BP603T · B.Pharm Semester VI · Theory Notes

Intellectual Property Rights

Unit II — Patents: Fundamentals and Process

Unit II (6 hours)

Pills & Python Notes

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

Syllabus coverage: Unit II (6 hours).

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CHAPTER 2: Patents – Fundamentals and Process

Course: BP603T Intellectual Property Rights — B.Pharm Semester VI **Unit II (6 hours):** Patents – Fundamentals and Process **How to read this chapter:** Each topic follows the same order — (1) Technical concept (the textbook definition), (2) Simple explanation (what it really means, in plain words), (3) Example (a pharmacy example you can picture), (4) Key takeaway (one line to remember). Work through every section in order. Do not skip the "Common Confusions" and "One-Minute Revision" boxes at the end — they are built from the mistakes students make most often in exams.

2.1 Learning Objectives

After studying this unit, you should be able to:

1 Define a patent and state its objectives in your own words.

2 Explain the three criteria for patentability — novelty, non-obviousness (inventive step), and utility (industrial applicability) — with one example each.

3 List the types of patents and identify non-patentable inventions in India, including examples under Section 3 of the Patents Act.

4 Describe, step by step, the procedure for filing a patent in India (provisional vs complete specification, examination, grant).

5 State the rights of a patent holder and the term of patent protection (20 years from the filing date).

6 Answer exam questions (short, long, MCQ, viva, and application-based) on all the above topics.

2.2 Definitions

Definition 1 — Patent (technical)

A patent is a statutory right granted by the Government to an inventor (or assignee) for an invention that is new, non-obvious, and industrially applicable, giving the holder the exclusive right to exclude others from making, using, offering for sale, selling, or importing the patented invention for a fixed term.

Simple explanation

Think of a patent as a "legal fence" the government builds around your invention. You discovered or created something new and useful. The government says: "For a limited number of years, nobody else can make, use, sell, or import your invention without your permission." In return, you must publicly describe exactly how your invention works, so that society can learn from it and use it freely once the patent expires.

Example

A scientist develops a new tablet coating that makes a bitter drug release slowly in the intestine instead of the stomach. She files a patent. For the patent term, no other company can make or sell that same coating without her permission — but after the term ends, every pharma company can use the idea freely.

Key takeaway

A patent = exclusive rights for the inventor in exchange for public disclosure of the invention, for a limited time.

Definition 2 — Invention (technical)

An invention is a new product or process involving an inventive step and capable of industrial application.

Simple explanation

An "invention" is not just any idea. It must be (a) something new, (b) something not obvious to a skilled person, and (c) something that can actually be made or used in industry. A daydream is not an invention. A sketch on a napkin is not an invention until it meets these three tests.

Example

"Wouldn't it be nice if pills didn't taste bitter?" — that is an idea, not an invention. A working formula for a taste-masking granule with exact ingredients, ratios, and manufacturing steps — that can be an invention.

Key takeaway

Invention = new + non-obvious + industrially useful. Ideas alone are never inventions.

2.3 Terminology

Term	Meaning in plain words
Patentee	The person or company who owns the patent (the patent holder).
Inventor	The person who actually created the invention (may be different from the patentee — e.g., a company can own a patent invented by its employee).
Prior art	Everything already known to the public before your patent filing — old books, journals, earlier patents, public use. If your invention already exists in prior art, it is not new.
Novelty	The invention must be new — not disclosed anywhere in the world before the filing date.
Inventive step / Non-obviousness	The invention must not be obvious to a person skilled in that field. It must involve a real creative jump, not a routine change anyone could make.
Industrial applicability / Utility	The invention must be capable of being made or used in an industry — it must actually work and have a practical use.
Specification	The written document describing the invention, filed with the patent office.
Provisional specification	A temporary, early description filed to secure the filing date while the invention is still being developed.

Term	Meaning in plain words
Complete specification	The full, final description of the invention with claims, filed later (or filed directly instead of a provisional).
Claims	The numbered sentences at the end of the specification that define exactly what the patent protects — the legal "fence lines."
Patent office	The government office that receives, examines, and grants patents. In India there are four: Chennai, Delhi, Mumbai, and Kolkata, all under the Controller General of Patents, Designs and Trade Marks (CGPDTM), with the portal ipindia.gov.in.
Filing date	The date the patent application is filed — the 20-year protection term is counted from this date.
Grant	The official decision by which the patent office gives the patent to the applicant.
Evergreening	A practice where a company tries to extend its monopoly by patenting small, trivial modifications of an old drug; Section 3(d) of the Indian Patents Act is the legal bar against this.
Infringement	Making, using, selling, or importing the patented invention without the patent holder's permission.

Key takeaway

Learn these words like a vocabulary list — patent examiners, viva examiners, and MCQ setters all use them exactly as defined here.

2.4 Explanation: Definition and Objectives of Patents

Technical concept

A patent is an intellectual property right — a legal monopoly granted by the state for a limited period. It does not give the holder the right to use the invention; it gives the right to **exclude others** from using it.

Simple explanation

Imagine you spent five years and crores of rupees developing a new medicine. Without a patent, the day you launch it, a hundred companies could copy it and sell it cheaper, because they did not pay for the research. A patent stops that. It says: "Only the inventor (or whoever the inventor gives permission to) can commercially exploit this invention for 20 years." Note the word *exclude* — a patent is a negative right. It does not say "you may make this"; it says "nobody else may make this without your permission."

The six objectives of patents — explained one by one

Objective 1: Reward and incentivise innovation. Research is expensive and risky. A patent is society's way of saying "thank you" to the inventor — a temporary monopoly as a reward for the effort and risk. Without this reward, companies would not invest in research.

> *Example:* Developing a new drug can take 10–15 years. A patent lets the company recover that investment.

Objective 2: Encourage public disclosure of knowledge. Instead of keeping the invention secret forever, the inventor must publish exactly how it works. This published knowledge helps other scientists learn and build further.

> *Example:* Once a drug patent is published, researchers worldwide can study the chemistry and design better drugs around it.

Objective 3: Promote technological and industrial progress. Because knowledge is disclosed, each invention becomes a stepping stone for the next. Industry moves forward faster.

> *Example:* The patent on one sustained-release tablet technology led to many improved versions by other researchers after they read the published specification.

Objective 4: Prevent misuse and unauthorised copying. The patent gives the holder legal power to stop copycats and claim damages from infringers.

> *Example:* If a rival company copies a patented tablet formulation, the patent holder can approach the court to stop the sales and claim compensation.

Objective 5: Facilitate technology transfer and commercialisation. A patent is property — it can be sold (assigned) or rented out (licensed). This lets small inventors earn from big companies, and lets industries share technology legally.

