

# Overview of Patent Regime

## Japan & China



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**PG Diploma In Patents**  
**NALSAR University of Law, Hyderabad Contact**  
**Class; Merch, 2021.**

# Japan – Patent Laws

- The first article of the Patent Act of Japan states that  
*“the purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions and thereby to contribute to the development of industry”.*
- Non-Japanese must meet at least one of the following requirements to be entitled to the rights related to patent:
  - To have a domicile or residence (or a place of business in the case of a legal entity) in Japan;
  - To be a national of a country which grants Japanese nationals equal national treatment or of a country which follows the principle of reciprocity; or
  - Requirements as provided for by other conventions.



# Japan – Invention



- The Japan Patent Act defines an invention as  
*“an highly advanced creation of technical ideas utilizing the laws of nature”*.
- Consideration for an invention includes:
  - The utilization of the laws of nature being a requisite, laws of nature themselves (such as gravity law), purely mental activities (such as mnemonics), laws based on pure scholarship (such as mathematic laws) and human conventions (such as trade methods) are not inventions under Japanese patent law.
  - An invention must be a technical idea; accordingly, it must be a concrete way of achieving a determined result, must be reproducible and must be likely to be implemented.
  - An invention being an act of creation, the mere discovery of pre-existing natural phenomena is not an invention under Japanese patent law.
  - The reference to an invention being —highly advanced - is used to distinguish patent inventions from utility model inventions.

# Japan – Patentability

## ➤ Industrial applicability

- The invention must have industrial implementability.
- “*Industrial*” is taken here in a broad acceptation and includes domains of economic activity not related to the manufacturing of goods, such as services or transport.

## ➤ Novelty

- An objective lack of novelty will prevent it from meeting the patentability requirements.
- The grant of a patent right implies the disclosure of a novel invention in exchange for protection, granting an exclusive right regarding an already known technology would go against the purpose of the patent system.

## ➤ Inventive Step

- Even if an invention has novelty, it isn’t deemed to meet the inventive step requirement in the case that it could have easily been made by a person having common knowledge in the technical field to which the invention pertains based on the existing prior art.

## ➤ Earliest Application (*first-to-file principle*)

- In the case that a third party has filed an earlier application, the application filed by the third party, provided it meets all requirements for patentability, will be registered, even if the applicant of the second application created the invention first.

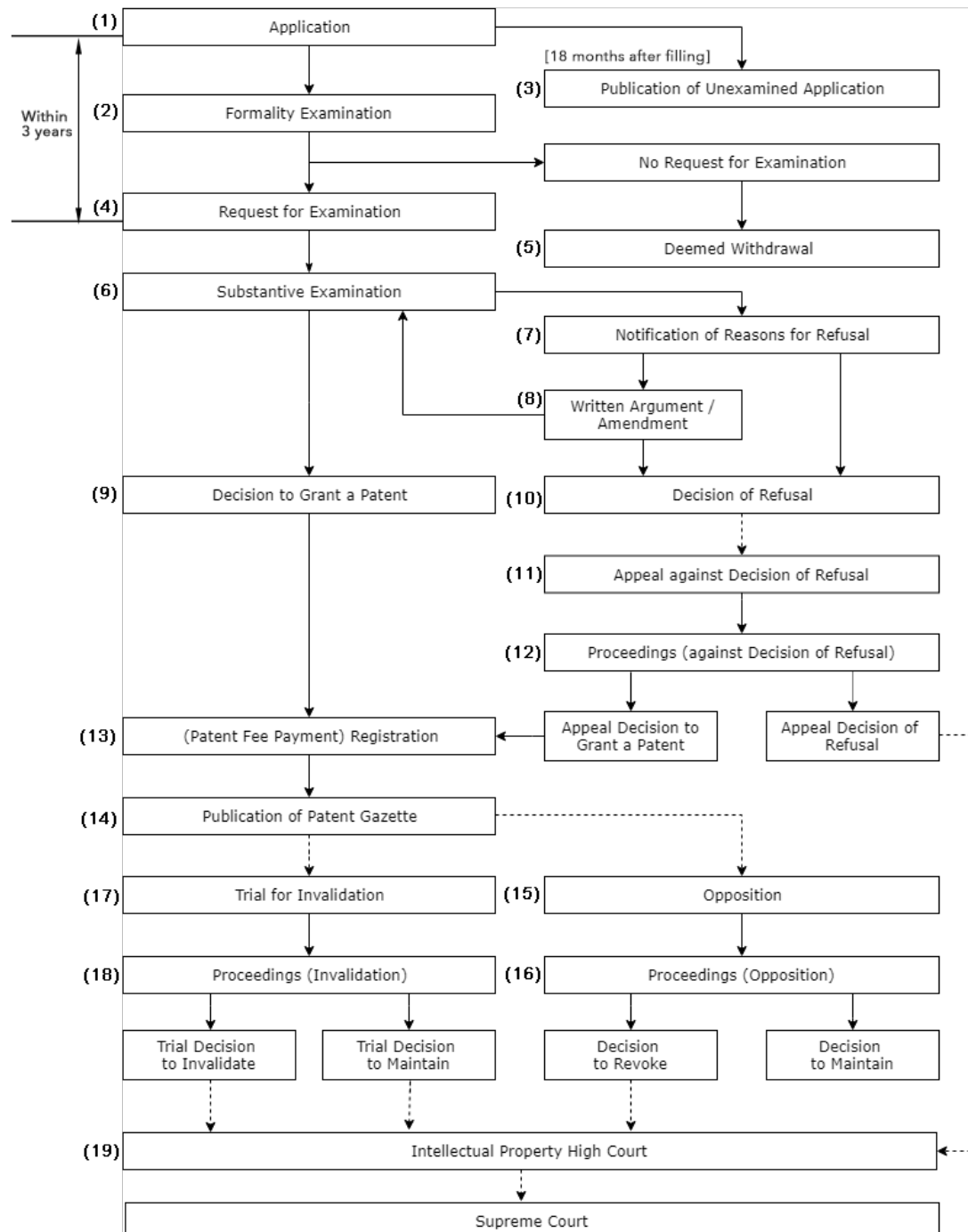
## ➤ *The invention hasn’t been disclosed in the description of an earlier application*

