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Review Article

PATENT DOCUMENTATION IN ASIAN AND EUROPEAN COUNTRIES: A MAJOR ROLE IN DRUG DEVELOPMENT

SURENDER VERMA, DEEPIKA*

Institute of pharmaceutical sciences, Kurukshetra University, Kurukshetra 136119, Haryana, India. Email: deepikapharmacy707@gmail.com

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ABSTRACT

A Patent is an intellectual property right relating to inventions and is the grant of exclusive right, for limited period, provided by the Government to the patentee, in exchange of full disclosure of his invention, for excluding others, from making, using, selling, importing the patented product or process producing that product for those purposes. The purpose of this system is to encourage inventions by promoting their protection and utilization so as to contribute to the development of industries and contributes to the promotion of technological innovation and to the transfer and dissemination of technology. Patents ensure property rights for the invention for which patent have been granted, which may be extremely valuable to an individual or a Company. The article also encompasses a discussion on all the steps of patent documentation in Asian and European countries. This article also covered how to file a patent and all the important documents required for patent documentation in Asian and European countries.

Keywords: Patent; Invention; Innovation; Intellectual property; Documentation; Legal.

INTRODUCTION

Advantages of Patent documentation[1]

Following are the Advantages of Patent Documents as a Source of Information:

- They contain information which is often not divulged in any other form of literature.
- They have a relatively standardized format including abstract, bibliographic information, a description of, and in most cases also drawings illustrating the invention and full details on the applicant.
- They are classified according to technical fields.
- They provide examples of industrial applicability of an invention.
- They cover practically every field of technology.
- When an applicant files an international application under the PCT, he will receive an International Search Report (ISR) approximately four months from the international filing date. In a direct foreign filing, on the other hand, the applicant may not receive a first office action on the merits of the invention until more than 18 months after the application was filed. Thus, by filing an international application under the PCT the applicant receives an earlier indication of the relevant prior art than he or she would by filing patent applications directly in foreign patent offices.
- Another advantage of using the PCT process is the delay in having to decide with which foreign patent offices to pursue patent rights. In most countries, a foreign patent application must be filed within one year of the filing date of any prior patent application on the same subject matter in order to receive benefit of the filing date of the prior application. While an international application filed under the PCT must also be filed within the same 12-month deadline, the time limit for entering the national phase in the various foreign patent office's designated by the applicant is 20 months from the priority date. The time limit can be delayed even further to 30 months from the priority date if the applicant files a demand before 19 months from the priority date. On April 1, 2002, an amendment to PCT Article 22 will take effect that changes the time limit for national phase entry to 30 months regardless of whether a Demand was filed. By being able to delay the foreign filing decisions by an additional 8 months or 18 months after the international application is filed, the applicant has more time to assess the commercial viability of his invention and to find financial backers to help cover costs. The PCT applicant can also delay paying foreign filing fees, fees associated with translating the application into other languages and fees for the services of foreign patent agents by using the PCT process. These fees are often exorbitant. Yet, when compared to the process of making direct foreign patent application filings, the PCT process advantageously provides the applicant with extra time and information before he or she must decide whether or not to make this often costly investment in pursuing national patent protection in any particular designated country.

The word patent originates from the Latin patere, which means "to lay open" i.e., to make available for public inspection,

A **patent** is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention. The procedure for granting patents, the requirements placed on the patentee, and the extent of the exclusive rights vary widely between countries according to national laws and international agreements. A patent application must include one or more claims defining the invention which must be new, non-obvious, and useful or industrially applicable. In many countries, certain subject areas are excluded from patents, such as business methods, treatment of the human body, and mental acts. The exclusive right granted to a patentee in most countries is the right to prevent others from making, using, selling, or distributing the patented invention without permission. It is just a right to prevent others use. A patent does not give the proprietor of the patent the right to use the patented invention, should it fall within the scope of an earlier patent. Under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, patents should be available in WTO member states for any inventions, in all fields of technology, and the term of protection available should be the minimum twenty years. The term patent usually refers to an exclusive right granted to anyone who invents any new, useful, and non-obvious process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof, and claims that right in a formal patent application. Examples of particular species of patents for inventions include biological patents, business method patents, chemical patents and software patents.

The Function of a Patent System

A patent system fulfils two roles:

- It provides legal protection for inventions.
- While, at the same time, it ensures that knowledge of those inventions is available to the public[2].

Need of Patent

Patent protection offers the following:

- **Exclusivity:** a patent offers you an exclusive right to use and develop your invention during the lifetime of the patent
- **Improved market position:** your patent gives you an edge on the competition. Thanks to the exclusivity of the patent, you have a 'unique selling point'; others can only use the invention under license
- **Marketing:** an innovative public image is an significant marketing instrument.
- **Licensing income:** you can sell licenses on your patent to other market parties.
- **Stronger negotiating position:** two patents are worth more than one. You can share a patent with a competitor in exchange for using their patent in your activities.
- **Enhanced company value:** patents and other intellectual property rights have an economic value [3].

Types of Patent

The USPTO issue several different types of patent documents offering different kinds of protection and covering different types of subject matter.

A recently issued PTO patent document is one of **six types**, generally described below:

* **Utility Patent** - Issued for the invention of a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof, it generally permits its owner to exclude others from making, using, or selling the invention for a period of up to twenty years from the date of patent application filing ++, subject to the payment of maintenance fees. Approximately 90% of the patent documents issued by the PTO in recent years have been utility patents, also referred to as "patents for invention."

