2. PATENT LAWS IN INDIA, U.S., EUROPE AND CHINA

2.1 Patent law in India

In India the governing law for patent protection is the Patents Act, 1970; and the Patents Rules, 2003. In order to comply with the TRIPS requirements, the Act was amended thrice, by the Patents (Amendment) Act, 1999, the Patents (Amendment) Act, 2002 and the Patents (Amendment) Act, 2005. The amended Patents Act consists of XXIII chapters comprising 162 Sections; and the Patents Rules consist of XVI chapters comprising 139 rules. There are four Schedules to the Patents Rules which prescribe fees (Schedule I); forms (Schedule II); form of patent (Schedule III); and details of cost to be awarded (Schedule IV). Salient provisions of the Indian Patents Act are described below.

2.1.1 Patentable subject matter and criteria of patentability

According to the Section 2(1)(j) of the Patents Act, “Invention” means a new product or process involving an inventive step and capable of industrial application.

Therefore, any product or process may be patentable in India, subject to the following three main conditions (criteria of patentability) -

1. Newness
2. Inventive step
3. Industrial applicability

2.1.1.1 Newness

A “new invention” u/s 2(1)(I) means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with
complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art\textsuperscript{53}.

2.1.1.2 Inventive step

“Inventive step” u/s 2(1)(ja) means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art\textsuperscript{54}.

2.1.1.3 Industrial applicability

“Capable of industrial application” u/s 2(1)(ac) in relation to an invention, means that the invention is capable of being made or used in an industry\textsuperscript{55}.

2.1.2 Not patentable subject matter

Sections 3 and 4 of the Patents Act enlist the subject matter explicitly excluded from the patentability.

The following are not inventions within the meaning of the Act (Section 3)\textsuperscript{56}:

(a) any frivolous invention or an invention which is clearly against the well established natural laws;

(b) an invention the use of which is against the public order/ morality or which may cause serious harm to human, animal or plant life/ health/ the environment;

(c) discovery of a scientific principle; or formulation of abstract theory; or discovery of any living thing/ non-living substance occurring in nature;

(d) discovery of a new form of a known substance which does not have an enhanced efficacy as compared to the known substance; or discovery of any new property/ new use for a known substance; or discovery of mere use of a known process/ machine/ apparatus unless such known process results in a new product or employs at least one new reactant. Under this
clause, to be patentable, polymorphs, salts, ethers, esters, metabolites, isomers, particle size, pure form, complexes and other derivatives of an already known drug must show an enhanced efficacy as compared to that drug.

(e) any substance produced by admixture of two or more substances possessing only an aggregation of the properties of the initial substances; or a process for producing such admixture;

(f) simple arrangement/ re-arrangement/ duplication of known devices, each of which function independently of one another in a known way;

(h) any process or method of agriculture or horticulture;

(i) any process of medicinal/ surgical/ curative/ prophylactic/ diagnostic/ therapeutic/ any other treatment of human beings; or a process for similar treatment of animals to render them free of disease/ increase their economic value or value of their products.

(j) plants and animals as a whole or any part of plants/ animals (excluding micro-organisms) but including seeds, varieties and species and essentially biological processes (consisting completely of natural phenomena) for production/ breeding of plants and animals;

(k) mathematical or business method/ algorithms/ a computer program per se;

(l) literary/ dramatic/ musical/ artistic work/ any other aesthetic creation including cinematrographic works and television productions;

(m) mere scheme/ rule or method of performing mental act/ method of playing game;

(n) presentation of information;

(o) topography of integrated circuits;

(p) an invention which is a part of traditional knowledge.

Inventions relating to atomic energy are not patentable (Section 4): No patent shall be granted for atomic energy related invention falling within Section 20(1) of the Atomic Energy Act, 1962 (33 of 1962)\(^{57}\).
2.1.3 Patentability of polymorphs/ new forms in India

A drug compound can exist in different crystalline or physical forms known as polymorphs. Polymorphs play a key role in the drug product development. Different polymorphs may have different properties, including solubility, stability and bioavailability. These properties significantly impact the manufacturing process as well as safety and efficacy of the drug. Some examples of polymorphic forms of the drugs are: Paroxetine hydrochloride hemihydrate; Ranitidine hydrochloride Form-II; and Cefadroxil monohydrate. Isomers, salts, active metabolites, pro-drugs, esters, and complexes are the other important “new forms” of the known drug compounds which also play an important role in the drug product development.

Patentability of polymorphs/ new forms in India is mainly governed under Section 3(d) of the Patents Act, 1970. As per this Section, a claimed polymorph/ new form shall be patentable only if it differs significantly in properties with regard to efficacy from the known drug compound. Section 3(d) aims to prevent a phenomenon commonly referred to as “patent evergreening”. Through “evergreening” pharmaceutical companies may abuse the patent system by obtaining patents on “minor improvements” to their pre-existing drug molecules and delaying the legitimate entry of the generic drug products in the market.

The issue of patentability of polymorphs in India was dealt in a judgement of the Supreme Court in the case Novartis AG vs. Union of India. The summary of this case is presented in the Chapter 3 in this thesis.

2.1.4 Type of patent applications

Type of patent applications that can be filed in India -

1. Ordinary application: Application not claiming priority of any foreign application, and filed directly at the Indian Patent Office.
2. Convention application: An application filed under the Paris Convention which claims priority of a foreign patent application.


4. Divisional application, which can result from division of a filed patent application.

5. Patent of addition: It can be filed subsequent to the filing of a patent application, for an improvement or modification in the invention.

2.1.5 Persons entitled to apply for patents
Any of the following persons can file a patent application in India either alone or jointly with each other:

(a) a person who claims himself the true and first investor of the invention;
(b) an assignee of the person who is claiming himself the true and first investor of the invention
(c) the legal representative of a deceased person who was entitled to make such an application before his/her death.

2.1.6 Patent offices and their jurisdiction
Indian patent offices are situated at four locations viz. Kolkata, Delhi, Chennai and Mumbai. The patent specification along with the prescribed form and fee shall be filed with the patent office having the appropriate jurisdiction. The patent application can also be filed online at the Indian patent office website i.e., http://www.ipindia.nic.in/.
2.1.7 Overview of patent grant procedure in India

Patent application filing at Indian patent office*
*(Assigning of filing date and patent application number)*

- Publication**
  *(After 18 months from the filing date)*

- Pre-grant opposition
  *(From the date of publication till patent rejection/ grant)*

- Request for examination
  *(Within 48 months from the filing date)*

- Examination

- Issue of First Examination Report (FER)

- Applicant’s response to the FER

- Patent application rejection#/ patent grant##

- Post-grant opposition
  *(Within 12 months of the patent grant)*

*Figure 4: Overview of patent grant in India*

* Application can be filed either with provisional or complete specification; complete specification shall be filed within 12 months of filing the provisional specification; only complete specification shall be published (Section 9).

** Applicant can make request in Form-9 for publication earlier than 18 months (early publication); the controller shall publish such application as soon as possible (Section 11A (2); Rule 24A).
A patent applicant can appeal at the Intellectual Property Appellate Board (IPAB) against the decision of controller rejecting the patent application [Section 117A (2)].

The time for putting an application in order for grant is 12 months from the date on which the First Examination Report (FER) is issued to the applicant to comply with the requirements. A first examination report shall be sent to the applicant ordinarily within 6 months from the date of the request for examination or six months from the date of publication, whichever is later [Rule 24B(3)&(4)].

### 2.1.8 Expedited patent examination

Currently option for expedited patent examination is not available in India. The Draft Patent (Amendment) Rules, 2015 has proposed to add the provision for expedited patent examination in India. As per the proposed rules, request for expedited examination shall be subject to the condition that the invention is being manufactured in India (at the time of patent filing) or the patent applicant will start manufacturing the invention within 2 years from the patent grant. The proposed rules for expedited examination have however been criticized by various organizations viz. American Intellectual Property Law Association (AIPL), Sinapse and Intellectual Property Owners Association (IPO) on different grounds including

- Condition of manufacturing the invention in India is discriminatory, as in the *Natco vs. Bayer* case the Bombay High Court and the IPAB have clarified that requirement of working of a patent could be satisfied even by importing the patented product if the patentee could satisfy that the patented product could not be manufactured in India.

- In the case of pharmaceutical inventions where regulatory approvals may take several years, commitment of commencing manufacture within 2 years from the patent grant seems unrealistic.
• Under the proposed rules, the applicant is required to produce the proof of necessary capital and facility for the manufacture of the invention at the time of making request for expedited examination. However, for individual inventors, small scale industries and start-ups it would be extremely difficult to arrange the necessary capital/facilities at the time of patent filing.

• The fee for expedited examination is non-refundable and extremely high especially for natural persons (Rs. 50,000 for e-filing; Rs. 55,000 for physical filing) and for small scale industries (Rs. 1,25,000 for e-filing; Rs. 1,37,500 for physical filing).

• Controller may allow only a limited number of requests for expedited examination per year.

Few suggestions have been proposed by the above mentioned organizations to strengthen the proposed rules for expedited examination in India. These suggestions are presented in the Chapter 6 in this thesis.

2.1.9 Duty to disclose information regarding foreign applications

As per the Section 8 of the Patents Act, an applicant for patent in India is required to submit information about any foreign patent application which he has filed/would file in respect of the same or substantially the same invention as described in the concerned Indian patent application$^{66}$.

Section 8 requires the applicant to submit the following information -

(a) Detailed particulars of the any foreign application(s) already filed, and an undertaking that, up to the date of grant of patent in India, the applicant would keep the controller informed in writing, from time to time, of detailed particulars of foreign application(s) which he would file in future [(Section 8(1)].
(b) Upon the request of the controller, any information relating to the processing of the foreign application (including information relating to patentability/ novelty objections of the invention) and/or claims of application allowed in the foreign country [(Section 8(2)].

The statement and undertaking u/s 8 shall be filed in Form 3. The prescribed time limit for submitting the required information is six months from the date of filing the foreign application; or six months from the date of filing the application in India (for already filed foreign applications); or six months from the date of communication by the controller asking such information.

Failure to comply with the Section 8 requirement is a ground of patent opposition u/s 25(1) and 25(2), and a ground of patent revocation u/s 64. Relevant case laws viz. Ajanta Pharma vs. Allergan and Roche vs. Cipla are discussed in the Chapter 3 in this thesis.

2.1.10 Provisional and complete specifications

Patent specification is a “techno-legal” document that describes about technical aspects of the invention in a manner to meet the requirements of the patent law. The applicant can file either the provisional or complete specification at the time of filing an ordinary application for patent.

However, only the complete specification application will be examined. A convention application and a PCT application shall be filed with a complete specification only. Sections 9 and 10 of the Patents Act describe the provisions relating to provisional and complete specifications respectively.

Provisional Specification: A provisional specification is typically filed at an early stage of research work, and the complete specification is filed subsequently when the invention is fully developed. Provisional specification does not require claims and abstract. No amendment of the provisional specification
specification is allowable. After filing a provisional specification the applicant gets patent application number and secures “priority right” over patent application of any other person in respect of the same or substantially the same invention being developed concurrently in some other part of the world.

Complete Specification: The complete specification is an essential document for the grant of patent. It must be filed within 12 months of filing the provisional specification. It may include improvement associated with the subject matter of the provisional application. The complete specification claiming priority of any provisional specification should be fairly based on the provisional specification.

Contents of complete specification⁶⁹:
1. Title of the invention
2. Field of the invention
3. Background of the invention/ Description of the prior art
4. Object of the invention
5. Brief summary/Statement of the invention
6. Brief description of the figures (if any)
7. Detailed description of the invention
8. Claim(s)
9. Figures/ Drawings (if any)
10. Abstract

2.1.11 Publication of the patent applications
After filing, all the patent applications (except the applications which are detrimental to the defense of India; or abandoned due to non-filing of complete specification within 12 months after filing the provisional specification or withdrawn within 15 months of the filing) are published in the
Patent Office Journal just after 18 months from application filing or priority date whichever is earlier\textsuperscript{70,71}.

Particulars of the patent applications including patent filing date, application number, name and contact details of the applicant and the abstract are published at the time of 18 months publication. The patent application becomes available for the public inspection only after its publication. After publication, the application may be inspected at the appropriate office or on the website of the patent office. In the case of patent infringement, a patent owner can claim for damages from the date of publication of the patent application. However, a suit for infringement can be instituted only after the patent is granted.

