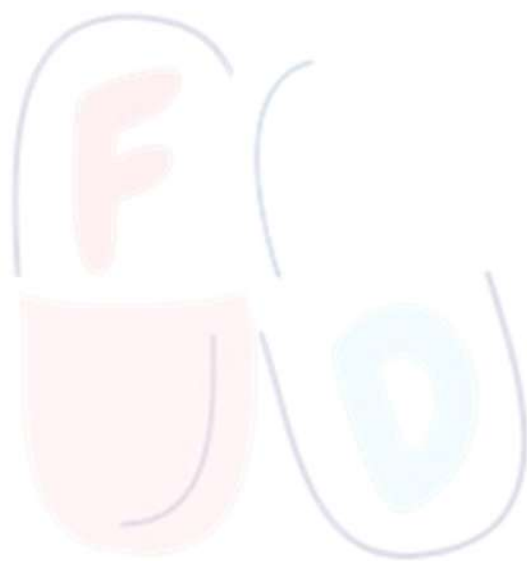


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HERBAL DRUG TECHNOLOGY

UNIT 4

TOPIC :

- **Patenting and Regulatory requirements of natural products :**
 - a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
 - b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma &Neem.

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Patenting and Regulatory Requirements of Natural

→ Natural products obtained from plants, animals, and microorganisms are widely used in medicine, cosmetics, nutraceuticals, and pharmaceuticals. Protection of these discoveries and inventions is important through patents and Intellectual Property Rights (IPR).

→ Patenting helps:

- Protect inventions
- Encourage research
- Prevent unauthorized use
- Promote innovation in herbal and pharmaceutical industries

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1. Patent

→ A patent is a legal right granted by the government to an inventor for a new invention or process for a limited period, giving exclusive rights to make, use, and sell the invention.

Duration

Generally:

- 20 years from the filing date

Conditions for Patentability

An invention must be:

1. Novel (new)
2. Useful
3. Non-obvious
4. Industrially applicable

Types of Patents

Type	Description
Product Patent	Protection for a product
Process Patent	Protection for manufacturing process
Design Patent	Protection for design or appearance

Importance of Patents

- Protects inventors
- Encourages innovation
- Prevents copying
- Provides commercial benefits
- Supports pharmaceutical research

Examples in Natural Products

- Herbal formulations
- Extraction techniques
- Novel drug delivery systems
- Plant-derived medicines

2. Intellectual Property Rights (IPR)

- Intellectual Property Rights are legal rights given to creators and inventors to protect their intellectual creations and inventions.
- These rights allow the owner to control the use of their invention or creation.

Types of IPR

Type	Description
Patent	Protects inventions
Trademark	Protects brand names and logos
Copyright	Protects literary and artistic works
Trade Secret	Protects confidential information
Geographical Indication	Protects region-specific products

Objectives of IPR

1. Encourage creativity and innovation
2. Protect inventions
3. Promote research and development
4. Prevent unauthorized use
5. Support economic growth

Importance in Herbal Industry

- Protection of herbal formulations
- Protection of traditional knowledge
- Commercialization of medicinal plants
- Promotion of research

3. Farmers' Rights

→ Farmers' rights are the rights given to farmers to:

- Save
- Use
- Exchange
- Sell farm-saved seeds and planting material

→ These rights also recognize the contribution of farmers in conserving plant genetic resources.

Features of Farmers' Rights

1. Right to save seeds
2. Right to use and exchange seeds
3. Recognition for traditional knowledge
4. Benefit sharing from plant resources
5. Protection against exploitation

Importance

- Protects traditional farming practices
- Supports biodiversity conservation
- Encourages cultivation of medicinal plants
- Prevents exploitation by companies

4. Breeders' Rights

→ Breeders' rights are legal rights granted to plant breeders for developing new plant varieties.

→ These rights allow breeders exclusive control over:

- Production
- Sale
- Marketing
- Distribution of new varieties

Requirements for Protection

The new plant variety should be:

1. Novel
2. Distinct
3. Uniform
4. Stable

This is called the DUS criteria:

- Distinctness
- Uniformity
- Stability

Importance

- Encourages plant breeding research
- Development of improved medicinal plants
- Better crop quality and yield
- Commercial protection for breeders

5. Bioprospecting

→ Bioprospecting is the systematic search for useful biological resources and traditional knowledge for commercial and scientific purposes.

→ It involves exploring:

- Plants
- Animals
- Microorganisms
for useful compounds.

Objectives

1. Discovery of new drugs
2. Development of herbal medicines
3. Identification of useful genes and compounds
4. Commercial use of biodiversity

Examples

- Search for anticancer compounds from plants
- Discovery of antibiotics from microorganisms
- Medicinal plant research

Advantages

- Drug discovery
- Economic development
- Conservation awareness
- Scientific advancement

Disadvantages

- Risk of exploitation
- Misuse of traditional knowledge
- Biodiversity loss

6. Biopiracy

→ Biopiracy is the unauthorized use or exploitation of biological resources and traditional knowledge without permission or compensation to local communities or countries.