* **Design Patent** - Issued for a new, original, and ornamental design for an article of manufacture, it permits its owner to exclude others from making, using, or selling the design for a period of fourteen years from the date of patent grant. Design patents are not subject to the payment of maintenance fees.

* **Plant Patent** - Issued for a new and distinct, invented or discovered asexually reproduced plant including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, it permits its owner to exclude others from making, using, or selling the plant for a period of up to twenty years from the date of patent application filing ++. Plant patents are not subject to the payment of maintenance fees.

* **Reissue Patent** - Issued to correct an error in an already issued utility, design, or plant patent, it does not affect the period of protection offered by the original patent.

* **Defensive Publication (DEF)** - Issued instead of a regular utility, design, or plant patent, it offers limited protection, defensive in nature, to prevent others from patenting an invention, design, or plant. The Defensive Publication was replaced by the Statutory Invention Registration in 1985-86.

***Statutory Invention Registration (SIR) -** This document replaced the Defensive Publication in 1985-86 and offers similar protection[4].

PATENT DOCUMENTATION IN ASIAN COUNTRIES[5]

Applicant An Application for a Patent for an invention may be made by any of the following persons either alone or jointly with any other person: True and first inventor True and first inventor's assignee Legal representative of deceased true and first inventor or his/her assignee The term "person" as defined in the Patents Act includes Government. The term —person as defined in the General Clauses Act, 1897 includes any company or association or body of individuals, whether incorporated or not. In the case of a limited partnership, the Application may be in the names of all personally responsible partners. True and first inventor does not include either the first importer of an invention into India or a person to whom an invention is first communicated from outside India. The applicant is required to disclose the name, address and nationality of the true and first inventor. Assignee can be a natural person or other than a legal person such as a registered company, a research organization, an educational institute or Government. Assignee includes assignee of an assignee also. Wherever, the inventor(s) is/are not the applicant, a proof of right to apply by way of an endorsement in the Application form (Form 1) or an assignment deed shall be submitted. Legal representative means a person who in law represents the estate of a deceased person. In such a case, the Legal Representative may be required to file appropriate legal instruments as Proof of Right. In case of a convention application, the legal representative or assignee of the applicant in the Convention country can also file a Patent Application in India.	Section 6, 134, 135 (Form-1)
Procedure to be followed in case of death of applicant, or in case the legal entity ceases to exist, substitution or addition of applicant If the applicant dies before the grant of patent, a request may be made by a person who would, by virtue of an assignment or agreement made in writing, or by operation of law, is entitled to an interest in the patent. If one or more of the joint applicant(s) die(s) before the grant of the patent, the survivor(s) may, with the consent of the legal representative of the deceased, request for preceding the application in the name of survivor(s). This procedure is also applicable to a legal entity, which ceased to exist before the grant of patent, as well to joint applicants where one of the applicants dies. In all these cases, when a request is made in Form-6, the Controller may allow such substitution. However, in case of joint applicants, the substitution can only be made with the consent of all the other joint applicants. When there is a dispute between the joint applicants, regarding such substitution, after giving opportunity to all the applicants, the Controller may give such directions as he thinks fit for enabling the application to proceed with. Accordingly, the Controller may direct that the application shall proceed in the name of one or more of the parties alone. Such directions may also relate to the manner in which the application should proceed.	Section 20 (Form-6)

The Controller shall not issue any such direction unless:
the invention is identified in the agreement or assignment by reference to the number of application for the patent, or
an acknowledgement, indicating that the assignment or agreement relates to the invention in respect of which the application is made, is produced before the Controller, or
The rights of the claimant in respect of the invention have been finally established by decision of a court.

Jurisdiction — Section 16, 74. Rule 4, 5.

Unlike many other Countries, for the purpose of facilitating the registration of patents, Indian Patent Office functions from four locations *viz.* Kolkata, Delhi Chennai and Mumbai.
Application for Patent shall be filed with the Patent Office having the appropriate jurisdiction. Territorial jurisdiction of a patent office is decided based on the following:
Place of residence, domicile or business of the applicant (first mentioned applicant in the case of joint applicants).
Place from where the invention actually originated.
Address for service in India given by the applicant, when the Applicant has no place of business or domicile in India (Foreign applicants).
Territorial jurisdictions are presented below:

Patent Territorial Jurisdiction

Office	
Mumbai	The States of Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhattisgarh, the Union Territories of Daman & Diu and Dadra & Nagar Haveli.
Delhi	The States of Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttarakhand, National Capital Territory of Delhi and the Union Territory of Chandigarh.
Chennai	The States of Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and the Union Territories of Pondicherry and Lakshadweep.
Kolkata	Rest of India (States of Bihar, Orissa, West Bengal, Sikkim, Assam, Meghalaya, Manipur, Tripura, Nagaland, Arunachal Pradesh and Union Territory of Andaman and Nicobar Islands)

When a patent application is filed with an appropriate office, it shall be processed by that office ordinarily.
The appropriate office for filing a divisional patent application is the office where the main application is filed, as a divisional application needs to be examined vis-à-vis its main application.
A foreign applicant is required to give an address for service in India and the jurisdiction will be accordingly decided.

Type of Patent Applications — Section 7, 54, 135

Ordinary Application, i.e., an Application which has been filed directly in the Indian Patent Office.
Convention Application.
PCT Application.
Divisional Application, which can result from division of a Patent Application.
Patent of Addition, which may be filed subsequent to the Filing of an Application for Patent, for an Improvement or modification.