2.1.12 Examination of the patent application

Patent application will be examined by the patent office only after the filing of the request for examination within a period of 48 months of filing. Patent examiner appointed by the controller of patents examines the application and submit the “First Examination Report” (FER) to the controller. During the examination the applicant or his agent may be asked to - submit some additional information; reply to the examiner’s queries; put forward defence for any opposition raised u/s 25(1); or to amend the application\textsuperscript{72,73}.

2.1.13 Patent opposition

Although, patent applications go through careful examination by the patent office before patent rights are granted to the patentees, still deficient or poor quality patents may be granted sometimes erroneously. To ensure quality of the granted patents, opposition mechanisms are provided in the patenting system.
Patent opposition can be defined as a request made by an opposing party to the patent office to either refuse a patent application or to revoke a granted patent. The Indian Patents Act provides a dual mechanism of opposing patents (u/s 25), both before (pre-grant) and after the grant (post-grant) of patents.

The options available for patent opposition in India are:
(a) Pre-grant opposition
(b) Post-grant opposition

2.1.13.1 Pre-grant opposition

U.S., Europe, China and many other countries of the world provide an ex-parte pre-grant procedure to the third parties for submitting relevant prior art to challenge grant of a patent. However, unlike in other countries, in India pre-grant opposition u/s 25(1) is an inter-partes procedure in which the third party is allowed to appear for hearings and participate in the opposition proceedings.

Any person may file a representation for opposition before the controller of patents at the appropriate patent office (Kolkata, Delhi, Mumbai or Chennai) against the grant of a patent. The representation can be filed any time after the patent application is published but before the grant of the patent. Further, the law mandates that no patent shall be granted before the expiry of a period of six months from the date of publication of the application, therefore third parties get at least six months after the publication of a patent application to file the representation.

The representation can be filed on any of the following grounds:
(i) wrongful obtaining of invention [Section 25(1)(a)];
(ii) anticipation by prior publication [Section 25(1)(b)];
(iii) anticipation by prior claiming in India [Section 25(1)(c)];
(iv) invention publicly known or publicly used in India [Section 25(1)(d)];
(v) lack of inventive step or obviousness [Section 25(1)(e)];
(vi) not patentable subject matter [Section 25(1)(f)];
(vii) insufficiency of disclosure [Section 25(1)(g)];
(viii) failure to disclose or suppression of information about foreign filing required by Section 8 [Section 25(1)(h)];
(ix) in the case of convention application, the application was not made within 12 months from the date of the first application made in a convention country [Section 25(1)(i)];
(x) non-disclosure/ wrong mention of the source of biological material [Section 25(1)(j)]; and
(xi) anticipation having regard to traditional knowledge of any community in India or anywhere in the world [Section 25(1)(k)].

The representation shall include a statement of the case, evidence (if any) in support of the representation and a request for hearing, if so desired. The representation should be filed along with the prescribed form [Form 7(A)]. There is no fee applicable for filing the representation. Such representation shall only be considered when a request for examination of the application has been filed. When representation is considered, the controller gives a notice to the applicant of such consideration, along with a copy of the representation. After receiving the notice, the applicant may file his statement and evidence (if any) in support of his application. The parties are then allowed to appear for hearings. After considering the representation and submission made during the hearing, the controller may ask the patent applicant to amend the complete specification. Finally, the controller either refuses the patent application or grants the patent (as such or in the amended form).

The Indian Patent Act does not provide any specific provision for appeals against controller’s decisions in pre-grant opposition. This matter was clarified
in two court cases viz. J. Mitra & Co. Pvt. Ltd. v Asst. Controller of Patents & Designs in the Supreme Court of India [2008] and UCB Farchim SA v Cipla Ltd. & Others in Delhi High Court [2010]. According to these case laws, in the pre-grant proceedings if the patent application is refused by the controller, the patent applicant may file an appeal to the Intellectual Property Appellate Board (IPAB) against the refusal. However, if the pre-grant opposition is rejected and patent is granted, the opposing person can file a writ petition in the High Court against the controller’s decision, or file a post-grant opposition u/s 25(2) (as long as that person happens to be a person interested)\textsuperscript{77}.

Rule of estoppel is not applicable in India at the pre-grant stage, and therefore same person can challenge a patent through both pre-grant and post-grant oppositions even on the same ground(s).

2.1.13.2 Post-grant opposition

Any “person interested” may file a notice of opposition u/s 25(2) to the controller of patents against a patent within one year from the grant of the patent. A “person interested” is a natural person who is carrying out/promoting research in the same field as that of the claimed invention; or is an organization engaged in manufacturing or trading goods connected with the patented article; or a natural person/organization possessing patent(s) relating to the same subject.

The grounds for filing a post-grant opposition are identical to the grounds of filing pre-grant opposition u/s 25(1)\textsuperscript{78}.

When a notice of opposition is filed, the controller constitutes a board viz. the “opposition board”. The board consists of three members and one of the members of the board is nominated as the chairman of the board by the controller. The examiner, who has taken part in the proceeding for grant of
patent to which the opposition relates, is not eligible to be a member of the opposition board.

The notice of opposition shall include a written statement setting out the nature of the opponent's interest, the facts upon which the case is based, relief which the opponent seeks, evidence (if any), prescribed form (Form 7) and the fee. The opponent shall forward a copy of the notice to the patent owner. The patent owner is then allowed to file his reply statement along with the supporting evidence in the prescribed time limit. The patent owner shall forward a copy of the reply statement and supporting evidence to the opponent. The patent owner and the opponent are given opportunity to appear in the hearings. After the hearings and taking into consideration the recommendation of the opposition board, the controller shall order either to maintain/amend/or to revoke the patent. Such order of the controller is appealable by the aggrieved party (patent owner or opponent) at the Intellectual Property Appellate Board (IPAB).

In India a granted patent can be revoked before three different forums viz. the patent office through a post-grant opposition u/s 25(2); the IPAB through a revocation petition u/s 64; and the High Court through a counterclaim in an infringement suit u/s 64. However, the patent law does not provide any specific provision for the admissibility/non-admissibility of parallel multiple revocation proceedings against the same patent. This issue was clarified by the Supreme Court in the case of Dr. Aloys Wobben v Yogesh Mehra and others [2014]. As per the Supreme Court decision, multiple patent revocation proceedings shall not be allowed simultaneously. Out of the three revocation proceedings available, a person interested shall be allowed to pursue only one revocation proceeding at a time, which he initiates first\textsuperscript{79}. It creates provision of estoppel at the post-grant stage in the patent prosecution.
There is no provision expressly provided in the Indian patent law relating to the settlement between the parties during the opposition proceedings. The opposing party may however, withdraw his opposition before the controller makes a decision on it. In such a case, the opposition proceeding is terminated.

2.1.13.3 **Statistics on patent opposition in India**

Table 1 and 2 provide recent statistics on pre- and post-grant oppositions in India. The information presented in the tables has been taken from the annual reports published by the Indian patent office and the controller’s decision published on the Indian patent office website.

**Table 1: Statistics on pre-grant opposition in India**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total oppositions filed</th>
<th>Controller’s decisions (Including of previous years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total decisions</td>
</tr>
<tr>
<td>2012-13</td>
<td>262</td>
<td>11</td>
</tr>
<tr>
<td>2013-14</td>
<td>309</td>
<td>22</td>
</tr>
<tr>
<td>2014-15</td>
<td>Not available</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>63</td>
</tr>
</tbody>
</table>

**Table 2: Statistics on post-grant opposition in India**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total oppositions filed</th>
<th>Controller’s decisions (Including of previous years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total decisions</td>
</tr>
<tr>
<td>2012-13</td>
<td>14</td>
<td>02</td>
</tr>
<tr>
<td>2013-14</td>
<td>08</td>
<td>05</td>
</tr>
<tr>
<td>2014-15</td>
<td>Not available</td>
<td>08</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>
Data provided in the above tables indicates that as compared to other fields of technology, pharmaceutical field is most affected by the opposition proceedings in India. In the last three years, majority of the controller’s decisions are on the opposition of patents relating to pharmaceutical inventions (44 out of the total 63 decisions in pre-grant opposition and 09 out of the total 15 decisions in post-grant opposition).

2.1.14 Grant of Patent
When an application for a patent is found to be in order, controller of patents grants the letters patent to the applicant u/s 43.

2.1.15 Term of patent
Term of every patent granted, under the Patents Act is 20 years from the date of filing of the patent application.

2.1.16 Transfer of the patent rights
Since patent is a form of property, the patentee can voluntarily transfer his patent rights to any other person through assignment, mortgage or grant of license. Such transfer shall be through a written agreement embodying all the terms and conditions governing rights and obligations of parties; and such agreement shall be registered by filing Form 16 to the controller of patents. Under some exceptional circumstances government can transfer the rights of the patentee without his consent to other person(s) through compulsory licensing.

2.1.17 Compulsory licensing
Research in the field of drugs & pharmaceutical is very expensive, time consuming and unpredictable in nature. Innovator pharmaceutical companies therefore try to get their research patented in order to prevent market entry of their competitor generic drug companies.
However, sometimes patent rights may be subject to abuse by the patent holder. Pharmaceutical company holding the patent right may not commercialize the patented drug in the country, or may not provide the drug in sufficient quantity to meet the requirements of the public, or may price the drug exorbitantly high. As drugs are an essential commodity, such abusive or monopolistic practice by the companies can severely aggravate the sufferings of the patients, especially of the poor ones.

To prevent such abuse of the patent rights, provisions of compulsory license are included in the patent laws. Compulsory licensing is defined by the World Trade Organization (WTO) as a practice in which the government allows someone else to produce the patented product or use the patented process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement.

Compulsory licence is an involuntary contract between a willing buyer and an unwilling seller imposed or enforced by the law. Compulsory licence authorizes a third party to make, use, or sell a patented invention without the consent of the patent holder.

Provisions related to the grant of compulsory license in India are prescribed under Sections 82-94 (Chapter XVI) of the Patents Act, 1970, and Rules 96-102 (Chapter XIII) of the Patents Rules, 2003. The Controller of Patents can issue compulsory license under following situations - compulsory license u/s 84; licensing of related patents u/s 91; special provision for compulsory licences on notifications by central government u/s 92; and compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances u/s 92A.
2.17.1 Compulsory license u/s 84

A compulsory license may be granted to an interested person after expiry of three years from the date of patent grant on any of the following grounds that the -

(a) reasonable requirements of the public with respect to the patented invention have not been satisfied; or

(b) patented invention is not available to the public at a reasonably affordable price; or

(c) patented invention is not worked in the territory of India.

Section 84(7) of the Patents Act identifies a list of circumstances, if any of which occurs, the reasonable requirements of the public shall be treated not to have been satisfied. These circumstances include - (a) the patentee refuses to give license and that results in harming the trade, industry or commercial activities in India; or demand for the patented article not being met; or market for export of the patented article not being developed (b) the patentee imposes unreasonable conditions upon the grant of licences which are prejudice to the development of trade and industry in India (c) the patentee imposes conditions of exclusive grant back, prevention to challenge the validity of patent or coercive package licensing (d) the patented invention is not worked in India on commercial scale to an adequate/ fullest extent in a reasonably practicable way; (e) working of the invention on a commercial scale in India is prevented due to importation of the patented article from abroad.

The Controller while determining a “reasonably affordable price” may take into account various factors such as the purchasing power of Indian public/end-user(s) of the patented product, cost of the production, availability and affordability of any substitute of the product etc.
General principles applicable to “working of patented inventions” are prescribed under Section 83 of the Patents Act. It is one of the general principles that the patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article in India [Section 83(b)]. Therefore, for a patented invention to be treated as “worked in the territory of India” the invention shall be manufactured to a reasonable extent in India. Further, the patentee must not abuse his patent rights by adopting any anti-competitive activity, or resort to practices which unreasonably restrain trade/adversely affect the international transfer of technology [Section 83(f)].

