National Patenting and Legal Aspects in India and its comparison with EU and US systems and procedures

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The European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and Japan Patent Office (JPO), collectively known as trilateral offices, have largely dominated the global IP landscape. In the past few decades, several emerging states such as India with rapidly growing economies and technological advancements are also catching up at the very fast pace.

This paper mainly highlights the important features of the Indian Patent system and its comparison with the US and EU Patent systems and procedures.

Historical background of US, EU and Indian Patent systems

United States (US)

The first US Patent statute was enacted with the object entitled “An Act to promote the Progress of Useful Arts”. It was a short Act that contained seven sections and specified the basic requirement to include “any useful art, manufacture, engine, machine or device, or any improvement therein not before known or used”. The power to grant patents for terms of up to fourteen years for inventions that were "sufficiently useful and important" was vested with the Patent Office provided that the grantee submitted a specification describing the invention to the Secretary of State at the time of the grant.

The said Act was amended which defined the patentable subject matter as, “any new and useful art, machine, manufacture or composition of matter, and any new and useful improvement on any art, machine, manufacture or composition of matter”.

After U.S. became the member of the Paris Convention in, there were two developments in U.S. influencing the development of patent law, the Sherman Act of 1890 and the Evarts Act of 1891.

In 1952, the structure of modern patent law was adopted and since then, several amendments have been made. The Patent law is Title 35 of the United States Code which governs all cases in the USPTO.

Europe (EU)

In Europe, two patent systems co-exist. Under the European Patent Organization (EPO & EPOrg) patents are granted which may cover up to 38 European states including the United Kingdom. The European Patent Organization is an intergovernmental organization that was set up on 7 October 1977 on the basis of the European Patent Convention (EPC) signed in Munich in 1973. It has two bodies, the European Patent Office and the Administrative Council, which supervises the Office's activities. The EPOrg has the European Patent Office (EPO) as the executive arm. The EPO provides a uniform application procedure for individual inventors and companies seeking patent protection in up to 38 European countries. As of January 2008, there are 34 Contracting States to the EPC, also called member states of the European Patent Org. In addition there are four extension states which are not Contracting States to the EPC but have instead signed extension agreements under which the protection conferred by European patent applications and patents is extended to the relevant country. Thus the EPO provides patent protection in up to 38 European countries.

In addition to the EPO patent system, each of the individual European states has its own patent system. The patent laws of the European Patent Organization and the individual European states are based in the same principles, although minor differences do exist.

Hence, the provisions for grant of patents in U.K. can be considered from the U.K. Patents Act 1977 (As amended) and also from the EPC (European Patent Convention).

India

India's patent law dates back to nearly 150 years. The 1856 Act was known as the Act VI of 1856 on protection of inventions and was based on the British Patent Law of 1852. This Act granted certain exclusive privileges to the inventors of new inventions for a period of 14 years.

This Act was later repealed and The Patents and Designs Protection Act was formally made public in 1872. This Act was amended from time to time. It was changed to "The Protection of Inventions Act" in 1883 and in 1888 this was changed to "The Inventions and Designs Act". Finally, in 1911 "The Indian Patents and Designs Act" was promulgated. After India gained independence in 1947, it still followed the old British Law. It was only in 1965 when a patent bill was placed before the Parliament and was passed as the Indian Patent Act of 1970. The Act came into force on April 20, 1972. This Act was further amended in 1999 and the Patents (Amendment) Act, 1999 got assent of the President on March 26, 1999.

India joined the World Trade Organization (WTO) in 1995 and automatically became a signatory of the Agreement on Trade-Related Aspects of International Property Rights (TRIPS) in 1995. Under its requirements, India needed to amend its patent law subject to transitional allowances provided for developing countries under Article 65 of TRIPS.

In order to meet the TRIPS requirements the Patents (Amendment) Act 2002 came into effect on May 20, 2003 and from January 1, 2005 the Patents (Amendment) Act 2005 has been given effect. The Patents (Amendment) Act 2005 takes care of India's TRIPS compliance requirement. The latest amendment in the year 2005 meet India's obligation under the Act TRIPS agreement and provides for product protection in the field of drugs, pharmaceuticals and chemicals.

Object behind granting Patent

- ✓ To encourage scientific research, new technology and industrial progress.
- ✓ Accelerate the technological and industrial development of the country.
- ✓ To induce an inventor to disclose his discoveries instead of keeping them as a trade secret.
- ✓ To offer a reward for the expenses of developing inventions to the stage at which they are commercially practicable.
- ✓ To provide inducement to invest capital in new lines of production.