Filing of a patent application — Section 7 First Schedule

A patent application shall be filed on Form-1 along with Provisional / Complete Specification, with the prescribed fee as given in First Schedule at an appropriate office. However, a provisional specification cannot be filed in case of a Convention Application (either directly or through PCT routes). Normal fee shall be applicable for applications containing up to thirty pages in specification and up to 10 claims. If the specification exceeds thirty pages or claims are more than ten in number, additional fee as given in First Schedule is payable.

Contents of Patent Application — Section 7. Rule 8, 12, 13, 135. (Form-1, 2, 3, 5, 26). Section 6 of the Biological Diversity Act,

Application for grant of patent in Form-1.
Applicant has to obtain a proof of right to file the application from the inventor. The Proof of Right is either an endorsement at the end of the ApplicationForm-1 or a separate assignment.
Provisional / complete specification in Form-2.
Statement and undertaking under Section 8 in Form-3, if applicable. An applicant must file Form 3 either along with the application or within 6 months from the date of application.
Declaration as to inventor ship shall be filed in Form 5 for Applications accompanying a Complete Specification or a Convention Application or a PCT Application designating India. However, the Controller may allow Form-5 to be filed within one month from the date of filing of application, if a request is made to the Controller in Form-4.
Power of authority in Form-26, if filed through a Patent Agent. In case a general power of authority has

already been filed in another application, a self attested copy of the same may be filed by the Agent. In case the original general power of authority has been filed in another jurisdiction, that fact may also be mentioned in the self attested copy.

7. Priority document is required in the following cases:

a. Convention Application (under Paris Convention).

b. PCT National Phase Application wherein requirements of Rule 17.1(a or b) of regulations made under the PCT have not been fulfilled.

The priority document may be filed along with the application or before the expiry of eighteen months from the date of priority, so as to enable publication of the application. In case of a request for early publication, the priority document shall be filed before/along with such request.

Every application shall bear the Signature of the applicant or authorized person / Patent Agent along with name and date in the appropriate space provided in the forms.

The Specification shall be signed by the agent/applicant with date on the last page of the Specification. The drawing sheets should bear the signature of an applicant or his agent in the right hand bottom corner.

If the Application pertains to a biological material obtained from India, the applicant is required to submit the permission from the National Biodiversity Authority any time before the grant of the patent. However, it would be sufficient if the permission from the National Biodiversity Authority is submitted before the grant of the patent.

The Application form shall also indicate clearly the source of geographical origin of any biological material used in the Specification, wherever applicable.

E-filing

The Patent Office provides the facility to file a Patent Application online from the native place of the agent of the applicant or applicant through e-filing.

For e-filing, applicant / agent must have a digital signature. For the first time, applicant / agent has to register as a new user and has to create login ID and password on the Patent office portal. (http://www.ipindia.nic.in).

A preliminary Software (Client Software) has to be downloaded from the above-mentioned site and has to be installed on the host computer. With the help of said software, an XML file gets generated and all the relevant documents (i.e. Form 1, Form 2, Form 3, etc.) in soft copy have to be uploaded. An Application number and CBR receipt gets generated after successful uploading.

Major objectives and purpose of providing the facilities of e-filing is to save time and other hazards to protect the priority date of Application and time line to enter into National Phase Application, Patent of Addition and Divisional Application within time frame, in case of last moment instruction from applicant to agent.

The applicant / agent will receive the filing receipt and CBR immediately after acceptance of Application in the software, with Patent Application number, date and time of filing.

The Office is in the process of upgrading the e-filing platform so as to enable an applicant to file all subsequent papers electronically. It is also proposed to make e-filing compulsory in the near future.

Steps for e-filing of Patent Application

E-filing user Manual

For using this Portal click on link **'On-line Registration for New User'.**

Complete On-line Registration process for getting User ID & Password.

Login to e-Patent portal after successful registration.

Download **Client Software** for preparing Patent

Application(s) offline.

Complete the Patent Application offline and generate an XML file using **Client Software**.

After creating Application (XML) file offline, digitally sign the XML file (Max. file size permitted 15 MB) for uploading to the IPO Server.

Login to e-Patent portal for uploading Application XML file on IPO Server.

Upload & submit digitally signed XML file to IPO Server.

Process the Application for EFT (Electronic Fee Transaction).

Review Application Status on e-Patent Portal.

On successful EFT, acknowledgement details would be displayed/ generated.

Print the Acknowledgement.

Detailed user manual in pdf format is uploaded on the official website where Certifying Authority, Authorized Bank, Prerequisites of e-filing, Procedure and guidelines of e-filing of Patent Applications are described in detail.

Leaving and serving documents at Patent Office

Rule 6

Any Application, notice or other document authorized or required to be filed, left, made or given at the Patent office, or to the Controller or to any other person under the Act or these rules, may be tendered by hand or sent by a letter addressed to the Controller at the appropriate Office or to that person through post or registered post or speed post or courier service or by electronic transmission duly authenticated.

If it is sent by post or registered post or speed post or courier service or by electronic transmission duly authenticated, it shall be deemed to have been filed, left, made or given at the time when the mail containing the same would have been delivered in the ordinary course of post or registered post or speed post or courier service, or by electronic transmission duly authenticated, as the case may be. In proving such sending, it shall be sufficient to show that the mail was properly addressed and transmitted.