- Due to the fact that the content of a patent application is disclosed after a determined period following the date of filing, there is a possibility that earlier applications haven’t been disclosed yet at the time of filing of a new application.

# Japan – Patentability

- *Not contrary to public order, morality or public health*
  - Inventions liable to injure public morality, public order or public health shall not be patented.
- *Discloses the invention in a manner sufficiently clear and complete for a person skilled in the art to carry it out*
  - Sufficiency of disclosure or enablement is a requirement according to which a patent application must disclose a claimed invention in sufficient detail for the notional person skilled in the art to carry out that claimed invention.
- *The statement of the claims is clear.*
- *The application meets the requirement for unity of invention*
  - A patent application can relate only to one invention or a group of closely related inventions.
  - The purpose of this requirement is administrative, as well as financial.
- *Format of the specification and application documents*
  - The JPO provides a specific format for the application documents.
  - A patent application must comprise a specification, a set of claims and (if required) drawings.
  - The objective is to enable the JPO to disclose the technical details of the invention, and to allow for easy reference of the scope of the right after registration.

# Japan – Obtaining a Patent



# Japan – Patent: Enforcement

- Following the issue of a Decision to grant a patent, the remittance of the registration fee allows the patent right to be registered by the JPO and to become effective.
- The effect of the patent right can be divided between active effect and negative effect, the former referring to the ability to work the invention on an exclusive basis and the latter to the ability of preventing third parties from working the invention.
- Limitations to the patent right are determined so as to promote public interest and industrial development and in order to maintain a balance with the rights of other parties.
- The effect of the patent right does not apply with regard to the working of the invention for experimental or research purposes, as such working may lead up to the creation of a better invention.
- Trial for invalidation:
  - Anyone may demand the commissioner of the patent office a trial for invalidation of a patent against the patentee.
  - A group of three or five trial examiners conduct the trial, gathering the parties to the patent office
  - The patentee may demand restriction of claims, or correction of errors or ambiguity to avoid the invalidation.
  - A lawsuit against patent infringement may be suspended until a trial decision of the patent office has become final and conclusive.

# Japan – Patent: Infringement

- The Patent Law is the principal source of substantive law governing patents.
- The Code of Civil Procedure and Rules of Civil Procedure are the principal sources of law and regulation relating to the procedural aspects of patent litigation in Japan.
- The Civil Provisional Remedies Law governs provisional relief in connection with patent infringement, including preliminary injunctions.
- A patentee has an exclusive right to work the patented invention commercially<sup>40</sup>. Therefore, the unauthorised commercial working by a third party of a claimed invention constitutes patent infringement.
- Under the Patent Law, "*working*" means the following acts:
  - In the case of an invention of a product (including a programme): the production, use, assignment, lease, export, import, or the offer for assignment or lease, of the product.
  - In the case of an invention of a process: the use of the process.
  - In the case of an invention of a process for manufacturing a product: the use, assignment, lease, export, import, or offer for assignment or lease, of the product manufactured by the process, in addition to the use of the process.
- The following five requirements must be satisfied for successfully asserting the doctrine of equivalents:
  - The part replaced is an insubstantial part of the claimed invention;
  - The replacement of the part achieves the object of the claimed invention and produces the same result as the claimed invention;
  - The replacement of the part would have been obvious to a skilled person at the time of making the accused product (the time of infringement);
  - The accused product was novel and non-obvious at the time when the application was made, which means that the accused product could be patentable; and
  - There is no proof showing that the applicant intentionally excluded the accused product from the claimed invention during the prosecution.