2.1.17.2 Terms and conditions of compulsory licence

General terms and conditions for the grant of compulsory licence u/s 84 are:

(i) paten**t**ee gets reasonable amount of royalty/remuneration with respect to the nature of the invention, expenditure incurred by the patentee in developing/making the invention and obtaining/keeping in force the patent and other relevant factors [Section 90(1)(i)];

(ii) patented invention is worked to the fullest extent by the licensee with reasonable profit to him [Section 90(1)(ii)];

(iii) patented articles are made available to the public at reasonably affordable prices [Section 90(1)(iii)];

(iv) licence is granted on non-exclusive basis [Section 90(1)(iv)];

(v) right of the licensee is non-assignable [Section 90(1)(v)];

(vi) licence is granted for the balance term of the patent [Section 90(1)(vi)];

(vii) licence is granted with a predominant purpose of supply in the Indian market, however the licensee may also export the patented product, if need be in accordance with the Section 84(7)(a)(iii) of meeting reasonable requirements of the public [Section 90(1)(vii)];

(viii) in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use [Section 90(1)(viii)];
(ix) in the case of any anti-competitive practice by the patentee, the licensee is permitted to export the patented product [Section 90(1)(ix)];
(x) the licensee is not authorized in general to import the patented product or product made by the patented process where such importation would constitute an infringement of the rights of the patentee, however if it is necessary in the public interest, controller may authorise (on the basis of the direction given by the central government) the licensee to import the patented product or product made by the patented process from abroad, subject to the conditions of royalty payable to the patentee, the quantum of import, the sale price of the imported article and the period of importation etc. [Section 90(2)&(3)].

2.1.17.3 Procedure for grant of compulsory license u/s 84-92-94

An application for the grant of a compulsory license shall be made only when before making the application the applicant has made efforts to obtain a voluntary licence from the patentee on reasonable terms and conditions, and such efforts were not successful within a reasonable period (six months). However, this condition shall not be applicable in case of national emergency or in circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee [Section 84(6)(iv)].

The application for the grant of a compulsory license shall contain a statement mentioning the nature of the applicant's interest, the facts upon which the application is based and other relevant particulars. Upon consideration of an application, if the controller is satisfied that a prima facie case has been made for the issue of a compulsory license, he directs the applicant to serve copies of the application upon the patentee, and shall publish the application in the official journal. The patentee within two months from the date of the publication of the application may give to the controller a notice of opposition
containing a statement of the grounds on which the application is opposed. The controller then notifies the applicant, and gives to the applicant and the patentee an opportunity to be heard before deciding the case.

While considering the application for the grant of a compulsory license, the controller shall take into account [under Section 84(6)(i-iii)] - nature of the invention, time which has elapsed since the grant of the patent, measures already taken by the patentee or any licensee to make full use of the invention, ability of the applicant to work the invention to the public advantage and the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

2.1.17.4 Termination of compulsory licence

Upon an application made by the patentee, the compulsory licence may be terminated by the controller, if the controller finds that circumstances based upon which the license was granted no longer exist and such circumstances are unlikely to recur in future. The holder of the compulsory licence can object to such termination. Before making any final decision on the termination of the compulsory licence, the controller shall take into account that the interest of the holder of the compulsory licence is not unduly prejudiced (Section 94).

2.1.17.5 Licensing of related patents u/s 91

After the grant of a patent ("the first patent"), any person who has the right to work any other patented invention ("the second patent") either as the patentee or as a licensee, where the second patent cannot be exploited without infringing the first patent, may apply to the Controller for the grant of a compulsory licence of the first patent, subject to the conditions that (i) the applicant is able and willing to grant a licence in respect of the second patent to the patentee of the first patent on reasonable terms; and (ii) that the invention described in the second patent has made a substantial contribution to
the establishment/ development of commercial or industrial activities in India. General procedure and terms and conditions of compulsory licences u/s 84 shall also be applicable under this provision96.

2.1.17.6 Special provision for compulsory licences on notifications by Central Government u/s 92
Compulsory license may be issued in the circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, including public health crises. If any of such situations arises, the central government shall make a declaration in the official gazette for the grant of compulsory licence by the controller with respect to any patent in force97.

After the notification is issued, the controller shall issue a compulsory licence after following the general terms and conditions of compulsory license specified under Section 90 and normal procedure such as notice to the patentee, hearing to objections, etc. specified under Section 87. The controller is also required to ensure that the articles are manufactured in India and made available to the public at the lowest price consistent with the patentees deriving a reasonable advantage from their patent rights98. In the case of any public health crises, relating to Acquired Immuno Deficiency Syndrome (AIDS), Human Immunodeficiency Virus, tuberculosis, malaria or other epidemics, the controller is exempted to follow any procedure specified in Section 87. In such cases, however the controller shall as soon as may be practicable inform the patentee of the non-application of the procedure.

2.1.17.7 Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances u/s 92A99
This provision allows manufacturing and export of pharmaceutical products to countries with insufficient or no manufacturing capabilities for the concerned pharmaceutical product to address public health problems. The compulsory licence can be issued only if such country has granted a compulsory licence to
the applicant (if the product is patented in such county) or allowed importation of the patented pharmaceutical products from India (if the product is not patented in such county). Pharmaceutical products here mean, any patented product, or product manufactured through a patented process, to address public health problems. It includes ingredients necessary for their manufacture and diagnostic kits required for their use.

2.1.17.8 Whether the compulsory licensing provisions in India are TRIPS compliant?
To examine whether India has complied with the TRIPS requirements for compulsory licensing, provisions for compulsory licensing under TRIPS agreement were studied and compared with the relevant provisions in India. Results of the comparison are presented in Table 3.

Compulsory licensing requirements under TRIPS: TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement administered by WTO (World Trade Organization) took effect in January, 1995. TRIPS has set the intellectual property rules for the multilateral trading system among the countries. It has established minimum standards/ requirements for intellectual property protection that are to be adapted by all its member countries. However, TRIPS agreement incorporates certain "flexibilities" (TRIPS flexibilities) that permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies e.g. protection of public health and promotion of access to medicines. The term “compulsory licensing” does not appear as such in the TRIPS agreement, however compulsory licensing is covered under Article 31 of the agreement. Compulsory licensing is a part of TRIPS flexibilities that aims to
strike a balance between promoting access to existing drugs and promoting research and development into new drugs\textsuperscript{101}.

The salient requirements for compulsory licensing (other use without authorization of the right holder) under the TRIPS Article 31 are:

1. **Grant on individual merits:** Each application for the grant of compulsory license shall be considered on its individual merits [Article 31(a)];

2. **Prior efforts of the applicant to obtain a voluntary license is necessary:** Compulsory license may only be permitted if, prior to making the application the applicant has already made efforts to obtain a voluntary license from the patentee on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time [Article 31(b)];

3. **Waiver of the prior efforts requirement:** The requirement of making prior efforts to obtain a voluntary license by the applicant may be waived in the case of a national emergency/ other circumstances of extreme urgency/ in cases of public non-commercial use. However, the patentee shall be notified as soon as practicable about waiving of such requirement [Article 31(b)];

4. **License in the case of semi-conductor technology:** In the case of semi-conductor technology, the compulsory license shall be issued only for public non-commercial use or to remedy an anti-competitive trade practice [Article 31(c)];

5. **Non-exclusive basis:** The compulsory license shall be granted on non-exclusive basis [Article 31(d)];

6. **Non-assignable:** Right of the licensee is non-assignable [Article 31(e)];

7. **Predominant use for the domestic market:** The compulsory licence shall be granted with a predominant purpose of supply in the domestic market of the country granting the license [Article 31(f)];
(8) **Termination of the compulsory licence:** The compulsory license may be terminated upon a request made by the patentee to the competent authority, if and when the circumstances based upon which the compulsory license was granted cease to exist and are unlikely to recur. Such termination shall be subject to the adequate protection of the legitimate interest of the compulsory license holder [Article 31(g)];

(9) **Adequate remuneration to the patentee:** The patentee shall be paid adequate remuneration, taking into account the economic value of the compulsory license granted [Article 31(h)];

(10) **Decision subject to judicial review:** The legal validity of any decision relating to the grant of compulsory license and/or payment to the patent holder is subject to judicial review in the country granting the compulsory license [Article 31(i) and (j)];

(11) **Special considerations in the case of anti-competitive practices:** If the patentee is found engaged in any anti-competitive practice then the member country is not obliged to apply the conditions of “prior efforts of the applicant necessary to obtain a voluntary license” and “predominant use for the domestic market” [Article 31(k)];

(12) **Licensing of related patents:** Holder of a patent ("the second patent") can apply for the grant of a compulsory license with respect to another patent ("the first patent"), where the second patent cannot be exploited without infringing the first patent, subject to the conditions that (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent [Article 31(l)].
The Doha Declaration on TRIPS and Public Health: WTO’s fourth ministerial conference was held in Doha, Qatar, on 14 November, 2001. In this conference the WTO members adopted the “Declaration on the TRIPS Agreement and Public Health”\(^{102}\). Through this declaration the WTO members recognized and affirmed:

(i) the need to address public health problems including HIV/AIDS, tuberculosis, malaria and other epidemics afflicting many developing and least developed countries;

(ii) that the TRIPS Agreement does not and should not prevent the members from taking measures to protect public health;

(iii) that the agreement should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and to promote access to medicines for all;

(iv) that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted;

(v) that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency;

(vi) that public health crises, including HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency;

(vii) that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement, and instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 (“Paragraph 6” of the declaration).

The “Paragraph 6” of the declaration recognized that the TRIPS agreement limited the effective use of compulsory licensing in those countries with insufficient or no manufacturing capacities in the pharmaceutical sector, since
originally the TRIPS Article 31(f) provided that compulsory licensing could only be used predominantly for the purposes of supply of the domestic market of the country in which the licence was issued\(^{103}\).

In 2003, the General Council of the WTO adopted the decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS and Public Health, which finally resulted in the form of Protocol to amend TRIPS Agreement in 2005\(^{104}\). The “Paragraph 6” decision amended the Article 31(f) obligation and allowed the member countries to issue compulsory license for export of patented pharmaceutical products to the countries with insufficient or no manufacturing capacities in this sector.

2.17.9 Comparison of the compulsory licensing provisions under TRIPS agreement and Indian Patents Act

Table 3: Comparison of the compulsory licensing provisions under TRIPS agreement and Indian Patents Act

<table>
<thead>
<tr>
<th>TRIPS requirements for compulsory licensing</th>
<th>Relevant Section in the Indian Patents Act</th>
<th>TRIPS compliance by India (Yes/ No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant of compulsory license on individual merits [Article 31(a)]</td>
<td>Section 84(6)(i-iii)</td>
<td>Yes</td>
</tr>
<tr>
<td>Prior efforts of the applicant to obtain a voluntary license is necessary [Article 31(b)]</td>
<td>Section 84(6)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>Waiver of the prior efforts requirement [Article 31(b)]</td>
<td>Section 84(6)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>License in the case of semi-conductor technology [Article 31(c)]</td>
<td>Section 90(1)(viii)</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-exclusive basis [Article 31(d)]</td>
<td>Section 90(1)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-assignable [Article 31(c)]</td>
<td>Section 90(1)(v);</td>
<td>Yes</td>
</tr>
<tr>
<td>Predominant use for the domestic market [Article 31(f)]</td>
<td>Section 90(1)(vii)</td>
<td>Yes</td>
</tr>
<tr>
<td>Termination of the compulsory licence [Article 31(g)]</td>
<td>Section 94</td>
<td>Yes</td>
</tr>
<tr>
<td>Adequate remuneration to the patentee [Article 31(h)]</td>
<td>Section 90(1)(i)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### TRIPS requirements for compulsory licensing

<table>
<thead>
<tr>
<th><strong>TRIPS requirements for compulsory licensing</strong></th>
<th><strong>Relevant Section in the Indian Patents Act</strong></th>
<th><strong>TRIPS compliance by India (Yes/ No)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision on compulsory license subject to judicial review [Article 31(i)&amp;(j)]</td>
<td>Section 117A (Decision of the Controller appealable at IPAB)</td>
<td>Yes</td>
</tr>
<tr>
<td>Special considerations in the case of anti-competitive practices [Article 31(k)]</td>
<td>Sections 84(6)(iv); 90(1)(ix)</td>
<td>Yes</td>
</tr>
<tr>
<td>Licensing of related patents [Article 31(l)]</td>
<td>Section 91</td>
<td>Yes</td>
</tr>
<tr>
<td>Export of patented pharmaceutical products (Paragraph 6 decision of the Doha Declaration)</td>
<td>Section 92A</td>
<td>Yes</td>
</tr>
</tbody>
</table>

In the above comparison, it was found that all the requirements for compulsory licensing prescribed under the TRIPS agreement are complied with in the Indian Patents Act. Hence, it was concluded that the compulsory licensing provisions under the Indian Patents Act are fully TRIPS compliant.

In March 2012, India issued its first compulsory license for patents. The compulsory license was issued to Natco Pharma Ltd. in patent number 215758 granted to M/s Bayer Corporation. The summaries of cases on compulsory licensing in India are presented in the Chapter 3 in this thesis.

