BCA DS 5sem
IPR Notes

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UNIT- 3

- Introduction to Patents: Overview, Historical Development, Concepts: Novelty, Utility.
- Patentable Subject-matter: Patent Act, 1970- Amendments of 1999,2000, 2002 and 2005
- Pharmaceutical Products and Process and Patent
- Protection, Software Patents, Business Method,
- Protection of Plant Varieties and Farmers' Rights Act, 2001
- Patenting Micro-organism.

TOPIC- Concept of Patent application specification & Provisional

This micro-course explores all concepts mentioned here, including how exclusive rights function in national and international contexts, the technical information needed in the application process, and how you can find and comprehend this technical information once it's disclosed.But what qualifies as a "product or process," and what is meant by "a new way of doing something" or "a new technical solution to a problem"? These ideas vary slightly internationally, but, in the U.S., this effectively includes:

- processes (intangible series of steps or acts to be performed to produce a given result);

- machines (tangible things, consisting of parts, that perform functions);
- manufactures (tangible things “given a new form, quality, property, or combination through man-made or artificial means”); and
- compositions of matter (tangible combinations of two or more substances, including gasses, fluids, solids, powders and extending to genetically modified microorganisms).

“Processes” also refers to innovative uses of existing inventions, which some patent experts consider an additional, distinct category. Taken individually or in combination with each other, these categories function as a general, but comprehensive, list of patent-protectable matter. Patent applicants do not need to specify a category, however, as overlap is expected.

Non-patentable innovations

- Inventions used specifically in the development of nuclear weapons;
- Human organisms;
- Mere ideas or suggestions (i.e., to be patentable, the patent application must include a full description of how an innovation would work); and
- Laws of nature, physical phenomena, and abstract ideas.

Specific Criteria Required for Patenting an Invention

- **usefulness (or “utility”),**
- **novelty, and**

- **non-obviousness.**

Usefulness

Usefulness is often the easiest criterion for patent applicants to satisfy. Basically, for an invention to be patentable, it needs to *work*. Patent examiners do not assess patent applications for level of helpfulness; inventors have successfully patented inventions as seemingly non-useful as a finger-mounted flyswatter

Novelty

The “novelty” and “non-obviousness” requirements both, hinge on the existence of “prior art.“Prior art” is one of the most important concepts in patent law. It refers to all publicly available information that anticipates, in part or full, the invention. What is considered “prior art” varies slightly based on country or region; however, “prior art” generally includes:

- Inventions disclosed in patents and patent applications internationally;
- Inventions disclosed in other types of publications (scholarly journals, conference proceedings, trade journals, newspaper articles, etc.); and
- Inventions currently for sale or in public use.

Patent examiners use all available prior art to determine an invention’s novelty. An invention’s novelty may manifest in its physical differences (such as the

addition, modification, or subtraction of a component), new combinations of existing parts, or new

Non-obviousness

“Non-obviousness” is the most challenging requirement to meet for many patent applicants. In short, the patent office may deem the invention obvious if a person with “ordinary skill” in the subject/discipline/field would conclude that the invention:

- combines prior art elements using known methods for predictable results;
- substitutes a known element or technique for predictable results; and/or
- is a minor variation on known work in one field used in a predictable way (in the same field or in another).

For instance, if you were trying to patent a small modification to a bicycle component, you might easily fulfill the novelty requirement by demonstrating that it is technically distinct from all similar components on the market, but unless you can credibly specify an unexpected difference this modification brings to a bike’s functionality, your patent application might be rejected for obviousness. Thus, successful patent applicants must demonstrate knowledge of prior art and also clearly explain an invention’s novelty and non-obviousness in relation to that prior art.

TOPIC - Pharmaceutical Products and Process and Patent

These discoveries led to the development of new life-saving medications, which must be secured by Intellectual Property Rights (IPRs). Patents grant pharmaceutical corporations exclusive rights to market pharmaceuticals and ban others from manufacturing, selling, or manufacturing these drugs for 20 years. IPR is required for pharmaceutical businesses to identify, plan, commercialize, and protect their inventions. It is also a crucial tool for safeguarding investment, time, and effort, as well as encouraging healthy competition, which promotes industrial progress and economic prosperity. IPRs also encourage pharmaceutical businesses to spend on research and development.

ROLE OF PATENT IN PHARMACEUTICAL

Patent Protection of Drugs

A patent protects a drug after it has been discovered or developed. It is possible to reverse engineer it and can safeguard the medicine through innovative approaches. However, the new manufacturing process used by that drug company is protected. A patent provides more protection than trade secret legislation. Because trade secrets law hasn't yet been published in India, a drug's only safeguard is patent protection.