# Japan – Patent: Remedies

## ■ Civil remedies

- Injunction: The patentee may exercise a right to demand an injunction against the person who infringes or is likely to infringe its rights. A —person who infringes or is likely to infringe the patent rights|| in that paragraph means a person who works a patented invention without the patentee's permission, or a person who commits an act of indirect infringement. In making a demand for an injunction, the patentee may also demand measures necessary for the prevention of an act of infringement, including the disposal of products constituting the act of infringement and the removal of facilities used for the act of infringement.
- Damages: Since a patent right is also a kind of property right, an act of infringement of a patent right constitutes a tort, and a patentee who sustains damages as a result of an act of infringement may demand damages from the infringer in tort. Unlike an ordinary tortious act however, in the case of the infringement of a patent right, it is often difficult to prove the amount of the loss, as well as intent or negligence on the part of the infringer. For that reason, the Patent Act contains a special provision for calculating the amount of loss, a provision on the presumption of negligence, and a provision permitting the determination of a reasonable amount of loss.

## ■ Criminal penalty

- Japanese patent law provides that patent infringement is a crime. A person who has infringed a patent right must be engaged in penal servitude for at most ten years, and/or must pay a fine of at most ten million Yen..
- In addition to the above penalty for an infringer, a firm that the infringer belongs to must pay a fine of at most 300 million Yen.

# Japan – Patent Term Extensions

- Patents have a 20-year patent life from the date of the filing of the patent application.
- The effective patent term is frequently less than 20 years in the field of pharmaceuticals and agrochemicals due to the requirements in the relevant laws that these products receive government approval before marketing.
- In order to encourage inventions in these fields, the patent life is extended to compensate patent holders for marketing time lost while developing the product and awaiting government approval.
- The Patent Act gives the requirements for extending the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years:
  - where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc., or
  - any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention.
- If multiple patents for the same product exist, each patent may be extended, based on its own application date alone - each patent may end up expiring on a different date, and the part of the invention whose patent expires earlier would no longer be protected.

# China – Patent Laws

- Patents in China are granted by the *China National Intellectual Property Administration*, (CNIPA), which was renamed in English on August 28, 2018 from *State Intellectual Property Office* (SIPO).
- Invention patents are substantively examined, while utility model patents are subject only to a formal examination.
- There are three types of patents available in China:
  - **Invention patents:** any new technical solution relating to a product, a process or an improvement thereof;
  - **Utility model patents:** any new solution relating to the shape, the structure or their combination, of a product, which is fit for practical use., and
  - **Design patents:** any new design regarding the shape, pattern, or their combination thereof, which creates an aesthetic feeling and is fit for industrial application.
- The term for invention patents in China is 20 years from the filing date.
- The duration of utility model and design rights is 10 years, which is also calculated from the date of filing.
- The Chinese Patent Law does not include any provisions on patent term extensions or supplementary protection certificates (SPCs).