> *Example:* A university patents a new herbal extraction process and licenses it to a pharma company for a royalty.

Objective 6: Protect public interest through a limited term. The monopoly is not forever — 20 years only. After expiry, the invention belongs to everyone. Society gets the long-term benefit.

> *Example:* Old antibiotic formulas whose patents expired are now made cheaply by many companies as generics.

Key takeaway

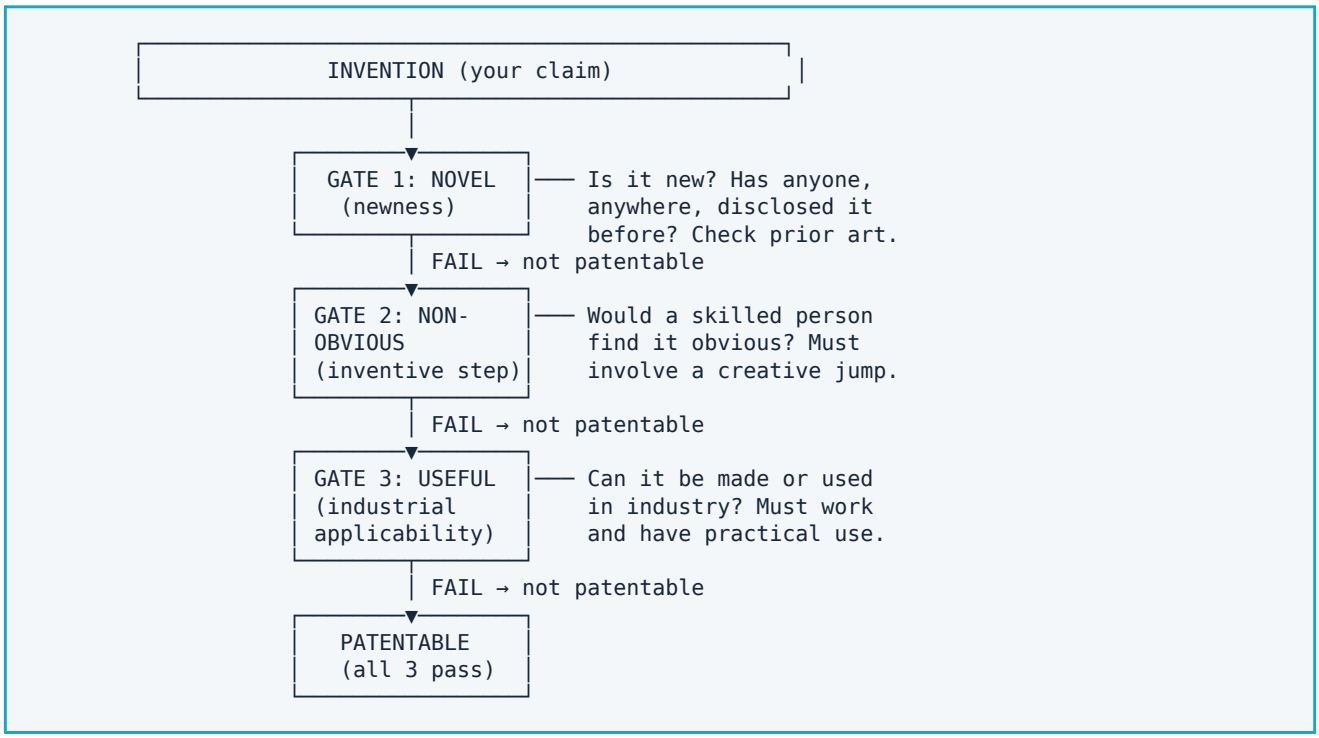
Patents balance two things: they reward the inventor (private benefit) and they enrich public knowledge (public benefit) — and the 20-year limit keeps the balance fair.

2.5 Explanation: Criteria for Patentability (the Three Tests)

Technical concept

An invention is patentable only if it satisfies three conditions simultaneously: (1) **novelty** — it must be new; (2) **inventive step (non-obviousness)** — it must not be obvious to a person skilled in the art; (3) **industrial applicability (utility)** — it must be capable of being made or used in an industry.

Textual diagram — The Three Gates of Patentability:



Test 1 — Novelty (innovation/newness)

Technical concept: The invention must be new — it must not have been disclosed to the public anywhere in the world, in any form (publication, public use, earlier patent), before the filing date of the patent application.

Simple explanation: Novelty means "nobody has seen this before." If your invention is already described in a journal, shown at a conference, sold in a shop, or written about on the internet before you file — it is not new, and you cannot patent it. The whole world's knowledge (prior art) is checked.

Example: A student publishes a paper describing a new herbal tablet formula, and *then* tries to file a patent on it. The patent will be refused — the invention lost its novelty the moment the paper was published.

Key takeaway: File the patent BEFORE you publish, present, or sell. Public disclosure kills novelty.

Test 2 — Non-obviousness (inventive step)

Technical concept: The invention must involve an inventive step — a feature that is not obvious to a person having ordinary skill in the art, having regard to the prior art.

Simple explanation: Even if something is technically "new," it must also be *clever*. If any ordinary pharmacist or chemist, looking at the existing knowledge, would say "oh, obviously you just do X," then there is no inventive step. The invention must involve a creative leap that a skilled person would not routinely make.

Example: Mixing two known painkillers into one tablet in the same doses already published in textbooks = probably obvious, no inventive step. But discovering that a specific unusual ratio of those two drugs unexpectedly doubles the effect with fewer side effects = a surprising result, hence an inventive step.

Key takeaway: New is not enough — the invention must also be non-obvious. A routine or predictable change fails this test.

Test 3 — Utility (industrial applicability)

Technical concept: The invention must be capable of industrial application — it must be capable of being made or used in any kind of industry, including agriculture.

Simple explanation: The invention must actually *work* and have a practical use. A beautiful theory that cannot be built, or a machine that violates the laws of physics, has no utility. In pharmacy, this usually means the drug, formulation, or process can actually be manufactured and used for a real purpose.

Example: A compound that cures a disease only in a computer simulation, with no proof it can be made or tested, fails the utility test. A compound with laboratory data showing it can be synthesised and works in a model has utility.

Key takeaway: The invention must be practical and workable — patents are for useful things, not for fantasies or pure theories.

Summary table — The three criteria at a glance

#	Criterion	Plain meaning	Question it answers	Fails when...
1	Novelty	It must be NEW	"Has anyone, anywhere, disclosed this before?"	It appears in any prior art (journal, patent, public use) before filing
2	Non-obviousness (inventive step)	It must be CLEVER	"Would a skilled person find this obvious?"	It is a routine, predictable change any skilled person could make
3	Utility (industrial applicability)	It must be USEFUL	"Can it be made or used in industry?"	It cannot be built, does not work, or has no practical use

Key takeaway

All three tests must be passed together. Fail any one gate, and there is no patent — remember "New, Clever, Useful."

