

Unit 5: Patents

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5.1 Patents: Indian and international patent laws

A patent is an exclusive right granted by a state for an invention, in exchange for full public disclosure of the invention, for a limited term, in the standard modern form twenty years from the filing date under the TRIPS built framework of Unit 2. The Indian law is the Patents Act, 1970, as amended, notably by the amendments that introduced product patents for pharmaceuticals in the TRIPS transition, administered through the Indian Patent Office under the Controller General of Patents, Designs and Trade Marks. Internationally there is no single world patent: rights are territorial, granted country by country, but two systems organise the work, the Paris Convention, which gives a priority right allowing an applicant a period to file abroad on the strength of the first filing, and the Patent Cooperation Treaty, which provides a single international filing and search route that then enters national phases where each office decides grant. For herbal and natural products the laws apply with the special tension this unit exists to explain: the inventions of an industry built on traditional knowledge and natural materials must pass the same tests of patentability as any other, and much of what the industry knows best fails those tests, as Sections 5.5 and 5.10 show.

5.2 Proposed amendments as applicable to herbal and natural products and process

The syllabus directs attention to proposed amendments as they bear on herbal and natural products and processes, and the durable way to teach a moving target is by the questions the amendments debate rather than by memorising any single bill. The recurring amendment themes in the Indian debate are these. Disclosure of source: whether applicants must disclose the source and geographical origin of biological material used in an invention, and declare compliance with biodiversity law, a requirement India built into its patent law and which bites directly on plant based inventions. Traditional knowledge protection: how the law should prevent patents on what traditional communities already know, through exclusions, prior art documentation and databases. The patentability boundary for natural products: where discovery of a substance occurring in nature ends and invention begins, for isolates, extracts and processes. Compulsory licensing and access: the balance between patent exclusivity and public access to medicines, a live question for patented phytopharmaceuticals as for any drug. And process protection for traditional preparations: whether and how improved processes for classical products should be rewarded without enclosing the classical knowledge itself. An examination answer that names the theme, states the interest on each side, and connects it to a herbal example satisfies the syllabus phrase in any year, whatever the current bill.

5.3 Geographical indication

A geographical indication, GI, is an intellectual property right that identifies a product as originating in a territory, region or locality where a given quality, reputation or other characteristic is essentially attributable to its geographical origin. For natural products GI is often the right that fits where patent cannot: the value of a regional crude drug, spice or traditional product lies precisely in its origin and the accumulated practice of its place, which no single inventor created and no patent should enclose. India protects GI under its Geographical Indications of Goods Act, with registration, an authorised user system for producers of the region, and remedies against outsiders using the name. The examination distinctions are GI against trademark, a GI belongs to the producers of a region collectively and cannot be assigned away like a

private mark, and GI against patent, GI protects the name and origin link, not any technical invention, and lasts while the link and registration are maintained rather than for a fixed invention term. For the herbal trade of Unit 2, GI is a marketing and protection instrument at once: it certifies origin to distant buyers and reserves the name to the region that built its reputation.

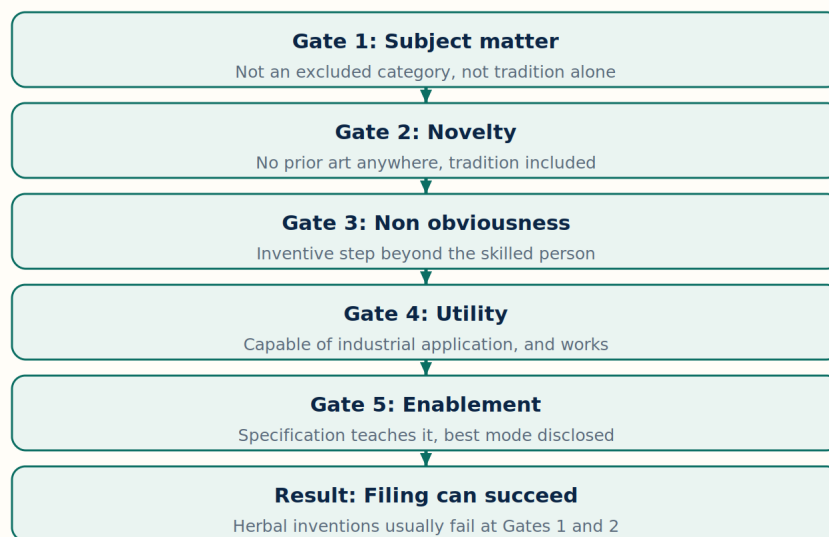
5.4 Copyright

Copyright is the right that protects original literary, artistic, musical and dramatic works and their modern statutory companions, arising automatically on creation and lasting, in the standard Indian provision, for the author life plus a statutory period for most works. Its place in a patents unit is as a neighbouring right with a different territory, and the distinctions are the marks. Copyright protects expression, not ideas, facts or inventions: the text of a monograph, a book on herbal industry, a database presentation, a label artwork and a company catalogue can be copyright works, while the process they describe is patent territory or no right at all. Facts and traditional knowledge as such are not owned by copyright, though an original compilation of them may be protected in its selection and arrangement. In the herbal enterprise copyright appears in publishing, documentation, software and branding materials, and its lesson for the student is negative and valuable: copyright cannot be used to monopolise a formulation or a traditional use, however original the book that describes it.