Progressive Economic Growth

Intellectual Property Rights contribute to the country's economic progress. Giving the rights to the inventor allows him to benefit while investing in drug research and development to generate more drugs and develop those already discovered. That is both cost-effective and consumer-friendly. Research and results in a country help the economy thrive while making the market more competitive.

Consumer Protection

The primary issue is public safety, and Intellectual Property Rights (IPR) helps to protect the public's interests. When a patent is granted, the safety and quality of a product are guaranteed, setting the consumer's mind at ease. It assists the consumer in making the best decision. Also, in the Indian market, where the product and the process are not protected, the companies compete and contribute to decreasing the product's price, which benefits the consumer base overall.

Safeguard against potential infringement

The pharmaceutical industry is taking severe action against fraudulent pharmaceuticals, thanks to intellectual property rights. These rights assist governments all around the world in ensuring the safety of their medical discoveries. Potential infringers who manufacture counterfeit medications are prosecuted for engaging in fraudulent activity against customers for profit, which the authorities forbid.

How does Intellectual Property Rights(IPR) protect the pharmaceutical industry

There are numerous ways in which Intellectual property protects the Pharma Industry as listed down below:

- It provides fair and effective incentives for innovative processes.
- It helps to protect any company against potential infringement.
- It provides a strong enforcement mechanism for defending infringement in the case of patented drugs.

Patent law in the Indian pharmaceutical industry

The law that regulates patents in India is given under the Patent Act, 1970. India is a signatory to both the Paris Convention of 1883 and the Patent Cooperation Treaty (PCT) of 1970. The Patents Act details out the prerequisites of a patent which are necessary to be satisfied for it to be granted protection:

- It should be new
- It should not be obvious
- It should be useful which can be the subject matter of a patent.

There are some non-patentable inventions under the Act which includes:

- Methods of agriculture or horticulture
- Processes for the medicinal,
- Processes of surgical, curative, or prophylactic

Or other treatment of human beings, animals or plants or substances which are just due to mere admixture which results in the aggregation of the properties of the components With regard to pharmaceuticals in India, the substances which are intended to be used or capable of being used as food compounds, drugs compounds, or even medicines or products which are produced by way of chemical processes and such processes are granted protection. Patents are granted for the processes or methods of manufacture of such products of chemical processes and not the whole compound product itself. Hence, pharmaceutical "products" are currently not given patent protection under Indian patent law due to the reasons mentioned below:

- Heavy dependence on the importing system.
- Bulk importing is costly and gives a more advantageous position to profit-making companies.
- Local brands are not encouraged to make these products as branded drugs have a better standing in the market.
- If the products are given protection, the costs will inflate.
- Cost inflation will reduce the affordability, and the consumer base will be disease-prone, and only higher economic strata consumers will be able to afford it.

- Research and Development of the local brands will suffer in the country.

Earlier, the product patent was protected under the Patents and Designs Act, 1911. However, in the year 1970, the government introduced the new Patents Act, which excluded pharmaceuticals and agrochemical products from getting patent protection. They were excluded only to break away India's dependence on the importing system of drugs and making a self-reliant drug discovery system that helps the economy from within and not creating a monopoly market by a profit-making company only.

Importance of Intellectual Property Rights in Pharmaceutical Company

Protection of invention

If there has been a discovery or development of a drug, a patent helps in the protection of the drug. It can be reverse engineered, and the drug can be protected by inventive methods. But the novel process by which that drug company manufactures that particular drug is protected. A patent gives better protection than trade secrets law. In India, trade secrets law is not codified, so the only protection drug has is patent protection.

Incremental economic growth and competitiveness amongst the Companies

Intellectual Property Rights help fund the growth of the economy of the country. Awarding the rights to the inventor helps him gain profits as well as invest that in the research and development of drugs to create more drugs and develop the already discovered ones. That is not only cost-effective but also consumer-friendly. Research and development in a country help the economy to grow and on the other hand, the market also becomes competitive.

Protects consumers and families

Public safety is the main concern and IPR helps to safeguard the interest of the people. While granting protection of a patent the safety of a product and the quality is assured which puts the mind of the consumer at ease. It helps the consumer to make the right choice. Also in Indian market where the product is not granted protection and the process is, the Companies compete and help to reduce the price of the product which helps the customer base at large.

Protection against the potential infringement of the drug discovery and development

Intellectual property rights allow pharmaceutical companies to take strict actions against fake drugs. These rights help countries across the globe to ensure safety in their medical inventions. The potential infringers who make counterfeit drugs are penalized for fraudulent behavior towards the consumers for the sake of creating profit only which the authorities prohibit.

