to nurture the new technology.

For linking the various components of technology it is required to catalogue resources related to business enterprises and connecting would-be entrepreneurs/researchers and other technology developers to outside entities which can help in the manufacturing and marketing of products.

Q5. How is the status of technology graded?

In terms of technology transfer, technologies can be categorized as developing technologies, emerging technologies and established technologies.

Developing technology is an innovative technology that currently is undergoing bench-scale testing, in which a small version of the technology is tested in a laboratory.

Emerging Technology is a technology that has been field-tested but lacks a long history of full-scale use. Information about its cost and how well it works may be insufficient to support prediction of its performance under a wide variety of operating conditions.

Established Technology is a technology for which cost and performance information is readily available. Only when a technology has been used at many different sites and the results are fully documented, a technology can be considered as established.

Q6. What are the basic steps to be considered while transferring the technology?

Technology transfer activities include

- Evaluation/assessment of the invention.
- Protection of intellectual property relating to the technology.
- Finding the most suitable partner for licensing
- Licensing to that entity.
- Demonstration of the working of technology

- Assist in Pilot level and later large scale manufacturing.

Q7. What is Freedom to Operate (FTO)?

Before commercializing a product in a country or region, generally a Freedom to operate search is suggested to confirm that the IP/technology being licensed does not infringe IP technology of another party. A Freedom to operate is typically a professional and extensive search in the field of intellectual property (not restricted to patents only).

A freedom to operate opinion related to patents usually includes the findings on patent searches in relevant jurisdictions and their expiration dates.

If the searches results into presence of valid IP rights of others that are likely to be infringed, one can negotiate with those parties to license their IP to facilitate bringing out the intended product into the market. FTO also helps the avoidable legal action by others,

Q8. How is the commercial potential of a technology assessed?

Commercialization potential is most significant aspect of an effective technology transfer. Establishing a technology's prospects for commercial success depends largely on five factors:

1. **Demand of the technology**: Technology must be new or improved version of the existing technology i.e. if it is simpler, cost effective or more efficacious.
2. **Technical Development**: The time, materials, and personnel needed to reduce the technology to practice and protect rights to the resulting product.
3. **Regulatory Clearance**: The testing needed to demonstrate the product's utility and safety, to meet regulatory requirements of the country in order to minimize or manage associated risks.
4. **Manufacturing Requirements**: Manpower, Facilities, and equipments needed to make the product.
5. **Market Development**: Plan for successful marketing, created by assessing perceived need for the product, size of potential market, expected sales, advantages over competing products, and the cost of promoting the product.
6. **Financial Feasibility**: The development cost, production cost, operating expenses in relation to sales potential, net profit, potential liabilities, and return on investment.

Q9. Does the sale of a technology constitute technology transfer?

Technology transfer is not about selling some hardware to a client who is then left with the task of using it as he/she deems fit. Technology transfer is the process of imparting of knowledge, skills and methodologies involved in the whole production cycle. Technology transfer is a system that encompasses the social and economic fabric of a country. Where technology has been effectively transferred, there should be a visible change - from the person to the production system as well as compatibility with the needs, in the institutional framework, skills, training, financial capacity, promotion, and active support of endogenous capacity and appreciation of the natural environment of the recipient country. Technology transfer also has to do with disseminating information on the technologies themselves.

Q10. How do academic institutions measure success in technology transfer? The success in technology transfer can be categorized as '**Numerical'** and '**Non-numerical'**. Under the numerical measures the 'early numerical measures' include the number of patents filed, license agreements executed and new companies formed. 'Late numerical measures' include revenues from license fees, royalties and cash from equity investments paid to the academic institutions and the numbers of products successfully introduced to the market. The 'Non-numerical' includes - university's ability to retain entrepreneurial faculty, attract outstanding graduate students, contribute to the institutional reputation for innovation, augment its research program through interaction with the private sector and enhance its reputation for providing highly trained students for the industrial work force. Success is also demonstrated by the impact the products have on the lives of general public.

Q11. What are the benefits of technology transfer efforts made by R&D institutes?

The licensing of innovations by Academic institutes, R&D institutes, and hospitals may be collectively termed as "Academic technology transfer", such a transfer may add substantial amount of money to the Indian economy and increased employment opportunities. Further, it contributes to the spawning of new businesses, creating new industries and opening new markets. Most importantly, successful tech transfer leads to new products and services that improve our quality of life, from new cancer treatments to faster gadgets environmental friendly devices etc. that make the way we live and work better.

