BP601T · B.Pharm Semester VI · Theory Notes

Advanced Pharmacognosy

Unit V — Patenting of Natural Products

Unit V (6 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit V (6 hours).

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CHAPTER 4: Patenting of Natural Products and Protection of Traditional Knowledge

4.1 Learning Objectives

After studying this chapter, you will be able to:

1 Define patent, IPR, farmers' rights, breeders' rights, bioprospecting, and biopiracy — and distinguish each pair.

2 Explain why patenting natural products is legally challenging.

3 Describe the role of TKDL in protecting Indian traditional knowledge.

4 Explain the role of the National Biodiversity Authority and the Nagoya Protocol.

5 Narrate the turmeric and neem case studies and their outcomes.

4.2 Definitions

- **Patent:** A legal right granted by the government giving the inventor exclusive rights to make, use, and sell an invention for a limited period (generally 20 years). In return, the inventor discloses the invention publicly.
- **Intellectual Property Rights (IPR):** The umbrella term for legal rights over creations of the mind — patents, trademarks, copyrights, designs, geographical indications, plant variety rights.
- **Farmers' Rights:** Rights of farmers (under India's Protection of Plant Varieties and Farmers' Rights Act, 2001) to save, sow, resow, exchange, and sell seeds, and to be recognized/rewarded for conserving plant varieties.
- **Breeders' Rights:** Rights of plant breeders over new plant varieties they develop (others cannot commercially exploit the variety without permission).
- **Bioprospecting:** Searching biodiversity (plants, microbes) for commercially valuable compounds — legal when done with permission and benefit-sharing.
- **Biopiracy:** Taking biological resources or traditional knowledge WITHOUT permission and WITHOUT sharing benefits — and often patenting it as one's "own invention."

4.3 Terminology Box

Term	Simple Meaning
Prior art	Knowledge already existing before a patent claim — if it exists, the "invention" is not new
Novelty	The invention must be NEW — not known before anywhere in the world
Inventive step	The invention must not be obvious to a skilled person
TKDL	Traditional Knowledge Digital Library — India's digitized database of traditional medicine

Term	Simple Meaning
NBA	National Biodiversity Authority — India's body regulating access to biological resources
Nagoya Protocol	International agreement (2010, under the Convention on Biological Diversity) on access and benefit-sharing (ABS)

4.4 Patent vs IPR vs Other Rights — Distinctions

	Patent	IPR (umbrella)	Farmers' Rights	Breeders' Rights
What	One type of right (for inventions)	The whole family of rights	Farmers' seed rights	Rights over new plant varieties
Granted to	Inventor	Creators/owners	Farmers, farming communities	Plant breeder
Example	A new extraction process	Patent + trademark + copyright together	Saving and exchanging seeds of a landrace	A new high-yield rice variety

Bioprospecting vs Biopiracy:

	Bioprospecting	Biopiracy
Permission	Taken from the country/community	Not taken
Benefit-sharing	Agreed and paid	None
Legality	Legal and encouraged	Illegal/unethical
Example	A company signs an ABS agreement with NBA, shares royalties	Patenting turmeric's wound-healing use without acknowledging Indian knowledge

Simple explanation: Bioprospecting is like taking mangoes from a farmer's orchard after asking and paying. Biopiracy is climbing over the wall at night, taking the mangoes, and then claiming you invented the mango.

4.5 Why Is Patenting Natural Products Challenging?

Technical concept: Patent law requires novelty, inventive step, and industrial application. A plant or its traditional use, known for centuries, fails the novelty test. You cannot patent a product of nature "as it exists in nature."

Simple explanation: You cannot patent the sun for giving light — it was already there. Similarly, you cannot patent turmeric powder for healing wounds if Indian grandmothers have done it for 2,000 years. But you CAN patent a NEW process to extract curcumin, or a NEW formulation nobody made before.

What CAN be patented (generally):

- A new extraction or purification process.
- A new semi-synthetic derivative (new chemical entity).
- A new formulation or combination with unexpected effect.
- A new medical use discovered through genuine research (in some jurisdictions).

What CANNOT be patented:

- The plant itself as found in nature.

- A traditional use already documented (it is "prior art").

Key takeaway: Patent offices ask three questions — Is it new? Is it non-obvious? Is it useful? Traditional knowledge destroys "newness," which is why documentation like TKDL matters.