#### 2.1.18 Cancellation/revocation of patent

A granted patent may be cancelled or revoked u/s 64 either by the Intellectual Property Appellate Board (IPAB) on a petition filed by an interested person; or by the High Court on a counterclaim in a suit for infringement. Grounds on which a patent may be revoked are:

(i) the patent was granted to a person who is not entitled to obtain such patent under the Patents Act;
(ii) the invention has been anticipated by prior publication, prior claim or prior use;

(iii) wrongful obtaining of invention;

(iv) the subject of any claim of the patent is not an invention or not patentable within the meaning of the Patents Act in India;

(v) the invention is obvious or does not involve any inventive step;

(vi) the invention is not useful;

(vii) that the complete specification does not sufficiently and fairly describe the invention; or it does not disclose the best method of performing it;

(viii) the scope of any claim in the patent is not defined sufficiently and in a clear manner; or the claim is not fairly based on the matter disclosed in the specification;

(ix) the patent was obtained on a misrepresentation of any information;

(x) the invention was used in a secret manner in India, before the priority date of the claim;

(xi) the applicant did not disclose to the controller the information required under the Section 8 or has furnished false information;

(xii) the applicant contravened any direction for secrecy passed under Section 35 or contravened the Section 39;

(xiii) the complete specification was amended under Section 57 or Section 58 by fraud.

(xiv) in the case of biological material used for the invention, the patent specification does not disclose or wrongly mentions the source/geographical origin of such material;

(xv) the invention was anticipated by the traditional knowledge available within any local or indigenous community in India or elsewhere.

A patent can also be revoked by the controller on application made by the central government or an interested person after the expiration of two years from the date of the grant of a compulsory licence on such patent, on the
grounds that despite the grant of a compulsory license, patented invention is not worked in the territory of India; or reasonable requirements of the public have not been satisfied with respect to the patented invention; or patented invention is not available to the public at a reasonably affordable price.  

2.1.19 Reporting of working of patents  
Under Section 146 of the Patents Act, each patentee and licensee of the patent is required to submit every year a statement mentioning the details of commercial scale working of the invention in India in that year. Such information shall be submitted in Form-27 (copy enclosed at Annexure-3) within three months of the end of the calendar year. The controller shall publish the information thereafter. Refusal or failure to furnish such information or statement shall be punishable with fine up to ten lakh rupees. If any person knowingly furnishes false information as required under the Section 146, he shall be punishable with imprisonment up to six months, or with fine, or with both. A new format of Form-27 (copy enclosed at Annexure-3) has been proposed in the Draft Patent (Amendment) Rules, 2015. Many defects were observed in the format of the Form-27, and suggestions to rectify the same have been proposed. These suggestions are presented in the Chapter 6 in this thesis.

2.1.20 Rights of patentees  
The Patents Act grants the following rights to the patentee:  
(a) In the case of product patent, exclusive right to prevent third parties from making/ using/ offering for sale/ selling or importing the patented product in India, without the permission/ authorization of the patentee.
(b) In the case of process patent, exclusive right to prevent third parties from using the patented process and from making/ using/ offering for sale/
selling or importing the product obtained directly by that process in India, without the permission/authorization of the patentee.

2.1.21 Patent infringement
Violation of the rights of the patentee by a third party is termed as patent infringement. A patentee can file a suit of infringement in an appropriate court which may be a District Court or a High Court. When a patent infringement suit is filed in a district court, and the defendant files a counter-claim for revocation of the patent, the suit is transferred to a High Court\(^{113}\).

2.1.22 Specialized IP/patent courts
Indian legislation does not provide for IP/patent specialized courts. The Intellectual Property Appeals Board (IPAB) is a specialized administrative tribunal which exclusively hears IPR appeals; however its jurisdiction is limited for the appeals against the decisions of the Patent and Trademark offices. IPAB cannot adjudicate upon infringement cases.

On December 31\(^{st}\), 2015 Indian government has enacted “The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015” (The Commercial Courts Act)\(^{114}\). Under the Act new Commercial Courts have been constituted at the district level and Commercial Divisions have been set up in all High Courts to exclusively adjudicate the “commercial disputes”. An appeal against the decision of the Commercial Court/Commercial Division can be filed at Commercial Appellate Division of the respective High Court. The commercial disputes include the disputes related with IPRs viz. patent, trademarks, copyright, design, geographical indications, domain names and semiconductor integrated circuits. Such disputes however shall be of more that Rs. 1 crores.
2.2 Patent law in U.S.

In 1952, the basic structure of the modern Patent Law in U.S. was laid out. The U.S. patent law was amended on September 16, 2011 by the Leahy-Smith America Invents Act (AIA). The AIA made many significant changes in the U.S. patent law including switch from the earlier “First-to-Invent” system to the present “First-Inventor-to-File” system.


Since, Indian law does not have provisions for plant patents and design patents, salient provisions relating to “Utility patents” under the U.S. patent law are described below.

2.2.1 Patentable subject matter and criteria of patentability

A utility patent may be granted for an invention or discovery of a new and useful manufacture, machine, composition of matter, process or any new and useful improvement thereof.\(^\text{115}\)

Here, the term “manufacture” refers to all manufactured articles; “composition of matter” means chemical compositions including mixtures of ingredients and new chemical compounds; and “process” primarily includes industrial or technical processes.\(^\text{116}\)
Patent shall be granted subject to the following conditions (criteria of patentability):

1. Novelty
2. Non-obviousness
3. Usefulness

2.2.1.1 Novelty
Before the date of filing of the patent application, the claimed invention shall not be already patented/ described in any printed publication/ in public use/ on sale/ available to the public; or described in an already issued U.S. patent/ published patent application which names another inventor\textsuperscript{117}.

2.2.1.2 Non-obviousness
Claimed invention would have not been obvious before the patent filing date to a person having ordinary skill in the art to which the claimed invention relates\textsuperscript{118}.

2.2.1.3 Usefulness
Usefulness means the subject matter has a useful purpose and it operates to perform its intended purpose\textsuperscript{119}.

2.2.2 Non patentable subject matter
There is no explicit list of subject matter excluded from the patentability provided in the U.S. patent law. However, limits to the patentable subject matter have been defined under various case laws in the U.S. Laws of nature, physical phenomena, and abstract ideas/ suggestions are not patentable. To be patented an idea or suggestion shall be converted into an operative material form e.g. a machine or an article, and a complete description of the same is also required\textsuperscript{120}. Tax methods and human organisms are un-patentable under the current America Invents Act (AIA).
Invention relating to utilization of nuclear material/ atomic energy in an atomic weapon is not patentable under the Atomic Energy Act, 1954.

2.2.3 Patentinability of polymorphs/ new forms in U.S.
There are no specific restrictions on the patentability of the polymorphic/ new forms of the known drug compounds stated in the U.S. Patents Act. However, as per the U.S. case laws, the claimed polymorph shall not be inherently disclosed in the prior art. Evidence of unexpected/ improved properties can be used to demonstrate non-obviousness of the claimed polymorph over the prior art\textsuperscript{121}. Relevant case law \textit{Pfizer vs. Apotex} is discussed in the Chapter 3 in this thesis.

2.2.4 Type of patent applications
Following type of patent applications can be filed at USPTO for the grant of patent\textsuperscript{122}:

(i) **Provisional patent application:** It is a U.S. national application filed under 35 U.S.C. 111(b). A provisional application is not required to include any patent claim, or oath/ declaration, or information disclosure (prior art) statement. Through filing a provisional application, the applicant receives an early effective filing date in a later filed corresponding non-provisional patent application (to be filed within 12 months of filing the provisional application).

(ii) **Non-provisional patent application:** It is an application filed under 35 U.S.C. 111(a) comprising all essential elements of a complete patent application. A non-provisional patent application shall include description, claim(s), drawings (if necessary), an oath/ declaration, application transmittal form/ letter, information disclosure statement, application data sheet and prescribed filing/ search/ examination fees.

(iii) **Design patent application:** An application filed to obtain a design patent under 35 U.S.C. 171.
(iv) **Plant patent application**: An application filed to obtain a plant patent under 35 U.S.C. 161.

(v) **Application under the Patent Cooperation Treaty (PCT)**: An international patent application filed under PCT designating U.S.

(vi) **Convention application**: Application filed under the Paris Convention, claiming priority of a foreign patent application (35 U.S.C. 119).

(vii) **Divisional application**: Application resulted from division of an earlier filed patent application that claimed two or more independent and distinct inventions (35 U.S.C. 121).

(viii) **Continuation and continuation-in-part (CIP) application**: These applications are filed subsequent to an earlier filed patent application (parent application) to cover additional claims of new improvements or modification in the invention. A continuation patent application is based on the same specification as of the parent application. A continuation-in-part (CIP) application discloses additional subject matter that was not included in the parent application.

(ix) **Reissue application**: If the patent owner finds an issued patent to be defective (defective specification/drawing; or the patentee claiming more or less than he had a right to claim in the patent), then the patent owner can surrender the issued patent to USPTO and refile the original application to correct the defect and get the patent reissued (35 U.S.C. 251).

2.2.5 **Who may apply for a patent?**

Under the U.S. law the inventor himself or a person to whom the inventor has assigned the invention may apply for a patent. If the inventor is deceased, the application may be made by his/her legal representatives.
2.2.6 Where to file the patent application?
A patent application can be filed by post/ fax/ by hand at the United States Patent and Trade Mark Office at Alexandria, Virginia. Application can also be filed online.

2.2.7 Overview of patent grant procedure in U.S.

* Patent application filing at USPTO*
  
  (Assigning of filing date and patent application number)

  ↓

  Publication**
  
  (After 18 months from the filing date)

  ↓

  Examination/ Expedited examination

  ↓

  Issue of first office action

  ↓

  Applicant’s response to the first office action

  ↓

  Notice of allowance (patent grant)
  or final office action (patent rejection)#

  ↓

  Request for continued examination§
  
  (After prosecution is closed)

  ↓

  Post-grant proceedings
  
  (After patent grant)

**Figure 5: Overview of Patent Grant in U.S.**

* Application can be filed either with provisional or complete specification; complete specification shall be filed within 12 months of filing the provisional specification; only complete specification shall be published [35 U.S.C. 111(b)].
** At the request of the applicant, the application can be published prior to 18 months from the filing date; the U.S. patent law permits the applicant to opt-out of the publication process, if at the time of filing the applicant certifies that he will not file any corresponding application in any foreign country which requires publication of applications 18 months after the filing date; after the applicant makes such certification USPTO does not published the application in the U.S. (35 U.S.C. 122).

# A patent applicant/patent owner may appeal to the Patent Trial and Appeal Board (PTAB) against the USPTO’s decision of claim rejection (35 U.S.C. 134).

$ U.S. patent law allows continued examination of a patent application even when the patent application is finally rejected by USPTO and prosecution is closed; the applicant is required to pay the prescribed fee to avail continued examination (35 U.S.C. 132).

### 2.2.8 Inventor’s oath or declaration

Each inventor/joint inventor shall submit an oath or declaration with the non-provisional application comprising statements that - (i) the declarant believes himself or herself to be the original inventor/joint inventor of a claimed invention; and (ii) the application was made or authorized to be made by him or her.

Under America Invents Act (AIA), if the inventor is deceased; or is under legal incapacity; or cannot be found/reached after diligent effort; or is under an obligation to assign the invention to the patent owner (e.g. under an employment contract), but refuses to do so, the patent owner is allowed to file a substitute statement in the place of inventor’s oath or declaration, and that would fulfil the legal requirements of an oath or declaration.
2.2.9 Derivation proceedings

The provision of derivation proceedings is introduced under the America Invents Act (AIA)\textsuperscript{125}, in the wake of switch from the “First-to-Invent” system to the present “First-Inventor-to-File” system in the U.S. derivation proceedings have replaced the pre-AIA interferences proceedings. Earlier, the interferences proceedings were used to decide which of the rival inventors invented the subjected matter first. For patent applications filed under the AIA, derivation proceedings are used to determine whether, an individual named in an earlier filed application as the inventor, without authorization derived the invention from the inventor named in the later filed application claiming the same invention.

2.2.10 Duty to disclose information regarding foreign applications

It is the duty of an inventor/ applicant/ assignee/ attorney/ agent associated with the patent application, to disclose to the USPTO all information known to him to be material to the patentability of any claim remaining under consideration in the application\textsuperscript{126}. Processing of the counterpart patent application(s) filed in the foreign patent office(s) is an important source of such information material to the patentability of the invention. Under this rule the information is considered to be material to the patentability, if it establishes a prima facie case of un-patentability of a claim; or based upon which the applicant fails to opposing an argument of un-patentability / fails to asserting an argument of patentability in a foreign patent office. A reference is also considered material, if there is a high probability that the examiner would consider it an important reference while deciding whether to grant a patent on the application\textsuperscript{127}.