Glossary

Abstract

A summary statement of the important points of a text. Brief description of the essential content of an the patent document

Access Rights

Licensees and user rights to practice knowledge or pre-existing know-how often owned by another person.

Access and Benefit Sharing (ABS)

Refers to granting permission to enter an (geographic) area for the purpose of sampling, collecting, and removing genetic or other resources. Benefit sharing refers to all forms of compensation for the use of genetic resources, whether monetary or non-monetary. This could also include participation in scientific research and development of genetic resources, and sharing the findings of any potential benefits resulting from this work.

Agreement

A negotiated and usually legally enforceable understanding between two or more legally competent parties. Although a binding contract can result from an agreement, an agreement typically documents the give-and-take of a negotiated settlement and a contract specifies the minimum acceptable standard of performance.

Annuity

Annual payment to keep a patent or patent application alive in countries where it has been filed.

Appeal

Asking a higher legal authority to review a decision.

Applicant

The entity filing the patent application. The patent applications are filed in the name of the actual inventors, who may then assign their rights to, for example, their employer. In India, the "assignee" and the "applicant" are the same.

Assignee

The person(s), agency or corporate body to whom all or limited rights under a patent are legally transferred. Assignee can be a natural person or other than natural person like registered company, research organization, educational institute or Government. Assignee also includes assignee of the assignee and the legal representative of a deceased assignee.

Assignor

A person who assigns the rights of a patent to assignee is called assignor.

Berne Convention

The Berne Convention is meant for the Protection of Literary and Artistic Works. It is an international agreement governing protection of copyright, which was first accepted in Berne, Switzerland, in 1886. It has been amended several times.

Biodiversity

Biological diversity – or biodiversity – is the term given to the variety of life forms on Earth. It is the variety within and between all species of plants, animals and micro-organisms and the ecosystems within which they live and interact.

Biomaterial / Biological Material

Any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

Biosimilar

A biosimilar product is a biological product showing that it is highly similar to an approved biological product, known as a reference product. It does not exhibit clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

Claim

Claims define the invention and legally enforceable matter in the application. The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as the true invention or discovery.

Co-inventor/ Joint Inventor

The invention generated not solely but with joint efforts with other inventor .More than one have inventor contributed to the conception of an invention.

Compulsory License

A license granted by the state upon request to a third party that, through the license, is permitted to exploit a patented invention after the owner of the patent has refused to provide a voluntary license under acceptable conditions.

Complete Specification

A complete specification describes the invention in toto and the best known method of carrying it out, and ends with one or more "claims" which define the scope of the invention. The application needs to disclose the full details of your invention and will be examined and may lead to the grant of a Patent.

Confidentiality Agreement

A legal document through which intellectual property or new knowledge can be disclosed by one party to another wherein the latter party is permitted to use the information/data for certain purposes, and only those purposes, that are stated in the agreement and agrees not to disclose the information to others.

Convention application

An application for a patent filed in respect of an invention, claiming a priority date based on the same or substantially similar application filed in one or more of the convention countries is called as convention application. A convention applicant should be filed within 12 months from the date of earliest priority application. It should be noted that a provisional specification cannot be filed in case of a Convention Application.

An application filed in accordance with an international treaty such as Patent Cooperation treaty (PCT). This application must be filed in any of the convention country within 12 month of priority date.

Convention of the International Union for the Protection of New Varieties of Plants (UPOV)

An international treaty that guarantees to plant breeders in member nations for national treatment and a right of priority. National plant variety protection statutes of member nations are brought into harmonization with the various UPOV provisions, for example, the requirements of distinctness, uniformity, stability, and novelty for new crop varieties.

Convention on Biological Diversity (CBD)

Articulated at the 1992 'Earth Summit', the Convention seeks to establish a comprehensive strategy for sustainable development, setting out commitments for maintaining the world's ecological underpinnings in light of increasing business and economic development.

Contracts

An agreement between two parties enforceable at law incorporating clauses defining the terms, objectives and other aspects of the agreement. Legally binding documents between parties to outline and enforce access and benefit sharing agreements as well as trade secrets. For example: Confidentiality/non-disclosure agreements, Exclusive licenses etc.

Copyright

Copyright is an exclusive right conferred by the government to protect works in creative fields such as arts, music, literature etc and excludes others from reproducing, adapting, distributing, performing it in public. etc..