# China – Invention



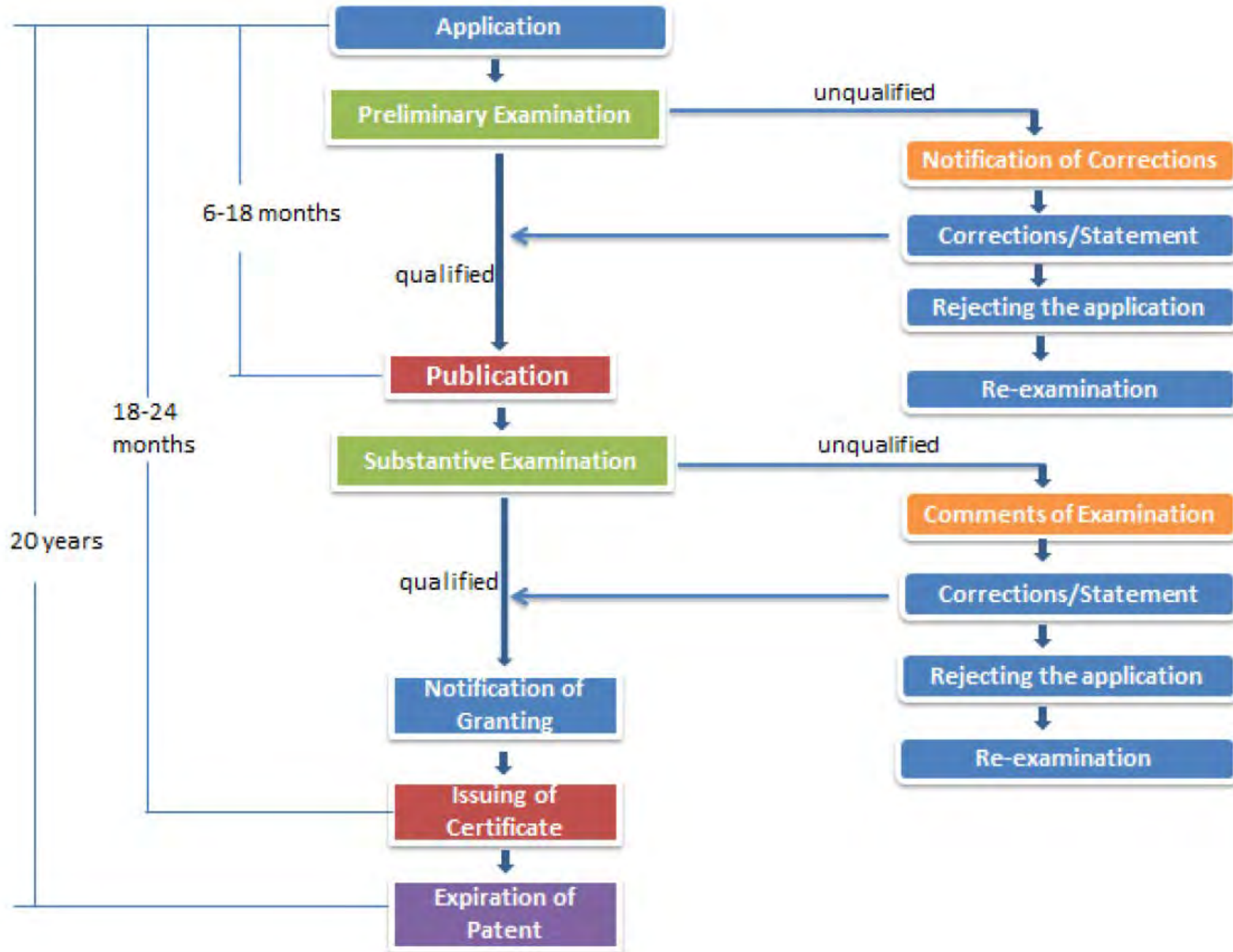
- China Patent Law defines an *"invention"* as  
*"any new technical solution relating to a product, a process, or improvement thereof"*.
- The terms *"technology"*, *"technical problem"*, *"technical effect"*, and *"technical feature"* are clearly defined in the Patent Law or the Regulations and the Guidelines but the Chinese Patent Law.
- According to the Chinese Patent Law, the following items are not patentable in China:
  - any invention-creation that is contrary to the law or social morality or that is detrimental to public interest;
  - invention-creations relying on genetic resources of which the acquisition or use is not consistent; with the provisions of the laws and regulations;
  - scientific discoveries;
  - rules and methods for mental activities;
  - methods for the diagnosis or treatment of diseases;
  - animal and plant varieties;
  - substances obtained by means of nuclear transformation;
  - two-dimensional designs of images or colours or combinations of the two that mainly serve as indicators.
- Computer programs as such cannot be patented, but they may be protected under the Regulations on Computers Software Protection, formulated in accordance with the Copyright Law.
- An invention containing a computer program may be patentable if the combination of software and hardware as a whole can actually improve the prior art, bring about technical results and constitute a complete technical solution.

# China – Patentability

- In order to be granted a patent right, the invention or utility model must possess
  - Novelty
    - Novelty means that, before the date of filing, the same invention or utility model has not been publicly used or made known to the public in China or abroad.
  - Inventiveness
    - Inventiveness means that, as compared with the technology existing before the date of filing, the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress.
  - Practical Applicability.
    - Practical applicability means that the invention or utility model can be made or used industrially and can produce effective results.
- Applications for patents for invention are subject to substantive examination (novelty, inventive step and industrial applicability).
- Utility model applications undergo a formal examination only.
- Any patentable design must possess novelty, i.e. it must not be identical with nor similar to any design which, before the date of filing, has been publicly disclosed inside or outside China.
- *"Service"* and *"Non-service"* Inventions:
  - A service invention is an invention made by an employee of a company in the performance of his duties. In such cases, the right to apply for a patent belongs to the company, which will also be the patent holder after grant.
  - Non-service inventions are those made by individual inventors.