Hence, Patent provides incentives to individuals by offering them recognition for their creativity and material reward for their marketable inventions. These incentives encourage innovation that assures that the quality of human life is continuously enhanced.

Under the Indian Patents Act, **Invention, Inventive Steps, new Invention and Pharmaceutical substance** are defined as under :

Invention: A new product or a process involving inventive step and capable of industrial application.

Inventive step: 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.

New invention: 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.

Pharmaceutical substance: means any new entity involving one or more inventive steps.

Procedure for obtaining Patent

- ➢ **Application for Patent**

- ✓ Every application for a patent shall be for one invention only.
- ✓ It shall be made in the prescribed form and filed in the patent office.
- ✓ Where the application is made by virtue of assignment of right to apply, proof of such right shall be filed.
- ✓ The application shall state that the applicant is in possession of the invention and give the name of the owner claiming to be the true and first inventor and where the person so claiming is not the applicant, the application shall contain

a declaration that the applicant believes the person so named to be the true and first owner.

- **Who can apply for patent**

- ✓ Any person claiming to be the true and first inventor of the invention.
- ✓ His assignees.
- ✓ The legal representatives of any deceased person who immediately before his death was entitled to make such an application.

It is the person who first applies for a patent who is entitled to the grant. A prior inventor of the invention who applies subsequently will not get the patent as against the first applicant.

- **Whom to apply**

- ✓ There are four patent offices in India, which are located in Mumbai, Calcutta, Delhi and Chennai.
- ✓ A right holder can file their patent application in any one of these patent offices, depending on the territorial jurisdiction.
- ✓ The patent law in India allows the applicant to file a patent application if they have a place of residence or business or a domicile in India.
- ✓ The applicant must be an Indian national or a national of a conventional country. Foreign applicants who do not having a place of business in India are required to file their patent application through an Indian patent agent.

- **Provisional and complete specification**

- ✓ Every such application is to be accompanied by a provisional or complete specification.
- ✓ Where the application is accompanied by a provisional specification, a complete specification should be filed within twelve months from the date of filling the application. If this is not done, the application shall be deemed to be abandoned.
- ✓ Every complete specification should
- ✓ Fully describe the invention and the method by which it is to be carried out.
- ✓ Disclose the best method of performing the invention known to the applicant.
- ✓ End with a claim or claims defining the scope of the invention for which protection is claimed.

- **Publication of application**

- ✓ The application shall not be open to the public for such period as may be prescribed.
- ✓ The applicant may request the controller to publish his application at any time before the expiry of prescribed period.
- ✓ Every application shall on expiry of the period prescribed, be published except in
- ✓ Where secrecy direction is imposed under sec 35.
- ✓ Has been abandoned under sec 9.

- ✓ Has been withdrawn 3 months prior to the period specified.

- ➢ **Examination of application**

- ✓ Within a period of forty eight months from the date of the filling of the application, the applicant or any other interested person may request the registrar to examine the application. If no such request is made then the application will be deemed to have been withdrawn and thereafter cannot be revived.
- ✓ When a request has been made, the controller refer the application to the examiner who makes an inquiry to see
- ✓ Whether it complies with the requirements of the act and rules.
- ✓ Whether there is any lawful ground of objection of the grant of the patent.
- ✓ Whether the invention has already been published or claimed by some other person.
- ✓ The examiner makes a search in the patent office for specifications of prior applications and patents to see whether the same invention has already been published or claimed or is the subject matter of existing or expired patents.
- ✓ A report is accordingly made to the controller within 14 months from the date of reference.
- ✓ The Patent Office after examination of the application will communicate to the applicant the objection, if any to the grant of a patent. An opportunity of being heard is given.

- ➢ **Grant of Patent**

- ✓ If the applicant satisfactorily removes the objections, the controller will accept the complete specification and advertise it in the official gazette.
- ✓ The Patent shall be granted as soon as possible with the seal of the Patent Office and the date on which the patent is granted shall be entered in the register. The term of Patent is 20 years from the date of application.