Co-owner/ Joint Owner

Co-ownership, also called Joint ownership, refers to a situation in which two or more persons have proprietary shares of an asset: they co-own a property. Joint ownership of IP, in particular, frequently arises in collaborative projects when the results have been jointly generated by the partners and the share of work is not easily ascertainable. Joint ownership may arise with regard to all the forms of IP, that is to say patents, copyright, trademarks and even trade secrets.

Counterfeit

Unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods. It is commonly used in case of drugs, and referred to as spurious, fake or substandard drugs.

Cross Licensing

In patent law, cross-licensing is an agreement according to which two or more parties grant a license to each other for the exploitation of the subject-matter claimed in one or more of the patents each owns. Usually, this type of agreement happens between two parties in order to avoid litigation or to settle an infringement dispute.

Data Exclusivity

Data exclusivity basically refers to protection of clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications. It is the extension of exclusivity right especially for medicinal products after the expiry of the term of patent.

Data Sharing

Data sharing is the practice of making data used for scholarly research available to other investigators.

Dependent claims

Dependent claims have reference to the independent claim and are proper subsets of their parents claim(s).

Design Patent

In a design patent application, the subject matter which is claimed is the design embodied in or applied to an article of manufacture (or portion thereof) and not the article itself. In India there is no design patent, only design registration provision.

Differential Pricing

The practice of setting different prices for different markets segments, i.e., two tiered pricing strategy; higher prices in richer markets and lower prices in poorer markets.

Disclosure (of an invention)

An invention disclosure is a confidential document written by a scientist or engineer for use by an organization's IP cell, or by an external patent attorney, to determine whether patent protection should be sought for the described invention.

Dissemination

Dissemination means the disclosure of knowledge by any appropriate means other than publication resulting from the formalities for protecting knowledge.

Divisional Application

A divisional application is one which has been "dissociated" from an existing application. The applicant, at any time before the grant of a patent can file a further application called divisional application, if he so desires or if an objection is raised by the examiner on the ground that the claims disclosed in the complete specification relates to more than one invention.

Due Diligence

Investigations undertaken to assess the ownership and scope of one or more IP rights that are being sold, licensed or used as collateral in a transaction. This is done in order to identify business and legal risks associated with the IP rights being analyzed.

Equitable Benefit Sharing

It is primarily used by traditional knowledge stakeholders and serves to balance the interests of the IP right holders and the TK generators, i.e., the traditional knowledge holders must be appreciated with compensatory payments or other non- monetary benefits for using their traditional knowledge for commercial or public health purposes.

Examination [Patent]

Examination is a process of review of the patent application, undertaken by a patent examiner, to determine whether the application complies with all legal requirements for patentability set out in the appropriate legislation. The examination process reviews prior art to ensure novelty.

Exclusive License Agreement

A legal document for licensing the intellectual property to another party for their exclusive use. The concerned intellectual property cannot be licensed to any other party for any use.

Evergreening

Legal, business and technological strategies by which producers extend their patents over products that are about to expire, in order to retain royalties from them, by either taking out new patents or by buying out for longer periods of time than would normally be permissible under the law..

First Examination Report (FER)

FER is communicated to the applicant or his agent after examination of the application and requires the party to address specific queries to render patentability to the invention and respond in a fixed period of time.

First to File

A rule under which patent priority is determined. The rule gives priority to the party that first files a patent application for an invention, rather than to the party that is first to invent. The first to file system is followed by almost every nation in the world.

Final Office Action

Applicant of a patent is notified from time to time by the patent examiner. When examiner examines the application for the first time, the observations are communicated to the applicant vide First Examination Report (FER) or First official action, similarly the examiner may issue a Second Examination Report called Second official action. Usually after examining the response towards the examination reports examiner issues a Final office action vide which a patent is either granted or rejected. In case of rejection of a patent or a claim the applicant's reply is limited to an appeal only as further amendment is restricted.

Freedom to Operate (FTO)

The ability to undertake research and/or commercial development of a product without illegally infringing on someone else’s ownership rights or protected technology. This usually involves comprehensive of both granted patents and pending patent applications.

Geographical Indication

Indication which identifies a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

Industrial Property

Industrial property is a subset of intellectual property, referring to those types of intellectual property that have an industrial application. Specifically, it refers to patents, trademarks, designs, mask works, and plant breeders' rights.