# China – Obtaining a Patent



# China – Patent: Enforcement

## ➤ Administrative Action

- Internal rules and regulations can be place-specific and often there are hidden issues that do not suit every case. Generally, an IP owner may file a complaint with relevant local enforcement authorities, for example:
  - ✓ The State Administration for Industry and Commerce ("SAIC") and its local branches regulate trade mark infringement and unfair competition acts;
  - ✓ The National Copyright Administration ("NCA") and its local offices regulate cases of copyright infringement; and
  - ✓ The State Intellectual Property Office ("SIPO") and its local offices deal with patent infringement.

## ➤ Civil Litigation

- Only the Chinese courts have the power to issue preliminary and permanent injunctions, and to order infringers to pay damages to the IP owner.
- There are specialised IP Courts, specialist panels or tribunals of expert judges to hear IPR cases - the tribunals recently installed in Wuhan, Nanjing, Chengdu and Suzhou.
- One of the main drawbacks to civil litigation in China are its high evidentiary burden and case filing formalities. - for documents from outside of China to be admitted as evidence, they have to be notarized, legalised, and translated.

## ➤ Criminal Action

- Under the PRC Criminal Law, IP infringements which reach certain monetary thresholds constitute criminal offences, and are investigated by the Public Security Bureaus ("PSB").
- In practice, the PSB most often relies on complaints filed by IPR owners to take action.

## ➤ Customs Action

- China has both entry and exit customs screenings.

# China – Patent: Infringement

- Most judges have no technical background.
- Expert testimony and reports from judicial appraisal centres and court-appointed appraisers can be used to help judges identify and understand the technical facts of a patent case.
- Since the end of 2014, China established three IP courts in Beijing, Shanghai and Guangzhou.
- Within the IP courts, there is a network of technical investigation officers.
- A single judge or a panel of judges decides civil cases, depending on the complexity of the case.
- A three-judge panel decides most patent cases.
- Jury trials do not exist in China.
- In addition to considering the literal scope of a patent claim, the patent scope is determined by considering features that are not specifically covered by, but are equivalent to, the technical features of a patent claim.
- Equivalent features are those that:
  - use substantially the same means, perform substantially the same function and produce substantially the same effect as the claimed technical features; and
  - could have been contemplated by a person with ordinary skill in the art without inventive labour before the date of the alleged infringement.



# China – Patent: Remedies

- Patent owners or interested parties may obtain preliminary injunctions (although it is rare for one to be granted in a patent case) from a court if the following are sufficiently demonstrated:
  - the patent owner or an interested party has a valid patent right or an interest in the valid patent right;
  - the party that the injunction is sought against is performing or is going to perform infringing acts;
  - the acts will likely cause irreparable harm; and
  - guarantee.
- Under the Patent Law, damages are determined as follows:
  - actual losses due to infringement;
  - gains of the infringer from infringement (if actual loss is difficult to determine);
  - an appropriate multiple of a reasonable royalty fee (if actual loss and gains are difficult to determine); or
  - statutory damages of between CYN 10,000 and CYN 1 million (if actual loss, gains and royalty fees are difficult to determine).
- A patent may be invalidated based on the following limited grounds:
  - Confidentiality examination requirements for inventions made in China were not satisfied before filing of the patent outside China.
  - There is a lack of novelty, inventiveness or usefulness.
  - There is insufficient disclosure.
  - The description does not support the claims.
  - Amendments to the patent application documents exceed the original scope.
  - Independent claims fail to state the essential technical features of the solution to the technical problem.
- A patent cannot be invalidated solely on the basis that the listed inventors are not the actual creators of the invention.
- In patent infringement cases, the courts can grant successful plaintiffs the following remedies:
  - preliminary injunctions;
  - final injunctions;
  - reasonable fees for pre-grant use between the publication date and patent grant date (available only for invention patents);
  - damages for post-grant infringement; and
  - court fees and reasonable costs incurred.