2.6 Classification: Types of Patents

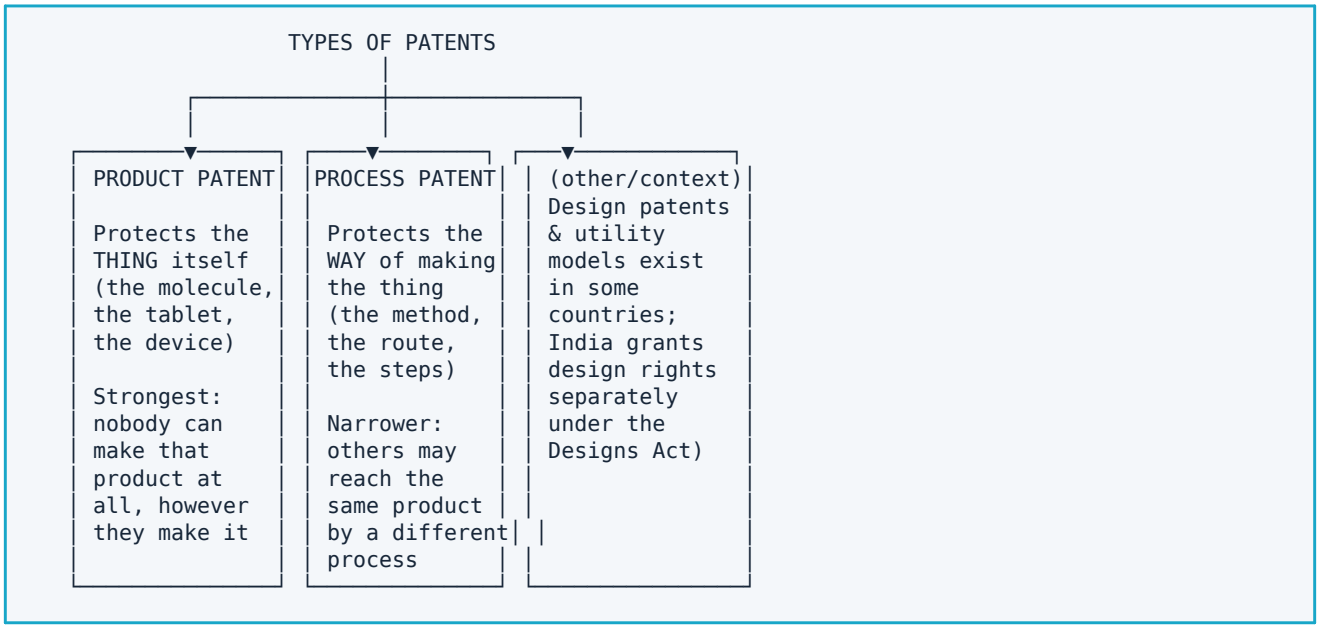
Technical concept

Patents are commonly classified by what they protect. The two most important types for pharmacy students are **product patents** and **process patents**.

Simple explanation

A patent can protect either the *thing itself* (the product) or the *way of making the thing* (the process). This distinction is very important in the pharmaceutical industry.

Textual diagram — Types of patents:



Type 1 — Product patent

Technical concept: A product patent protects the product *per se* — the chemical compound, formulation, or device itself, however it is made.

Simple explanation: This is the strongest protection. If you patent the *molecule*, nobody can make or sell that molecule at all — no matter what clever manufacturing route they invent. It covers the thing itself.

Example: A company discovers a brand-new antibiotic molecule and gets a product patent. No other company can manufacture or sell that molecule for the patent term, even if they find a cheaper way to synthesise it.

Key takeaway: Product patent = "this thing is mine, however anyone makes it." Strongest protection.

Type 2 — Process patent

Technical concept: A process patent protects a new method or process of manufacturing a product, not the product itself.

Simple explanation: Here the *recipe* is protected, not the *dish*. If you patent a new, cheaper way of making a known drug, others cannot use your method — but they are free to make the same drug by a

different method.

Example: A company invents a new one-step synthesis for a known painkiller that earlier needed five steps. The process is patented. A rival may still make the same painkiller, but must use a different manufacturing route.

Key takeaway: Process patent = "my way of making it is mine, but the product itself is free for others to make differently."

India context — why this distinction matters in India

For much of its history, India granted only process patents for pharmaceuticals and food products, which helped build India's generic drug industry. As per the latest amendments/notifications, India now grants product patents in all fields of technology, including pharmaceuticals. This is why understanding both types — and the Section 3(d) safeguard against evergreening — is essential for Indian pharmacy students.

Comparison table — Product patent vs Process patent

Point	Product patent	Process patent
What is protected	The product itself (molecule, formulation, device)	The method/process of making the product
Strength	Stronger — blocks all manufacture of the product	Narrower — blocks only that particular process
Others can make the same product?	No	Yes, if they use a different process
Pharmacy example	New antibiotic molecule	New one-step synthesis of a known drug

Key takeaway

Product patent protects the *what*; process patent protects the *how*. In pharma, the product patent is the more powerful right.

2.7 Non-Patentable Inventions in India (Section 3)

Technical concept

The Patents Act lists certain inventions that are **not patentable** even if they are new, non-obvious, and useful. These exclusions are given in Section 3 of the Act, and students should know the important ones with examples.

Simple explanation

The law says: some things can *never* be patented, no matter how clever they are. The reasons are public interest, ethics, and preventing abuse of the system. Think of Section 3 as a "NO ENTRY" board at the patent office — the items below are turned away at the gate.

The important exclusions — explained one by one

1. Mere discovery of a scientific principle or abstract theory. A discovery is finding something that already exists in nature; an invention is creating something new. You cannot patent a law of nature.

> *Example:* Discovering that a particular plant leaf contains a chemical that lowers blood sugar = discovery (not patentable). Developing a new tablet formulation using that chemical = possible invention (patentable).

2. Mere discovery of a new form of a known substance which does not result in enhancement of known efficacy — Section 3(d) (the "evergreening" bar). This is the most exam-important exclusion. If a company takes a known drug and patents a slightly modified form (a new salt, a new crystal form, a new combination) that does NOT work significantly better than the old form, no patent is granted. This stops companies from extending their monopoly forever by making trivial changes ("evergreening").

> *Example:* A company's patent on a drug is about to expire. It applies for a patent on the same drug in a slightly different salt form that works the same as before. Under Section 3(d), this is refused — there is no real improvement in efficacy.

