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MRA104T Regulations and Legislation in India and IPR, M.Pharm Semester 1

Unit 5: Intellectual Property Rights

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5.1 The IPR family: five instruments, five different monopolies

Intellectual property rights are the legal monopolies a state grants over creations of the mind, and the syllabus's five instruments protect five different things by five different logics. A **patent** protects an invention: a technical solution, granted for a fixed term in exchange for disclosure. A **trademark** protects a sign that distinguishes one trader's goods: it can last forever, but only while it is used and renewed. **Copyright** protects expression, the text, image or code itself, and arises automatically without registration. An **industrial design** protects the appearance of an article, its shape, configuration or pattern. A **geographical indication** protects a name that ties a product's qualities to its place of origin, and belongs to a community of producers rather than to one firm. A pharmaceutical product typically carries several of these at once: the molecule may be patented, the brand is a trademark, the pack artwork is copyright, the device shape may be a registered design, and a regional herbal product may trade on a geographical indication. Regulatory affairs lives inside this family because market exclusivity in practice is the sum of the patent position, the data position and the brand position, and the sections that follow take each instrument in the syllabus's order.

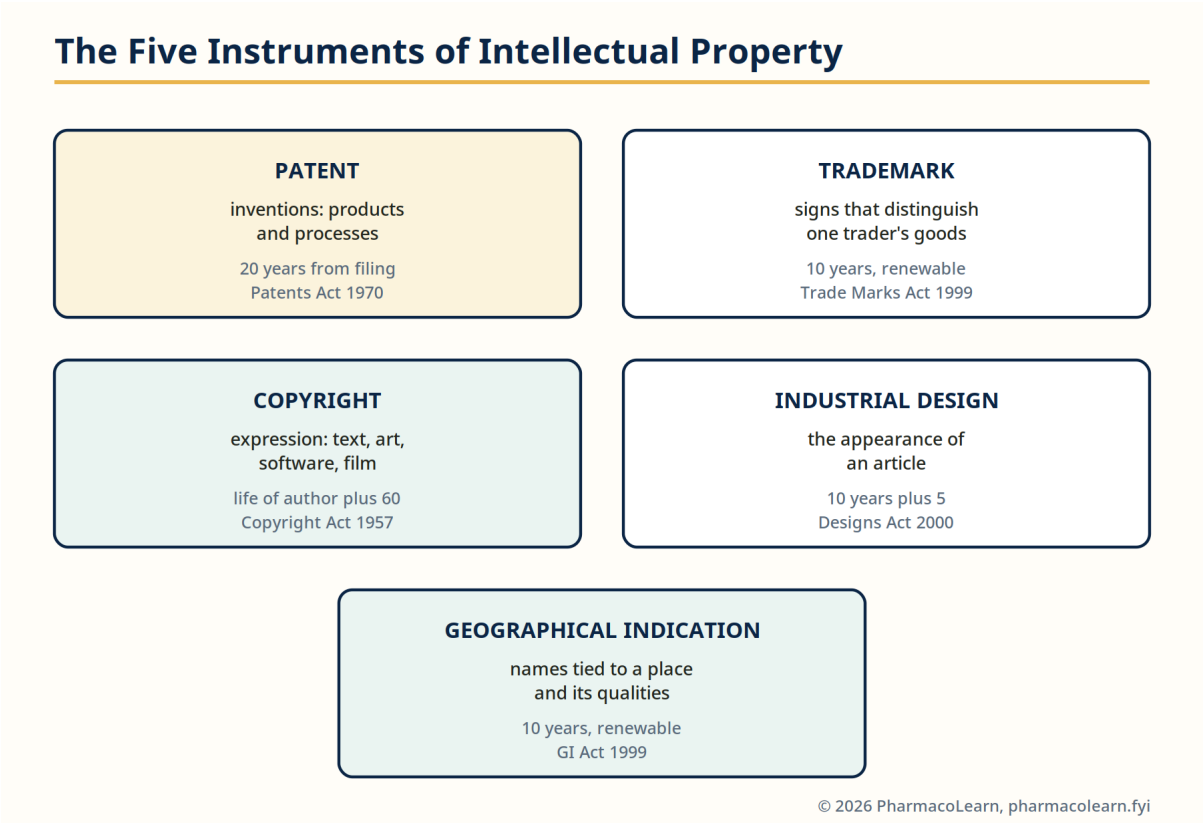

Figure: The five instruments of Unit 5: patent, trademark, copyright, industrial design and geographical indication, with the subject matter and term of each (Unit 5, section 5.1).