Comparative study on US, EU and Indian Patent laws

Development of technology and improvements in industrial techniques, which are so essential for the economic welfare of human society, depend largely on the growth of inventions capable of industrial application. In order to encourage the creation and manufacture of new articles and improvements in existing articles or their manufacturing processes, a system of granting a limited monopoly to the inventors in return for the disclosure of the invention to the public has developed in almost all countries. This is the genesis of patent law worldwide. Generally, the basic principles of Patent law are broadly the same throughout the world; differences exist mainly in the procedures of each system.

While quite a few aspects of patent law have been harmonized internationally, there still are many important differences between the systems followed in US, U.K and India. The following are the points of differences between the US, EU and Indian Patent system.

a) First to File vs. First to Invention:

In EU [Article 60 of the EPC] and in India [Section 2(y), 6 and 7 of the Patents (Amendment) Act, 2005] when two or more people apply for a patent on the same invention, the first person to have filed the patent application is considered as the inventor. Assuming that the invention is patentable, the first to file the patent application will get the patent for the invention. The filing date is what is considered and is given the first priority even if a second person comes up with the invention before the first.

While, in the US, in case of two or more applications for the same invention a determination is made as to who invented it first. If two or more applications are filed by different inventors claiming substantially the same patentable invention a proceeding known as an "interference" is instituted by the USPTO to determine who is the first inventor and entitled to the patent. (35 U.S.C. Section 135) provided that the patent has not been issued, nor the application been published, for more than one year prior to the filing of the conflicting application, and provided also that the conflicting application is not barred from being patentable for some other reason.

The priority question is determined by the Board of Patent Appeals and Interferences on the evidence submitted.

Invention in the US is seen to comprise two steps: (1) conception of the invention and (2) reduction to practice of the invention. These terms are encountered in connection with issues related to priority of the invention [35 U.S.C. Section 201(g) and 35 U.S.C. Section 102(g)(1)].

Conception of the invention refers to the completion of the devising of the means for accomplishing the result.
Reduction to practice refers to the actual construction of the invention in physical form: in the case of an article or composition it includes the actual making of the article or composition, in the case of a process it includes the actual carrying out of the steps of the process. Actual operation, demonstration, or testing for the intended use is also usually necessary.

The filing of a regular application for patent completely disclosing the invention is treated as equivalent to reduction to practice. The inventor who proves to be the first to conceive the invention and the first to reduce it to practice will be held to be the prior inventor.

When an inventor conceives of an invention and diligently reduces the invention to practice, the inventor's date of invention will be the date of conception. Thus, provided an inventor is diligent in reducing an application to practice, he or she will be the first inventor and the inventor entitled to a patent, even if another files a patent application (reduces the invention to practice) before the inventor.

However, the first applicant to file has the prima facie right to the grant of a patent. Should a second patent application be filed for the same invention, the second applicant can institute interference proceedings to determine who was the first inventor and thereby who is entitled to the grant of a patent.

Thus in the US, the patent goes to the first to invent and not to the first to file. Recently a bill has been introduced to amend this provision and to change the system from first to invent to first to file. Every Patent Office in the world is based on a "first to file" system.

b) Grace period

In EU (Article 54 EPC) and in India [Sections 2(l), 29, 30 and 31 of the Patents (amendment) Act, 2005] if the invention has become publicly available in any way before the patent application was filed, the application will be rejected. Publicly available includes public use, public sale, a publication, giving a lecture about it, showing it to an investor without a non-disclosure agreement, publishing it in a magazine, a patent or any combination of these and so on. It does not make a difference whether the person making it publicly available is the inventor, one of the inventors, or an independent third party.

While in the US has a one-year grace period (35 US Code Section 102). This means that the inventor can publish his invention 1 year before filing the patent without losing patent rights. However, if the inventor discloses his or her own work more than 1 year before the filing of the patent application, then he/she is barred from obtaining a patent. The applicant is barred from obtaining a patent if the public came into possession of the invention on a date before the 1-year grace period ending with the U.S. filing date.

The one-year grace period is absent in the EU and Indian Patent statutes. If an inventor makes his/her work public a year before he files a patent for the said work, he/she automatically loses all potential patent rights in EU and in India (as well as many other countries in the world).

c) Patentability

▪ Types of patents

In EU and India there are two types of patents given- product patents and process patents whereas in the US there are three types of patents given, namely, utility patents, design patents and plant patents.

