Unit I

2 Marks

1. Expand – IP and IPR

Intellectual property and Intellectual property rights

2. Define – patent

A patent is a form of intellectual property that gives its owner the legal right to exclude others from making, using, selling and importing an invention for a limited period of years.

3. Define Trademark

A trademark is a type of intellectual property consisting of a recognizable sign, design, or expression which identifies products or services of a particular source from those of others.

4. Define Copyright

Copyright is the exclusive right given to the creator of a creative work to reproduce the work, usually for a limited time. The creative work may be in a literary, artistic, educational, or musical form.

5. Define Traditional knowledge

Traditional knowledge is a part of the identity of most indigenous communities. The knowledge systems that comprise traditional knowledge are an essential ingredient in achieving sustainable development.

6. Define Geographical indications

Geographical indication is a sign used on goods that have a specific geographical origin and it possess qualities or a reputation due to that place of origin.

5 Marks

1. Explain about – patent

- A patent is a form of intellectual property that gives its owner the legal right to exclude others from making, using, selling and importing an invention for a limited period of years.
- There are three types of patents: utility patents, design patents, and plant patents. Each type of patent has its own eligibility requirements.
- **Utility patent** – It covers processes, compositions of matter, machines, and manufactures that are new and useful. A utility patent can also be obtained for new and useful improvements to existing processes, compositions of matter, machines, and manufactures
- **Design patent**, - A design is defined as the "surface ornamentation" of an object, which can include the shape or configuration of an object.
- **Plant patent** – It can be obtained to protect new and distinctive plants.

2. Trademark and copyright

- **Trademark**
  - ✓ It's a type of intellectual property consisting of a recognizable sign, design, or expression which identifies products or services of a particular source from those of others.
  - ✓ That a company can register a trademark for its business name, slogans, logos and other items that essentially brand the product or company.
  - ✓ Registering a trademark first requires doing a trademark search to ensure it's not already in use. Because of the legal ramifications, most trademark experts recommend using an attorney to assist in trademark registration.
- **Copyright**
  - ✓ It protects original works created in a fixed form including "literary, dramatic, musical, artistic, and certain other intellectual works.
  - ✓ Example, a business can copyright its books, reports, audio or video materials.
  - ✓ Work is automatically copyrighted at the time of creation; however, registration is required if a business wants to sue over the use of the material by another party.
  - ✓ Copyright registration requires the filing of a form, paying a fee, and sending a copy of the work to the Copyright Office.

3. Traditional knowledge

- Traditional knowledge is a part of the identity of most indigenous communities.
- It is important to preserve the social and physical environment of which the traditional knowledge is an integral part.
- This form of protection focuses on the use of any indigenous knowledge as technical, ecological, scientific, medical or cultural by a traditional community.
- Protect and develop traditional knowledge and any such protective strategy needs to consider the community, national, regional and international dimensions.
- **Types -** Positive protection and Defensive protection

4. Geographical indications

- A geographical indication is a sign used on goods that have a specific geographical origin
- Possess qualities or a reputation due to that place of origin.
- It consists of the name of the place of origin of the goods.
- Agricultural products typically have qualities that derive from their place of production and are influenced by specific local geographical factors, such as climate and soil.
- WIPO administers a number of international agreements that deal partly or entirely with the protection of geographical indications.

5. Importance of IPR

- Provides incentive to the individual for new creations.
- Providing due recognition to the creators and inventors.
- Ensuring the material reward for intellectual property.
- Ensuring the availability of the original products.

- For economic growth and advancement in technology sector protection of Intellectual property protection is important.
- They are benefited for the growth of the business in the field of technology.

6. WIPO

WIPO is the global forum for intellectual property (IP) services, policy, information and cooperation and it was self-funding agency of the United Nations, with 192 member states. To lead the development of a balanced and effective international IP system that enables innovation and creativity for the benefit of all.