3. Methods of agriculture or horticulture. Farming methods cannot be patented.

> *Example:* A new method of sowing wheat seeds cannot be patented.

4. Methods of medical, surgical, curative, prophylactic, diagnostic, or therapeutic treatment of humans or animals. A doctor's method of treating a patient cannot be patented — medical treatment must remain free for all doctors to use.

> *Example:* A new surgical technique for eye operations cannot be patented. (Note: the *instrument* used in the surgery could be patented — the method cannot.)

5. Mere admixture or arrangement of known things (mere aggregation). Just mixing known ingredients without any new combined effect is not patentable.

> *Example:* Mixing two known syrups together where each works exactly as before, with no new combined benefit = not patentable.

6. Inventions contrary to public order, morality, or harmful to human, animal, or plant life or the environment. The patent office will not grant rights over something illegal, immoral, or dangerous.

> *Example:* A new chemical weapon or a process that causes serious environmental damage cannot be patented.

Summary table — Key Section 3 exclusions

#	Exclusion (Section 3)	Plain meaning	Pharmacy example
1	Mere discovery of scientific principle	Finding inventing	Discovering a natural compound in a leaf — not patentable

#	Exclusion (Section 3)	Plain meaning	Pharmacy example
2	Section 3(d): new form of known substance without enhanced efficacy	No evergreening by trivial changes	New salt form of old drug with same effect — refused
3	Methods of agriculture/horticulture	Farming methods excluded	New sowing technique — not patentable
4	Methods of treatment (medical/surgical/therapeutic/diagnostic)	Doctors' methods stay free	New surgical technique — not patentable (but the instrument may be)
5	Mere admixture/aggregation	Just mixing known things	Mixing two known syrups with no new combined effect — not patentable
6	Contrary to public order/morality or harmful to life/environment	Illegal/immoral/dangerous excluded	Chemical weapon — not patentable

Key takeaway

Section 3 is the "NO ENTRY" list. The most important for exams: Section 3(d) against evergreening, and the bar on methods of treatment.

2.8 Mechanism: Procedure for Filing a Patent in India (Step by Step)

Technical concept

Obtaining a patent in India is a multi-stage administrative process: filing the application (with provisional or complete specification), publication, examination (on request), responses to objections, and finally grant (or refusal).

Simple explanation

Getting a patent is like applying for a government licence — you submit papers, the office checks them, asks questions, you answer, and finally you get the certificate. It takes time (often a few years), and each step has a purpose. Below is the complete journey of a patent application in India.

Flowchart — Patent filing procedure in India:

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STEP 1: PREPARE & FILE THE APPLICATION
   |
   |  • Draft the specification describing the invention
   |  • File at one of the four Patent Offices
   |    (Chennai, Delhi, Mumbai, Kolkata) or online via ipindia.gov.in
   |  • Pay the prescribed fee
   |  • TWO OPTIONS at filing:
   |       (a) Provisional specification → secures the FILING DATE early
   |           while the invention is still being developed; the
   |           complete specification must follow later
   |       (b) Complete specification → full description + claims,
   |           filed directly when the invention is ready
   |  • You receive an application number and the FILING DATE
   |    (the 20-year term is counted from this date)
   |
   ▼
STEP 2: PUBLICATION
   |
   |  • The application is published in the official Patent Journal,
   |    normally after 18 months from the filing date
   |    (early publication can be requested)
   |  • Purpose: the public can see what is claimed; oppositions
   |    may be filed
   |
   ▼


STEP 3: REQUEST FOR EXAMINATION (RFE)
   |
   |  • Examination does NOT start automatically
   |  • The applicant must file a Request for Examination
   |    within the prescribed time limit
   |    (as per the latest rules/notifications — check ipindia.gov.in
   |    for the current deadline)
   |  • If no request is filed in time, the application is treated
   |    as withdrawn
   |
   ▼
STEP 4: EXAMINATION BY THE PATENT OFFICE
   |
   |  • A patent examiner studies the application
   |  • Checks: novelty, inventive step, industrial applicability,
   |    and Section 3 exclusions
   |  • Searches prior art (Indian and international databases)
   |  • Issues the First Examination Report (FER) listing objections,
   |    if any
   |
   ▼
STEP 5: RESPONSE TO OBJECTIONS
   |
   |  • The applicant replies to the FER — amends claims,
   |    submits arguments and evidence
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   │  • May go through hearings with the Controller
   │  • Purpose: convince the office the invention is patentable,
   │    or narrow the claims to overcome objections
   │
   ▼
STEP 6: GRANT OR REFUSAL
   │
   │  • If the Controller is satisfied → PATENT GRANTED
   │    • Entered in the Register of Patents
   │    • Published in the Patent Journal
   │    • Letters Patent (certificate) issued
   │  • If not satisfied → application REFUSED (applicant can appeal)
   │
   ▼
STEP 7: AFTER GRANT — MAINTAIN THE PATENT
   │
      • Pay renewal (maintenance) fees periodically to keep
        the patent alive for the full 20-year term
      • If renewal fees are not paid, the patent lapses (dies early)
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Provisional vs complete specification — explained simply

Point	Provisional specification	Complete specification
When filed	Early, when the idea is formed but details are still being worked out	When the invention is fully developed, OR filed directly without a provisional
Purpose	Secures the filing date ("my place in the queue")	Fully describes the invention with claims defining protection
Detail level	Brief description — enough to show what the invention is	Full description: background, detailed working, drawings, numbered claims
What must follow	The complete specification must be filed later within the prescribed time (as per latest rules)	Nothing further needed at filing — this is the final document
Analogy	Booking a train ticket in advance (seat reserved)	Boarding the train with the confirmed ticket (full journey details)

Simple explanation of each step (walk-through with a pharmacy example)

Imagine Dr. Meera invents a new fast-dissolving tablet for migraine:

1. **Filing:** She files a provisional specification describing the basic idea — this locks her filing date, say 5 October 2026. Nobody who files later can claim they invented it first.
2. **Complete specification:** Within the allowed time, she files the complete specification with exact formula, manufacturing steps, and numbered claims.
3. **Publication:** After about 18 months, her application appears in the Patent Journal for the public to see.
4. **Request for examination:** She files the RFE (with fee) within the time limit — otherwise her application dies automatically.
5. **Examination:** The examiner searches worldwide prior art and sends a First Examination Report with objections (e.g., "Claim 2 looks obvious in view of this 2019 journal article").
6. **Response:** Dr. Meera's patent agent replies, amends the claims, and attends a hearing.
7. **Grant:** Satisfied, the Controller grants the patent. It is valid for 20 years from 5 October 2026 (the filing date). She must pay renewal fees to keep it alive.