4.6 TKDL — Traditional Knowledge Digital Library

- **What:** A digitized database created by India (CSIR + AYUSH) documenting traditional medicinal knowledge from Ayurveda, Unani, Siddha, and Yoga texts — translated into international patent-classification languages.
- **Role:** Gives patent examiners worldwide searchable "prior art." When someone tries to patent a traditional Indian use, the examiner finds it in TKDL and rejects the patent for lack of novelty.
- **Why it was needed:** Patent examiners in the US/Europe could not read Sanskrit or access ancient texts — so traditional knowledge was "invisible" to them, and wrongful patents were granted (see turmeric case).
- **Simple explanation:** TKDL is like putting the village grandmother's recipe book into a computer that patent officers can search — so nobody can steal the recipe and call it their invention.

4.7 National Biodiversity Authority (NBA) and the Nagoya Protocol

- **NBA:** Set up under India's Biological Diversity Act, 2002. Anyone (especially foreigners/companies) wanting to access Indian biological resources or associated traditional knowledge for research or commercial use must get NBA approval and agree to **benefit-sharing** (money, technology, or joint ownership flowing back to India and local communities).
- **Nagoya Protocol (2010):** International agreement under the Convention on Biological Diversity. It says: genetic resources belong to the country of origin; users must take **prior informed consent** and share benefits fairly (**Access and Benefit-Sharing — ABS**).
- **Simple explanation:** Nagoya Protocol is the international rule-book; NBA is India's referee enforcing it at home.
- **Pharmacy relevance:** Any company developing a drug from an Indian plant must route access through NBA and share benefits — this is examinable and practically important for industry.

4.8 Case Study 1: Turmeric — The US Wound-Healing Patent and Its Revocation

The story:

1. In 1995, the US Patent Office granted a patent (US 5,401,504) to the University of Mississippi Medical Center for "use of turmeric in wound healing."
2. India's CSIR challenged it, presenting evidence that turmeric for wounds was ancient Indian knowledge — documented in Sanskrit texts and in a 1953 paper in an Indian medical journal.
3. In 1997, the USPTO **revoked** the patent — the "invention" was not novel; it was prior art.

Lessons:

- Traditional knowledge IS prior art, even if not in English or in modern databases.

- The case directly led to the creation of TKDL — so it never happens again.
- **Key takeaway:** Turmeric case = the victory that proved documentation protects traditional knowledge.

4.9 Case Study 2: Neem — The Biopiracy Battle and Patent Cancellation

The story:

1. For centuries, Indian farmers used neem for pest control and medicine.
2. In the 1990s, a European patent was granted (to W. R. Grace & Co. and the US Department of Agriculture) on a neem-oil-based fungicide/extraction process.
3. Indian groups (notably the Navdanya movement led by Vandana Shiva), along with European greens and others, opposed it at the European Patent Office, presenting evidence of centuries of traditional Indian use.
4. After a long legal battle, the EPO **revoked** the patent (2000; confirmed on appeal in 2005) — the claimed "invention" lacked novelty and inventive step given traditional knowledge.

Lessons:

- Even a "process" patent fails if the process is essentially traditional.
- Public-interest opposition by NGOs and scientists can defeat biopiracy.
- **Key takeaway:** Neem case = the long battle proving that traditional use defeats patent claims in any country.

4.10 Comparison of the Two Cases

	Turmeric Case	Neem Case
Patent office	USA (USPTO)	Europe (EPO)
Claimed invention	Use of turmeric for wound healing	Neem-oil fungicide / extraction process
Challenger	CSIR (Government of India)	Navdanya + European groups (NGOs/scientists)
Outcome	Patent revoked (1997)	Patent revoked (2000, confirmed 2005)
Legacy	Led to creation of TKDL	Strengthened global anti-biopiracy movement

4.11 Infographic Concept Box — "The Three Shields of Traditional Knowledge"

Draw three shields labelled: **1. TKDL** (documents knowledge destroys novelty of wrongful patents), **2. NBA** (controls access permission + benefit-sharing), **3. Nagoya Protocol** (international law countries must respect ABS). Caption: "Document it, control access to it, and make the world respect it — that is how India protects its green heritage."