The WIPO main functions are:

- ✓ assisting campaigns development to improve IP protection all over the world and to harmonize national legislations in this field;
- ✓ signing international agreements on IP protection;
- ✓ applying the administrative functions of the Paris and Berne Unions;
- ✓ rendering technical and legal assistance in the field of IP;
- ✓ collecting and disseminating the information, conducting researches and publishing their results;
- ✓ ensuring the work of the services facilitating the international IP protection;

10 Marks

1. Patentable and non-patentable

- Patentable – the invention must be new and not known to public.
- Patentable - Plants, animals, newer compounds,etc.
- Non patentable – Invention which cannot be granted to patent under section 3 of Indian patent act 1970 are called non patentable.
- Section 3(A) – An invention is frivolous or that claims anything obviously contrary to well established natural laws (Ex: machine gives more than 100% performance)
- Section 3(F) – Rearrangement of duplication of known devices (Ex: An umbrella with fan)

2. Legal protection to biotechnological inventions

- Inventions in the field of biotechnology must meet patentability requirements in the same way as inventions in other technical areas.
- The invention must be new, involve an inventive step, and be industrially applicable (Article 52 EPC - European Parliament Council).
- In deciding whether a biotechnological invention is patentable, one must also consider the exception stated in Article 53(b) of the EPC.
- Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.
- Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety and if said plants or animals are not exclusively obtained by means of an essentially biological process.

- A microbiological or other technical process or a product obtained by means of such a process other than a plant or animal variety.

3. IP relevance to biotechnology with case studies

- Patent Protection - Inventions are majorly protected under patents and any new product or process can be patented. A patent helps in gaining that pivotal edge in the market.
- Revenue Generation - License is awarding of a body the permission to use your patent. This license can be awarded in exchange for royalty or any form of compensation

- Protection with no restriction - It is very important that protection to any form intellectual property has to be awarded and IPR no matter what provides that. In India, plants cannot be patented but a different IPR has been designed to protect it.
- Case studies - Biocon's early success was attributable to its enzyme manufacture. The company's big breakthrough came in the 1990s, when it invented a new fermentation technology to replace the conventional tray-based culture of microorganisms. Fermentation of enzymes is at the core of biotechnology and is a required process in the development of most biopharmaceutical products to make them suitable for human use.

Unit II

2 Marks

1. Expand PCT

Patent Cooperation Treaty is an international treaty with more than 145 Contracting States.

2. Define infringement

Violating an owner's exclusive rights to intangible assets such as musical, literary, or artistic work

3. Define litigation

It is the legal process that unfolds when someone who owns the patent for a particular invention enforces their right by suing another for manufacturing or selling the invention without permission.

5 Marks

1. Explain about – PCT filling procedure

Patent is a grant of exclusive rights to the owner , to exclude others from making, using, offering for sale, selling or importing patented invention.

- **Filling provisional application** - A provisional application is a temporary application which is filed when the invention is not finalized and is still under experimentation.
- **Publication** - Once the complete specification is filed patent office will publish the application Indian patent office within 18 months from priority date.
- **Pre grant opposition** - After publication invention is available to public so any person/ party interested can file request to controller and can oppose the patent
- **Examination** - Application is examined on request and can be made either by the applicant.
- **Response from the Applicant** - If objections are met, grant of patent is approved
- **Grant of patent**

2. Disclosure and non-disclosure for patent

- The disclosure will be in the form of a patent application that serve as a provisional patent application
- Steps in disclosure – formulate a strategy and plan, study prior inventions, outline claims, write the specifications, refine claims, pursue application and result
- Non-disclosure is a legal contract between two or more parties
- Elements in non-disclosure – never release the information, obligations of the receiving party

3. Financial assistance for patent

- Application for financial assistance (FA) for patenting must be submitted to NRDC on the requisite forms along with a non-refundable processing fee
- FA for patenting is given to Indian National only for protecting inventions i.e. a new product of process involving an inventive step and capable of industrial application.
- There is no bar to the number of cases for FA.
- Decision of the Corporation is final in this regard and no further correspondence will be entertained.

- FA for patenting is given normally to individuals working in Univertisities, Laboratories and R&D Institutes, Micro, Small and Medium Enterprises, etc.
- Financial assistance shall be granted only if your invention is new (novel), useful (industrially applicable).

4. Patent licensing agreement

A patent license agreement is a contract between a patent owner (licensor) and a licensee that defines the terms under which the licensee may make, sell, and use a patented invention.

- **Exclusive Patent License Agreement -** An exclusive patent license agreement affords a single licensee (business) the rights to manufacture and sell a government invention for any commercial application worldwide.
- **Partially-exclusive Patent License Agreement -** A partially-exclusive license allows multiple companies to obtain rights to manufacture and sell a government invention but only in certain, specified commercial applications or in certain, defined geographic locations.
- **Non-exclusive Patent License Agreement -** Non-exclusive licenses can allow any number of companies to obtain the same government technology and use it in many different products or commercial applications and make it for sale in many different geographic locations.