To fulfil the duty of disclosure an “Information Disclosure Statement”\textsuperscript{128} is filed at the USPTO. The duty to disclose exists until the claim is cancelled/ withdrawn; or the application becomes abandoned; or the patent is granted.
Failure to comply with the disclosure requirement can result in court’s ruling that the applicant was engaged in inequitable conduct; which in turn can lead to the invalidation of the patent\textsuperscript{129}.

2.2.11 Expedited patent examination

USPTO provides a number of programs to expedite the examination of U.S. patent applications. Participation in any of these programs is subject to some eligibility criteria/conditions. These programs are\textsuperscript{130-132}.

1. **Track one-Prioritized Examination**: This program was introduced under the America Invents Act (AIA). In this program, USPTO places the patent application on a prioritized track by assigning it a prioritized status. The applicant pays an additional fee to participate in the program. The patent office provides the final disposition of the application i.e. final rejection or patent grant (allowance) within twelve months of assigning the prioritized status to the application.

2. **Accelerated Examination**: It also allows applicants to expedite the examination of the patent application by paying an additional fee. USPTO provides final disposition within a year, however the applicant is required to prepare and submit to USPTO an examination support document, explaining in detail how each of the claims in the application is patentable over the prior art references.

3. **Patent Prosecution Highway (PPH)**: There is no additional fee to participate in this program. This program is available for the patent applicants who are pursuing patent applications in two or more member country of Global PPH or IP5 PPH programs. In PPH program, the applicant can expedite the patent examination in other member countries based on a favorable finding on the patent application received in one member country. U.S. is a member of both Global PPH and IP5 PPH programs. China is a member of IP5 PPH program. India is currently not a member of these programs.
4. **Petition to Make Special:** A petition may be filed to make a patent application special to accelerate its examination. The petition may be filed based on the applicant's age (age 65 or above); applicant's health; invention enhances the quality of environment; invention contributes to the development/conservation of energy resources; or invention contributes to counterterrorism. If the petition is accepted, the application is examined faster than a regular filed patent application. No fee is required to make petition in this program.

5. **Full First Action Interview (FAI) Pilot:** Under this program, a prior art search is conducted by the examiner and a report citing relevant prior art and identifying proposed rejections/objections is provides to the applicant. The applicant is then permitted to schedule an interview with the examiner to submit and discuss the proposed amendments and/or arguments. No additional fee is required to participate in this program.

6. **After-Final Consideration Pilot (AFCP 2.0):** Under this program, if the examiner issues a final rejection of the application, he is allowed some additional time to search and/or consider applicants response, and to conduct an interview to discuss his findings with the applicant. Although there is no guarantee of expedited final disposition of the application in FAI or AFCP 2.0, however rate of patent grant is observed much higher under these programs as compared to the regular patent examination. Use of these programs allows applicants to improve communication with the examiner and to address examiner’s concerns regarding the prior art and patentability in shorter time.

### 2.2.12 Supplemental examination

Provision of supplemental examination is established under the America Invents Act (AIA). After the grant of a patent, a patent owner may request the USPTO to conduct a supplemental examination of the patent to consider, reconsider, or correct information which the patent owner believes to be
relevant to the patent”. Within 3 months of receiving the request, the USPTO shall conduct the supplemental examination and determine whether a “substantial new question of patentability” has been raised with respect to the claimed invention. And if it is determined that a “substantial new question of patentability” has been raised, then the patent shall be re-examined under 35 U.S.C. 302.

This provision provides the patent holder a chance to correct actions which may have led to a finding of inequitable conduct on his part in future infringement litigation. An inequitable conduct includes - intentionally misrepresenting or not disclosing a material fact by the patent applicant during patent examination. It becomes a basis of patent revocation in a infringement law suit related to such patent.

2.2.13 Patent opposition
Under the current law, third parties may challenge patents at U.S. Patent and Trade Mark Office (USPTO) through the following processes:
(A) Preissuance submissions by third parties
(B) Post-grant proceedings
   (a) Post-grant review
   (b) Inter partes review
   (c) Ex parte re-examination

2.2.13.1 Preissuance submissions by third parties
Any third party may challenge the pending patent applications by submitting relevant prior art in writing to USPTO [35 U.S.C. 122 (e)]. The prior art may be submitted after the publication of the patent application and may be in the form of any patent, published patent application, or other printed publication of potential relevance to the examination of the application. The submission must be made before the earlier of - (i) the mailing of a Notice of Allowance;
or (ii) the later of - 6 months after publication date; or the date of first rejection of any claim.

The submission shall include (i) a concise description of the relevance of each submitted prior-art document, (ii) a statement by the submitter that the submission complies with the law, and (iii) the prescribed fee. The submissions can also be made electronically on the USPTO website. During the process of third party submission, a real party in interest can remain anonymous by having someone else make the third-party submission for them (straw man approach)\textsuperscript{135}.

The submitted material is placed in the patent application file for consideration by the examiner. If the submission is made within the statutory time limit, the submitted prior art can become an important ground of rejecting the deficient patent claim(s). This is an \textit{ex-parte} procedure therefore, the prior art submitter (third party) can not contest the patent grant in-person by requesting a hearing or to contact the examiner personally. However, this procedure has the advantage of avoiding undue delays in patent grant. At the same time, it also helps in enhancing examination effectiveness and efficiency by bringing the most relevant prior art to examiner’s attention at an early stage during the patent prosecution\textsuperscript{136}. In contrast to post-grant review and \textit{inter partes} review, third party pre-grant submission does not precludes the third party to rely upon the submitted prior art to contest the validity of the issued patent in future (the estoppel is not created)\textsuperscript{137}.

This provision is applicable for any patent application filed before, on, or after September 16, 2012.
2.2.13.2 Post-grant proceedings

The U.S. patent law provides a number of administrative post-grant proceedings through which third parties can challenge the validity of the granted patents at USPTO, and request for the revocation of one or more of the granted claims. These proceedings are - post-grant review, inter partes review and ex parte re-examination.

(a) Post-grant review

Post-grant review (PGR) is applicable for patents having effective filing date on or after March 16, 2013.

Any third party may file a petition with the USPTO to institute a post-grant review of a patent requesting to cancel its one or more claims as unpatentable (35 U.S.C. 321-329). The post-grant review can be filed on any of the grounds of - non-patentable subject matter; lack of novelty; obviousness; failure to comply with the written description; enablement or definiteness requirements of 35 USC § 112 and failure to comply with requirements with respect to reissue patents. PGR shall be filed within nine months of the grant or reissuance of the patent.\(^{138}\)

The petition shall identify all real parties in interest (petitioner cannot remain anonymous). It must identify and provide detailed arguments and evidence against the disputed claims and be accompanied with the applicable fee. The petitioner must supply copies of the petition and the evidence to the patent owner.\(^{139}\) PGR is conducted by the Patent Trial and Appeal Board (PTAB) sitting in panels of three administrative judges having both legal and technical competence.

PGR is instituted only if the USPTO determines that it is more likely than not that at least one of the claims challenged in the petition is unpatentable or if
the petition raises a novel or unsettled legal question that is important to other patents or patent applications (threshold to institute PGR). The parties to PGR (patent owner and the petitioner) have the right to appear in oral hearing as part of the proceeding.

A PGR shall not be instituted, if before filing the PGR, the petitioner files a civil action in the US court challenging the validity of a claim of the patent. If the petitioner files the civil action after filing the PGR, that civil action shall be automatically stayed. However, the stay shall be lifted if the patent owner moves the court to lift the stay; or the patent owner files a civil action or counterclaim alleging that the petitioner has infringed the patent; or the petitioner moves the court to dismiss the civil action.

During a PGR, the patent owner can amend the patent either by cancelling any challenged claim or proposing a reasonable number of substitute claims. The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter.

The PTAB shall issue final decision on PGR within one year from the instituting the PGR. This time limit is extendable by maximum six additional months. Any party to the PGR may appeal the final decision to the Court of Appeals for the Federal Circuit. In the case of a settlement between the petitioner and the patent owner occurs, PGR can be terminated upon a joint request made by both the parties.

After the PTAB issues a final decision, the petitioner will be estopped from challenging the validity of the same patent on any of the ground(s) already raised by him during the PGR in any subsequent proceedings. This estoppel will not be applicable in the case of termination of PGR due to settlement between the parties.
The law also provide for a specific type of PGR for patents claiming covered business methods (methods for performing data processing and other operations used in administration of financial products or services). This provision is transitional in nature and would be valid till September 16, 2020.

**(b) Inter partes review**

Once the window for post-grant review (PGR) has passed, *Inter Partes Review* (IPR) provides an additional option for the third parties to challenge validity of the granted patents (35 U.S.C. 311-319). IPR is applicable for any patent issued before, on, or after September 16, 2012.

Any third party may file a petition with the USPTO to institute *Inter partes* review nine months after the grant or reissuance of the patent or after conclusion of PGR, whichever is earlier.

An IPR is instituted only if the USPTO determines that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition (threshold to institute IPR)\(^{140}\). IPR can be filed only on the grounds of lack of novelty and obviousness. Remaining provisions of IPR are similar to that of the PGR.

**(c) Ex parte reexamination**

Through *ex parte* reexamination, any person including a third party or the patent owner may request USPTO to re-examine one or more claim(s) of a granted patent on the basis of any prior art consisting of patents or printed publications (35 U.S.C. 302-307). The request must be in writing and must be accompanied by payment of the prescribed re-examination fee.

Ex parte re-examination is conducted by the Central Reexamination Unit ("CRU") of USPTO. USPTO will conduct the re-examination proceedings if it
determines that a “substantial new question of patentability” affecting any claim of the concerned patent exists (threshold to institute *ex parte* reexamination). After such a determination by USPTO, the patent owner is asked to file a statement on such question, including any amendment to his patent and any new claim(s) he may wish to propose. The requestor of the *ex parte* re-examination is then allowed to file a reply to the statement filed by the patent owner. After filing the reply, the requestor would not be allowed to participate further in the re-examination proceedings\(^\text{141}\). The patent owner will then be permitted to propose any amendment to his patent and/or any new claim(s). The amendment however, must not enlarge the scope of the claim(s).

The patent owner can appeal the final decision of USPTO in the *ex parte* re-examination to the Patent Trial and Appeal Board (PTAB). No legal estoppel for the requestor is created by an *ex parte* re-examination proceeding.

### 2.2.14 Compulsory licensing

There are no provisions on compulsory licensing explicitly provided in the U.S. patent law. However, there are other domestic laws in the U.S. which allow the use of patented inventions by others without the consent of the patentee, just similar to compulsory licensing\(^\text{142}\). 28 U.S.C. 1498(a) permits the U.S. government to take a compulsory license and use or manufacture an invention described in a U.S. patent without the consent of the patentee. The patentee can claim for the recovery of reasonable compensation for such use or manufacture from the government in the United States Court of Federal Claims\(^\text{143}\). In 2001, in the wake of several mail anthrax cases, the U.S. government threatened the pharmaceutical company Bayer to issue compulsory license under 28 U.S.C. 1498(a) on its patented drug Ciproflaxin. Bayer subsequently dropped price of the drug drastically\(^\text{144}\).
Compulsory licence is also available in the anti-trust cases under the Sherman Antitrust Act. In an anti-trust case “United States vs. Glaxo Group”, the Supreme Court held that Glaxo Group and Imperial Chemical Industries Ltd. (ICI) were engaged in restraining trade of the patented anti-fungal drug griseofulvin. Glaxo and ICI each owned patents covering various aspects of griseofulvin. They pooled their patents on griseofulvin i.e. cross-licensed patents one another, subject to express licensing restrictions that the drug must not be resold in the bulk form. The purpose of this restriction was to keep the drug out of the hands of small generic companies that might act as price-cutters. Consequently, the court ordered mandatory sales and compulsory licensing against Glaxo and ICI145.

In the case of patent infringement, the patentee may seek for injunctive relief through the U.S. court. However, as per the Supreme Court’s decision in eBay Inc. vs. MercExchange, in the case of non-working of the patent, the U.S. courts may deny injunctive relief to the patentee allowing compulsory license to the alleged infringer. In such case the patentee shall be entitled to receive damages in the form of reasonable royalties146.