In case of a postal or courier delay, the Controller follows the provisions of the above paragraph with regard to the date of receipt of the document.

Any written communication addressed to a patentee at his address as it appears on the register of patents or at his address for service given under rule 5, or to any applicant or opponent in any proceedings under the Act or these rules, at the address appearing on the Application or notice of opposition, or given for service, shall

be deemed to be properly addressed.
All notices and all written communications addressed to a patentee, or to any applicant or opponent in any proceedings under the Act or these rules, and all documents forwarded to the patentee or to the said applicant or opponent, shall, except when they are sent by special messenger, be sent by registered post or speed post or courier service or by electronic transmission duly authenticated.
The date of a notice or a written communication addressed to a patentee or to any applicant or opponent in any proceedings under the Act and these rules shall be the date of dispatch of the said notice or written communication, by registered post or speed post or courier or fax or electronic transmission duly authenticated, as the case may be, unless otherwise specified under the Act or these rules.
In case of delay in receipt of a document or a communication sent by the Patent office to a party to any proceedings under the Act or these rules, the delay in transmitting or resubmitting a document to the Patent office or doing any act by the party may be condoned by the Controller if a petition for such condoning of delay is made by the party to the Controller immediately after the receipt of the document or a communication along with a statement regarding the circumstances of the fact and evidence in support of the statement:
Provided that the delay condoned by the Controller shall not exceed the period between the date on which the party was supposed to have received the document or communication by ordinary course of mail or electronic transmission and the actual date of receipt of the same.

Receiving documents in Office:

The application and any other documents with accompanying fees and/or without accompanying fees is received at the Patent Office at separate counters known as Fee Counter (FC) and Non-Fee Counter (NFC) respectively.
Both the counters stand closed at **5 pm** for facilitating further processing and no papers will be received after **5 pm**.
All documents by post/courier are received at a separate counter. The fee bearing documents are sent to the fee counter and the non-fee bearing documents are sent to the non-fee counter.
The staff at the fee counter makes relevant entries in the module and generates the Cash Book Receipts (CBRs). The staff at the non-fee counter makes relevant entry in the document receipt module.
The staff at the fee counter stamps the documents so received and enters the CBR number, date, amount of fee received, application number, patent number or other relevant entries. The staff at the non-fee counter also stamps the documents after making entries in the module.
The documents from both the counters are sent on an hourly basis to the Electronic Data Processing (EDP) Section for digitization.
Documents requiring no digitization are sent to the concerned section on daily basis.

Rule 9

Language and Paper size etc.

All documents and copies of documents to be furnished shall be written or typewritten or printed either in Hindi or in English language in large and legible characters with deep indelible ink with lines widely spaced upon one side only of strong white paper of a size A4 with a margin of at least 4 centimeters on the top and left hand part and 3 centimeters on the bottom and right hand part thereof.
It is desirable that the documents are prepared with lines spacing of 1 1/2 or double space in non-script type font (e.g., Arial, Times Roman, or Courier), preferably in a font size of 12.

Signature

Any signature which is not legible or which is written in a script other than Hindi or English shall be accompanied by a transcription of the name either in Hindi or in English in block letters.

Rule 9

Sequence listing

In case the Application for Patent discloses sequence listing of nucleotides and/or amino acids, the same shall be filed in electronic form. However, the fee with respect to the equivalent number of pages shall be payable.

Section 142
Rule 7
First Schedule

Fee

Fee payable under the Act may either be paid in cash or through electronic means or may be sent by bank draft or cheque payable to the Controller of Patents and drawn on a scheduled bank at the place where the appropriate office is situated. If the draft or cheque is sent by post, the fee shall be deemed to have been paid on the date on which the draft or cheque would have reached the Controller in the ordinary course of mail.
Where a fee is payable in respect of a document, the entire fee shall accompany the document.
Where a fee is payable in respect of the doing of an act by the Controller, the Controller shall not do that act until the fee has been paid.
In case an application processed by a natural person is fully or partially transferred to a person other than a natural person, the difference, if any, in the scale of fee(s) between the fee(s) charged from a natural person and the fee(s) chargeable from the person other than a natural person in the same matter shall be paid by the new applicant with the request for transfer.
Fee once paid in respect of any proceedings shall not be ordinarily refunded whether the proceedings have taken place or not.
Prescribed fee for various proceedings under the Act is given in First Schedule.

Processing of Application

Initial processing

On receipt of an application, the Office accords a date and serial number to it. PCT national phase Applications

and non-PCT Applications are identified by separate serial numbers.
All applications and other documents are digitized, verified, screened, classified and uploaded to the internal server of the Office.
Patent applications and other documents are arranged in a file wrapper and the Bibliographic sheet is prepared and pasted on the file cover, so that the files move on for storing in the compactors.
The Application is screened for:
International Patent Classification.
Technical field of invention for allocation to an examiner in the respective field.
Relevance to defense or atomic energy.
Correcting/completing the abstract, if required. If found not proper, the abstract will be recasted suitably, so as to provide better information to third parties. However, such amendments should not result in a change in the nature of invention.
Requests for examination are also accorded separate serial number.