4.12 Common Confusions

Confusion	Clarification
Patent vs IPR	Patent is ONE type; IPR is the whole family (patent, trademark, copyright...).
Farmers' rights vs breeders' rights	Farmers' rights = rights of farming communities over seeds/landraces they conserved. Breeders' rights = rights of the breeder over a NEW variety they developed.
Bioprospecting vs biopiracy	Prospecting = with permission + benefit-sharing (legal). Piracy = without (unethical/illegal).
"TKDL gives patents"	No — TKDL PREVENTS wrongful patents by providing prior art.
NBA vs Nagoya	NBA = Indian authority (national). Nagoya = international agreement (global).

4.13 Common Mistakes Students Make

1. Saying the turmeric patent was granted to an Indian company — it was a US university; CSIR got it revoked.
2. Writing that neem patent was American — the famous battle was at the European Patent Office.
3. Claiming natural products "cannot be patented at all" — new processes, derivatives, and formulations CAN be.
4. Mixing up IND/NDA (Chapter 3) with patents — patents protect ownership; IND/NDA seek regulatory approval. Different systems!

4.14 Mnemonic

"PIN-BB" for the key terms: **P**atent, **I**PR, farmers' rights (**N** for "kisaaN" — farmer), **B**reeders' rights, **B**ioprospecting vs **B**iopiracy. And **"T-N-N"** for protection: **T**KDL documents, **N**BA controls, **N**agoya binds the world.

4.15 Exam Summary

- Patent = exclusive rights for ~20 years; IPR = umbrella; farmers' rights (seed rights of communities) vs breeders' rights (new variety rights); bioprospecting (legal, with ABS) vs biopiracy (without permission).
- Natural substances as found in nature and traditional uses fail novelty not patentable; new processes/derivatives/formulations may be.
- TKDL = digitized prior art blocking wrongful patents. NBA (Biological Diversity Act, 2002) = access + benefit-sharing approvals. Nagoya Protocol (2010) = international ABS rules.
- Turmeric: US wound-healing patent (1995) revoked (1997) after CSIR evidence led to TKDL. Neem: European fungicide patent revoked after opposition citing traditional use.

4.16 One-Minute Revision

A patent needs novelty — so ancient traditional uses can't be patented, but new processes and derivatives can. Bioprospecting is legal searching with permission and benefit-sharing; biopiracy is theft. India protects its heritage three ways: TKDL (documents prior art for patent examiners), NBA (controls access under the Biological Diversity Act, 2002), and the Nagoya Protocol (global ABS rules). Turmeric's US patent was revoked in 1997; neem's European patent was revoked after opposition — both because traditional

Indian use destroyed novelty.

4.17 Exam Questions

MCQs

1 The turmeric wound-healing US patent was revoked mainly because:

a) Turmeric is toxic b) The use lacked novelty — it was traditional Indian prior art c) The fee was not paid d) Turmeric is not a medicine **Answer: b**

1 TKDL's main role is to:

a) Grant patents b) Provide prior art to patent examiners to prevent wrongful patents c) Sell herbal drugs d) Conduct clinical trials **Answer: b**

1 The Nagoya Protocol deals with:

a) Drug prices b) Access and benefit-sharing of genetic resources c) Hospital rules d) Pesticide limits **Answer: b**

1 India's NBA was set up under:

a) Drugs and Cosmetics Act b) Biological Diversity Act, 2002 c) Patent Act d) Food Safety Act **Answer: b**

1 Biopiracy means:

a) Legal biodiversity research b) Using biological resources/traditional knowledge without permission or benefit-sharing c) Pirating films d) Patenting a new machine **Answer: b**

1 Farmers' Rights in India are protected under:

a) PPV&FR Act, 2001 b) IPC c) GST Act d) Forest Act **Answer: a**

1 The neem patent battle was fought at:

a) USPTO b) European Patent Office c) Indian Patent Office d) Japanese Patent Office **Answer: b**

Viva questions

1 Why can't a traditional use of a plant be patented?

2 What can be patented in the natural-products area? Give two examples.

3 How did the turmeric case lead to TKDL?

Application-based

1 A foreign company wants to develop a drug from an Indian medicinal plant. What permissions and agreements does it need, and why?

2 A researcher discovers a new semi-synthetic derivative of andrographolide with double the potency. Can it be patented? Justify using patentability criteria.

4.18 References

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