Infringement

Infringement of an IPR includes making, using, or selling a patented product or process without permission, fabrication of designs, unauthorized use or imitation of a trademark, reproducing, adapting, distributing, performing in public, or displaying in public the copyrighted work of someone else. Infringements of industrial property are aimed to deceive, confuse, or mislead others.

Independent claim

Claims that do not have reference to any other claim. First claim of any application is usually an independent claim.

Industrial Design

An industrial design is a two- or three-dimensional design that increases the aesthetic value of a product used to produce a product, industrial commodity or handicraft.

Intellectual Property

Inventive and/or creative ideas and expressions of the human mind that may have commercial values and have been conferred legal protection of a property right. Intellectual property rights enable owners to restrict the access and usage of their property and to protect it from unauthorized use..

International Bureau

International bureau administers various conventions by WIPO and also international Patent applications may be filed directly with the International Bureau as Receiving Office, similar to a competent national or regional Office.

International Depository Authority (IDA)

An International Depository authority is in principle a culture collection facility, which is recognized by the World Intellectual Property Organization (WIPO) in accordance with the Budapest treaty for deposition of microbial strain, in case of patent filing based on a microbial inventions. WIPO has recognized 46 facilities as IDA in various countries. An applicant does not need to deposit the strain at all the depositories corresponding to the national phase of the PCT but deposition in only a single IDA is adequate.

International Patent Application

PCT is an international filing system for patents in which an applicant files in the receiving office in a country and gains an early priority date in all the designated countries without affecting the priority date. It is governed by World Intellectual Property Organization, and can be valid in upto 148 countries.

International Patent Classification (IPC)

The International Patent Classification system (IPC), established by the Strasbourg Agreement 1971, is a hierarchical system which uses language-independent symbols to classify patents and utility models according to the area of technology to which they relate.

International Search Report (ISR)

The International Search Report is published by the International Bureau for all PCT applications and it serves as a basis for any examination of the International application by the designated Offices.

Inventor

An individual or, if a joint invention, the individuals collectively who invented the subject matter of the invention. Inventor names are recorded for all patents.

Issue Date

Issue date is the date on which the patent becomes enforceable.

Know How

Information other than the protected information in a patent which enables a person to accomplish a particular task or to operate a particular device or process.

Lapse of patent

If the renewal/maintenance fee is not paid by the patent holder within prescribed time as mentioned in the Patent Act, patent gets lapsed i.e. ceases to exist. .

Layout-design

Layout-design means a layout of transistors, and other circuitry elements and wires connecting such elements and expressed in any manner in a semiconductor integrated circuit.

License

A written agreement granting permission to use an intellectual property right within a defined time, context, market line, or territory.

Licensee

The party obtaining rights under a license agreement.

Licensor

The party granting rights under a license agreement.

License fee

Licensing fees is a negotiated and fixed amount of money which is usually paid as a part of licensing agreement defining the terms and other aspects pertaining to licensing of an intellectual property.

Lisbon Agreement
The Lisbon agreement is an international agreement supervised by WIPO for the Protection of Appellations of Origin and their International registration, which entered into force on September 25, 1966.

Loss of Right (dubious)

When an originally filed patent application is abandoned, either intentionally or unintentionally or even though a patent is issued on an application, patent rights are lost to inventions that are disclosed in the patent but not claimed. (Need to discuss with Mam)

Madrid Agreement

An agreement administered by WIPO concerning international registration of Trademarks. It provides a centralized system for protecting a trademark in 98 members by registering the mark in one country.

Maintenance Fees

Fees for maintaining a patent in force. The fees typically have to be paid at definite intervals, depending on the jurisdiction, and significantly increase over time.

Material Transfer Agreement (MTA)

A contract between the owner of a tangible material and a party seeking the receipt of such material. The agreement covers the right to use the material with purpose to document the transfer and outline the objectives and terms of use, including identification of the research or assessment project, terms of confidentiality, publication, liability and others.

Method Claim

A claim which covers a way of doing something, usually expressed as a series of "steps". The method of manufacturing a particular drug or a vaccine can fall under method claim such as recombinant DNA technology.

Microbiological Process

The inventions which concern a microbiological process involving or performed upon or resulting in microbiological material or a product**.**

Micro-organism

Any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture.

National phase application

An international application made according to Patent Cooperation Treaty enters national phase, in the designated countries within 31 months from the international filing date. The designated countries then prosecute the applications in accordance with laws.