5.2 Patents: the Patents Act 1970 and the 2005 settlement

The governing statute is the **Patents Act 1970**, administered by the Indian Patent Office under the Controller General of Patents, Designs and Trade Marks, with offices at Kolkata (the head office), Delhi,

Mumbai and Chennai. An invention is patentable if it is **novel**, involves an **inventive step** and is **capable of industrial application**, and is not excluded by the Act. The exclusions of Section 3 are the examinable heart of Indian patent law for this branch: methods of treatment and diagnostic methods are excluded; plants, animals and essentially biological processes are excluded; mere discoveries and new uses of known substances are excluded; and clause 3(d) excludes **the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance**, with its explanation treating salts, polymorphs, isomers and other derivatives as the same substance unless they differ significantly in efficacy. The Supreme Court's 2013 judgment in the Novartis case, refusing a patent on the beta crystalline form of imatinib mesylate, made 3(d) the world's best known anti evergreening provision: a follow on form must show enhanced **therapeutic** efficacy to be an invention. The Act's modern shape is the work of the **2005 amendment**, which completed India's TRIPS transition by restoring product patents for pharmaceuticals (suspended since 1970, when the original Act admitted only process patents for drugs, a design that built the Indian generics industry), closed the mailbox of applications filed during the transition, and strengthened the opposition system, with both pre grant and post grant opposition now available. The patent **term is 20 years from the filing date**, with maintenance by renewal fees; applications are published at 18 months and examined on request; and the state retains corrective powers, of which compulsory licensing, a licence granted to a third party against the patentee's will on grounds including public health need and unaffordable pricing (first exercised in 2012 for the anti cancer drug sorafenib), and government use, are the standard teaching examples.

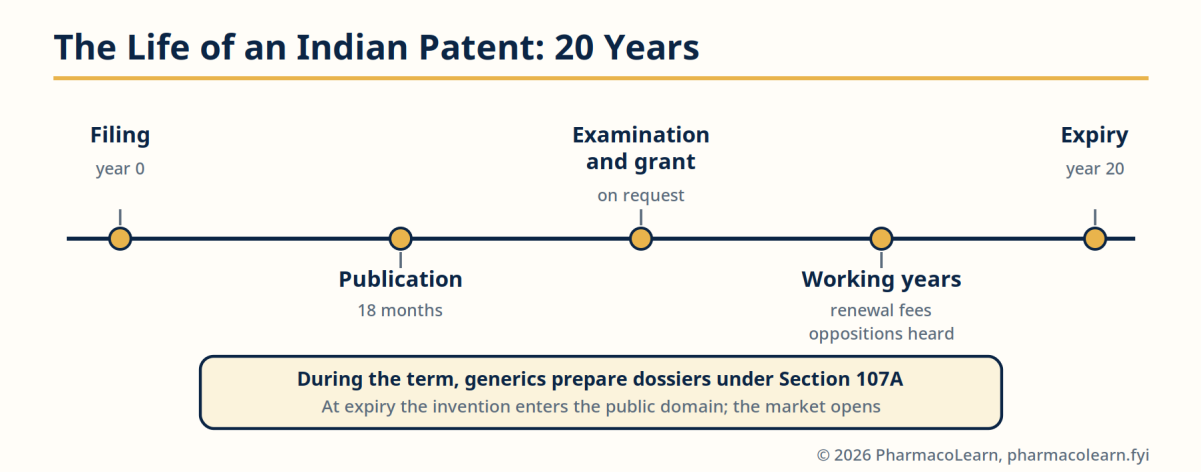

Figure: The life of an Indian patent: filing, publication at 18 months, examination and grant, working and renewal, expiry at 20 years and the opening of the market (Unit 5, section 5.2).