Scrutiny of application

The Office checks whether the Application has been filed in appropriate jurisdiction. If the jurisdiction is not appropriate, the application shall not be taken on record and the applicant is informed accordingly.
The Office checks for proof of right to file the application. If the proof of right is not filed along with the application, it shall be filed within a period of six months from the date of filing of the application. Otherwise, the applicant shall file the same along with a petition under Rule 137/138.
The Office checks whether the application and other documents have been filed in the prescribed format i.e. prescribed forms, request, petitions, assignment deeds, translation etc. Further, the Office checks whether:
the documents are prepared on a proper sized paper, typed in appropriate font with proper spacing,
the documents are duly signed.
abstract, drawings (if any) have been filed in proper format,
meaningful Claim(s) are present in a complete Specification,
Power of Attorney or attested copy of General Power of Attorney (if any) is filed,
Form-5 has been filed(along with complete after Provisional or for filing PCT-NP/ Convention Application),
the invention has been assigned to another person and Form 6 has been duly filed. If the right is assigned from an individual to a legal entity, the legal entity is invited to pay the balance fees.

Secrecy Directions and consequences thereof

Section 35, 36, 37, 38

If in the opinion of the Controller an invention pertains to a subject matter relevant for the purpose of defense as notified by the Central Government, the Controller issues a secrecy direction prohibiting the publication of the application to the applicant and refers the matter to the Central Government for their consideration as to whether the application is prejudicial to the defense of India.
The Central Government, after considering the merits of the secrecy direction, may give notice to the Controller as to whether the secrecy direction needs to be continued or not.
The Central Government reviews the matter at an interval of six months. The applicant may request for a reconsideration of the secrecy direction and if the same is found reasonable by the Controller, he may request the Central Government for a review.
If the Central Government is of the opinion that an invention in respect of which the Controller has not imposed a secrecy direction and is relevant for defense purposes, it may at any time before the grant of the patent notify the Controller to that effect. Thereupon, the Controller invokes the provisions of Section 35(1).
So long as any directions under Section 35 are in force, the Controller shall not take a decision on grant/refusal of the application.

Inventions relating to Atomic Energy

Section 4.
Section 20 of the Atomic Energy Act, 1963.
S.O.61(E)

No Patent is granted in respect of an invention relating to atomic energy falling within sub-section (1) of Section 20 of the Atomic Energy Act, 1962.
According to Section 20(1) of Atomic Energy Act, atomic energy means energy released from atomic nuclei as a result of any process including the fission and fusion processes. Under this Act, "prescribed substances" means any substance including any mineral which the Central Government may, by notification, prescribe, being a substance which in its opinion is or may be used for the production or use of atomic energy or research into matters connected therewith and includes uranium, plutonium, thorium, beryllium, deuterium or any of these respective derivative or compounds or any other materials containing any of the aforesaid substances. The Act defines the term "radioactive substances" or "radioactive material" as any substance or material, which spontaneously emits, radiation in excess of the levels prescribed by notification by the Central Government.-"Prescribed Substances, Prescribed equipment and Technology" have been notified by the Government of India, Department of Atomic Energy vide S.O.61 (E), published in the Gazette of India (extraordinary, Part II, Section 3, sub-section (ii), dated 20th January, 2006.
Any person desiring to apply for a patent abroad for an invention relating to or which he has reason to believe relates to atomic energy shall obtain prior permission from the Central Government before making the application abroad or communicating the invention to any person abroad, unless six weeks have elapsed since his request for permission was made to the Central Government and no reply was received by him.
Upon screening, if an Application is found to be falling within the purview of the Atomic Energy Act, the Controller refers the Application to the Central Government.
The Central Government upon consideration may issue a direction to the Controller, which is binding.
The opinion of the Central Government is not open to an appeal.

Withdrawal of patent application

Section 11A(3)(c), 11B(4). First Schedule

The applicant may, at any time after filing the application but before the grant of a patent, withdraw the

	application by making a request in writing and by paying the prescribed fee. However, if the applicant makes a request for withdrawal within 15 months from the date of filing or priority of the application, whichever is earlier, the application will not be published. It is desirable that the applicant specifies in the request that such withdrawal is under Section 11A (3)(c).	