Future of the Indian pharmaceutical industry and patent laws

The absence of product patent protection for pharmaceuticals and agrochemicals has led many multinationals to limit their portfolios of drugs that have expired or only a few exist. This has resulted in an erosion of their market share because local manufacturers have introduced the most advanced medicines through reverse engineering methods.

Topic - Patenting a Microorganism in IPR

Intellectual property consists of protection for various innovations and creations that have commercial application for the creator of the innovation. Intellectual property has helped various creators and various innovators to safeguard their invention and allow them to exercise their exclusive right to exploit their invention

for their own gains and control over their invention to do whatsoever the inventor or the creator wishes to do with his invention. Intellectual property consists of safeguarding rights for patents, trademarks, copyrights, designs, geographical indications along with protection for semiconductors and integrated circuits, plant varieties as well.

Indian Patents Act, 1970 initially did not comprise patentability for the microorganisms and thus they were not granted protection but the microorganisms were granted protection after the amendments were made in the Patents Act, 1970 by the Patents (Amendment) Act of 2002. It was inculcated in the patentability criteria and it complied with the TRIPS Agreement. Section 3(j) of the Patents Act, 1970 mentions 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' which states that the microorganisms can also be patented.

History of patenting of Microorganisms

In India the protection for the microorganisms was added in the Patents Act, 1970 after the landmark judgment of the Calcutta High Court case of Dimminaco A.G. v. Controller of Patents and Designs. In this case, the appeal was filed against the Assistant Controller of the Patents and Designs where the process of preparation of infectious Bursitis Vaccine was refused on the grounds that the live virus used in the process of preparation of vaccine cannot be considered as manufactured and cannot be treated as a substance or an inanimate object. The Calcutta High Court reversed the order and started that the process of preparing a vendible commodity which contains a live substance is not excluded from the purview of the word 'manufacture'. The product created was novel, non-obvious and was capable of industrial application thus making it an invention.

Case - Study Diamond v. Chakraborty in 1980 (land mark case)

Process for Patenting a Microorganism

Section 3(j) of the Patents Act, 1970 allows the microorganisms to be patented. The Patent application may be made for Indian patent as well as international patent. Following are the steps in order to patent a microorganism:

1. Applicant needs to fill out the necessary Forms that are mentioned in the second schedule of Patents Rules, 2003 and pay the prescribed fees. Also the applicant has to prepare the specifications that contain the detailed information of the patentable microorganism/s.
2. Request for the examination of the patent should be made by the applicant or the assigned person by the applicant. After that, the patent is published in the journal which is then available to the public for opposition if anyone is interested in. If anyone opposes the grant of the patent then the applicant has to respond to the patent office within the stipulated time.
3. Once the Examination is done by the controller of the patents, the examination report is produced by him. If there are objections made by the controller regarding the patent application then the applicant needs to file a response to that application within six months from the date of that examination report.
4. Once the objections are resolved by the applicant, then the patent is granted to the applicant by the patent office.

TOPIC - Patentable Subject-matter: Patent Act, 1970- Amendments of 1999,2000, 2002 and 2005

Patents Act in India – Overview

What is a patent?

A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.

- The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted.
- The Patents Act, 1970 is the legislation that till date governs patents in India. It first came into force in 1972.
- The Office of the Controller General of Patents, Designs and Trade Marks or CGPDTM is the body responsible for the Indian Patent Act.
- The Patent Office has its headquarters in Calcutta and has branches in New Delhi, Chennai and Mumbai. The office of the CGPDTM is based in Mumbai. Nagpur hosts the office of the Patent Information System and also the National Institute for Intellectual Property Management.
- The Controller General supervises the Act's administration and also offers advice to the government on related matters.
- The Patents Act has been repeatedly amended in 1999, 2002, 2005, 2006 respectively. These amendments were required to make the Patents Act TRIPS compliant. TRIPS stands for Trade-Related Aspects of Intellectual Property Rights.
- The major amendment in the Patent Act was in 2005, when product patents were extended to all fields of technology like food, drugs, chemicals and microorganisms. The Rules under Patent Act were also amended in 2012, 2013, 2014.

Patent Law Amendment Act 2005

Salient features of the Patents (Amendment) Act 2005 related to product patents:

1. Extension of product patent protection to products in sectors of drugs, foods and chemical.
2. Term for protection of product patent shall be for 20 years.
3. Introduction of a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity; provided such importing country has either granted a compulsory license for import or by notification or otherwise allowed importation of the patented pharmaceutical products from India (in accordance with the Doha Declaration on TRIPS and Public Health)
4. Section 3 (d) regarding patentability.