Key takeaway

File (provisional or complete) Publish (18 months) Request examination Examination & objections Reply Grant Pay renewals for 20 years from filing. Miss the examination request deadline and the application is dead.

2.9 Rights of a Patent Holder and Term of Patent Protection

Technical concept

The patentee has the exclusive right to prevent third parties from making, using, offering for sale, selling, or importing the patented product or the product obtained by the patented process in India. The term of every patent is 20 years from the date of filing of the application.

Simple explanation

Once granted, the patent is the holder's property. The holder can stop others from commercially exploiting the invention, and can also make money from it by selling or licensing it. But this power lasts exactly 20 years from the filing date — not from the grant date — and only stays alive if renewal fees are paid.

The rights of the patent holder — explained one by one

Right 1: Exclusive right to exclude others (the core right). The holder can stop anyone from making, using, selling, offering for sale, or importing the patented invention in India without permission.

> *Example:* A company holds a patent on a new insulin pen device. A rival starts selling a copy — the patent holder can get a court order stopping those sales.

Right 2: Right to assign (sell) the patent. The patent can be sold to another person or company, like selling a house.

> *Example:* An inventor sells her tablet-coating patent to a large pharma company for a lump sum.

Right 3: Right to license (rent out) the patent. The holder can permit others to use the invention in exchange for royalty payments, while keeping ownership.

> *Example:* A university licenses its patented extraction process to three companies, earning royalty on every kilogram produced.

Right 4: Right to sue for infringement. If someone uses the invention without permission, the holder can approach the court for an injunction (stop order) and damages (compensation).

> *Example:* The insulin-pen company proves copying in court and receives damages from the infringer.

Right 5: Right to use the patent as commercial property. The patent can be mortgaged or used as an asset in business deals.

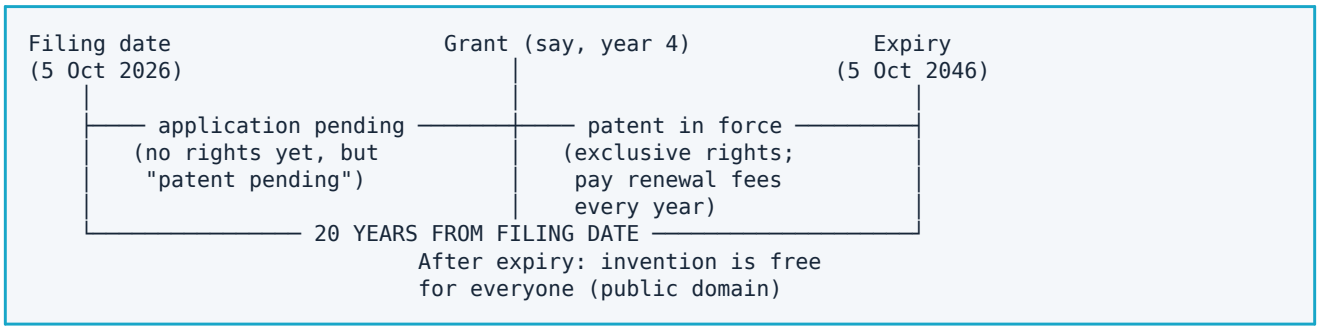
Example: A startup shows its patent portfolio to investors to raise funding.

Term of protection — the 20-year rule

Technical concept: The term of every patent in India is 20 years from the date of filing of the patent application, subject to payment of renewal fees.

Simple explanation: Count 20 years from the day you filed — not the day the patent was granted. If filing took place on 5 October 2026 and the patent was granted in 2030, it still expires on 5 October 2046. Also note: if you stop paying the yearly renewal fees, the patent lapses (ends early).

Textual diagram — The 20-year timeline:



Key takeaway

Rights = exclude others + sell + license + sue. Term = 20 years from filing date, kept alive by renewal fees; after expiry, the invention belongs to the public.

2.10 Infographic Concept Box

INFOGRAPHIC IDEA — "The Patent Journey: From Idea to Expiry"

Design brief for a one-page visual summary (for the student's notebook or classroom poster):

Layout: A horizontal timeline road with 7 milestone flags, left to right:

1. **IDEA** — "New + non-obvious + useful?" (three small gate icons: New, Clever, Useful) 2. **FILE** — Provisional (reserve the date) or Complete specification; 4 Patent Offices: Chennai • Delhi • Mumbai • Kolkata; portal: ipindia.gov.in 3. **PUBLISH** — Patent Journal, ~18 months after filing 4. **EXAMINE** — Request for Examination Examiner checks novelty, inventive step, utility, Section 3 First Examination Report 5. **RESPOND** — Reply to objections, amend claims, hearing 6. **GRANT** — Exclusive rights: exclude, assign, license, sue 7. **20 YEARS** — From filing date; pay renewals; then FREE FOR ALL (public domain)

Side panel — "NEVER patentable (Section 3)": discoveries • 3(d) evergreening • farming methods • treatment methods • mere mixtures • immoral/harmful inventions

Colour coding: green = go steps, amber = waiting/check steps, red = barred items. **One-line caption at bottom:** "Patent = 20-year exclusive fence around a new, clever, useful invention — in exchange for telling the world how it works."

2.11 Tables (Quick-Reference)

Table A — Patentability criteria

Criterion	Meaning	Exam keyword
Novelty	New — not in prior art before filing	"New"
Non-obviousness (inventive step)	Not obvious to a skilled person	"Clever"
Utility (industrial applicability)	Can be made/used in industry	"Useful"

Table B — Types of patents

Type	Protects	Example
Product patent	The product itself	New antibiotic molecule
Process patent	The method of manufacture	New one-step synthesis of a known drug

Table C — Section 3: non-patentable inventions (must-know list)

Exclusion	Example
Mere discovery of scientific principle	Finding a natural compound in a plant
Section 3(d) — new form of known substance without enhanced efficacy	New salt form, same effect (evergreening blocked)
Methods of agriculture/horticulture	New sowing technique
Methods of treatment (medical/surgical/therapeutic/diagnostic)	New surgical technique (instrument may still be patentable)
Mere admixture/aggregation	Mixing two known syrups, no new effect
Contrary to public order/morality; harmful to life/environment	Chemical weapons

Table D — Filing procedure at a glance

Step	What happens	Key point
1. Filing	Provisional or complete specification at Chennai/Delhi/Mumbai/Kolkata or ipindia.gov.in	Filing date starts the 20-year clock
2. Publication	Patent Journal, ~18 months	Public can view/oppose
3. Request for examination	Must be filed within prescribed time	No request = application withdrawn
4. Examination	Examiner checks 3 criteria + Section 3; issues FER	Objections listed
5. Response	Reply, amend claims, hearing	Overcome objections

Step	What happens	Key point
6. Grant/refusal	Controller decides	Grant = 20-year rights; refusal = appeal possible
7. Renewals	Periodic fees	Non-payment = patent lapses

Table E — Rights and term

Right	Meaning
Exclude others	Stop making/using/selling/importing without permission
Assign	Sell the patent
License	Rent out use for royalty
Sue for infringement	Court action: injunction + damages
Term	20 years from filing date, subject to renewal fees

2.12 Examples (Worked Mini-Cases)

Example 1 — Novelty lost by early publication. A researcher presents a new sustained-release capsule formula at a national conference in January, then files a patent in June. *Result:* No patent — the conference presentation is prior art; novelty was destroyed in January.