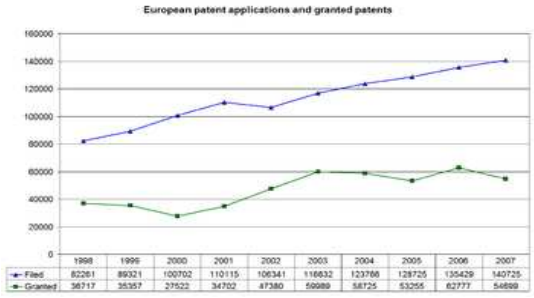
Publication of Application

	Publication of Patent Application An Application for Patent is not open to public before the expiry of 18 months from the date of filing or date of priority, whichever is earlier. At the end of 18 months period from the date of filing or from the date of priority whichever is earlier, the Application is published in the Official Journal except in the cases where: Secrecy direction u/s 35 is in force. Application abandoned u/s 9(1) (i.e., complete Specification not filed within twelve months from the date of filing of Provisional Specification). Withdrawn three months prior to the publication period, i.e., before the end of 15th month from the date of filing or priority, whichever is earlier. This will apply for National Phase entry of PCT Applications as well, if such application has been filed in India before the expiry of 15 months from the date of priority. The Patent Office publishes the Application in the Official e-Journal ordinarily within one month from the date of expiry of 18 months from the date of filing or priority, whichever is earlier. In cases, where a secrecy direction has been given, the Application is published, when the secrecy direction is revoked subject to the expiry of the 18- month period. No application will be published unless a power of Authority, if applicable, is filed.	Section 11A, Rule 24
	Early Publication A request for early publication may be made in Form-9 with the prescribed fee of Rs.2500/- for natural person(s) or Rs.10000 for legal entity other than natural person(s). The request for early publication will be considered if it does not pertain to subject matter relevant for defense or atomic energy. Where a request under (a) above is made, the application is published within one month from the date of such request.	Section 11A(2) Rule 24A (Form-9)
	Particulars of Publication The official Patent Office Journal is published on every Friday with the following particulars: Application number Date of filing Title of invention Publication date International Patent Classification Name and address of the applicant Name of the inventor(s) Priority details like priority document number, date, country etc. Reference to Patent of Addition / Divisional Application along with filing date of the parent Application. Abstract No. of claims Drawings (if any)	Section 11A
	Effects of Publication Upon publication, the Patent office makes the Specification (complete as well as Provisional, if any), and drawings filed in respect of the Application available to the public on its website or on payment of the prescribed fee as given in the First Schedule if such a request is filed. After publication of the Application for Patent the depository institution will make the biological material	Section 11A (6). Rule 27, 55(1A).

	mentioned in the specification, available to the public. A patentee can claim damages from the date of publication of his/her application. However, the patentee can institute a suit for infringement only after a patent is granted. The rights of patentee with respect to applications filed under section 5(2) before 1st day of January, 2005 will accrue from the date of grant of the patent. Further, in such a case, after the grant of a patent, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises. No patent shall be granted before the expiry of six months from the date of Publication of the Application.	

PATENT DOCUMENTATION IN EUROPEAN COUNTRIES[6]

Graph of European patent applications filed and granted between 1998 and 2007. The average time from filing to grant in 2007 was 43.7 months (3.6 years)



The grant procedure before the European Patent Office (EPO) is an ex parte, administrative procedure, which includes the filing of a European patent application, the examination of formalities, the establishment of a search report, the publication of the application, its substantive examination, and the grant of a patent, or the refusal of the application, in accordance with the legal provisions of the European Patent Convention (EPC). The grant procedure is carried out by the EPO under the supervision of the Administrative Council of the European Patent Organization. The patents granted in accordance with the EPC are called European patents.

In other words, the grant procedure before the EPO is the procedure leading to the grant of a European patent or to the refusal to grant a European patent. The procedure starts with the filing of an application and ends with the grant of a European patent or the refusal of the patent application by the EPO, or the withdrawal of the application by the applicant, or its deemed withdrawal. The prosecution of European patent applications until grant typically takes several years.

Filing

EPO headquarters at Munich

European patent applications can be filed at the EPO at Munich, Germany, at The Hague, Netherlands, at Berlin, Germany, or "if the law of a Contracting State so permits, at the central industrial property office or other competent authority of that State". This latter provision is important in some countries. For example, in the United Kingdom, it used to be required to obtain clearance for all inventions but now it is only prohibited for a UK resident to file an overseas patent application for inventions in certain sensitive technical areas without obtaining clearance through the United Kingdom Intellectual Property Office first. European patent applications cannot be validly filed at the EPO in Vienna, Austria.

Within one month after the filing of an application, a filing fee and a search fee must be paid. Additional fees may also be due depending on the size of the application and the number of claims. Namely, if the application comprises more than 35 pages, an additional fee is due (of 12 Euros, as of April 2009) for the 36th and each subsequent page. Furthermore, if the application contains more than fifteen claims at the time of filing, claim fees are due. As of April 2009, a claims fee of 200 Euros is due for the 16th and each subsequent claim up to the limit of 50, and a claims fee of 500 Euros for the 51st and each subsequent claim.

European patent applications must be filed in one of the three official languages of the EPO, in English, French or German. However, some applicants are allowed to file European patent applications in "admissible non-EPO languages", provided that a translation in English, French or German is filed in due time, "within three months after the filing of the European patent application, but no later than thirteen months after the date of priority". In the case of a European divisional application, or in the relatively rare case of a new European patent application under Article 61(1) (b) EPC, "the translation may be filed at any time within one month of the filing of such application". The official language of the EPO in which the application is filed, or the language used when the application was filed in an "admissible non-EPO language", is used as the language of the proceedings.

Formalities examination

The examination of whether the requirements for the accordance of a filing date and other formal requirements are satisfied is carried out by the EPO, in accordance with Article 90 EPC. If a date of filing cannot be accorded, the application is not be dealt with as a European patent application. If the European patent application has been accorded a date of filing, but if there are other formal deficiencies, the applicant is offered an opportunity to correct these deficiencies. If the deficiencies are not corrected, the European patent application is refused, unless a different legal consequence applies.

Oral proceedings may exceptionally take place before the Receiving Section, to give an opportunity to the applicant to be heard on an issue involving formality requirements.

Publication

A European patent application is published as soon as possible "after the expiry of a period of eighteen months from the date of filing or, if priority has been claimed, from the date of priority", or "at the request of the applicant, before the expiry of that period". While early publication of a European patent application can be requested, there are no provisions in the EPC which would permit any delaying of the publication.

Substantive examination

The substantive examination of European patent applications includes the examination of patentability of the claimed invention, i.e. whether the invention is not excluded as unpatentable subject-matter by policy, whether the invention is new, involves an inventive step, and is susceptible of industrial application. The invention must be sufficiently disclosed in the application, and the claims must be clear and concise.