Under the Bayh-Dole Act, the government contractors (e.g. universities, small business or non-profit institutions) may acquire patents on inventions that they have made using the government funding. The Act allows the government to issue compulsory license on such patents owned by the contractors, if the contractor fails to work the invention or fails to satisfy the health and safety needs of the consumers147.

2.2.15 Extensions of Patent Term

Patents are granted for a limited term of 20 years. However, the effective term of patent protection frequently remains less than 20 years, either due to delay in patent grant by USPTO; or delay by USFDA in approving the drug product covered under the patent. To compensate these delays, the term of a granted patent could be lengthened beyond the normal 20 years term through the following mechanisms -

1. **Patent term adjustment**\(^{149}\): It compensates the loss in patent term due to delay by USPTO during patent examination. Subject to certain limitations, the period of patent term adjustment is calculated by deducting the number of days during which the applicant failed to put reasonable efforts to conclude the prosecution of the application from the total number of days the grant of the patent was delayed.

2. **Patent term restoration**\(^{150,151}\): Research in the field of pharmaceuticals is very expensive, time consuming and unpredictable in nature. Characteristic of the pharmaceutical research that sets it apart from the research in the other fields is that in the other fields the inventions can be kept as secret and the patent filing can be delayed until the moment they are marketed. Therefore, in the other fields, the patent owners can gain the maximum advantage of 20 years patent term. However, in the pharmaceutical field, the effective term of the patent protection frequently remains less than 20 years, as the patents are filed at an early stage of the research work since the products are subjected to the regulatory approvals by the USFDA. In such a scenario any delays in the product approval by the drugs control agency (USFDA) would further lessen the effective term of the patent. Patent term restoration compensates loss in the patent term due to such regulatory delays. In the U.S. the term of one patent can be extended per product for a maximum of 5 years. The total patent life with the patent extension cannot exceed 14 years from the product’s approval date (Title II of the Hatch-Waxman Act).
2.2.16 Patent infringement

U.S. patent law defines infringement as “without authority making, using, offering to sell, selling or importing a patented invention within the United States”\textsuperscript{152}. Actively inducing someone else to commit patent infringement is also termed as infringement. Making, using, selling or importing any component(s) of a patented product is called as the contributory infringement.

2.2.17 Patent linkage

Patent linkage is a mechanism provided under the Drug Price Competitions and Patent Term Restoration Act (Hatch-Waxman Act, 1984) in the U.S. which links the generic drug approval to the patent system. Patent linkage provides a communication system between the drug regulatory agency (FDA) and the patent office (USPTO) with the aim to prevent patent infringement dispute between the innovator and generic drug companies after the marketing approval of the generic drugs. Patent linkage therefore provides a pathway for adjudication of patent validity and infringing issues before the marketing of generic drugs or biosimilar products\textsuperscript{153}.

Under the patent linkage system, USFDA requires the applicant (innovator) to submit patent number and the expiration date of any patent which claims the new drug for which the application (New Drug application or NDA) is submitted. FDA lists the patent information in the “Orange Book” database along with the details of the approved drug.

A generic drug company when files an application (Abbreviated New Drug Application or ANDA) to USFDA for seeking approval of a generic drug, the company is required to certify its intent regarding each of the innovator’s orange book listed patents, that -

(1) the drug has not been patented; or
(2) the patent on the drug has already expired; or
(3) The date on which the patent will expire, and the generic drug shall be introduced in the market only after the expiry of such patent; or
(4) the listed patent is either invalid or will not be infringed by the generic drug.

These are referred to as paragraphs I, II, III and IV certifications respectively. In the case if the generic company files a paragraph IV certificate, the innovator is allowed to file a law suit of infringement against the generic company. Such law suit creates a stay of 30 months on the approval of the generic drug by the USFDA. The generic company may launch the generic drug either when the law suit is over and resolved in generic company’s favour, or when the concerned patent is expired.

2.2.18 Specialized IP/ patent courts
Courts in the U.S. are arranged mainly in three levels viz. District Courts, Courts of Appeals and the Supreme Court. There are 94 District courts in the U.S. They are the trial courts having general jurisdiction to hear all kind of cases. There are 13 appellate courts (Courts of Appeals) below the U.S. Supreme Court. A court of appeals hears appeals against the decision from the district court located within its circuit (geographic area). In 1982 the U.S. Court of Appeals for the Federal Circuit was established (“the Federal Circuit court” or “Federal Circuit”; in case citations, Fed. Cir. or C.A.F.C.). The Federal Circuit is a unique court, as it is the only appellate court in the U.S. whose jurisdiction is limited by subject area and not by geography. Federal Circuit is located in Washington, D.C. and has the nationwide jurisdiction.

Federal Circuit is a specialized court having jurisdiction over certain types of appeals, most notably in the cases of patents, regardless of the jurisdiction of the district court that heard the case.
Due to dealing in the specialized jurisdiction such as patents over the last 30 years, it is a generally-accepted view that the Federal Circuit has greatly improved the reliability and predictability of patent litigation in the United States. International Intellectual Property Institute (IIP) and United States Patent and Trade Mark Office (USPTO) in its report on “Study on Specialized Intellectual Property Courts”, has recommended to now establish specialized patent trial courts in the U.S. at the district level\textsuperscript{154,155}.
2.3 Patent law in Europe

European patent refers to a patent granted under the European Patent Convention (EPC). European Patent Office (EPO) grants the European patents via a single, harmonised procedure. A granted European patent becomes enforceable in any/all of the 38 member countries to the EPC when the patent owner validates the patent in the concerned member country/countries. For validating a patent, the prescribed fee along with the translation of the patent specification shall be submitted at the national patent office within the prescribed time limit by the patent owner. Applicants seeking worldwide patent protection may file an international patent application under the PCT at EPO. Patent may also be obtained in any of the European country via national route by filing a patent application directly at the national patent office of the concerned country. A patent granted by the national patent office shall be enforceable in the concerned country only.

Salient provisions under the European Patent Convention (EPC) (15th edition, 2013) are described below.

2.3.1 Patenable subject matter and criteria of patentability

A European patent may be granted for an invention belonging to any field of technology. The invention shall be new, involve an inventive step and industrially applicable.\textsuperscript{156}

2.3.1.1 Novelty

An invention is considered new if it is not a part of the state of the art, means it shall not be disclosed in written/oral form, used or available in any other way to the public anywhere in the world before the date of filing/priority.\textsuperscript{157} For determining novelty, disclosure in a single source of prior art shall only be considered.
2.3.1.2 Inventive step

To be inventive an invention shall not be obvious to a person skilled in the state of the art. Inventive step is evaluated on the basis of the "problem-solution" approach, under which, the solution presented to the problem described in the patent application shall not be obvious to a person skilled in the art. For assessing the inventive step, disclosures available in multiple sources of prior art may be applied\(^{158}\).

2.3.1.3 Industrial application

An invention shall be capable of being made or used in any kind of industry, including agriculture industry\(^{159}\).

2.3.2 Not patentable subject matter

Following are not patentable under the EPC\(^{160}\):

(i) discoveries;
(ii) scientific theories;
(iii) mathematical methods;
(iv) aesthetic creations;
(v) schemes/ rules/ methods for performing mental acts; or playing games; or doing business;
(vi) programs for computers;
(vii) presentations of information;
(viii) inventions, commercial exploitation of which is against public order or morality;
(ix) plant or animal varieties in whole or biological processes for their production (this provision excludes microbiological processes or the resulting products of such processes);
(x) surgical, therapeutic or diagnostic methods for humans or animals (this provision does not apply on the products, substances or compositions for use in any of these methods).
2.3.3 Patentability of polymorphs/ new forms in Europe

Although no specific restrictions on the patentability of polymorphs/ new forms has been explicitly prescribed under the EPC. However, as per the case laws in Europe, in the absence of any technical prejudice (widely accepted but incorrect opinion about a technical fact) or any unexpected property, the crystalline forms showing obvious advantages of crystalline materials over the amorphous form, could not be regarded as being inventive. Hence, the claimed polymorph can be held un-patentable in such case. Decision of Boards of Appeal of the European Patent Office on the patentability of Atorvastatin polymorph (Warner-Lambert vs. Teva; Case number - T777/08) is discussed in the Chapter 3 in this thesis.

2.3.4 Persons entitled to apply a European patent application

Regardless of the nationality and place of residence/ business, a European patent application may be filed by any of the following -

(a) any natural person;
(b) any legal person;
(c) a body equivalent to a legal person.

A European patent application may also be filed by two or more than two applicants jointly or by the applicants designating different contracting states.

2.3.5 Where to file the patent application?

A European patent application can be filed by post/ fax/ by hand at the European Patent Office (EPO), at its HQ in Munich/ branch in Hague/ sub-office in Berlin. European patent application can also be filed at the patent office of any of the member states. Application can also be filed online.
2.3.6 Overview of European patent grant procedure

Patent application filing at EPO*

*(Assigning of filing date and patent application number)*

\[\downarrow\]

Formalities examination**

\[\downarrow\]

European search report & non-binding opinion on patentability@

\[\downarrow\]

Publication#

*(After 18 months from the filing date)*

\[\downarrow\]

Request for examination & payment of the designation fee

*(Within 6 months of the publication of search report)*

\[\downarrow\]

Opportunity to amend claims and description

\[\downarrow\]

Substantive Examination##

\[\downarrow\]

Communication (report) by the examiner

\[\downarrow\]

Applicant’s reply to the examiner’s communication (report)

\[\downarrow\]

Patent application rejection$\slash$ patent grant

\[\downarrow\]

Validation in member country(ies)$$

\[\downarrow\]

Post-grant opposition

*(Within 9 months of the patent grant)*

---

Figure 6: Overview of European patent grant procedure

* A European patent application shall contain one or more claims (Article 78).
During formalities examination it is checked by EPO that the application documents are correct and complete, and accompanied by the prescribed fee. The applicant is required to correct the deficiencies (if any) in the application within the specified time limit. If the application passes through the formalities examination then it is published, else it is rejected (Article 90; Rule 57).

@ EPO carries out prior art search and issues to the applicant a search report listing all the relevant prior art found during the search, along with an opinion on whether the invention meets the requirements of the EPC. Both search report and opinion together are called as extended European search report. After going through the search report, the applicant may decide whether to pursue the patent grant procedure at EPO and in which of the member countries it is would be worthwhile to pursue it. The applicant is also given a chance to amend the specification (description, claims and drawings). Within six months of the publication of search report the applicant shall file the request for examination (along with the prescribed examination fee), and pay the designation fee for each member country for which the applicant wish to designate the application (Article 123; Rule 70a)

# At the request of the applicant, the application can be published prior to 18 months from the filing date [Article 93(1)(b)].

## ## During substantive examination, the application is examined for patentability of the invention and whether it conforms to the EPC patent law and implementing regulations.

$ All EPO decisions including the decision of patent rejection are open to appeal at the Board of Appeal.

$$ For validating the patent, the patent owner is required to submit the prescribed fee and file a translation of the specification in an official language at the national patent office within the prescribed time limit.
2.3.7 Expedited patent examination (Accelerated prosecution)

(a) PACE program: Prosecution of a European patent application can be accelerated under “Programme for Accelerated Prosecution of European Patent Applications” (PACE)\textsuperscript{162}. It is available free of charge for all the pending applications at the EPO. An applicant can make a request to accelerate search or examination by submitting the “EPO Form 1005” online\textsuperscript{163}. The accelerated prosecution is provided subject to the workload of search and examining divisions at the EPO. An applicant who has multiple applications pending at EPO will be required to limit the number of requests by selecting the applications which are the most urgent for him. While the application is being prosecuted under PACE, the applicant is required to respond to the examiner’s communications under the strict deadlines else his application shall be removed from the program. A patent can be expected to be granted within 12 months under PACE as compared to around 3.5 years in an ordinary case\textsuperscript{164}.

(b) Patent Prosecution Highway (PPH) programme: EPO being a member of PPH program, allows for the accelerating processing of a European patent application when the claims of a corresponding application have been accepted to be patentable by any of the other PPH member patent office.