Example 2 — Inventive step present. Two known drugs are combined in a specific ratio that unexpectedly removes a serious side effect neither drug showed alone. *Result:* Patentable — the surprising result shows an inventive step beyond obvious mixing.

Example 3 — Section 3(d) evergreening refused. A company patents a well-known blood-pressure drug. Just before expiry, it seeks a patent on a new crystalline form with the same therapeutic effect. *Result:* Refused under Section 3(d) — new form of a known substance without enhanced efficacy.

Example 4 — Method of treatment not patentable. A surgeon develops a faster technique for cataract surgery. *Result:* The method cannot be patented (Section 3), though a new surgical instrument she designed for it could be.

Example 5 — Process patent scope. Company A holds a process patent on a 2-step synthesis of a known vitamin. Company B makes the same vitamin by a completely different 4-step route. *Result:* No infringement — the process patent covers only A's method, not the vitamin itself.

Example 6 — Term calculation. Application filed 1 March 2020; patent granted 15 September 2024. *Result:* The patent expires on 1 March 2040 (20 years from filing, not from grant).

Key takeaway

In exams, always test the facts against the three gates (new? clever? useful?) and then check the Section 3 "NO ENTRY" list before concluding.

2.13 Analogies (to lock the concepts in memory)

1. **Patent = a rented shop in a market.** The government (market owner) gives you exclusive use of one shop for 20 years. You must display your goods openly (disclosure). When the rent period ends, anyone can use the shop.
2. **Novelty = a "first-time" stamp.** Like a cricket record — it counts only if nobody did it before. Once someone publishes it, the record is gone.
3. **Inventive step = the jump, not the step.** Walking up one stair is obvious; jumping clean over a wall surprises everyone. Patents reward the jump.
4. **Provisional specification = reserving a train berth.** You book early to hold your place; you give full passenger details later with the complete specification.
5. **Claims = the fence around your farm.** The specification describes the whole farm; the numbered claims are the fence lines that say exactly where your land ends and others' begins.
6. **Section 3(d) = the "no repainting" rule.** You cannot extend your house lease forever by just repainting the walls each time — you need a genuinely better house (enhanced efficacy).
7. **20-year term = a fixed-term lease.** The clock starts on the day you sign (filing date), not the day you move in (grant date).

Key takeaway

When you forget a definition in the exam hall, reach for the analogy first — the technical words usually follow.

2.14 Pharmacy Relevance

Why must a B.Pharm student master patents? Because the entire modern pharmaceutical industry runs on them:

1. **Drug discovery careers:** Every new molecule, formulation, or drug-delivery system in industry is evaluated for patentability before crores are invested. Pharmacists in R&D write and read patent specifications daily.
2. **Generic industry:** India's strength as the "pharmacy of the world" depends on knowing exactly when patents expire — generic companies launch the day after expiry. Reading patent expiry dates is a core industry skill.
3. **Regulatory and IPR roles:** Pharma companies employ IPR specialists to file patents, respond to examination reports, and watch competitors' patents — a direct career path for B.Pharm graduates.
4. **Formulation strategy:** Choosing between a product patent and a process patent strategy decides how strongly a company's invention is protected.
5. **Public health balance:** Section 3(d) and the 20-year limit show how patent law balances company profits with affordable medicines for patients — a pharmacist must understand both sides.
6. **Academic research:** Universities patent new drug-delivery technologies and license them to industry — today's student researcher is tomorrow's inventor.

Key takeaway

Patents are not just law — they are the business language of pharmacy. Learn to speak it.

2.15 India Context

- **The law:** Patents in India are governed by the Patents Act, and the detailed working rules are in the Patents Rules (as per the latest amendments/notifications — always check ipindia.gov.in for current fees, forms, and timelines).
- **The offices:** Four Patent Offices — Chennai, Delhi, Mumbai, Kolkata — all functioning under the Controller General of Patents, Designs and Trade Marks (CGPDTM). Applications can be filed online through the ipindia.gov.in portal.
- **Product patents for drugs:** India grants product patents in all fields of technology including pharmaceuticals (as per the latest amendments/notifications).
- **Section 3(d) — India's famous safeguard:** The bar on patenting new forms of known substances without enhanced efficacy protects India from "evergreening" and keeps medicines affordable. It is one of the most discussed provisions of Indian patent law internationally.
- **Public-health balance:** Indian patent law tries to reward inventors while ensuring that life-saving medicines remain accessible — the 20-year limit, Section 3 exclusions, and provisions such as compulsory licensing (covered in later units) all serve this balance.
- **For the student:** Any Indian pharmacy graduate who joins R&D, regulatory affairs, or the generics industry will deal with the Indian Patent Office system described in this chapter.

Key takeaway

India's patent system = global patent principles + strong public-health safeguards (especially Section 3(d)).

2.16 Key Points (rapid-fire revision)

1. Patent = exclusive right to **exclude** others from making, using, selling, or importing the invention — a negative right.
2. Three patentability criteria: **novelty, non-obviousness (inventive step), utility (industrial applicability)** — all three must pass.
3. Novelty is destroyed by ANY public disclosure before filing — file first, publish later.
4. Inventive step = not obvious to a person skilled in the art; routine changes fail.
5. Product patent protects the **thing**; process patent protects the **way of making** it.
6. Section 3 lists non-patentable inventions — most important: mere discoveries, **Section 3(d)** evergreening bar, methods of agriculture, **methods of treatment**, mere admixtures, immoral/harmful inventions.

7 Filing: **provisional** specification (reserves the date) or **complete** specification (full description + claims).

8 Procedure: file publish (~18 months) request examination examination (FER) respond grant/refusal pay renewals.

9 No request for examination within the prescribed time = application treated as withdrawn.

10 Patent holder's rights: exclude, assign, license, sue for infringement.

11 Term = **20 years from the filing date** (not the grant date), kept alive by renewal fees.

12 After expiry, the invention enters the public domain — free for all.

2.17 Common Confusions (cleared up)

Confusion 1: "A patent gives me the right to make and sell my invention." *Clear-up:* No. A patent gives you the right to **stop others** from doing so. (You might still need other approvals — e.g., drug regulatory approval — to sell a medicine.)