Unless the application is directly ready for grant, communications under Article 94(3) EPC are issued by the Examining Division and notified to the applicant or the appointed representative. In such communications, the Examining Division invites the applicant to reply within a given period, by correcting the "deficiencies noted and

[amending] the description, claims and drawings", where appropriate. If amendments are filed, the amendments must not extend the content of the application was filed, or, in other words, there must not be any added subject-matter.

During the examination phase, oral proceedings may take place at the request of the EPO or at the request of the applicant. They are held before the Examining Division itself, in Munich or the Hague, and are not public, in contrast to oral proceedings in opposition, which are public unless very particular circumstances apply. The right to oral proceedings is a specific and codified part of the procedural right to be heard. A decision is often taken at the end of the oral proceedings. Decisions by Examining Divisions to refuse a European patent application, like any other final decisions of first instance divisions, are appealable.

Communication under Rule 71(3) EPC and grant

If the Examining Division considers that a European patent may be granted, it issues the communication under Communication under Rule 71(3) EPC. By issuing such communication, the Examining Division informs the applicant of the intention to grant a patent based on the prosecuted application. The claims must then be translated in the other two official languages of the European Patent Office, and fees for grant and publishing must be paid If the applicant pays the fees for grant and publishing and files the translation of the claims in due time, he is deemed to have been approved the text intended for grant. If not, the European patent application is deemed to be withdrawn. The time limit for paying the fees for grant and publishing, and for filing the translation of the claims is four months. This time limit is non-extendable.

The decision of the Examining Division to grant a European patent takes effect on the date on which the mention of the grant is published in the European Patent Bulletin. The Examining Division is then bound by its final decision on an application, which can be set aside only following an admissible, allowable appeal. The decision to grant ends the examination procedure. Nevertheless, linguistic errors, errors of transcription and obvious mistakes in the decision to grant may be corrected, as in any decision of the European Patent Office.

After grant

Once granted, a European patent is enforceable on a country-by-country basis. In addition, once the 9-month opposition period is terminated, third parties wanting to invalidate a European patent must institute revocation proceedings in each country where the patent is in force. In addition, once a European patent is granted or more precisely within three months (or six months for Ireland) from the date of grant, the patent must be translated in an official language of each country in which the patentee wants patent protection. If the translation of the European is not provided to the national patent office within the prescribed time limit, the patent "shall be deemed to be void ab initio in that State".

Additional considerations and special cases:

Renewal fees

Renewal fees are payable to the European Patent Office in respect of pending European patent applications in respect of the third year from the date of filing. These fees are paid in advance of the year in which they are due (such that the renewal fee for the third year falls due two years from the date of filing) and fall due on the last day of the month containing the anniversary of the date of filing.

Observations by third parties

After the publication of a European patent application, anyone can file observations regarding the patentability of the invention which is the subject to the application. This is a form of public participation in the examination of patent applications. A person filing observations during examination proceedings does not however become party to the proceedings. This notably means that such person has no right to attend oral proceedings before the Examining Division, which are not public. This contrasts with the filing of a post-grant opposition, wherein the opponent becomes party to the proceedings, therefore acquiring, notably, the right to be heard before any decision is taken.

Divisional applications

A divisional application of a European patent application can be filed, as long as the latter is still pending, and subject to specific time limits. The specific rules regarding the time limits for filing divisional applications were significantly amended in 2010. European divisional applications must be filed directly or by post with one of the filing offices of the EPO, i.e. at the European Patent Office at Munich, The Hague, or Berlin. It may also be filed using the so-called epoline online filing software. The filing of a European divisional application with a national authority has no effect in law.

Euro-PCT applications:

PACE programme

The programme for accelerated prosecution of European patent applications, or PACE programme, "enables applicants who want their applications processed rapidly to obtain the search report, the first examination report and any communication under Rule 71(3) EPC within tight deadlines". A written request ("PACE request") must be filed. The PACE requests are excluded from public inspection provided that they are filed on the appropriate form or on a separate sheet of paper. As of 2009, accelerated processing under PACE was reported to be requested in only 6.3% of files.

BEST programme

Under the so-called "Bringing Examination and Search Together" programme or BEST programme (also referred to as "BEST system"), the EPO's examination procedure was reorganized in 1990, with the primary examiner of the Examining Division being the examiner who had carried out the search.

Withdrawal of an application

Withdrawal of an application is the gravest procedural step that can be taken, since the application becomes dead without possibility of revival. A European patent application may be withdrawn at any time by the applicant, except when a third party has initiated proceedings concerning entitlement to the grant of the European patent. One reason for withdrawing an application may be to avoid its publication, if for instance it has been decided to keep the invention secret instead of applying for a patent. To avoid publication, the withdrawal must occur before "the termination of the technical preparations for publication". Another reason for withdrawing an application may be to obtain a refund of the search fee and/or examination fee, if it has been decided not to pursue the application further. According to the EPO Guidelines,

"The application may be withdrawn by means of a signed declaration, which should be unqualified and unambiguous. The applicant is bound by an effective declaration of withdrawal, but may make it subject to the proviso that the content of the application is not made known to the public."

Statistics

The EPO received its first application in 1978. The one millionth application was published on May 17, 2000, and two millionth one on December 10, 2008.

HOW TO FILE A PATENT[7]

A patent gives you the exclusive right to make, use or sell a product, device or process for a set period of time. Today utility patents (the most common kind) are good for at least 17 years.