Effects of Patent Amendment Act 2005

1. Due to the new patent regime, increased prices of products was considered to be a major hindrance during the time. However, the government has taken proactive measures to ensure low prices for essential drugs, and has used compulsory licensing as a tool to keep exorbitant prices under check.
2. The amendment intended to make Indian drug and pharmaceutical industries competitive at par with multinational companies.
3. Despite initial reservations, Indian pharmaceutical companies manufacturing generic drugs have flourished in the last decade.
4. Also, MNCs have opened Research and Development Centres in India.

TOPIC - Protection of Intellectual Property Rights in Software Patents and Business Methods

Introduction

Intellectual Property Rights (IPR) play a crucial role in fostering innovation, especially in the rapidly evolving fields of software and business methods. As technology advances, the protection of intellectual property in these areas has become increasingly complex and contentious.

Software Patents

1. **Definition**: Software patents protect specific algorithms, processes, or methods that are implemented through software. These patents grant the holder exclusive rights to use, produce, and sell the patented software solution.
2. **Importance**: The protection of software through patents incentivizes innovation by ensuring that developers can monetize their inventions without the fear of unauthorized use by competitors. This is particularly critical in the tech industry, where R&D investments are substantial.
3. **Challenges**:
    - **Patent Eligibility**: The eligibility of software for patent protection varies significantly by jurisdiction. In the U.S., the Supreme Court's decision in *Alice Corp. v. CLS Bank International* (2014) established a stricter standard for what constitutes a patentable invention, leading to increased uncertainty and a decline in software patent filings.
    - **Prior Art and Obviousness**: Determining what constitutes "prior art" in software can be challenging, given the rapid pace of technological development. Additionally, many software inventions may be deemed obvious, making them ineligible for patent protection.

Business Method Patents

1. **Definition**: Business method patents protect methods of conducting business, including innovative ways of providing services or conducting transactions. These can involve software, but they also encompass broader operational processes.
2. **Importance**: Like software patents, business method patents aim to encourage innovation by providing businesses with exclusive rights to their methods. This can lead to improved efficiencies and competitive advantages in the marketplace.

3. **Challenges**:
    - **Controversy and Debate**: The validity of business method patents has been a subject of significant debate. Critics argue that many such patents are overly broad or abstract, stifling competition and innovation rather than promoting it.
    - **Legal Precedents**: Similar to software patents, business method patents have been impacted by legal decisions that scrutinize their validity. The *Bilski v. Kappos* case (2010) questioned the patentability of business methods, leading to a more rigorous evaluation of such patents.

Topic - Protection of Plant Varieties and Farmers Rights:

- It is a law under the Protection of Plant Varieties and Farmers Rights (PPV&FR) Act, 2001.
- It recognizes the contributions of both commercial plant breeders and farmers in plant breeding activity.
- It also aims to implement TRIPs agreement to support the specific socio-economic interests of all the stakeholders including private, public sectors and research institutions, as well as resource-constrained farmers.

What are the rights available under the PPV&FR Act, 2001?

- **Breeders Rights:** They will have exclusive rights to produce, sell, market, distribute, import or export the protected variety.
    - They can appoint an agent/ licensee and may exercise for civil remedy in case of infringement of rights.
- **Researchers Rights:** A researcher can use any of the registered varieties under the Act for conducting an experiment or research.

    - This includes the use of a variety as an initial source of variety for the purpose of developing another variety but repeated use needs the prior permission of the registered breeder.
- **Farmers Rights:** A farmer who has evolved or developed a new variety is entitled to registration and protection in like manner as a breeder of a variety.
- Farmer's variety can also be registered as an extant variety;
- Farmers are eligible for recognition and rewards for the conservation of Plant Genetic Resources of land races and wild relatives of economic plants;
- They can save, use, sow, re-sow, exchange, share or sell their farm produce which includes seed protected under the PPV&FR Act, 2001;
- They can get compensation for non-performance of variety under Section 39 (2) of the Act, 2001;
- They are not liable to pay any fee in any proceeding before the Authority or Registrar or the Tribunal or the High Court under the Act.

Objective of the new notification:

- It has been made to protect the rights of Kerala farming communities over the traditional plant varieties.
- Any person/group or any governmental/non-governmental organization can claim compensation on behalf of those communities.

Drawbacks:

- Detrimental to the culture of freedom in innovation and research.
- Private investments take a back seat if not incentivised.
- Big foreign players get away from investing.
- Inhibits transfer of cutting edge technological know-hows.