5.5 Patentable subject matters

Patentable subject matter is the class of things the law allows to be patented at all, before the tests of Section 5.6 are applied. The positive statement: a patent may be granted for a product or a process that is an invention, a new product or process involving an inventive step and capable of industrial application. The Indian Act then excludes whole categories in its Section 3, and the exclusions that govern herbal and natural products must be known individually. Discoveries of living things or substances occurring in nature are not inventions. Plants and animals and essentially biological processes are excluded, with the statutory treatment of microorganisms and plant varieties, the latter protected in India by the separate plant varieties legislation, standing apart. Methods of agriculture and horticulture are excluded. Methods of treatment are excluded. Inventions whose use would be contrary to public order or morality or cause serious prejudice to life or environment are excluded. And, decisive for this subject, an invention which in effect is traditional knowledge, or an aggregation or duplication of the known properties of traditionally known components, is not patentable. From these exclusions the positive herbal map follows: a new extraction process, a genuinely new formulation with demonstrated technical advance, a new standardisation or stabilisation technique, a novel isolated and characterised compound or a new use developed by inventive work may be patentable subject matter; the plant, its traditional use and the classical formulation as inherited are not. The patentability gates are drawn below.

The patentability gates



Each gate is passed in order; failure at any gate ends the claim

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Figure: The patentability gates in order. Herbal inventions most often fail at the first gate, subject matter, or at novelty, because traditional knowledge is prior art.

5.6 Novelty, non obviousness and utility

Three criteria decide whether patentable subject matter is actually patented, and each has a precise meaning. Novelty: the invention must be new, not anticipated by prior art, the whole of what was published, used or otherwise made available to the public anywhere before the priority date. For herbals, prior art includes the classical texts and documented traditional practice, which is why the Traditional Knowledge Digital Library exists: to put that prior art in the search path of patent examiners worldwide. Non obviousness, the inventive step: the invention must not be obvious to a person skilled in the art from the prior art; a routine extraction solvent change or an expected combination of known herbs fails here even if the exact mixture was never written down. Utility, in Indian language capability of industrial application: the invention must work and be capable of being made or used in industry; a claimed use unsupported by the specification invites objection. The three criteria divide the failures instructively. Traditional knowledge cases fail novelty. Mere mixtures of known herbs for their known properties fail inventive step and the Section 3 exclusion together. Speculative natural product claims fail utility and the enablement requirement of the next section. A candidate who can assign a refused herbal application to its correct failing criterion has understood the unit.

5.7 Enablement and best mode

Enablement is the disclosure side of the patent bargain: the specification must describe the invention and the method of performing it fully and particularly, in terms clear enough that a person skilled in the art can carry it out without undue experiment. For a herbal process that means the drug, its part and preparation, the solvent system, conditions and the characterisation of the product must be disclosed to a working standard; a specification that hides the operative detail behind a plant name and a promise is not enabling. Best mode is the companion requirement in the Indian Act: the applicant must disclose the best method of performing the invention known to the applicant at filing. The pair protect the public side of the bargain: the state grants exclusivity only for knowledge actually handed over. Their herbal edge is sharp, because natural material varies: an enabling specification for an extract process should characterise starting material and product by the identity and assay standards of Unit 3, so that performance does not silently depend on

one undisclosed batch of drug. Failure of enablement is a ground of opposition and revocation under Sections 5.11, which is where weak specifications are finally tested.

5.8 Procedure for Indian patent filing

The Indian filing procedure should be known as an ordered sequence. One, prepare the application: the prescribed form, the specification, provisional where the invention is not yet complete, giving an early priority date with the complete specification to follow within the statutory period, or complete at once; claims defining the protection sought; abstract; and, for plant based inventions, the declarations and permissions the law requires, including disclosure of source and geographical origin of biological material and, where applicable, approval of the National Biodiversity Authority. Two, file at the appropriate Patent Office, the office of territorial jurisdiction among the Indian patent offices, or electronically, receiving the application number and filing date that anchor priority. Three, publication: the application is published after the statutory period, earlier on request, entering the public record and the prior art. Four, request examination: substantive examination does not begin until requested within the statutory period; the examiner searches and issues a first examination report of objections, on patentability, clarity, enablement and formal grounds. Five, respond and be heard: the applicant answers objections, amends within the permitted limits and may be heard. Six, grant or refusal follows, the subject of Section 5.9. The filing staircase below compresses the sequence for revision.