10 Marks

1. Patent infringement

Patent infringement occurs when another party makes, uses, or sells a patented item without the permission of the patent holder.

- **Direct Infringement**: This occurs when a product covered by a patent is manufactured without permission.
- **Indirect Infringement:** An indirect infringer may induce infringement by encouraging or aiding another in infringing a patent. It refers to the unfair practice that does not give a clear indication that the patent is bought and sold in the market
- **Contributory Infringement**: This occurs when a party supplies a direct infringer with a part that has no substantial non-infringing use.
- **Literal Infringement**: This exists if there is a direct correspondence between the words in the patent claims and the infringing device.

Remedies of Patent Infringement

- **Monetary Relief -** Compensatory damages and Increased damages
- **Equitable Relief** - Preliminary injunctions and
- **Cost & Attorney's Fees**

2. Litigation with case studies

- Patent holders must bring infringement actions within six years from the date of infringement, if the suit is not brought in this time limit.
- Patent litigation proceeds like any other federal cases.
- The complicated legal issues surrounding patent, validity of the patent and infringement are reserved for the court's determination.
- Although some patent litigation cases use juries for other aspects of the overall case.

Case studies

Diamond v. Chakrabarty, 447 U.S. 303 (1980), was a case of the United States Supreme Court which dealt with whether organisms that are genetically modified can be patented or not. Ananda Mohan Chakrabarty was a Genetic engineer who was working for General Electric. He had created a bacterium that was derived from the Pseudomonas genus –presently known as *Pseudomonas putida*. This bacterium was competent of breaking down crude oil, which he offered to use in the treatment of oil spills. His case was argued in SCOTUS on March 17, 1980, and was decided on June 16, 1980. The court decided in favor of Chakrabarty, affirming that "a live, human-made micro-organism" is a patentable.

Unit III

2 Marks

1. Expand – GATT, TRIP

GATT –The General Agreement on Tariffs and Trade
TRIPS – Trade Related Aspects of Intellectual Property

2. Define – bioethics, ethics, trade secret

5 Marks

1. Explain about –GATT agreement

- GATT provides an international forum, encouraged trade between member states and regulates tariffs.
- It reduce the barriers to international trade and divided into 3 phases
- India was one of the 23 founding contracting parties to GATT that was concluded in October 1947.
- After GATT agreement only, India is allowed to patent their drugs but the price of the patent was high.
- Mode of trade - cross border trade, consumption abroad, commercial presence, movement of natural persons.

2. TRIPS agreement

- Trade Related Aspects of Intellectual Property is an international agreement administered intellectual agreement by the world trade organization
- It's the new agreement adopted as part of the Urugary Round
- Design of Part I – Scope, adoption of existing intellectual property conventions, National treatment and most favored nation
- Design of Part II – Standards, Art 27 – patentable subject matter
- Design of Part III – Other use without authorization, Art 32 - revocation

3. Madrid agreement

- Registration of trademarks in multiple jurisdictions around the world is governed by two independent treaties – Madrid agreement and Madrid protocol
- To create a system, of simple and inexpensive international trademark registration
- In Madrid agreement – no need for basic registration, facility priority claim
- Covering many countries, taking less time consuming process

4. Hague agreement

- The Hague Agreement provides a mechanism for acquiring, maintaining and managing design rights in countries.
- Intergovernmental organizations that are members of the Hague Union through a single international application filed with the International Bureau of the World Intellectual Property Organization (WIPO)
- The results in a single international registration with individual effect in each of the Contracting Parties (States or intergovernmental organizations) designated therein.
- The Hague Agreement allows users to save time and money by enabling them to easily and swiftly acquire design protection in multiple markets, as a single international application
- The Hague Agreement is constituted by two international treaties:
    - ✓ The Geneva Act of July 2, 1999 (the "1999 Act")
    - ✓ The Hague Act of November 28, 1960 (the "1960 Act").

5. Budapest agreement

- International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or Budapest Treaty, is an international treaty signed in Budapest, Hungary, on April 28, 1977.
- The treaty allows "deposits of microorganisms at an international depositary authority to be recognized for the purposes of patent procedure.
- The range of materials able to be deposited under the Budapest Treaty includes:

    - ✓ cells, for example, bacteria, fungi, eukaryotic cell lines, plant spores;
    - ✓ genetic vectors (such as plasmids or bacteriophage vectors or viruses) containing a gene or DNA fragments;
    - ✓ Organism used for expression of a gene (making the protein from the DNA).
    - ✓ There are many types of expression systems: bacterial; yeast; viral; plant or animal cell cultures.