In the US, utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof;

In the US, design patents may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture. The design patent protects only the appearance of an article, but not its structural or functional features. The proceedings relating to granting of design patents are the same as those relating to other patents with a few differences. A design patent has a term of 14 years from grant, and no fees are necessary to maintain a design patent in force. If on examination it is determined that an applicant is entitled to a design patent under the law, a notice of allowance will be sent to the applicant or applicant's attorney, or agent, calling for the payment of an issue fee. The specification of a design application is short and ordinarily follows a set form. Only one claim is permitted, following a set form that refers to the drawing(s).

In the US, plant patents may be granted to anyone who invents or discovers and reproduces any distinct and new variety of plant including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state.

d) Requirement of Novelty, Utility and Non-obviousness/ Inventive step

The legal systems of US, EU and India have certain features in common that is the standard requirements of Novelty, Non-obviousness / inventive step and utility for the inventions to possess to be patentable.

The requirement of utility is valid in case of utility patents in the US and not in case of design and plant patents.

Besides being industrially applicable, two most important requirements in EU and in India are that, to be patentable, an invention must be novel and involve an inventive step (Article 52 EPC). This is comparable to the US requirement that the invention must be novel, industrially applicable and must not be obvious (35 US Code sections 102 and 103).

However, there is a more strict interpretation of this term in India and EU. A European patent application involves an inventive step if it solves a technical problem in a non-obvious way. This introduces two extra requirements: it must solve a problem (no problem solved means no inventive step), and that problem must be technical (solving economic problems means no inventive step).

e) Non-patentable inventions

Section 3 and Section 4 of the Patents Amendment Act, 2005 and Articles 52 (2) and 53 of the EPC provides for what is not regarded as invention and cannot be patented.

According to the EPC [Articles 52(2) and 53], the following in particular relevant to the pharmaceutical industry shall not be regarded as inventions:

Discoveries, scientific theories and mathematical methods;

- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.
- Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

According to Section 3 and Section 4 of Patents (Amendment) Act, 2005, India, the following in particular relevant to pharmaceutical industry are not inventions :

- An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.
- The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature.
- The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
- A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.
- A method of agriculture or horticulture.
- A method of producing a new form of a known plant even if it involved a modification of the conditions under which natural phenomena would pursue their inevitable course is not patentable.
- Any process for the medicinal, surgical, curative, prophylactic diagnostic therapeutic or other treatment of human being or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
- Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals
- An invention which in effect, is traditional knowledge or which in an aggregation or duplication of known properties of traditionally known component or components.

In US, the statute indicates only the inventions that are patentable under Section 101 of the U.S.C. According to the Section "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." It does not expressly exclude anything from the regime of patent protection except those which are under the statutory bars contained in Sections 102(b),(c) and (d). But the statutory bar exception is confined to the technical aspects of patent application.

Hence, it is seen that exclusions from patentability vary in the three legal systems. The discovery of a new form of a known substance, not having an enhanced known efficacy maybe patentable in the US and EU but not in India [Section 3(d) of the Act]. A business method is patentable in the US but not in EU and India. What is observed is that there is less restriction on what can be patented before the USPTO than in EU and India.

f) Best mode requirement

US patent law requires the inventor to include the best way to practice the invention in the patent application (35 US Code Section 112). Under the US patent system a specification shall contain a written description of the invention, and of the manner and

process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In India, Section 10 (4)(b) of the Patents (amendment) Act ,2005 requires an applicant to disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection. The specification should disclose the best mode of carrying out the invention and if there is more than one best mode of carrying out the invention, should describe all of them.

In contrast, in EU there is no such requirement. At least one way of practicing the invention must be included in the application but there is nothing that states this way must be the best way.

g) Publication of patent applications

Until recently, US patents were only published after grant. This has been changed as on November 29, 2000 , and now in the US patent applications are published 18 months after their filing date [U.S.C Section 122(b)], unless they have been withdrawn or they are filed with a non-publication request. This is very similar to the situation in EU (Article 93) and India (Section 11, rule 24), where all patent applications are published 18 months after their filing date, unless they have been withdrawn. The difference is that a non-publication request cannot be made in EU and India.

h) Rights conferred by a granted Patent

An Indian or US Patent is a property right that is enforceable in the whole territory of India or USA respectively. It allows the Patent holder to prevent anyone from making, using or selling the invention in the Country.