Features of Biopiracy

- Illegal patenting
- Exploitation of indigenous knowledge
- No benefit sharing
- Commercial misuse of natural resources

Examples of Biopiracy

Example	Description
Neem Patent Case	Patent on neem properties challenged by India
Turmeric Patent Case	Patent on wound healing property cancelled
Basmati Rice Case	Patent dispute over basmati rice varieties

Effects of Biopiracy

- Economic loss to local communities
- Exploitation of traditional knowledge
- Loss of biodiversity rights
- Ethical and legal issues

Patenting Aspects of Traditional Knowledge and Natural Products

- Traditional knowledge (TK) refers to the knowledge, skills, and practices developed by indigenous and local communities over generations. Natural products and herbal medicines are important parts of traditional knowledge.
- Patenting of natural products has become a major issue because many companies try to obtain patents on traditional medicinal uses already known in countries like India.
- Important concerns:
 - Protection of traditional knowledge
 - Prevention of biopiracy
 - Benefit sharing
 - Conservation of biodiversity

Traditional Knowledge (TK)

- Traditional knowledge is the knowledge, innovations, and practices developed by local and indigenous communities through experience and passed from generation to generation.

Examples

- Ayurvedic medicine
- Use of turmeric for wound healing
- Use of neem as pesticide and antiseptic
- Herbal remedies used in folk medicine

Natural Products

Natural products are chemical substances obtained from natural sources such as:

- Plants
- Animals
- Microorganisms
- Marine organisms

They are widely used in:

- Pharmaceuticals
- Cosmetics
- Nutraceuticals
- Traditional medicine

Patenting Aspects of Traditional Knowledge and Natural Products

General Principles

Natural products and traditional knowledge can only be patented if:

1. They are novel
2. They involve inventive step
3. They are industrially useful

Traditional uses already known to the public cannot be patented because they lack novelty.

Problems in Patenting Traditional Knowledge

1. Lack of Documentation

Traditional knowledge is often:

- Oral
- Undocumented
- Community based

This makes it vulnerable to misuse.

2. Biopiracy

Foreign companies may:

- Patent traditional remedies
- Claim ownership over existing knowledge
- Exploit biological resources

3. Benefit Sharing Issues

Local communities may not receive:

- Recognition
- Financial benefits
- Royalties

4. Ethical Concerns

Patenting community knowledge raises:

- Moral issues
- Cultural concerns
- Ownership disputes

Protection of Traditional Knowledge

Methods of Protection

1. Documentation

Recording traditional knowledge in databases.

Example:

Traditional Knowledge Digital Library (TKDL) in India.

2. Patent Laws

Prevent granting patents for already known uses.

3. Biodiversity Laws

Protect biological resources and indigenous rights.

4. Benefit Sharing

Ensures local communities receive benefits from commercialization.

Traditional Knowledge Digital Library (TKDL)

→ TKDL is a digital database developed by India to document traditional medicinal knowledge.

Objectives

1. Prevent biopiracy
2. Protect Ayurvedic knowledge
3. Help patent examiners verify prior art

Importance

- International patent offices use TKDL
- Protects Indian traditional medicine
- Prevents misuse of herbal knowledge

Case Study 1: Curcuma (Turmeric) Patent Case

→ Turmeric is obtained from rhizomes of *Curcuma longa*.

Uses:

- Wound healing
- Anti-inflammatory
- Antiseptic
- Cosmetic uses

Turmeric has been used in India for centuries in Ayurveda.

Turmeric Patent Dispute

Patent Granted

→ In 1995, the United States Patent and Trademark Office granted a patent to the University of Mississippi Medical Center for the wound healing property of turmeric.

Problem

India argued that:

- Turmeric use for wound healing was already known in traditional medicine.
- The claim lacked novelty.

This was considered a case of biopiracy.

Challenge by India

The Council of Scientific and Industrial Research challenged the patent by submitting evidence from:

- Ancient Ayurvedic texts
- Sanskrit literature
- Traditional medicinal practices

Result

The patent was cancelled in 1997 because:

- The claimed use was not new.
- Traditional knowledge existed prior to the patent.

Importance of Turmeric Case

1. Major victory against biopiracy
2. Highlighted importance of traditional knowledge protection
3. Led to development of TKDL
4. Increased awareness about IPR issues

Case Study 2: Neem Patent Case

→ Neem is obtained from *Azadirachta indica*.

Uses:

- Antibacterial
- Antifungal
- Insecticidal
- Skin disorders
- Agricultural pesticide
- Neem has been traditionally used in India for centuries.

Neem Patent Dispute

Patent Granted

→ The European Patent Office granted a patent to the W. R. Grace and Company and the United States Department of Agriculture for a neem-based fungicidal product.

Problem

Indian activists and scientists argued that:

- Neem's pesticidal properties were already known in India.
- The patent lacked originality.

This was another example of biopiracy.

Opposition

The patent was challenged by:

- Indian scientists
- Environmental groups
- International activists

Evidence from traditional agricultural practices was submitted.

Result

In 2000, the patent was revoked by the European Patent Office because:

- The invention lacked novelty.
- Traditional use of neem was already known.

Importance of Neem Case

1. Protection of traditional agricultural knowledge
2. International recognition of indigenous knowledge
3. Strengthened opposition to biopiracy
4. Encouraged biodiversity protection laws