# Patent Regimes



|                 |                           |                                                                                                                      |                                                                                                                    |                                                                                                      |                                                                                          |                                                                                          |
|-----------------|---------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Governing Rules | Law                       | U.S. Patent Law (35 U.S.C.); as amended by Leahy-Smith America Invents Act (AIA), 2011                               | European Patent Convention (EPC) - 15 <sup>th</sup> edition, 2013                                                  | Act No. 121 of 1959 as amended in Act No. 55 of 2015                                                 | Patent Law of the PRC, 1984; as amended in 1992, 2000 and 2008                           | Patents Act, 1970; as amended in 1999, 2002. and 2005                                    |
|                 | Rules/ Regulations        | U.S. Patent Rules (37 C.F.R); as updated in November, 2015                                                           | Implementing Regulations to the EPC, 2014                                                                          | Examination Guidelines for Patent and Utility Model in Japan, as revised on March 10, 2020.          | Implementing Regulations of the Patent Law of the PRC, 2001; as amended in 2002 and 2010 | Patents Rules, 2003; as amended in 2005, 2006, 2012 and 2014                             |
| Patentability   | Patentable Subject Matter | Invention or discovery of a new & useful process/ machine/ manufacture/ composition of matter or improvement thereof | Invention which is new, involve an inventive step; & industrially applicable, belonging to any field of technology | Inventions in the form of highly advanced creation of technical ideas utilizing the laws of nature". | Inventions in the form of new technical solution or improvement to a product/ process    | New product or process involving an inventive step and capable of industrial application |
|                 | Criteria of Patentability | Novelty; Non-obviousness; Usefulness                                                                                 | Novelty; Inventive step; Industrial application                                                                    | "Novelty; Inventive step; Industrial application"                                                    | Novelty; Inventive step; Practical applicability                                         | Newness; Inventive step; Industrial applicability                                        |



|            |                                                                                                 |                                                                                                                                                                                                                       |                                                                                                                                                                                                                                  |                                                                                                                           |                                                                                                                                                                                         |                                                                                                                                                             |
|------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Polymorphs | Specific restrictions on the patentability of polymorphs/ new forms in the governing law/ rules | No specific restrictions                                                                                                                                                                                              | No specific restrictions                                                                                                                                                                                                         | No specific restrictions                                                                                                  | No specific restrictions                                                                                                                                                                | Under Section 3(d) of the Patents Act, to be patentable a new form of the known substance must show enhanced efficacy as compared to the existing substance |
|            | Regulations by case laws/ patent prosecution/ examination guidelines                            | The new form shall not be a result of routine “experimentation”; it shall not be “obvious to try”; and it shall not be “inherently disclosed” in the prior art; “unexpected results” can be used to rebut obviousness | The polymorph shall merely not provide only the “obvious advantages” of a crystalline material over the amorphous form; in the absence of any “technical prejudice” and “unexpected property” it cannot be regarded as inventive | The need to fully disclose the conditions used to synthesize the crystal (solvents, temperatures, times, pH values, etc.) | An “unexpected effect” of the claimed polymorph shall be demonstrated; “obvious advantages” of the polymorph such as better stability is not sufficient to establish the inventive step | Term “efficacy” in Section 3(d) means “therapeutic efficacy”                                                                                                |
| Filing     | Where/ how to file the patent application                                                       | At USPTO office; or through e-filing                                                                                                                                                                                  | At EPO in Munich/ Hague/ Berlin; or through e-filing                                                                                                                                                                             | At JPO, Tokyo; or its representative offices; or through e- filing                                                        | At SIPO, Beijing; or its representative offices; or through e- filing                                                                                                                   | At patent offices in Kolkata, Delhi, Chennai or Mumbai; or through e-filing                                                                                 |
|            | Provisional specification filing                                                                | Allowed                                                                                                                                                                                                               | Not allowed                                                                                                                                                                                                                      | Not allowed                                                                                                               | Not allowed                                                                                                                                                                             | Allowed                                                                                                                                                     |



|             |                                                      |           |                                                                                 |                                                                                 |                                                                                 |               |
|-------------|------------------------------------------------------|-----------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------|
| Prosecution | Stages in patent examination                         | One stage | Two stages viz.<br>Formalities<br>examination and<br>Substantive<br>examination | Two stages viz.<br>Preliminary<br>examination and<br>Substantive<br>examination | Two stages viz.<br>Preliminary<br>examination and<br>Substantive<br>examination | One stage     |
|             | Request for early publication                        | Possible  | Possible                                                                        | Possible                                                                        | Possible                                                                        | Possible      |
|             | Option to opt- out of the<br>publication             | Available | Not available                                                                   | Not available                                                                   | Not available                                                                   | Not available |
|             | Issue of search report & opinion on<br>patentability | No        | Yes                                                                             | No                                                                              | No                                                                              | No            |
|             | Expedited patent examination                         | Available | Available                                                                       | Available                                                                       | Available                                                                       | Available     |
|             | Member of<br>PPH program                             | Yes       | Yes                                                                             | Yes                                                                             | Yes                                                                             | Yes           |
|             | Supplemental<br>examination                          | Yes       | No                                                                              | No                                                                              | No                                                                              | No            |
|             | Continued examination/ re-<br>examination            | Yes       | No                                                                              | No                                                                              | Yes                                                                             | No            |



