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. 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.

Q6. 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.

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.

Q7. 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.

Q8. 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.

Q9. 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.

Q10. 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)

Q11. 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.

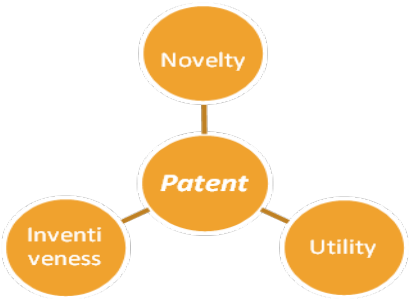
How is the right established?	Examination	Examination	Use in trade	Origination	Use in trade
What is needed to get protection?	Invention must be novel, useful, and not obvious to a skilled person. It must be disclosed in detail	Cosmetic appearance must be new and not obvious.	Know how must be well defined, not generally known, and must be safeguarded.	Concrete realization of the expression.	Mark must be distinctive rather than descriptive
How long does protection last?	Up to 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.

Q12. 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.

Q13. 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.



Q14. 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)

Q15. 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).

Q16. 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

Q17. 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.

Q18. 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.

Q19. 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.

Q20. 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.

Q21. 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 60year 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.

Q22. 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.

Q23. 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.

Q24. 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.

Q25. 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.

Q26. 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.

Q27. 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.

Q28.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.

Q29. 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.

Q30. 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.

Q31. 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.

Q32. 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.

Q33. 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”.

Q34. 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.

Q35. 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.

Q36. 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.

Q37. 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.

Q38. 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.

Q39. 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.

Q40. 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.

Q41. 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.

Q42.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)

Q43. 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.

Q44. 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.

Q45. 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.

Q46. 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.

Q47. 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.

Q48. 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.