Confusion 2: "If my invention is new, I automatically get a patent." *Clear-up:* New is only gate 1 of 3. It must also be non-obvious and industrially applicable, and must not fall under Section 3.

Confusion 3: "Discovery and invention are the same." *Clear-up:* Discovery = finding what already exists in nature (not patentable). Invention = creating something new with an inventive step (patentable).

Confusion 4: "The 20 years start when the patent is granted." *Clear-up:* The 20 years are counted from the **filing date** of the application, not the grant date.

Confusion 5: "A process patent stops everyone from making the product." *Clear-up:* No — a process patent stops only that particular *process*. Others may make the same product by a different process. Only a product patent blocks the product itself.

Confusion 6: "I can patent my new method of treating diabetes." *Clear-up:* No — methods of treatment of humans/animals are excluded under Section 3. (A new drug or device used in the treatment may be patentable.)

Confusion 7: "Provisional specification means my patent is granted." *Clear-up:* No — a provisional only secures your filing date. The complete specification, examination, and grant all come later.

Key takeaway

Examiners love testing exactly these confusions — especially filing date vs grant date, and product vs process patent scope.

2.18 Common Mistakes (what students get wrong in exams)

1 **Writing only two criteria** for patentability — always write all three: novelty, inventive step, utility.

2 **Mixing up novelty and inventive step** — novelty = "not seen before"; inventive step = "not obvious." They are different gates.

3 **Forgetting Section 3(d)** when asked about non-patentable inventions — it is the single most expected answer.

4 **Saying the term is 20 years from grant** — it is 20 years from **filing**.

5 **Omitting the Request for Examination step** in the procedure answer — without it, the application is withdrawn; examiners check that you know this.

6 **Listing only "Chennai" or one patent office** — there are four: Chennai, Delhi, Mumbai, Kolkata.

7 **Confusing assignment with licensing** — assignment = ownership transferred (sold); licensing = permission given, ownership retained (rented).

8 **Writing the procedure as one paragraph** — always present it as numbered steps; step-wise answers score higher.

2.19 Mnemonics

The three criteria — "NCU" ("New, Clever, Useful"):

- **N**ovelty — New
- **C** (non-obviousness) — Clever (inventive step)
- **U**tility — Useful

The filing procedure — "Please Publish, Examine, Respond, Get Renewals" (P-P-E-R-G-R):

- **P**rovisional/complete filing
- **P**ublication (~18 months)
- **E**xamination (on request — FER)
- **R**esponse to objections
- **G**rant
- **R**enewals for 20 years

Section 3 exclusions — "D-FAME-T" (say "defame-T"):

- **D**iscovery (mere scientific principle)
- **F**orms of known substances without enhanced efficacy — 3(d)
- **A**griculture methods
- **M**edical/treatment methods
- **E** (admixtur**e**) — mere aggregation
- **T** — con**T**rary to morality / harmful

Patent holder's rights — "EALS" ("eels"):

- **E**xclude others

- **A**ssign (sell)
- **L**icense (rent out)
- **S**ue for infringement

Key takeaway

NCU P-P-E-R-G-R D-FAME-T EALS. Four mnemonics cover the whole unit.

2.20 Exam Summary (the whole unit in one page)

- **Patent:** a statutory exclusive right to exclude others from making, using, selling, or importing an invention, granted for a limited term in exchange for public disclosure.
- **Objectives:** reward innovation; encourage disclosure; promote industrial progress; prevent unauthorised copying; enable licensing/technology transfer; serve public interest via a limited term.
- **Patentability — three gates (NCU):** (1) Novelty — new, not in prior art before filing; (2) Non-obviousness/inventive step — not obvious to a skilled person; (3) Utility/industrial applicability — capable of being made or used in industry.
- **Types:** product patent (protects the thing itself — strongest) vs process patent (protects the method of manufacture only).
- **Non-patentable (Section 3):** mere discoveries; Section 3(d) new forms of known substances without enhanced efficacy (anti-evergreening); agriculture methods; treatment methods; mere admixtures; immoral/harmful inventions.
- **Procedure:** file provisional or complete specification (4 offices: Chennai, Delhi, Mumbai, Kolkata; ipindia.gov.in) publication (~18 months) request for examination (mandatory, within prescribed time) examination & First Examination Report response/amendment/hearing grant or refusal renewal fees to maintain.
- **Rights:** exclude others; assign; license; sue for infringement.
- **Term:** 20 years from the date of filing, subject to renewal fees; then public domain.

2.21 One-Minute Revision

A **patent** is a 20-year exclusive right to **exclude** others from your invention, given in exchange for publicly disclosing how it works. To be patentable, an invention must be **NCU: New** (novelty — not disclosed before filing), **Clever** (non-obvious inventive step), and **Useful** (industrial applicability). **Product** patents protect the thing; **process** patents protect the way of making it. **Section 3** bars patenting discoveries, **3(d)** evergreening tweaks, farming methods, treatment methods, mere mixtures, and harmful inventions. **Filing:** provisional (reserve date) or complete specification at Chennai/Delhi/Mumbai/Kolkata via ipindia.gov.in publish (~18 months) **request examination** examiner's report reply **grant** pay renewals. Rights: **EALS** — Exclude, Assign, License, Sue. Term: **20 years from filing**, then free for all.

2.22 Exam Questions

A. Short-answer questions (2–5 marks)

1 Define a patent in one sentence.

2 State any four objectives of the patent system.

3 What is "prior art"? Why does it matter for novelty?

4 Distinguish between novelty and inventive step.

5 What is meant by "industrial applicability"?

6 Distinguish between a product patent and a process patent with one example each.

7 What is a provisional specification? How does it differ from a complete specification?

8 Name the four Indian Patent Offices and the authority they function under.

9 What happens if the applicant does not file a Request for Examination in time?

10 State the term of a patent in India and the date from which it is counted.

11 What is "evergreening"? Which provision of the Patents Act bars it?

12 List any four inventions that are not patentable under Section 3.

13 What are "claims" in a patent specification?

14 Mention any two rights of a patent holder.

B. Long-answer questions (10–15 marks)

1 Define a patent and explain in detail the objectives of the patent system, with suitable pharmacy examples.

2 Explain the three criteria for patentability — novelty, non-obviousness (inventive step), and utility (industrial applicability) — with one example for each, and show why all three must be satisfied together.

3 Describe the types of patents. Explain the difference between product patents and process patents and discuss why the distinction is important for the pharmaceutical industry in India.

4 Discuss the categories of inventions that are not patentable in India under Section 3 of the Patents Act, with examples. Explain the significance of Section 3(d) in preventing evergreening.