|                                     |                                           |                                                                                                                                                                                                                          |                                                                                                                                                                                        |                                                                                                                                                                 |                                                                                                                                                                                         |                                                                                                                                                                                                                             |
|-------------------------------------|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Disclosures of Foreign Applications | Provision under the Law                   | All information material to the patentability of the invention shall be disclosed to USPTO                                                                                                                               | Copy of the results of prior art search/ patent examinations (priority search reports) shall be provided to EPO                                                                        | There is no ongoing duty to submit additional citations that you are aware of from the results of prosecution in corresponding applications in other countries. | Copy of the results of prior art search/ patent examinations (priority search reports) shall be provided to SIPO                                                                        | Detailed particulars of the corresponding foreign patent application(s) must be submitted to the Indian Patent office from time to time                                                                                     |
|                                     | Case Laws                                 | Information is material to the patentability if it establishes a prima facie case of un-patentability; or based upon which un-patentability could not be opposed; or patentability of the claim could not be established | -----                                                                                                                                                                                  | -----                                                                                                                                                           | -----                                                                                                                                                                                   | Conflicting decisions; IPAB held that failure to comply due to any reason whatsoever is a violation; whereas as per High Court decision omission of information due to unintentional/ clerical/ bona-fide error is exempted |
|                                     | Consequence/ Penalty on Failure to Comply | Failure to comply is an inequitable conduct; during a counter claim of infringement, patent can be invalidated                                                                                                           | Application deems to be withdrawn if priority search reports are not provided by the applicant to EPO upon request by the office; not a ground of patent revocation after patent grant | -----                                                                                                                                                           | Application deems to be withdrawn if priority search reports are not provided by the applicant to SIPO upon request by the office; not a ground of patent revocation after patent grant | Ground of patent opposition u/s 25(1) and 25(2); Patent can be revoked after the grant u/s 64(1)(m).                                                                                                                        |



| Oppositions - Pre Grant  | Proceeding                            | Ex-parte preissuance submissions by third parties | Ex-parte observations by third parties | Ex-parte observations by third parties | Ex-parte observations by third parties | Inter-partes pre-grant opposition       |
|--------------------------|---------------------------------------|---------------------------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|-----------------------------------------|
|                          | Fee                                   | No                                                | No                                     | No                                     | No                                     | No                                      |
|                          | Estoppel Provision                    | No                                                | No                                     | No                                     | No                                     | No                                      |
|                          | Threshold to Institute the Proceeding | Not applicable                                    | Not applicable                         | Not applicable                         | Not applicable                         | No threshold prescribed                 |
| Oppositions - Post Grant | Proceeding - 1                        | Inter partes post-grant review                    | Inter partes post-grant opposition     | Inter partes post-grant invalidation   | Inter partes post-grant invalidation   | Inter partes post-grant opposition      |
|                          | Threshold to Institute the Proceeding | Yes                                               | No                                     | No                                     | No                                     | No                                      |
|                          | Estoppel Provision                    | Yes                                               | No                                     | Yes                                    | Yes                                    | Yes (as per the Supreme Court decision) |
|                          | Proceeding - 2                        | Inter partes review                               | No similar provision                   | No similar provision                   | No similar provision                   | No similar provision                    |
|                          | Proceeding - 3                        | Ex parte re-examination                           | No similar provision                   | No similar provision                   | No similar provision                   | No similar provision                    |



|                    |                              |                |                 |                |                |                                                                                                                                                                                                       |
|--------------------|------------------------------|----------------|-----------------|----------------|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Working of Patents | Is reporting mandatory?      | No             | No              | No             | No             | Yes (in Form-27)                                                                                                                                                                                      |
|                    | Penalty on failure to comply | Not applicable | Not applicable  | Not applicable | Not applicable | Failure to furnish the information is punishable with fine up to ten lakh rupees; knowingly furnishing false information is punishable with imprisonment up to six months, or with fine, or with both |
| Term Extension     | Patent term adjustment       | Available      | Not allowed     | Not allowed    | Not available  | Not available                                                                                                                                                                                         |
|                    | Patent term restoration      | Available      | Available (SPC) | Available      | Not available  | Not available                                                                                                                                                                                         |