2.3.8 Duty to disclose information regarding foreign applications

An applicant of European patent application claiming priority of any foreign patent application shall file a copy of the prior art search/ patent examination reports of the corresponding foreign patent application(s)\textsuperscript{165}. In case the prior art search results are not available to the applicant at the time of filing the European patent application, the applicant is required to file the same without delay after such results have been made available to him. The EPO during examination of the patent application, may also invite the applicant to provide a copy of the prior art search results. The applicant within two months of
receiving such invitation shall either provide EPO the copy of the search result or file a statement that the results of the search are not available to him. If the applicant does not reply to the invitation in due time, the European patent application shall be deemed to be abandoned. Although, such abandonment is not permanent and the application can still be revived under the “Further processing” rules\textsuperscript{166} by paying the prescribed fee within the prescribed time limit of two months. Applicants claiming priority of a patent application filed in Austria, Japan, U.K., U.S., Korea or in Denmark are exempted from filing the copy of search results. Unlike in India, failure to disclose the prior art search results is not a ground of opposition/patent revocation in Europe.

2.3.9 Patent opposition
The EPC provides for the opposition of patents through:

(A) Observations by third parties
(B) Post-grant opposition

2.3.9.1 Observations by third parties
After the publication of the European patent application, any third party may file observations at EPO concerning the patentability of the invention described in the patent application (Article 115)\textsuperscript{167}. However, the party shall not be allowed to take part in the proceedings. The observation can be filed on the grounds of lack of novelty and/or inventive step, clarity, sufficiency of disclosure, patentability and unallowable amendments.

The observations must be filed in writing in English, French or German and shall include (i) a statement of the grounds on which they are based and (ii) the documentary evidence and publications in support of the arguments. The evidence may be filed in any language, however, the EPO may request to file its translation into one of its official languages, and otherwise the evidence will be disregarded. Filing observations at EPO is free of charge and it can be
made electronically on the EPO website. The third parties may remain anonymous, if they so wish while filing the observations\textsuperscript{168}.

The filed observations are communicated promptly to the patent applicant and the applicant is allowed to comment on it. If the examiner finds that the observations raise any question on the patentability of the invention, they are taken into account during the remaining prosecution of the patent application. Observations received after the conclusion of prosecution will not be taken into account and will simply be added to the non-public part of the file. There is no rule of estoppel creation during filings the observations by third parties at EPO.

\subsection*{2.3.9.2 \textit{Post-grant opposition}}

Regulations relating to post-grant opposition are prescribed under EPC Part V (Article 99-105c). Within nine months of the grant of a European patent, any person may file notice of opposition of the patent at EPO\textsuperscript{169}. The opposition applies to the European patent in all the contracting states in which that patent has been enforced. The patent owner and the opponents shall be the parties to the opposition proceedings and can take part in the oral hearings.

Opposition may be filed on the grounds of - lack of patentability under Articles 52 to 57 of EPC, insufficient disclosure and incorporation of subject matter beyond the scope of the application as filed\textsuperscript{170}. The notice of opposition shall be filed in writing and should identify the patent opposed. The notice shall include the particulars of the person filing the opposition, a statement of the extent to which the patent is opposed and of the grounds on which the opposition is based, evidence that supports the grounds for opposition and the prescribed fee\textsuperscript{171}. The actual opponent can remain anonymous, if he so wishes by filing the opposition through his/ her representative.
The Opposition Division of the EPO is responsible for the examination of oppositions against any European patent. It consists of three technically qualified examiners, at least two of whom shall not have taken part in the proceedings for grant of the patent to which the opposition relates. One of these two examiners shall be the chairman of the Opposition Division. Opposition Division gives the patent owner an opportunity to file observation and/or amend the patent. The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter\textsuperscript{172}.

Unlike in U.S., in Europe there is no automatic stay in national courts if a civil action for the revocation of the patent is filed in parallel with the post-grant opposition. National courts have discretion to either stay the national proceedings until the ongoing opposition proceeding is completed or allow the revocation proceedings to continue.

There is no rule of estoppel creation during post-grant opposition at EPO, which precludes an opponent to challenge the same patent at the national level on the same grounds raised at the EPO. During the opposition, if the parties reach a settlement, EPO may still continue the opposition proceedings despite the settlement.

There is no fixed time limit set for the announcement of final decision in the opposition proceedings at EPO. An opposition generally may last about two years. Any party to the post-grant opposition may appeal the final decision of the Opposition Division to the EPO Board of Appeal.

\subsection*{2.3.10 Compulsory licensing}
As per the Doha Declaration on TRIPS and Public Health, European Regulation (EC) No 816/2006 has prescribed provisions on compulsory licensing of patents relating to the manufacture of pharmaceutical products for
export to countries with public health problems. This regulation has set the following main requirements for the grant of compulsory license:

(i) The applicant shall prove that he made efforts to obtain voluntary authorisation from the patentee and that such efforts have not been successful within a period of thirty days before submitting the application.

(ii) Above requirement shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

(iii) The licence granted shall be non-assignable.

(iv) The amount of the product manufactured under the compulsory licence shall not exceed to the requirement of the importing country (ies) cited in the application.

(v) The product made or imported under the compulsory licence shall not be sold or put on the market in any country other than that cited in the application.

(vi) Products manufactured under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation.

(vii) Before shipment to the importing country the licensee shall post on a website - name of the importing country (ies); the quantity of the product(s) being supplied; the distinguishing features of the product(s). The website address shall be communicated to the competent authority.

(viii) The competent authority may access to books and records kept by the licensee, to check whether the terms of the licence, have been met.

(ix) The licensee shall pay adequate remuneration to the patentee. In the situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4% of the total price paid by the importing country. In all other cases, the remuneration shall be determined taking into account
the economic value of the product and humanitarian or non-commercial grounds relating to the issue of the licence.

(x) The competent authority may refuse an application if any of the conditions essential for the grant of the license as prescribed under this regulation are not met. However, before refusing the application, the competent authority shall give the applicant an opportunity to rectify the application and to be heard.

(xi) If at any time after the issue of a compulsory licence, the competent authority found that the licence conditions are not being met by the licensee, the licence may be terminated. Such termination shall be subject to adequate protection of the legitimate interests of the licensee.

Directive 98/44/EC, on the legal protection of biotechnological inventions has provided for mandatory compulsory cross-licenses of certain biotechnology inventions. Under this directive, where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for the invention protected by the patent. If such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for the plant variety protected by that right. If such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.174

2.3.11 Supplementary Protection Certificates (SPC)

Patents are granted for a limited term of 20 years. For doing marketing of new medicinal products companies require regulatory approvals from the concerned government agencies. Time that elapses between filing a patent application for a new medicinal product and getting marketing authorization
for such product makes the effective term of patent protection insufficient to recoup the investment put into the Research & Development. Supplementary Protection Certificates (SPC) is a *sui generis* intellectual property right in Europe that provides additional monopoly after the patent expiry to compensate loss in patent term due to the lengthy regulatory process.

Regulation (EC) No 469/2009 governs the grant of SPC in Europe\(^\text{175}\). The SPC may be filed for a product if the patent is in force and the marketing authorization has been obtained for that product. The SPC is filed and granted on national basis. An application for SPC shall be filed within six months of receiving the marketing authorisation or within six months of obtaining the basic patent, whichever is the later.

The maximum term of the SPC is 5 years. A six months extension in the SPC term may be obtained if clinical trials have been done on the paediatric use of the medicinal product in accordance with an agreed Paediatric Investigation Plan (PIP) under Article 36 of the Regulation (EC) No. 1901/2006.

### 2.3.12 Regulations for service/ employee inventions

Service/ employee invention is an invention accomplished by an employee in the course of performing his/ her employment duties. Under the EPC, the right to a European patent shall be determined according to the law of the State in which the employee is employed or else according to the law of the State in which the employer has the place of business\(^\text{176}\). National laws in European counties such as United Kingdom (UK), France, Germany, Belgium and Netherlands provide regulations for employee compensation in case of service inventions\(^\text{177}\).
2.3.13 Specialized IP/patent courts

The European patenting system is moving towards a new mechanism called as “European patent with unitary effect”, that will lead to the grant of “Unitary patents”. This mechanism is under consideration at present and is expected to be implemented by 2017. The unitary patent will be a new type of patent that will be valid in all the member states of the European Union. As per the new proposed mechanism, upon grant a European patent could be registered for unitary effect, under which there will be no requirement to validated the European patent individually in the member countries. Rather, there will be a single renewal fee, a single ownership, a single court (the Unified Patent Court) and uniform protection for the patent. Under the proposed unitary patent mechanism, Unified Patent Court (UPC) shall also be established. The UPC will be a specialized patent court that will hear cases regarding patent infringement and revocation related to the European patents including the unitary patents\textsuperscript{178,179}.

In Europe, some countries have established specialized IP courts at the national level, e.g., in the U.K. there are two type of specialized courts are constituted for the resolution of patent disputes viz. Patents Court and Patents County Courts\textsuperscript{180}. 
2.4 Patent law in China

There are three types of patents recognized under the Chinese law viz. invention patents, utility model patents and design patents (Article 2). Salient provisions under the Chinese patent law are discussed below.

2.4.1 Patentable subject matter and criteria of patentability
The patent law in China defines inventions as a new technical solution or improvement to a product/process\(^1\). Inventions for which patent is to be granted shall be novel, involve inventive step and having practical applicability (conditions for granting patent rights)\(^2\).

2.4.1.1 Novelty
The claimed invention shall be a new technology. It must neither be known to the public (published or used/made) both within the country and abroad before the date of filing of the patent application, nor shall be disclosed in any earlier filed patent application at the SIPO\(^3\).

2.4.1.2 Inventive step
Inventive step means, as compared to the existing technologies, the claimed invention shall possess prominent substantive features and represents notable progress\(^4\). For assessing the prominent substantive features, it shall be determined that with reference to the closest prior art and the technical problem solved, whether the claimed invention is obvious to a person skilled in the art. Presence of a notable progress is assessed by determining that as compared with the prior art whether the invention has produced advantageous technical effects\(^5\).
2.4.1.3 Practical applicability

Practical applicability means, the invention must be capable of being made or used in an industry and can produce effective results\textsuperscript{186}.

2.4.2 Not patentable subject matter

The patent law in China excludes from patentability the following - scientific discoveries; rules and methods for mental activities; methods for the diagnosis/treatment of diseases; methods of nuclear transformation and substances obtained thereof; designs of pictures/colors or the combinations thereof; animal or plant varieties as a whole (production methods of animal or plant varieties are patentable); invention which violate the law/social morality; invention detrimental to the public interests; human body or various stages of its formation/development such as germ cell and embryo; human embryonic stem cell and methods of producing the same; and the inventions based on genetic resources obtained/used in violation of the prevailing laws/regulations\textsuperscript{187,188}.

2.4.3 Patentability of polymorphs/new forms in China

Although no specific restrictions on the patentability of the polymorphs/new forms are prescribed under the Chinese patent law, however for establishing the inventiveness, an unexpected effect of the claimed polymorph shall be demonstrated. Some properties of the polymorph, such as stability, may be considered to be obvious as it is commonly accepted that polymorphs are better stable than the amorphous form\textsuperscript{189}. SIPO, Guideline for Patent Examination specifies that for establishing inventive step of chemical compounds having structure similar to a known compound, an unexpected use or effect shall be demonstrate\textsuperscript{190}. 
2.4.4 Where to file the patent application?

A Chinese citizen can file patent application by post or by hand at SIPO or its representative offices situated at all state capitals and district headquarters\textsuperscript{191,192}. Application can also be filed through China Patent Electronic Application System. However, a foreign applicant who does not have a regular residence or business site in China shall appoint a legally established patent agency for filing the patent application\textsuperscript{193}. Application can be filed in Chinese or English. If filed in English, the Chinese translation of the application shall be submitted within 30 months of the priority date. To encourage patent filing by the domestic applicants, Chinese government provide subsidy in the patent filing/examination fee to them. This has been proved to be highly successful in China\textsuperscript{194}.