6. Indian Patent act 1970

- In India the grant of patent is governed by the patent Act 1970 and rules 1972.
- The patent office under the Ministry of commerce and industry. It has established to administer the various provisions of the patents law.
- Located in Kolkata, Mumbai, Delhi and Chennai
- Section 3(a) – inventions contrary to well established natural laws
- Section 3(b) – commercial exploitation or primary use of invention

10 Marks

1. Patent infringement

- Any person exercises the exclusive rights of the patent holder without permission within the country of patent grant.
- A person is liable for infringement if his product or process is same as the patented invention
- Types – direct and indirect infringement
- Direct infringement – It directly states that the third party has willfully stolen the technology from the inventor without his prior permission
- Types of Direct infringement – Literal and equivalence infringement
- Indirect infringement – not directly use the technology from the inventor
- Types of indirect infringement- Induced and contributory infringement

2. Patent enforcement

- Patent enforcement is a lawsuit filed by the patent holder against parties who have infringed upon their patent rights.
- Patent enforcement usually results in one of two legal remedies.
- The first is a monetary damages award, where the infringing party agrees to reimburse the patent holder for any economic losses caused by the infringement, as well as royalties.
- The second involves an injunction, which is basically an order requiring the defendant to cease their infringing activities.
- In many patent enforcement claims, a common defense is that the plaintiff's patent is actually invalid.
- If the patent is expired, or if the patent was never really obtained.
- Thus, patent infringement lawsuits may require extensive research with the U.S. Patent and Trademark Office (USPTO).

Unit IV

2 Marks

1. Define – bioethics

The study of the ethical and moral implications of new biological discoveries and biomedical advances, as in the fields of genetic engineering and drug research

2. Define cloning

The generation of a new animal that has the same nuclear DNA as a previously existing animal.

3. Define non-maleficence

Non-harming or inflicting the least harm possible to reach a beneficial outcome.

4. Define informed consent

Informed consent is one of the founding principles of research ethics. It contains full information the research going to take part, and that they give consent before they enter the research.

5 Marks

1. Bioethics in drug testing

- Patient abuse can be a significant problem in the workplace, contributing to impaired productivity and job performance, increased accidents and injuries, violations of security and theft of company property
- Patient abuse includes not only the ingestion of illegal Patients but also the misuse and abuse of prescription and non-prescription medications.
- This guidance is pertinent to drug testing done under the following circumstances: pre-placement assessment
    - ✓ job transfer evaluation
    - ✓ periodic mandatory medical surveillance
    - ✓ post-incident/accident
    - ✓ reasonable suspicion/cause
    - ✓ random testing of those in safety- and security-sensitive positions
    - ✓ special work-fitness examinations

2. Bioethics in human cloning

- In bioethics, the ethics of cloning refers to a variety of ethical positions regarding the practice and possibilities of cloning, especially human cloning.
- Human cloning are theoretical, as human therapeutic and reproductive cloning are not commercially used; animals are currently cloned in laboratories and in livestock production.
- The development of therapeutic cloning in order to generate tissues and whole organs to treat patients who otherwise cannot obtain transplants
- To avoid the need for immunosuppressive drugs, and to stave off the effects of aging.
- Reproductive cloning believe that parents who cannot otherwise procreate should have access to technology.
- Opponents have also raised concerns about how cloned individuals could integrate with families and with society at large

10 Marks

1. Bioethics in Informed consent

- Informed consent is one of the founding principles of research ethics.
- It contains full information the research going to take part, and that they give consent before they enter the research.
- Consent should be obtained before the participant enters the research (prospectively).
- There are two distinct stages to a standard consent process for competent adults:

  ✓ **Stage 1 (giving information):** the person reflects on the information given; they are under no pressure to respond to the researcher immediately.

  ✓ **Stage 2 (obtaining consent):** the researcher reiterates the terms of the research, often as separate bullet points or clauses; the person agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole. Consent has been obtained.