5.3 Trademarks

A trademark, governed by the **Trade Marks Act 1999** and registered with the Trade Marks Registry, is a mark capable of graphical representation that distinguishes the goods of one undertaking from another's. Registration runs for **10 years and is renewable indefinitely** in further 10 year periods, and the register is searched and opposed much as patents are. Pharmaceutical trademarks carry subject specific disciplines. The generic or international nonproprietary name (INN) of a drug cannot be monopolised, and a mark that appropriates an INN or its stem invites objection and rectification; brand names must also survive the licensing authority's scrutiny at the product permission stage, because two confusingly similar brand names for different medicines are a medication error hazard, and Indian courts and regulators alike have treated look alike and sound alike naming as a safety question, not merely a commercial one. After patent expiry the trademark is usually the originator asset that remains, which is why brand strategy, and the regulatory management of brand extensions and umbrella branding, belong to the regulatory timetable and not only to marketing.

5.4 Copyright

Copyright, under the **Copyright Act 1957**, protects original literary, dramatic, musical and artistic works, cinematograph films and sound recordings, and it subsists automatically on creation, registration being evidentiary only. Its term for literary works is the life of the author plus 60 years. In pharmaceutical practice copyright is the quiet instrument: it protects the text and artwork of packaging and patient information (never the information itself, for copyright guards expression, not facts or ideas), product literature and promotional material, clinical and regulatory documentation as text, photographs and illustrations, and computer software, which Indian law protects as a literary work and which therefore covers the submission and laboratory systems of MRA101T and MRA102T. Its regulatory relevance is mostly defensive: a generic entrant must write its own label text expression around the same mandatory content, a company's dossier templates and standard texts are its copyright assets, and plagiarism of an originator's distinctive artwork can found an action even where every patent has expired.

5.5 Industrial designs

The **Designs Act 2000** protects the features of shape, configuration, pattern, ornament or composition of lines or colours applied to an article by an industrial process, judged solely by the eye; purely functional features and trademarks are outside it. Registration runs for **10 years from registration, extendable by a further 5 years**. The pharmaceutical footprint is real but narrower than the other instruments: the shape and get up of inhalers, insulin pens and other drug delivery devices (a field where design, patent and trademark claims are routinely layered), distinctive tablet shapes and embossing where they are truly ornamental, blister and bottle forms, and packaging configurations. Design registration is fast and inexpensive compared with a patent, and in device and consumer health portfolios it is the standard first filing; its weakness is the subject matter limit, since a shape dictated by function cannot be kept from competitors by calling it a design.

5.6 Geographical indications

A geographical indication, under the **Geographical Indications of Goods (Registration and Protection) Act 1999**, identifies goods as originating in a territory, region or locality where a given quality, reputation or other characteristic is essentially attributable to that origin. Registration runs for **10 years, renewable**, and the right belongs to an association of producers or an authority, not to a single proprietor: no individual may own Darjeeling tea. Pharmaceutical India meets GI at its herbal and traditional edge: origin named raw materials and regional products of the AYUSH and food sectors (the classic Indian registrations run from Darjeeling tea to regional spices, textiles and crafts) can trade on protected names, and a nutraceutical or Ayurvedic manufacturer sourcing a GI named ingredient takes both a marketing asset and a sourcing obligation. For examination purposes GI is the contrast case in the family: collective, renewable, tied to place, and incapable of assignment to an outsider in the way a patent or trademark can be sold.

Instrument	Governing Act	Protects	Term	Registration needed
Patent	Patents Act 1970	Inventions: products and processes	20 years from filing	Yes
Trademark	Trade Marks Act 1999	Signs distinguishing goods and services	10 years, renewable indefinitely	Yes, for the statutory rights
Copyright	Copyright Act 1957	Expression: text, art, software, film	Life of author plus 60 years (literary works)	No, subsists automatically
Industrial design	Designs Act 2000	Appearance of an article	10 years plus 5 on extension	Yes

Instrument	Governing Act	Protects	Term	Registration needed
Geographical indication	GI Act 1999	Names tied to origin and quality	10 years, renewable	Yes, by a producers' association