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Draft the specification and claims; check patentability and prior art
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File the application (provisional or complete) at the Patent Office
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Application published; request substantive examination
|
Examination report issues: objections on the statutory grounds
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Respond, amend as permitted, attend hearing if called
|
Grant and publication of the patent, or refusal
|
Pay renewal fees; work the patent; defend or face opposition
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Indian patent filing procedure



Priority is won at filing, patentability at examination, life by renewal

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Figure: The Indian patent filing procedure. Priority is won at filing, patentability is won at examination, and the right is kept alive by renewal.

5.9 Patent processing, grant of patents and rights of patents

Patent processing is the administrative and substantive journey of Section 5.8 seen from the office side: formal checking, classification, publication, allocation to an examiner, search and examination report, consideration of the response, and the decision to grant or refuse, with the Controller deciding contested and discretionary matters. On grant, the patent is entered in the Register of Patents and published, and the patentee receives the rights of the patent: for a product patent, the right to exclude others from making, using, offering for sale, selling or importing the product in India; for a process patent, the corresponding rights over the process and over products obtained directly by it. Rights are territorial and time limited, maintained by renewal fees, assignable and licensable, and bounded by statutory exceptions and by the government use and compulsory licence provisions that keep the monopoly answerable to public interest. The patentee corresponding duties should travel with the rights in any full answer: work the invention, mark and renew, and expect the grant to be tested by the opposition and revocation routes of Section 5.11.

5.10 Cases of patents

The syllabus asks for cases of patents, and for herbal and natural products the canonical teaching cases are the traditional knowledge cases, taught qualitatively in every standard text. The turmeric case: a United States patent on the use of turmeric in wound healing was granted in the 1990s and then revoked on re examination after Indian authorities produced documentary prior art of the traditional use, the case that proved documentation defeats wrongful grant. The neem case: a European patent on a neem based antifungal preparation was opposed and ultimately revoked by the European Patent Office after evidence that the use was traditional knowledge in India, the leading case on opposition as a remedy, Section 5.11. The basmati case: a United States patent claiming basmati rice lines and grains was challenged by India, and its broad claims were withdrawn or cancelled on re examination, leaving a narrowed position and a permanent lesson in the defence of geographical and traditional assets, linking back to geographical indication in Section 5.3. Read together the three cases teach one doctrine from three angles: novelty is judged against all prior art including traditional knowledge; grant is not the end, because re examination, opposition and revocation can correct it; and a country that documents its traditional knowledge, as the Traditional Knowledge Digital Library does, converts an oral heritage into searchable legal evidence. No invented figures are needed for the doctrine to carry full marks.

5.11 Opposition and revocation of patents

Opposition is the procedure by which a grant is contested by others. Indian law provides pre grant opposition, by any person after publication and before grant, and post grant opposition, by a person interested, within the statutory period after grant, on the statutory grounds, which should be listed: wrongfully obtained invention; prior publication or prior use; obviousness and lack of inventive step; non patentable subject matter, including the traditional knowledge exclusion; insufficient and unclear disclosure, the enablement failure of Section 5.7; failure to disclose biological material source; and anticipation by knowledge, oral or otherwise, available within a local or indigenous community. The Controller hears the parties and may refuse, grant, or grant with amendment. Revocation is the stronger remedy, the removal of a granted patent, sought by petition to the higher forum the law provides, or by counterclaim in an infringement suit, on grounds that substantially mirror opposition, with the additional routes of revocation in the public interest by the government in the cases the Act specifies. For the herbal industry these procedures are working tools, not abstractions: they are how wrongly granted traditional knowledge patents were undone in Section 5.10, and how a company clears its freedom to operate when a blocking patent should never have been granted.

5.12 Patent search and literature

Patent search is the systematic searching of patent and non patent literature to answer a defined question, and the question decides the search. A novelty or patentability search asks whether an invention is new before money is spent filing it. A freedom to operate search asks whether making a product would infringe live claims in the markets of sale, a Unit 2 regulatory task. A validity search hunts prior art against a granted patent for opposition or revocation. A state of the art search maps who is doing what in a field, such as standardised extracts, for research and business planning. The literature searched is of two families: patent literature, the published applications and granted patents of the world offices, searchable through the Indian Patent Office search system and the international databases of the European and world offices, classified by the International Patent Classification and by keywords and applicants; and non patent literature, journals, books, pharmacopoeias and, for this industry above all, the traditional knowledge resources that record classical use. Search craft is examinable in outline: define the question, choose classes and keywords including synonyms and botanical names, search, read claims rather than titles for legal questions, and record the search so it can be repeated and defended. A search that is not recorded did not, for quality purposes, happen.