5 Describe step by step the procedure for filing and obtaining a patent in India, from the provisional/complete specification to grant. Explain the importance of the Request for Examination.

6 Explain the rights of a patent holder and the term of patent protection in India. What happens to the invention after the patent expires?

C. Multiple-choice questions (with answer key)

Q1. A patent is best described as: (a) A right to manufacture any product (b) An exclusive right to exclude others from exploiting the invention (c) A permanent ownership of an idea (d) A government subsidy for research **Answer: (b)**

Q2. Which of the following is NOT a criterion for patentability? (a) Novelty (b) Inventive step (c) Industrial applicability (d) Commercial success **Answer: (d)**

Q3. Novelty of an invention is destroyed by: (a) Filing a provisional specification (b) Public disclosure before the filing date (c) Paying the renewal fee (d) Licensing the patent **Answer: (b)**

Q4. "Non-obviousness" means the invention must: (a) Be expensive to develop (b) Not be obvious to a person skilled in the art (c) Never have been imagined before (d) Be useful only in pharmaceuticals **Answer: (b)**

Q5. A product patent protects: (a) Only the manufacturing process (b) The product itself, however it is made (c) Only the packaging of the product (d) The brand name of the product **Answer: (b)**

Q6. Under Section 3(d), a new salt form of a known drug is NOT patentable when: (a) It is cheaper to manufacture (b) It does not show enhancement of known efficacy (c) It is manufactured outside India (d) It is filed as a provisional specification **Answer: (b)**

Q7. Which of the following is NOT patentable in India? (a) A new tablet-coating machine (b) A new surgical method for cataract operations (c) A new sustained-release formulation (d) A new chemical synthesis process **Answer: (b)**

Q8. The patent application in India is normally published after: (a) 6 months from filing (b) 12 months from filing (c) 18 months from filing (d) Only after grant **Answer: (c)**

Q9. If the applicant fails to file a Request for Examination within the prescribed time, the application is: (a) Automatically granted (b) Treated as withdrawn (c) Published immediately (d) Transferred to another office **Answer: (b)**

Q10. The term of a patent in India is: (a) 20 years from the date of grant (b) 20 years from the date of filing (c) 14 years from the date of filing (d) Lifetime of the inventor plus 60 years **Answer: (b)**

Q11. Which of the following is a right of the patent holder? (a) Right to stop others from importing the patented product without permission (b) Right to extend the patent term indefinitely (c) Right to patent a law of nature (d) Right to skip examination **Answer: (a)**

Q12. "Evergreening" refers to: (a) Environment-friendly manufacturing (b) Extending monopoly through trivial modifications of a known drug (c) Planting trees around factories (d) Renewing a patent after 20 years **Answer: (b)**

Q13. The Indian Patent Offices are located at: (a) Chennai, Delhi, Mumbai and Kolkata (b) Only New Delhi (c) Bengaluru and Hyderabad (d) Chennai and Pune **Answer: (a)**

Q14. A provisional specification is filed mainly to: (a) Get the patent granted immediately (b) Secure the filing (priority) date while the invention is still being developed (c) Avoid paying any fees (d) Publish the invention at once **Answer: (b)**

Q15. After a patent expires, the invention: (a) Can never be used by anyone (b) Belongs to the government only (c) Enters the public domain and can be freely used by all (d) Must be re-patented by the inventor **Answer: (c)**

D. Viva questions (with model answers)

V1. What is a patent? A statutory exclusive right granted to an inventor to exclude others from making, using, selling, or importing the invention for a limited term, in exchange for public disclosure.

V2. Name the three criteria for patentability. Novelty, non-obviousness (inventive step), and utility (industrial applicability) — "New, Clever, Useful."

V3. What is the difference between discovery and invention? Discovery is finding something already existing in nature (not patentable); invention is creating something new with an inventive step (patentable).

V4. What is Section 3(d)? The provision that refuses patents on new forms of known substances unless they show enhancement of known efficacy — India's anti-evergreening bar.

V5. How long does a patent last in India? 20 years from the date of filing of the application, subject to payment of renewal fees.

V6. What is a provisional specification? An early, brief description filed to secure the filing date while the invention is still being developed; the complete specification follows later.

V7. What is the difference between assignment and licensing? Assignment transfers ownership of the patent (sale); licensing gives permission to use it while ownership stays with the patentee (rent).

V8. Can a method of treating a disease be patented in India? No — methods of medical/surgical/therapeutic treatment are excluded under Section 3, though the drug or device used may be patentable.

V9. What happens if renewal fees are not paid? The patent lapses (ends before the 20-year term).

V10. Where can a patent be filed in India? At any of the four Patent Offices — Chennai, Delhi, Mumbai, Kolkata — or online via the ipindia.gov.in portal, all under the Controller General of Patents, Designs and Trade Marks.

E. Application-based questions

E1. A pharma researcher publishes a journal article describing a new herbal wound-healing gel in March 2026 and files a patent application for it in September 2026. Will the patent be granted? Give reasons. *Guidance for answering:* No. The March publication is prior art and destroys novelty — the invention was disclosed to the public before the filing date. File before publishing.

E2. Company X holds a product patent on Drug D. Company Y develops a cheaper, completely different manufacturing process for Drug D and starts selling it. Has Y infringed X's patent? What if X held only a process patent on its own manufacturing method? *Guidance:* Yes — infringement, because a product patent blocks the product however made. If X held only a process patent, Y's different process would not

infringe.

E3. A company's 20-year patent on a hypertension drug expires next year. It now applies for a patent on a new crystal form of the same drug that shows the same blood-pressure-lowering effect. Advise the company on the likely outcome under Indian law. *Guidance:* Likely refusal under Section 3(d) — a new form of a known substance without enhancement of known efficacy is not patentable; this is evergreening.

E4. An applicant files a patent application but forgets to file the Request for Examination within the prescribed time. What is the status of the application, and what should the applicant have done? *Guidance:* The application is treated as withdrawn. The applicant should have filed the Request for Examination (with fee) within the prescribed time limit (check the latest rules on ipindia.gov.in), since examination does not begin automatically.

E5. Dr. Rao files a patent application on 10 June 2026 and the patent is granted on 20 December 2030. Until when is the patent valid, assuming renewal fees are paid? What happens after that date? *Guidance:* Valid until 10 June 2046 — 20 years from the filing date, not the grant date. After expiry, the invention enters the public domain and anyone may use it freely.

2.23 References

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Note on legal details: Patent law is amended from time to time. For current forms, fees, and time limits (such as the deadline for the Request for Examination or for filing the complete specification after a provisional), always verify as per the latest amendments/notifications on ipindia.gov.in.