5.7 The Indian patent scenario

The Indian patent scenario is the story of a system built twice. The 1970 Act, by admitting only process patents for drugs and shortening their term, deliberately made room for a domestic industry that learned to make every important medicine by an alternative route; by the 1990s that industry supplied a large share of the developing world's affordable medicines. TRIPS then required product patents, and the **2005 amendment** delivered them with the safeguards this unit has met: Section 3(d) against evergreening, pre and post grant opposition, compulsory licensing, and a research and regulatory review exemption, so that India's settlement is accurately described as full TRIPS compliance engineered to preserve generic competition. The working indicators of the current scenario are qualitative but consistent: filings at the Indian Patent Office have grown year on year with a rising resident share, pharmaceutical and biotechnology applications form a significant and contested stream in which oppositions are a normal part of practice, Indian firms file aggressively abroad while challenging weak patents at home, and the Patent Rules have been repeatedly amended to compress timelines and digitise procedure. For the regulatory affairs student the scenario matters as market structure: the Indian launch question for any medicine is a joint question, what is its approval status under Units 1 to 4, and what is its patent status under this unit.

5.8 IPR versus Regulatory Affairs

The syllabus closes by setting the two disciplines against each other, and the working relationship has five fixed points. First, **the approvals are independent**: the drug regulator grants marketing authorization on quality, safety and efficacy and does not adjudicate patents; India operates **no patent linkage**, so a marketing approval can issue while a patent subsists, leaving enforcement to the patentee's civil action, and conversely a patent confers no right to market without approval. Second, **data**: India has no standalone data exclusivity statute; undisclosed test data receive the protection against unfair commercial use that TRIPS Article 39.3 requires, and the Indian system's answer in practice is the bioequivalence route, under which a generic proves sameness against the approved product rather than repeating its trials, which is why the BE machinery of Unit 4 is the hinge between the two disciplines. Third, **the regulatory review exception**: Section 107A of the Patents Act provides that acts of making, using or importing a patented invention solely for developing and submitting information required by a drug regulator, in India or abroad, are not infringement, the Bolar type provision that lets generics prepare their dossiers during the patent term and launch at expiry. Fourth, **the expiry interface**: launch planning runs off the patent calendar, oppositions and compulsory licence applications are regulatory events with commercial consequences, and the label, brand and pack (sections 5.3 and 5.4) are cleared as IP at the same table as they are approved as regulatory documents. Fifth, **the public health overrides**: compulsory licensing, government use and price control (section 1.7) are the state's standing reservations against both patent and market exclusivity. The professional conclusion is the semester's: regulatory affairs and IPR are two permissions for the same product, and a filing strategy that sequences only one of them will fail on the other.

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The generic launch decision: two permissions, one calendar
Patent position (this unit)
   subsisting product patent? --yes--> wait, license, or challenge
        | no / expired / licensed                (opposition, CL)
        v
Regulatory position (Units 1 to 4)
   approval route + BE data ready under s.107A shelter
        |
        v
Brand, label and pack cleared as IP (5.3, 5.4)
        |
        v
Launch at patent expiry with approval in hand
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Frequently Asked Questions

Q: What is the difference between the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules? The Act of 1940 states the law: definitions of drug and cosmetic, the quality offences of misbranded, adulterated and spurious drugs, the institutions and the licensing powers. The Rules of 1945 carry the operative detail made under the Act: licence forms and conditions, the schedules (M for GMP, G, H, H1 and X for sale control, C and C1 for biologicals) and the day to day procedures. The pair is always read together, and modern subjects such as clinical trials and medical devices now sit in newer rulebooks (NDCT Rules 2019, Medical Devices Rules 2017, Cosmetics Rules 2020) made under the same Act.

Q: Which authority approves a new drug in India, and who licenses its manufacture? Approval of a new drug, including permission for its clinical trials and its marketing authorization, is central, with the Central Licensing Authority in CDSCO, headed by the Drugs Controller General (India), under the New Drugs and Clinical Trials Rules 2019. Once the new drug is authorized, the manufacturing licence for the factory is issued by the State Licensing Authority of the state where the plant is located, after inspection against Schedule M. Sale and distribution licences are also state licences; import registration and licensing are central.