2. Bioethics in Medical

- Bioethics is the study of the ethical issues emerging from advances in biology and medicine.
- It is also moral discernment as it relates to medical policy and practice.
- Medical ethics is the study of moral values and judgments as they apply to medicine.
- The four main moral commitments are respect for autonomy, beneficence, non-maleficence, and justice
- **Autonomy -** The patient has the right to refuse or choose their treatment.
- **Beneficence** - Beneficence is a concept in research ethics which states that researchers should have the welfare of the research participant as a goal of any clinical trial
- **Non-maleficence** - non-harming or inflicting the least harm possible to reach a beneficial outcome.
- **Justice** - justice could be described as the moral obligation to act on the basis of fair adjudication between competing claims.

Unit V

2 Marks

1. Expand – GM and GMO

Genetically Modified and Genetically Modified Organism

2. Define GMO

It is an organism whose genetic material has been altered using genetic engineering techniques.

3. Define stem cells

A cell that have an ability to continuously divide and differentiate into various type of cells.

5 Marks

1. Biopiracy

- It can be defined as an unauthorized appropriation of genetic resources.
- Commercial exploitation of genetic resources in developing countries by others.
- It's an unfair, unethical and a threat to the existence of indigenous cultures
- Example : Neem, turmeric ad basmati rice
- In 1994 the multinational corporation W.R. Grace and the US Department of Agriculture was granted a patent by the EPO "covering a (special) method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil" that is diluted with a certain percentage of water.
- This patent was challenged by the Indian Council for Scientific and Industrial Research (CSIR) in 1996 on the ground of prior art.
- In the re-examination process the CSIR claimed "that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not novel".

2. Reproductive cloning

- The generation of a new animal that has the same nuclear DNA as a previously existing animal.
- Artificial Embryo Twinning: A blastomere is induced to split, forming identical twins.
- Nuclear Somatic Transfer: The nucleus of an adult body (somatic) cell is transferred into an egg which has had its nucleus removed.
- After treatment to make it begin dividing, the embryo is transplanted into a host uterus.
- Dolly was created using nuclear somatic transfer
- Extremely inefficient, most eggs do not develop into an organism

3. Therapeutic cloning

- Uses the process of nuclear somatic transfer to create an embryo.
- The embryo is destroyed and harvested for stem cells.
- Stem cells are undifferentiated and retain the ability to develop into many cell types depending on their potency.
- Totipotent cells can develop into any tissue in the human body, plus tissues needed for development such as placental cells.
- Pluripotent cells can develop into almost all cells, but cannot produce a new organism.

4. Ethical implications of cloning

- **Value** - when doing experimentation with cloning, we must first decide whether or not the conclusions will lead to some sort of improvement in health and well-being.
- **Scientific Validity** – there must be a clear objective for cloning. Cloning research must be based on proven scientific knowledge and methods.
- **Fair Subject Selection -** In choosing subjects to take part in cloning, there mustn't be any biases or discrimination.
- **Favorable risk-benefit ratio** – to minimize the risk and maximize the benefits of cloning.
- **Independent Review** – A board reviews the topics and ethical issues of cloning.
- **Consent –** When human cloning begins it will be relevant that the subject give consent to the experimentation.
- **Respect for Enrolled Subjects** – Those who take place in cloning research or processes must be guaranteed their human rights and be given the proper respect.

10 Marks

1. Legal and socioeconomic aspects of gene therapy

- Gene therapy involves making changes to the body's set of basic instructions, it raises many unique ethical concerns. The ethical questions surrounding gene therapy include:
- Should people be allowed to use gene therapy to enhance basic human traits such as height, intelligence, or athletic ability?
- Current gene therapy research has focused on treating individuals by targeting the therapy to body cells such as bone marrow or blood cells.
- This type of gene therapy cannot be passed to a person's children.
- Gene therapy could be targeted to egg and sperm cells (germ cells), however, which would allow the inserted gene to be passed to future generations. This approach is known as germline gene therapy.

- The idea of germline gene therapy is controversial. It could spare future generations in a family from having a particular genetic disorder, it might affect the development of a fetus in unexpected ways or have long-term side effects that are not yet known.
- Because people who would be affected by germline gene therapy are not yet born, they can't choose whether to have the treatment.

2. Ethical implications of human genome project

- Fairness in the use of genetic information
- Psychological impact – due to an individual genetic information
- Reproductive issues – includes adequate and informed consent and use of genetic information
- Clinical issues – include the education of doctors and other health service providers
- Health and environmental issue – concern genetically modified food and microbes
- Commercialization of products - including property rights and accessibility of data and materials