2.4.5 Overview of patent grant procedure in China

Patent application filing at SIPO\textsuperscript{*}

\textit{(Assigning of filing date and patent application number)}

\begin{center}
\begin{tikzpicture}
  \node (filing) {Patent application filing at SIPO\textsuperscript{*}};
  \node (preliminary) [below of=filing] {Preliminary examination\textsuperscript{**}};
  \node (publication) [below of=preliminary] {Publication\textsuperscript{#}};
  \node (request) [below of=publication] {Request for examination \textit{(Within 3 years from the filing date)}};
  \node (substantive) [below of=request] {Substantive examination\textsuperscript{##}};
  \node (issue) [below of=substantive] {Issue of first office action};
  \node (response) [below of=issue] {Applicant’s response to the first office action};
  \draw[->] (filing) -- (preliminary);
  \draw[->] (preliminary) -- (publication);
  \draw[->] (publication) -- (request);
  \draw[->] (request) -- (substantive);
  \draw[->] (substantive) -- (issue);
  \draw[->] (issue) -- (response);
\end{tikzpicture}
\end{center}
Figure 7: Overview of patent grant in China
* The patent application shall contain one or more claims (Article 26).
** During preliminary examination the application is checked for any obvious and substantial flaws/defects; proper filing documents and fees; and whether the invention falls within the patentable subject matter. The applicant is required to correct the defect(s) (if any) within the specified time limit. If the application passes through the preliminary examination then it is published, else it is rejected (Article 34; Rule 44).
# Applicant can make request for publication earlier than 18 months (early publication); SIPO shall publish such application immediately (Article 34; Rule 46).
## During substantive examination, the application is examined for patentability of the invention and whether it conforms to the patent law and implementing regulations.
$ An applicant who is not satisfied by the decision of rejection of patent application by SIPO, can make application for re-examination of the application to the Patent Re-examination Board (PRB) after paying the prescribed fee. The re-examination of the application remains restricted to the grounds and evidences upon which the decision of application rejection was based (Article 41; Rules 60-64). The applicant who is not satisfied with the decision of patent re-examination may institute legal proceedings in the people's court within 3 months of the notification of such decision to him.
2.4.6 Expedited patent examination (Accelerated prosecution)
SIPO being a member of Patent Prosecution Highway (PPH) program, allows for accelerating processing of patent application when the claims of a corresponding application have been accepted to be patentable by any of the other PPH patent offices viz. US, Canada, EPO, Japan, Korea, Russia, Austria, Germany, Portugal, Poland, Spain, Finland, Denmark, Mexico, and Singapore195.

2.4.7 Duty to disclose information regarding foreign applications
The patent applicant shall submit the prior art reference materials relating to the invention. If the applicant has filed patent for the same invention in a foreign country, SIPO may require the applicant to submit, within a specified time limit, results of search/examination made in the country. If the applicant fails to comply this requirement, the application shall be deemed to be withdrawn196,197. Unlike in India, failure to disclose the prior art search results is not a ground of patent revocation (invalidation) in China.

2.4.8 Patent opposition
Patents in China can be challenged through:
(A) Observations by third parties
(B) Post-grant invalidation

2.4.9 Observations by third parties
According to the implementing regulations of the Chinese patent law (Rule 48), after publication of a patent application any person can submit observations at SIPO regarding non-conformity of the application with the provisions of the Patent Law198,199. The observations can be submitted until the date of announcing the grant of the patent. Third party observations are admissible for invention patents only and not for utility model patents.
Observations can be submitted on any ground of rejecting a patent application by SIPO, including lack of novelty, creativity or practical use; insufficiency of disclosure; ineligible subject matter; double patenting, etc.

Third parties can submit their arguments and the documentary evidence (if any) along with the official form prescribed by SIPO for submitting the observations, either electronically or in paper form. There is no official fee for filing the observations. The third party can also file the observations anonymously. There is no rule of estoppel creation during filings the observations by third parties at SIPO.

2.4.10 Post-Grant Invalidation

Prior to 1992, the Chinese patent law provided for a pre-grant opposition procedure. However, due to delays in the grant of patents, the pre-grant opposition was abolished in 1992, and a new post-grant opposition procedure was introduced. From 1992 to 2000, SIPO had a post-grant opposition procedure and a post-grant invalidation procedure. The differences between the two procedures included time allowed for filing a petition, the grounds on which the claim(s) can be invalidated and the forum for resolving the petition. However, the two overlapping proceedings, specifically post-grant opposition, increased the burden of examination on the SIPO and therefore, in 2001 the patent opposition system was completely abolished in China.

Currently, the only way to challenge a granted patent in China is through the post-grant invalidation procedure (Article 45-47). Any individual or entity may submit request to the Patent Re-examination Board (PRB) to declare a patent invalid on the ground that such patent does not conform to the conditions for granting patent rights under the law. Requests for invalidation can be filed in writing at any time after the grant of a patent.
The request for patent invalidation includes a written statement about the grounds of invalidity, supporting evidence and the prescribed fee. The requestor may file supplemental grounds and evidence within one month from the date of filing of the request. There are a large number of grounds available for patent invalidation \(^{202}\) including - claimed invention not a technical solutions for a product/ process/ improvement thereof; lack of novelty, creativity or practical use; violation of the provision of confidentiality examination; insufficiency of disclosure; inadequate enablement; nonpatentable subject matter; addition of new matter after patent filing; double patenting; claims are not supported by the description; claims lacking clarity or being indefinite; or the applicant is not entitled to be granted the patent right \(^{203}\).

A panel consisting of 3-5 examiners is designated for the invalidation case. If the panel is satisfied that the request for invalidation complies with all formality requirements, it will forward a copy of the request and all relevant documents to the patent owner. The patent owner is then allowed to file his written response along with the supporting evidence in the prescribed time limit. Upon request by any of the parties, an oral hearing may be held. Oral hearings are similar to court sessions, including questioning of evidence, identifying facts, and debate by the two parties. At the end of the oral hearing, the panel may ask one or both parties to submit supplemental written comments \(^{204}\). The patent owner may amend the patent claim(s). The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter.

PRB issues its final decision on the proceedings, in which the patent may be maintained as such, maintained as amended, completely invalidated or partially invalidated. The party who is dissatisfied with the decision of PRB
may appeal the decision in the Intermediate People's Court, within three months from the date of receipt of the notification of the decision.

Rule of estoppel is applicable in which, when a decision on invalidation of the patent right is made, PRB shall not accept another request for invalidation of those patent right based on the same grounds and evidence.

In China, patent litigation proceedings are bifurcated in which patent validity and infringement issues are dealt by separate bodies (validity by PRB and infringement by the People’s Courts). Due to this bifurcated system, no parallel revocation proceeding of the patent is allowed in the People’s Courts. However, a parallel patent infringement proceeding is possible at the People’s Courts, which is typically not stayed pending the outcome of invalidation action at the PBR\textsuperscript{205}.

The person requesting invalidation may withdraw his request before the PRB announces a decision on it. In such a case, the invalidation proceeding is terminated. The invalidation proceeding usually takes about two years to complete.

2.4.11 Compulsory licensing

Provisions related to compulsory licensing are prescribed under the Chapter VI (Article 48-58) of the Chinese patent law. Further, in March, 2012 China State Intellectual Property Office (SIPO) issued “Measures for Compulsory Licensing of Patent Implementation” via the office order No.64. These measures were formulated to standardize the procedures relating with grant, fees adjudication and termination of compulsory licenses of patents\textsuperscript{206,207}. 

\textsuperscript{205}\textsuperscript{206}\textsuperscript{207}
Main provisions for compulsory licensing under the Chinese patent law are:

(i) SIPO can grant a compulsory license upon application made by an applicant, three years after the date of patent grant and four years after the date of patent application submission, on the grounds that - (a) the patentee, without legitimate reasons, fails to exploit/fully exploit the patent; or (b) the patentee's exercise of the patent right has been confirmed as monopoly and its negative impact on competition needs to be eliminated or reduced (Article 48).

(ii) SIPO can grant a compulsory license, if national emergency or any extraordinary state of affairs occurs, or it is required in the public interest (Article 49).

(iii) For the benefit of public health, compulsory license may be granted for the manufacture of a drug and for the export to the countries that conform to the provisions of the relevant international treaties e.g. TRIPS or Doha Declaration (Article 50).

(iv) In the case of related patents, where exploitation of a patent “the second patent” relies on the exploitation of another patent “the first patent”, and invention described in the second patent represents a major technological advancement of remarkable economic significance, SIPO may, upon application made by the holder of the second patent grant him a compulsory license to exploit the invention described in the first patent. In such condition, holder of the first patent shall also be eligible to acquire a license to exploit the invention described in the second patent (Article 51).

(v) In the case of semi-conductor technology, the compulsory license shall be issued only for purpose of public interests or to remedy monopoly and its negative impact on competition (Article 52);

(vi) Except in the cases of monopolistic practice by the patentee or license granted for the export of drug(s), compulsory license shall mainly be exercised for the supply to the domestic market (Article 53).
(vii) For an application made under the above clauses (i) or (iv), the applicant shall provide evidence to show that before making the application he has, under reasonable terms, made efforts to obtain patentee's permission to exploit the patent, but fails to obtain such permission within a reasonable period of time (Article 54).

(viii) Upon request made by the patentee, if it is found that the reasons justifying the grant of the compulsory license cease to exist and are unlikely to recur, the compulsory license shall be terminated (Article 55).

(ix) Compulsory license shall be granted on non-exclusive basis (Article 56).

(x) The license holder shall pay reasonable royalties to the patentee (Article 57).

(xi) A patentee who is dissatisfied with the decision made by SIPO on granting of the compulsory license or regarding the royalties, he may take legal action before the people's court within three months from the date of receipt of the notification of the decision (Article 58).

The “Measures for Compulsory Licensing of Patent Implementation, 2012” has prescribed detailed guidelines on various aspects relating to the grant and termination of compulsory license in China. The guideline consists of the following chapters:

- General provisions
- Submission and acceptance of petitions for compulsory licensing
- Examination and determination of petitions for compulsory licensing
- Examination and adjudication of fee adjudication requests of a compulsory license
- Examination and decision regarding terminating the compulsory license
- Supplementary provisions
Although China has not yet issued any compulsory license per se, however in 2005, amid the bird flu outbreak, China threatened Roche Pharma to issue compulsory license of its patented drug Oseltamivir (Tamiflu). As a result, Roche entered into voluntary agreement with two generic companies to ensure sufficient supply of the drug to meet the public requirements in China\textsuperscript{208}.

2.4.12 Patent linkage

Patent linkage is the practice that links the marketing approval for generic drugs to the patent status of the innovator drug. The Drug Registration Rules in China provide a basic framework of patent linkage. Under these rules the innovator drug company is required to submit patent status information for relevant patents to the China Food and Drug Administration (CFDA). CFDA then publishes such patent information on its website. A generic drug applicant is required to submit a letter to CFDA stating that the generic drug will not infringe on the patent rights of others. China’s patent linkage system has however been criticized for not being effective, timely or transparent adjudication mechanism\textsuperscript{209}.

2.4.13 Specialized IP/ patent courts

Specialized courts to adjudicate matter related with IP rights have been set up in China in 2014. Three IP courts are established in Beijing, Shanghai and Guangzhou. The new IP courts hear civil and administrative cases (not the criminal cases) involving IP rights. In these courts the cases are heard by judges specialized in IP laws. To deal effectively with the cases involving complex technologies, technology investigators are appointed. These technology investigators do not have any judicial power, however they provide in-house technical capability for the judges. The Chinese court system consists of four levels of courts viz. lower courts, intermediate courts, high courts and the Supreme Court. The IP specialized courts have the position of intermediate courts in the hierarchy of Chinese courts\textsuperscript{210,211}. 
2.4.14 Regulations for service/ employee inventions

Service inventions are the invention created in the execution of employment tasks by the employees. The Chinese patent law provides specific mechanism to ensure adequate rewards/ remunerations for the inventors of service inventions. According to the Article 16 of the Chinese patent law, in the case of service inventions, the patent owner (employer) shall give a reasonable amount of remuneration to the inventor (employee) based upon the application of the invention and the economic results obtained after the commercial exploitation of such invention\textsuperscript{212}. The patent rules stipulate that this obligation can be fulfilled either through employment contract or in-house regulations, by monetary or other suitable means. However, in the absence of any such contract or in-house regulations the minimum remuneration for one invention shall not be less than RMB 3000 and for one utility model/ design patent shall not be less than RMB 1000\textsuperscript{213,214}. In April, 2015 SIPO published a draft on the “Service Invention Regulations”. These regulations aim to further strengthen the provisions relating to service inventions and rights of the employee-inventors in China\textsuperscript{215}.

2.4.15 Utility model patents

In addition to the invention patents, the Chinese patent law also provide for utility model patents. Utility models present new technical solutions relating to the shape/ structure or combination thereof, of a product, which are fit for practical use\textsuperscript{216}. Utility model patents are granted on the criteria of novelty, inventiveness and practical use. Criteria of novelty are same for invention patents and utility model patents. However, inventive step threshold is much lower for the utility models. The grant procedure for utility model patent is much simpler and quicker. There is no substantive examination carried out for the grant of utility models, they are granted on the basis of preliminary examination only. The term of utility model patents in China is 10 years\textsuperscript{217}.