Q: What do Schedules G, H, H1 and X control? They control how medicines may be sold. Schedule G drugs must bear the caution that it is dangerous to take the preparation except under medical supervision. Schedule H drugs are prescription only, carrying the Rx symbol and the prescription warning. Schedule H1, added in 2013 for specified antibiotics, anti tuberculosis drugs and habit forming medicines, requires the retailer to maintain a separate record of the prescriber, patient and quantity, kept for three years. Schedule X covers narcotic and psychotropic substances, demanding a special licence and prescriptions in duplicate, and it works together with the NDPS Act 1985.

Q: How does price control work under the DPCO 2013? The Drugs (Prices Control) Order 2013, issued under the Essential Commodities Act 1955 and implemented by the National Pharmaceutical Pricing Authority (established 1997), fixes ceiling prices for scheduled formulations: the strengths and dosage forms of medicines in the National List of Essential Medicines. The ceiling is a market based figure, essentially the simple average price of brands holding at least one percent of the market, and no manufacturer may sell above it. Non scheduled formulations are not price fixed, but their prices may not rise by more than ten percent in a year.

Q: How are medical devices classified and licensed under the Medical Devices Rules 2017? Devices are classified by risk into Class A (low), Class B (low to moderate), Class C (moderate to high) and Class D (high). Since 2020 all medical devices are notified as drugs under the Drugs and Cosmetics Act and regulated under the 2017 Rules. The State Licensing Authority licenses manufacture of Class A and Class B devices (Class B after notified body audit of the quality system), while the Central Licensing Authority

licenses Class C and Class D manufacture and all imports. Every obligation in the Rules, documentation, audit and clinical investigation, keys off the class.

Q: What is the difference between the drug route and the FSSAI route for a nutraceutical? The dividing line is the claim and the dose. A product presented to cure, treat or prevent disease is a drug and must be approved and licensed under the drug framework whatever it is called. A nutraceutical or health supplement is a food, licensed by FSSAI under the Food Safety and Standards Act 2006 and its health supplements and nutraceuticals regulations, may use only permitted ingredients within the prescribed limits, and may make only the claims those regulations allow. Nutraceutical manufacture requires a central FSSAI licence, and nutrients above the thresholds the drug rules specify are pulled into the drug framework.

Q: What is a BCS biowaiver? Under the Biopharmaceutics Classification System a drug substance is placed in one of four classes by solubility and permeability. For an immediate release generic of a Class I substance (high solubility, high permeability), and under tighter conditions Class III, regulators following the harmonised ICH M9 guideline accept in vitro dissolution comparison in place of an in vivo bioequivalence study: that substitution is the biowaiver. The statistical acceptance for an in vivo study that is run remains the 90 percent confidence interval for AUC and Cmax ratios lying within 80.00 to 125.00 percent.

Q: What is CPCSEA and what does its approval chain look like? CPCSEA is the Committee for the Purpose of Control and Supervision of Experiments on Animals, the statutory committee created under the Prevention of Cruelty to Animals Act 1960. An establishment that breeds experimental animals or performs experiments must register with CPCSEA, and within it the Institutional Animal Ethics Committee, which includes CPCSEA's nominees, must approve every protocol before the work begins and monitors the facility thereafter. The chain matters to drug approval because animal data generated outside it cannot properly support a regulatory filing.

Q: What does Section 3(d) of the Patents Act do? Section 3(d) excludes from patentability the mere discovery of a new form of a known substance that does not result in enhancement of the known efficacy of that substance, and its explanation treats salts, polymorphs, isomers, metabolites and other derivatives as the same substance unless they differ significantly in properties with regard to efficacy. In the Novartis judgment of 2013 the Supreme Court read efficacy for a medicine as therapeutic efficacy and refused the patent on the beta crystalline form of imatinib mesylate. The clause is India's statutory answer to evergreening: a new form must be a better medicine, not merely a newer filing.

Q: Is there patent linkage or data exclusivity in India? No to both, in the statutory sense. India operates no patent linkage: CDSCO and the state authorities grant approvals on quality, safety and efficacy and do not check or enforce patent status, leaving infringement to the civil courts. And India has no standalone data exclusivity law: undisclosed data are protected against unfair commercial use on the TRIPS Article 39.3 pattern, while generic applicants establish their case by bioequivalence against the approved product (Unit 4) and may prepare their dossiers during the patent term under the regulatory review exception in Section 107A of the Patents Act.

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