|                              |               |                                                                                            |                                                                                                                                                                                                                            |                                                                                                                                                                          |                                                                                                                                                 |                                                                                                                            |
|------------------------------|---------------|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Patent Linkage               | Provision     | Hatch- Waxman Act, 1984                                                                    | Not available                                                                                                                                                                                                              | Price competition between original drugs and generic drugs is limited even after the market entry of generic drugs, compared with price competition among generic drugs. | Basic frame work under the Drug Registration Rules                                                                                              | Not available                                                                                                              |
| IP Specialized Court         | Patent Courts | The Federal Circuit court is specialized to deal with appeals related with patent disputes | IP specialized courts are constituted at national level in some countries e.g. U.K.; Unified Patent Court (UPC) is going to be constituted under forthcoming unitary patent system.                                        | The IP High Court is a court specialized in IP cases and specifically established by the legislative body by way of a special provision to the Court Organization Law    | Three IP courts have been established in Beijing, Shanghai and Guangzhou                                                                        | No IP/ patent specialized courts; IP cases worth > Rs 1 crores shall be adjudicated in the newly created Commercial Courts |
| Service/ Employee inventions | Regulation    | No specific regulation                                                                     | EPC distinguishes between the rights of employers and the employee- inventors; the comparative right of employer/ employee on the service inventions to be determined according to the laws of the individual member State | No specific regulation                                                                                                                                                   | Under Article 16 of the Chinese patent law specific mechanism to ensure adequate rewards/ remunerations for the inventors of service inventions | No specific regulation                                                                                                     |



|                    |                                                                                                                 |                                                                                               |                             |                                                                                    |                      |                                                                                                                        |
|--------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------|------------------------------------------------------------------------------------|----------------------|------------------------------------------------------------------------------------------------------------------------|
| Compulsory Licence | Use of patented invention by or for the government                                                              | 28 U.S.C. 1498(a)                                                                             | -----                       | The applicable law of Japan does not provide exceptions related to government use. | Article 49           | (1) Sec. 92: CL on notifications by central government<br>(2) Sec. 99-103: Use of invention for purposes of government |
|                    | Anti- competitive/ anti-trust practice by the patentee                                                          | Sherman Antitrust Act                                                                         | -----                       | No similar provision                                                               | Article 48           | Sect. 83(f): Anti-competitive practice is a ground for the issue of CL                                                 |
|                    | Non-working of the patent by the patentee                                                                       | Denial of injunctive relief as per the Supreme Court's decision in eBay Inc. vs. MercExchange | -----                       | Article 93                                                                         | Article 48           | Sec. 84(1)(c): Non-working of the patent is a ground for the issue of CL                                               |
|                    | Non-working of patents acquired under government funded projects                                                | Bayh-Dole Act                                                                                 | No similar Act              | No similar Act                                                                     | No similar Act       | No similar Act                                                                                                         |
|                    | Export of patented pharmaceutical products under paragraph 6 decision of the Doha Declaration                   |                                                                                               | Regulation (EC) No 816/2006 |                                                                                    |                      | Section 92A                                                                                                            |
|                    | Mandatory cross- licensing between the owners of patented biotechnology inventions and registered plant variety | No similar provision                                                                          | Directive 98/44/EC          | No similar provision                                                               | No similar provision | No similar provision                                                                                                   |



|                    |                                                                           |                       |                       |                       |                                                                  |                       |
|--------------------|---------------------------------------------------------------------------|-----------------------|-----------------------|-----------------------|------------------------------------------------------------------|-----------------------|
| Compulsory Licence | Public health crises                                                      |                       |                       | Article 83            | Article 50                                                       | Section 92            |
|                    | Export of patented drugs                                                  |                       |                       |                       | Article 50                                                       | Section 92A           |
|                    | Licensing of related patents                                              |                       |                       |                       | Article 51                                                       | Section 91            |
|                    | Predominant use for the domestic market                                   |                       |                       |                       | Article 53                                                       | Section 90(1)(vii)    |
|                    | Prior efforts of the applicant to obtain a voluntary license is necessary |                       |                       | Article 83            | Article 54                                                       | Section 84(6)(iv)     |
|                    | Termination of the compulsory licence                                     |                       |                       | Article 83            | Article 55                                                       | Section 94            |
|                    | Non-exclusive basis                                                       |                       |                       | Article 83            | Article 56                                                       | Section 90(1)(iv)     |
|                    | Adequate remuneration to the patentee                                     |                       |                       | Article 83            | Article 57                                                       | Section 90(1)(i)      |
|                    | Decision on compulsory license subject to judicial review                 |                       |                       |                       | Article 58                                                       | Section 117A          |
|                    | Detailed guidelines on CL                                                 | No similar guidelines | No similar guidelines | No similar guidelines | Measures for Compulsory Licensing of Patent Implementation, 2012 | No similar guidelines |



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**Dr. Anindya Sircar**

Visiting Faculty

NALSAR University of Law, Hyderabad

<Anindya\_Sircar@yahoo.com>