National Biodiversity Authority

The National Biodiversity Authority (NBA) is a statutory autonomous body under the Ministry of Environment and Forests, Government of India established in 2003 to implement the provisions under the National Biological Diversity Act, 2002, after India signed Convention on Biological Diversity (CBD) in 1992.

National treatment When a member country under Paris Convention treats a foreign applicant as it's own national while protecting an invention in the given country, it is termed as National treatment.

Non-disclosure agreement

An agreement to treat specific information confidentially.

Nonexclusive License

A license under which owner's rights (licensor) are granted to the other party (licensee) but not exclusively; the licensor reserves the right to give the same or similar rights to use the licensed materials to other parties.

Non-obviousness

One of three conditions for patentability which means that invention would not be obvious to someone with knowledge and experience in the technological field of the invention.

Novelty

One of three conditions for patentability which obligates an invention to be new and original. That is, the invention must never have been made in public in any way, anywhere, before the date on which the application for a patent is filed.

Obviousness

The condition of an invention whereby a person with ordinary skill in a field of technology can readily understand it from publicly available information (prior art).

Office Action

Once a patent application is filed, it will be assigned to an Examiner, who will examine it for scope of protection, format and wording, and do a search for prior art. The document which the Examiner provides to explain why the application is rejected/accepted is called an "Office Action"

Official Gazette

The Controller publish periodically an official journal which contains such information as may be required to be published by or under the provisions of the Act or any rule made thereunder.

Omnibus Claim

A claim which merely claims the invention without any detail, as "the widget as shown in the drawings" as described in the specification". These claims are, however, not permitted in India.

Opposition Proceeding

An opposition proceeding is an administrative process available under the patent and trademark law of many jurisdictions which allows third parties to formally challenge the validity of a pending patent application ("pre-grant opposition"), of a granted patent ("post-grant opposition"), or of a trademark.

Ordinary Application

A patent application filed for the first time without claiming priority from any other application such as conventional or PCT application is called an ordinary application.

Paris Convention

The main international treaty governing patents, trademarks, and unfair competition. It is administered by the World Intellectual Property Organization (WIPO) and has principal provisions for '*national treatment, level of protection, Convention priority, and administrative framework within the Paris Union'*.

Patent

A patent is a document that defines the legal right for inventors and assignees to make use of and exploit their inventions for a given period of time. .

Patentee

A person to whom a patent has been granted; who appears on the official government registry of patent owners or, if the patent monopoly has been sold or handed through an estate, to that assign.

Patent Agent

A person who has qualified the exam conducted by Patent Office and has got his name registered in the register of patent agent, shall be called a registered patent agent under the Act and will be authorized to prepare all the documents to apply and obtain the patents and practice before the Controller.

Patent Application

A technical document describing in detail an innovation for which a patent is sought.

Patent Assignee

The individual(s) or corporate body to whom all of limited rights of the patent are legally transferred.

Patent Attorney

Patent Attorneys are specialist legal advisors, often with legal qualifications , who advice their clients how to protect their intellectual property and are involved in drafting of patent specifications and corresponding filing, subsequent prosecution and correspondence with the patent office, representing the applicant's case at the hearings, filing opposition proceedings or defending an application against an opposition.

Patent of Addition

Patent of addition is an application made for a patent in respect of any improvement or modification of an invention described or disclosed in the complete specification for which a patent has already been granted or a patent application is filed. A patent of addition lapses with the cessation of the main patent.

Patent Co-operation Treaty (PCT)

The Patent Co-operation Treaty (PCT) is an international treaty that provides a mechanism through which an applicant can file a single application which when certain requirements have been fulfilled, may be pursued as a regular national filing in any of the PCT member nations. PCT has came into force on January 24, 1978.

Patent Database

Patent databases are the comprehensive archive of the patents. There are freely available databases from PCT, USPTO, EPO, etc. and paid databases such as Delphion, STN, Derwent etc. Patent databases, some of which are commercial, are useful to determine the novelty of the invention and are also a mean to assess the technological development and help in technology transfer, licensing and other business activities involving patents.

Patent number

A patent number is a unique identifier of a patent and is 6 digit number (e.g. 266115). Patent numbers are assigned to each patent document by the patent-issuing authority.

Patent of Procedure

A patent that covers a way of obtaining a product that may have previously been known, in contrast to a patent for a product.

Patent Pending

A "Patent Pending" notice on a product informs others that an application for a patent has been filed, and that legal protection may be forthcoming.