5.13 Controllers of Patents

The Controllers of Patents are the statutory officers who administer the patent system and decide the matters the Act reserves to them. At the head stands the Controller General of Patents, Designs and Trade Marks, who superintends the Patent Office and its branches and also administers the related intellectual property offices, with Controllers, Joint, Senior Joint, Deputy and Assistant Controllers exercising delegated powers in examination and proceedings. The Controller functions in the life of an application should be listed: receiving and processing applications, ordering examination, considering examination reports and applicant responses, hearing parties in applications, oppositions and rectification matters, deciding grant or refusal, extending and restoring in the cases the Act permits, deciding compulsory licence applications, maintaining the Register of Patents and publishing the official journal of applications, grants and proceedings. The Controller is a quasi judicial authority in these functions: decisions are reasoned, hearings are governed by natural justice, and appeals lie to the higher forum the law provides. For the student the office completes the unit map: Sections 5.8 and 5.9 describe a journey, and the Controller is the officer who decides its contested steps, the human address of the patent system. With that, the subject closes its circle: an industry built from authenticated plants, standardised extracts and pharmacopoeial standards, tested for quality and stability, and trading under a legal framework whose sharpest instrument, the patent, rewards genuine invention and, properly defended, refuses to enclose the traditional knowledge the industry inherited.

Frequently Asked Questions

Q: What is MPG104T in M.Pharm Pharmacognosy? MPG104T is Industrial Pharmacognostical Technology, the fourth theory subject of M.Pharm Pharmacognosy Semester 1 under the PCI syllabus. It carries 4 credits and 60 hours, taught at 4 hours per week for 100 marks, and covers the herbal drug industry, its regulation and quality systems, herbal drug monographs, testing and stability of natural products, and patents.

Q: What is a standardised extract? A standardised extract is an extract made by a controlled process from an authenticated drug of defined drug extract ratio and adjusted, within stated limits, to a defined content of active or marker constituents. Standardisation is achieved by controlled extraction and by blending or permitted adjustment of batches, never by spiking with isolated marker, which counts as adulteration.

Q: What are the main stages of pilot plant scale up for a herbal extract? First define the critical process parameters and quality attributes at small scale, then run the process at pilot scale and compare the product with the small scale specification, identify which parameters are scale sensitive and fix their production ranges, and finally confirm the process at production scale with validation batches documented as evidence of control.

Q: How do TQM, GMP, GLP and ISO 9000 differ? GMP is the mandatory legal system for consistent manufacture and control of products. GLP is the required system for the planning, conduct, recording and archiving of non clinical laboratory safety studies. TQM is a voluntary management philosophy of total involvement and continuous improvement across the whole organisation. ISO 9000 is a voluntary international quality management system standard, certified by external audit, which attests the management system and does not replace GMP.

Q: What are the general parameters of a herbal drug monograph? Definition with botanical name, family and part used, description of macroscopic characters, identification by microscopy, chemical tests and chromatographic fingerprinting, purity tests including foreign matter, ash and extractive values, moisture and contaminant limits, assay of active or marker constituents, and directions for storage and labelling.

Q: Which pharmacopoeias are compared in MPG104T Unit 3? The Indian Pharmacopoeia, the United States Pharmacopoeia, the Ayurvedic Pharmacopoeia of India, the Siddha Pharmacopoeia of India, the Unani Pharmacopoeia of India, the American Herbal Pharmacopoeia and the British Herbal Pharmacopoeia, together with the WHO guidelines on quality assessment of herbal drugs.

Q: What does stability testing of a natural product include? A written protocol fixes the batches, packs, storage conditions, long term and accelerated, time points, tests and acceptance criteria. Attributes followed include description, moisture, marker or active assay, fingerprint comparison with the initial profile, degradation behaviour and microbial quality. Shelf life, storage statements and packing are assigned from the trended results.

Q: Why is traditional knowledge generally not patentable in India? The Patents Act excludes from patentability an invention which in effect is traditional knowledge, or an aggregation or duplication of the known properties of traditionally known components. Traditional knowledge is also prior art, so claims covering it fail novelty. The turmeric, neem and basmati cases show such patents being revoked or narrowed when documented traditional use was produced.

Q: What are the criteria of patentability taught in MPG104T? The subject matter must be patentable and not fall in an excluded category, the invention must be novel against all prior art, it must involve an inventive step and not be obvious to a person skilled in the art, and it must be capable of industrial application. The specification must also enable the invention and disclose the best mode of performing it known to the applicant.

Q: Are the MPG104T unit wise PDFs free to download on PharmacoLearn? Yes. PharmacoLearn provides the MPG104T notes as free unit wise PDF downloads, one PDF for each of the five units, with the frequently asked questions appended to the Unit 5 PDF. The same page carries the complete notes for M.Pharm Pharmacognosy Semester 1 students.

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