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OVERVIEW OF PATENT PROCEDURE UNDER PATENT LAW

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A patent is an exclusive statutory right granted to an inventor for a novel, non-obvious, and industrially applicable invention. Patent law aims to encourage innovation by offering inventors a period of monopoly in exchange for public disclosure of their invention. The patent procedure refers to the structured steps that need to be followed from conceiving an invention to obtaining and maintaining the patent. While the procedure varies slightly across jurisdictions, the underlying stages are similar worldwide. In India, the procedure is governed by the Patents Act, 1970 and the Patents Rules, 2003, and operates under the oversight of the Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM).

1. Pre-Filing Stage: Patentability Assessment

Before filing a patent application, it is essential to determine whether the idea qualifies for a patent. The inventor or applicant must check:

1. Patentable Subject Matter – The invention must not fall under non-patentable categories such as discoveries of natural principles, mathematical methods, business methods, computer programs "per se", atomic energy, or traditional knowledge (as per Sections 3 and 4 of the Indian Patent Act).

2. Novelty – The invention must be new and not disclosed anywhere in the world prior to the filing date.

3. Inventive Step (Non-Obviousness) – The invention must not be obvious to a person skilled in the relevant field.

4. Industrial Applicability – The invention must be capable of being made or used in industry.

#Conducting a Prior Art Search through databases like WIPO's PATENTSCOPE, Google Patents, or the Indian Patent Office database is a crucial step. Many inventors also conduct a Patentability Opinion with professional help to reduce risk of rejection.

2. Filing the Patent Application

Once the invention qualifies, the next step is filing a patent application. Filing can be done by the true inventor, an assignee, or a legal representative. The Indian system provides multiple types of applications:

1. Provisional Application – Filed when the invention is at a developing stage. This establishes a priority date and gives 12 months to file the complete specification.

2. Complete Specification Application – Includes full details of the invention, claims, drawings, and abstract.

3. Convention Application – Filed within 12 months of filing in a convention country to claim priority.

4. PCT Application (Patent Cooperation Treaty) – Allows the applicant to seek patent protection in multiple countries through a single international filing. It has two phases—International Phase (WIPO) and National Phase (individual country's patent offices).

5. Divisional Application – Filed when a patent application contains more than one invention.

6. Patent of Addition – For improvement or modification of an already filed or granted patent.

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Documents required include the specification, claims, abstract, statement of undertaking, form for applicant details, and power of attorney (if filed through a patent agent).

3. Publication of Application

After filing, the patent application is ordinarily published after 18 months from the date of filing or priority date. Early publication can be requested for faster processing, after which publication usually occurs within a month. Publication provides public access to the invention but does not grant enforceable rights; however, damages may later be claimed retrospectively from the date of publication once the patent is granted.

4. Examination of Patent Application

Publication is followed by the examination stage, which determines the patentability of the invention. It is not automatic—applicants must file a Request for Examination (RFE) within 48 months from the date of filing or priority. The application is then allocated to an Examiner, who conducts a detailed examination and issues a First Examination Report (FER).

The FER highlights objections related to novelty, inventive step, clarity of claims, sufficiency of disclosure, and compliance with statutory requirements. The applicant must respond to these objections within 6 months (extendable by 3 months). During this stage, the examiner may also cite prior art documents that challenge novelty or inventive step. The applicant may amend claims, provide clarifications, and attend a hearing if required.

5. Pre-Grant and Post-Grant Opposition

Opposition mechanisms enhance transparency and protect public interests.

Pre-Grant Opposition – Any person can file an opposition after publication but before grant. Grounds include wrongful obtainment, prior publication, lack of inventive step, non-patentable subject matter, or insufficient disclosure.

Post-Grant Opposition – Can be filed by any interested person within 12 months of grant. It is heard before the Opposition Board.

Oppositions ensure that unworthy or frivolous patents are prevented from surviving, thus maintaining balance between innovation and public access.

6. Grant of Patent

If all objections are successfully addressed and no valid opposition remains, the Controller grants the patent. It is then recorded in the Patent Register and published in the Patent Journal. The inventor receives exclusive rights to make, use, sell, license, or assign the patented invention for 20 years from the filing date. For PCT national phase applications, the 20-year term is calculated from international filing date.

7. Post-Grant Compliance and Maintenance

Granting a patent is not the end of the procedure. Patent rights need to be maintained through annual renewal fees starting from the third year onward till the patent expires. Failure to pay renewal fees results in lapse of the patent, although restoration may be sought within a specified period. Patentees must also comply with working requirements, where they must file Form 27 annually to declare the extent to which the patent has been commercially worked in India.

8. Enforcement of Patent Rights

A granted patent gives the owner the legal right to enforce it against infringement. Patent infringement includes making, selling, importing, or using the patented invention without authorization. Remedies available include injunctions, damages, account of profits, and destruction of infringing goods. Indian courts also encourage settlement through licensing agreements, compulsory licensing, and technology-sharing mechanisms in public interest.