Patent Pooling

A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or to third parties. A patent pool allows interested parties to gather all the necessary tools to practice a certain technology.

Patent Searching

A process carried out by the patent examiner/attorneys for checking the novelty of a patent application. The subsequent patent research report lists published items comprising both patent and non patent literature relevant to the subject of the invention.

Patent specification

A description of the invention. This may be published several times, first as the applicant wrote it, then after a patent examiner has amended it, and then finally after any objections from third parties have been taken into account.

Patent-issuing authority

Any country or organization with the authority and the power to issue patents

Petition

A petition is a signed, written request presented to change something, most commonly made to a government official or public entity.

Petty Patent

Petty patents/ utility models confer patent-like protection to some products. These are usually not examined (or are examined only as to form, and not novelty), and have a shorter term than regular patents. In some systems, these must be examined before bringing suit against an infringer, in others they are examined in court during the suit.

Post grant opposition

An individual or an organization has right to Oppose the filing or grant of a patent on the grounds specified in the Indian Patent Act. Post-grant opposition can be filed within one year of the grant of the patent with a statement and evidence in support of the opposition. For details refer, chapter 3, Invention and patent.

Power of attorney

Authorization of patent agent or any other person

Pre grant opposition

Pre-grant opposition can be filed after the publication of patent application and before the grant of patent by any person with a statement and evidence in support of the opposition.

Preliminary Search

A search through intellectual property records before submitting an application for registration in order to verify whether a patent, trademark or industrial design has been previously applied for or registered. The search may disclose conflicting registrations, and show that the application process would be in vain.

Prior art

The disclosed information against which an invention is judged to determine if it is novel and non-obvious and justified for patenting.

Prior Informed Consent

The consent given by a party to an activity after being fully informed of all material facts relating to that activity. The Convention for Biological Diversity requires that access to genetic resources shall be subject to the Prior Informed Consent of the Country providing the resources.

Priority application

Under the right of the priority provision, an application may be filed in one or more contracting states or countries within 12 months of the first application. In this case the original application number becomes the priority application date.

Priority Date

A priority date is the date of first filing of patent application and is used to determine if the invention is new. If the invention is known to the public before this date, the patent applicant is not entitled to patent the invention.

Provisional Application

Redrafted: A provisional patent application precedes the complete application upon which the grant is based, and is filed to establish a priority date for disclosure of the details of an invention and allows a period of up to 12 months for development and refinement of the invention before the patent claims take their final form in a complete application.

Prosecution

The applicant's side of the examination process, convincing the examiner to issue a patent.

Process Claim

A claim of a patent that covers the method by which an invention is performed by defining the steps to be followed, in contrast to a product claim or an apparatus claim, which covers the structure of a product.

Product-By-Process Claim

In a patent claim a product is claimed by defining the process by which it is made. The product-by-process form of claim is most often used to define new chemical compounds, since many new chemicals, drugs, and pharmaceuticals can practicably be defined only by their process

Proof of right

If the patent application is made by the assignee, a proof of right must be submitted along with the application for patents which prescribes that the application is made by virtue of an assignment of the right to apply for a patent for an invention.

Provisional Rights

While patents are only enforceable after they issue, a patentee may ask for a reasonable royalty for activities of an infringer which occur between the publication of the application on which the patent was based and the date of issue, if the invention claimed in the published application and the issued patent are "substantially identical". The ability to ask for pre-issue damages is called "provisional rights".

Public Domain

The status of an invention, creative work, commercial symbol, or any other creation that is not protected by some form of intellectual property. Items that have been determined to be in the public domain are available for copying and use by anyone.

Publication of Patent

The publication of a patent application is different from the publication in learned society, in this the patent office published the applications after 18 months of filing of the patent application or from the date of priority (whichever is earlier) in the official gazette of the Indian Patent office for inspection by public and checking for objections.

Reference

A piece of prior art; an act or instance of referring or citation to some previously documented literature.

Rejection

In an Office Action, the Examiner may reject claims based on form (section 112, Indian Patents act), patentability of the subject matter (section 101, Indian Patents act), or as unpatentable in view of the prior art (sections 102 or 103, Indian Patents act).

Renewal Fee

After a patent has been granted, renewal fees must be paid for maintaining the patent in force. The renewal fees are due before the expiry of each succeeding year and in case of nonpayment of renewal fee within the prescribed time limit, the patent ceases to exist. .