Here, the European Patent holds a unique feature. European Patent Office (EPO) grants European Patents for the member states of the European Patent Convention. An applicant files a single European Patent application and designates the countries in Europe in which he wants to have Patent protection. The EPO grants the applicant, the same Patent rights in the countries he designated, as would have been granted in the case of a national application. A European Patent is therefore, sometimes referred as a bundle of rights.

i) Opposition after grant

Once a European Patent has been granted, anyone has the right to oppose it within nine months after grant. If the Patent is found to be invalid, it is revoked in all countries simultaneously. After nine months, the Patent can only be revoked separately for each Country in which it was granted. This is substantially more expensive and time consuming. It has often arisen that a European Patent has been a subject of litigation at a national level, for e.g. an infringement dispute must be dealt with according to the national Patent law in each country and opposition proceedings in the EPO simultaneously. An appeal may be preferred against the decision in the opposition proceedings.

The Indian Patent law deals only with the opposition to the patent where the application for patent has been published but before a patent has been granted. While the USA has a re-examination procedure which is not same as an opposition. In re-examination, anyone can present reasons and evidence to USPTO to challenge the validity of a granted Patent.

j) Challenging patent validity after grant:

Within 9 months after the grant of a patent in EU (Article 99 EPC) and within 1 year after the grant of a patent in India [Section 25 of the Patents (Amendment) Act, 2005], anyone can file an opposition, stating with arguments and evidence why the patent should not be granted. The patent office takes a decision based on facts and arguments presented by both sides. There is a hearing and both sides are allowed to argue with each other. This system of "opposition proceeding" does not exist in the US as it does in India and EU. The US has a system of "reexamination proceeding". The re examination procedure does not work the same as an opposition. A reexamination proceeding may be initiated by any party during the life of the patent. Any person can present reasons and evidence to the USPTO to challenge the validity of a granted patent. In case of a challenge, the patent holder engages in a discussion with the USPTO examiner to establish the validity of the reasons. The person challenging the validity of the patent is not a part of these proceedings. The USPTO patent examiner is the arbiter of the patentability, novelty, usefulness, and non obviousness requirements and judges the standards against the prior art in the field. Prosecution of the patent has been characterized as a "give-and-take affair," with negotiation and renegotiation between the patentee and the examiner that ordinarily continues up to 2-3 years.

k) Patent term extension:

The patent term in India and EU is twenty years from the date of filing the application [Section 53(2) of the Act and Article 63 of the EPC].

In US the patent term for utility patents and plant patents is twenty years [35 U.S.C. 154(A)] whereas for design patents it is 14 years. The US patent system also includes provisions for patent term extension.

Utility and plant patents may be eligible for patent term adjustment under 35 U.S.C. Section 154(b). There are three main bases for PTA under the said section. The first basis for PTA is the failure of the Office to take certain actions within specific time frames set forth in 35 U.S.C. 154(b)(1)(A). The second basis for PTA is the failure of the Office to issue a patent within three years of the actual filing date of the application as set forth in 35 U.S.C. 154(b)(1)(B). The third basis for PTA is set forth in 35 U.S.C. 154(b) (1)(C), and includes delays due to interference proceedings under 35 U.S.C. 135(a), secrecy orders under 35 U.S.C. 181, or successful appellate review.

l) Two-part claims

Another unique feature of European Patent application is that it contains two-part claims. The first part of claims is the former features that are found in the prior art. And the second part of claims is what constitutes the invention, often called the characterizing features. In contrast, US and Indian Patent applications will almost always have one part claims.

m) Types of Patent

Patenting is possible in three categories in the US: Utility Patents (Protecting functional characteristics), Design Patents (Protecting ornamental features) and Plant Patents (Protecting plant varieties). Patenting from India is mainly done in Utility Patents.

n) Language

The US and Indian Patent Office deals only with the English language. Whereas the official languages of European Patent Office are English, French and German. Patent applications may be filed in any language provided that a translation into one of the official language is submitted within two months.

Implications of the difference between US, EU and Indian Patent systems

On closely analyzing the patent laws of EU, India and US, it can be said that the procedure of grant of patents in India is quite similar to that of EU and different from that of US.

Almost every Country has its own Patent law, and when you desire a Patent in a particular Country, you must make an application for Patent in that country, in accordance with that country's requirements. Patentability rules are not uniform across the world.

An effort must be made to bring the patent laws of different countries in compliance with each other. This is a step that is essential to maximize the benefit to the inventors all over the globe, thus allowing patent laws to truly serve those it IS meant to protect.