9. Patent Revocation and Compulsory Licensing

Even after grant, a patent can be challenged through revocation on grounds such as lack of

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novelty or non-patentability. Additionally, to balance monopolies with public welfare, the law provides for Compulsory Licensing after three years of grant if:

the invention is not reasonably available to the public,

it is not affordable

it is not being worked in India.

This ensures access to essential technologies, especially in fields like pharmaceuticals.

CASE STUDIES REGARDING THIS:

1) Novartis AG v. Union of India (Gleevec) — examination, inventive-step/Section 3(d) & pre-grant opposition

What happened (short): Novartis sought patent protection for the β-crystalline form of imatinib mesylate (Gleevec). The Indian Patent Office rejected the application; after oppositions and appeals the Supreme Court (2013) upheld the rejection under Section 3(d) (anti-evergreening provision), finding no demonstration of enhanced therapeutic efficacy over the known compound.

Procedure stage illustrated: substantive examination + impact of statutory exclusions (how national patentability thresholds beyond novelty/non-obviousness affect grant). Also shows how third-party pre-grant opposition can be decisive.

Practical takeaways:

For pharma filings, include comparative data showing enhanced therapeutic efficacy if claiming new forms of known compounds.

Keep public disclosures of earlier forms in mind — prior disclosure can block patents even for improved crystal forms.

Pre-grant oppositions are powerful; a robust prosecution record and early experimental evidence help resist oppositions.

2) Bayer v. Natco (Nexavar) — compulsory licence (access vs monopoly)

What happened (short): Natco sought a compulsory licence for Bayer's cancer drug Nexavar on grounds of unaffordability and inadequate working in India. The Controller (and later IP bodies) granted India's first major compulsory licence (2012), imposing conditions (royalty, quality, scope). The case illustrates post-grant remedies and public-interest balancing.

Procedure stage illustrated: post-grant remedies (compulsory licensing under statutory criteria), plus appeals to IP appellate forums.

Practical takeaways:

Patent holders should anticipate public-interest arguments (price, availability) in pharma; pricing/working strategies matter.

Applicants and counsels must preserve records showing adequate working in the jurisdiction and consider voluntary licences or tiered pricing where feasible.

3) Roche v. Cipla — injunctions, interim relief, and evidence on infringement

What happened (short): Roche sued Cipla for infringement of an erlotinib patent. The courts scrutinised the scope of claims, the patent specification, and whether the plaintiff proved infringement and entitlement to interim injunctions; the Delhi courts denied automatic relief and required clear proof.

Procedure stage illustrated: enforcement after grant — preliminary injunctions, proving infringement and damages, and the court's discretionary approach.

Practical takeaways:

To obtain interim relief, patentees must show prima facie validity + balance of convenience + irreparable harm — include strong claim construction and infringement evidence.

Defendants can challenge sufficiency of disclosure, claim breadth, or non-infringement as effective tactical defence.

4) Pre-grant & post-grant opposition role — procedural mechanics & recent clarifications;

What happened (short): Indian practice allows third parties to file pre-grant oppositions during prosecution and post-grant oppositions after grant. Recent decisions (and practice notes) clarify the scope of participation — e.g., opponents don't supplant the Controller's independent examination (opposition material is considered but the Controller assesses patentability afresh). See recent commentary and case updates (including 2024 summaries).

Procedure stage illustrated: opposition proceedings (timing, grounds, interplay with examiner's role).

Practical takeaways:

Use pre-grant opposition to stop weak claims before grant, but don't assume opponents can steer the examination — produce strong documentary/experimental evidence if challenging or defending.

For applicants: prepare robust claim charts, search reports and evidence to address predictable opposition grounds (novelty, inventive step, sufficiency).

5) Recent administrative clarifications & procedural lessons (examples from 2023–2024 opinions)

What happened (short): A string of administrative and court rulings in 2023–2024 clarified procedural points: timeliness and scope of pre-grant oppositions, the Controller's independent assessment, and limits on opponents' direct participation during examination. These help set expectations about timelines and what evidence matters.

Procedure stage illustrated: how patent office procedure and case law shape prosecution timelines, use of evidence, and strategies for both applicants and third parties.

Practical takeaways:

Track recent Controller & appellate decisions; small procedural rulings can change tactical choices (e.g., whether to fight at pre-grant stage or wait for post-grant appeal).

Consider cost/benefit of oppositions: while pre-grant opposition can delay or block a grant, it may also alert applicants and improve claim drafting.

Short checklist for patent procedure (drawn from the case studies)

1. Before filing: do a thorough freedom-to-operate and prior art search; for pharma, include polymorph/crystal-form literature.

2. Drafting: include data showing technical advantage (especially for incremental improvements) and clear enablement.

3. Prosecution: respond to examiners with experimental proof where needed; anticipate pre-grant opposition grounds.

4. If opposed: prepare claim construction charts, comparative data, and legal briefs focusing on statutory tests.

5. After grant: monitor for post-grant oppositions and be ready to show working/availability to counter compulsory licence arguments.

Sources:

Supreme Court: Novartis AG v. Union of India (judgment and analyses).

Bayer v. Natco (compulsory licence — Controller/IPAB analyses and retrospectives).

Roche v. Cipla — Delhi High Court / case reports on injunction & evidence.