Request for examination (RFE)

A request for examination (RFE) in form-18 is to be filed simultaneously with the patent filing or within 48 months from the date of filing or earliest priority date; in case the RFE is not filed the corresponding application will not be examined and will be deemed as withdrawn. A request for examination may be normal or express (fast track).

Research Tool

A method, utility, application or material which promotes and improves research are called research tools. For eg.: Browzine by NIH.

Restoration

A patent that is lapsed because of failure to pay the prescribed fees within the prescribed period can be restored by making an application for restoration by the patentee or his legal representative. The application for restoration of patent should be made within eighteen months from the date on which the patent lapsed.

Royalty

Payment by a licensee to the owner of a patent under the terms of a license. Royalties are usually either a percentage of the sales price of a product, or a fixed dollar amount per unit, and are usually paid on a periodic basis - monthly, quarterly or annually defined in the licensing agreement. .

Specification

The specification is a techno-legal document containing scientific information constituting patent rights. The specification, thus, forms a crucial part of the patent documents. It is mandatory on the part of the inventor to disclose clearly and completely various features constituting the invention. Under the patent law, the disclosure is in the form of provisional and complete specification.

Sublicense / Sublicensee

A license giving rights of production or marketing of products or services to a person or company that is not the primary holder of such rights. The holder of the sublicense is known as a sublicensee.

Sui generis Right

A system of protection for plant varieties. In India plant protection came into being for new plant varieties as Protection of Plant Varieties and Farmers' Rights (PPVFR) Act in 2001.

Technology transfer

Technology transfer is the formal transfer of rights to a party to use and commercialize new inventions and innovations resulting from scientific research. The major steps in this process include the disclosure of innovations, patenting the innovation concurrent with publication of scientific research and licensing the rights on innovations to industry for commercial development.

Technology transfer fee

Fees charged for the transfer of technology, i.e., transfer of rights to a party to use and commercialize new inventions and innovations resulting from scientific research.

Territorial jurisdiction

Patents are territorial in nature, i.e. if a patent is granted in India, then anyone in India is prohibited from making, using, selling or importing the patented item, while people in other countries may be free to exploit the patented invention in their country.

Trademark

Trademarks are marks, logos or patterns which identify one seller's goods, are used to advertise, promote, assist in selling goods and distinguish them from goods sold by others. They signify that all goods bearing the mark come from or are controlled by a single source and are of an equal level of quality..

Trade Secret

Business/technical information that is the subject of reasonable efforts to preserve confidentiality and has value because it is not generally known in the trade.

Traditional Knowledge

Traditional knowledge includes creations, innovations, literary, artistic or scientific works, performances and designs originating from or associated with a particular people or territory and communicated from generation to generation.

TKDL

Traditional Knowledge Digital Library (TKDL) is an Indian digital knowledge repository of the traditional knowledge, especially about medicinal plants and formulations used in Indian systems of medicine..

Trade Related Aspects of Intellectual Property Rights (TRIPS)

TRIPS is an international agreement administered by the World Trade Organization (WTO) that sets minimum standards for intellectual property regulation as applied to nationals of other WTO Members. It also introduced intellectual property law into the international trading system.

Unity of invention

The international application must relate to only one invention or to a group of inventions which are so linked as to form a single general inventive concept.

Utility

The usefulness of a patented invention. To be patentable, an invention must operate and be capable of use, and it must perform some "useful" function. It is also called industrial application.

Utility Patent

Issued for the invention of a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof and generally permits owner to exclude others from making, using, or selling the invention for a period of up to twenty years from the date of patent application filing, subject to the payment of maintenance fees.

Withdrawal of Application

The applicant may, at any time after filing the application but before the grant of a patent, withdraw the application by making a request in writing along with the appropriate form at the concerned patent office.

World Intellectual Property Organization (WIPO)

World Intellectual Property Organization is an international organization established by United Nations and is dedicated to promote use and protection of intellectual property and ensure that the rights of creators and owners of intellectual property are protected worldwide while they also get recognized and rewarded for their innovations and creations.

World Trade Organization

World Trade Organization (WTO) is an international organization which develops agreement, frameworks and various other processes to facilitate globalization, liberalization and expansion of international trade.

Written Opinion (from International Searching Authority)

For a PCT application, a written opinion is issued by International Searching Authority along with the international search report, to identify whether or not the claimed invention appears to be novel, non-obvious and industrially applicable, and briefly explains the issues rose on patentability, if any.