Following steps are necessary to file a Patent:

1. Determine whether your idea warrants patent protection. The Patent and Trademark Office (PTO) has an online patent database at www.uspto.gov.
2. Compose a written patent application consisting of a number of subparts required by the PTO, which typically include a detailed description of the invention's structure and operation;

a listing of the attributes that set the invention apart from previous related inventions (known as the 'prior art'); a precise description of what aspects of the invention deserve the patent (the patent claims); and a signed oath or declaration.

3. Create a drawing of the invention that shows all the invention's parts or aspects. You can either submit formal drawings with your application or submit simple sketches until your patent is approved, at which point you'll be required to submit detailed drawings of your invention before the patent will issue.
4. Determine your filing fee by checking the fee schedule at the PTO Web site. For utility patents, the filing fee is $380 for independent inventors and companies with fewer than 500 employees and $760 for large companies. (Expect additional fees of more than $3,000 for getting the patent issued and maintaining it in force until its expiration date.)
5. File the application, drawings or sketches, and fee with the assistant commissioner for patents at the PTO.
6. Communicate with the patent examiner regarding the scope of your invention and its qualifications for a patent. Typically, this takes more than a year. Some self-help resources, such as www.nolo.com, provide detailed information for every step of this complicated process.
7. If a patent is issued, pay the issue fee of $605 for small entities and $1,210 for large entities.

Tips & Warnings:

- To get the earliest possible date for your invention, you may also file a Provisional Patent Application (PPA) for $75. A PPA must contain a detailed description of the invention but need not include most of what must go into a regular patent application.
- If you do file a PPA, you must file a regular patent application on the same invention within one year in order to preserve the PPA's filing date.
- To preserve your right to obtain a patent on your invention, you must file a regular or provisional patent application within one year of the date your invention is offered for sale in the United States, publicly used in the United States or described in a printed publication anywhere in the world (which almost certainly includes descriptions in electronic formats).
- This information is not a substitute for professional legal counsel. Refer to legal references and consult an attorney for up-to-date, comprehensive guidance.

DOCUMENTS REQUIRED FOR PATENT FILING[8]

Following are the documents which are required for patent filing**:**

- Details of the Applicant [name, address, residence or principal place of business, telephone number, telegraphic address, teleprinter address (if any)].
- Basis of the Applicant's right to the patent must be disclosed where the applicant is not the inventor i.e. whether the Applicant is the legal representative/assignee of the inventor, or the Applicant is the owner of the invention which was made while the inventor was in the employment of the applicant or by the inventor in the performance of the contract for the execution of work etc.
- Details of the Preliminary Examination Report issued by WIPO.
- The name of the National, Regional or International Organization issuing the International Search Report.
- At the filing stage the following additional documents are required:

1. A POA duly signed by the applicant - need *not* be notarized or legalize
2. The PCT application
3. Search Report
4. Specifications – containing the description/claims/drawings
5. Priority document - issued by the Patent Office of the Country where the Original application was filed.

At the initial stage of filing it is sufficient to submit a fax copy of the Power of Attorney and a copy of the PCT application with the local application form. The other documents can be forwarded subsequently (within a reasonable time).

Table: Time limits prescribed by the Patents Act, 1970 and Patents Rules, 2003[5]

	Description	Time	Provision
1.	Proof of right to make an application	Six months from the date of filling of application	Section 7(2) Rule10
2.	Statement and undertaking regarding foreign applications	Six months from the date of filing of application	Section 8(1) Rule 12(1A)
3.	Subsequent information corresponding to foreign filing	Six months from the date of filing of application outside India	Section 8(1)(a) Rule 12(2)
4.	Information relating to objections in respect of novelty, patentability etc. in foreign filing	Six months from the date of communication by Controller	Section 8(2) Rule 12(3)
5.	Filing a complete specification after filing provisional specification	Twelve months from the date of filling of the Provisional Specification	Section 9(1)
6.	Declaration of Inventor ship (Form 5)	With the complete specification or within one month from the date of filing of the complete specification	Rule 13(6)
7.	Reference to deposit of biological Material	Three months from the date of filing of application	Section10(4) Rule 13(8)
8.	Convention application	Twelve months from the date of filing of the basic application	Section 135(1)
9.	Convention application (in case of multiple priorities)	Twelve months from the date of filing of first filed basic application	Section 135(1)
10.	Convention application (cognate)	Twelve months from the date of earliest filed specification	Section 135(2)
11.	PCT national phase application	Thirty one months from the priority date	Rule 20(4)(i)
12.	Priority document (for convention application)	Three months from the date of communication from the Controller	Section 138(1) Rule 121
13.	Publication of application	Ordinarily within one month from the expiry of eighteen months from the date of filing or priority or one month from the date of request for early publication, whichever is earlier	Rule 24, 24A
14.	Withdrawal of application to prevent	Fifteen months from date of filing or priority, whichever is	Sec 11A(3)(c)

	publication	earlier	
15.	Request for examination	Forty eight months from the date of filing or priority, whichever is earlier	Section 11B Rule 24B
16.	Request for examination, where secrecy direction imposed	Forty eight months from the date of filing or priority or sixth months from the date of revocation of secrecy direction, whichever expires later	Rule 24B(1)(iii)
17.	Request for examination (Divisional Application)	Forty eight months from date of filing or priority of first mentioned application, or within six months from date of filing of further application, whichever expires later	Rule 24B(1)(iv)
18.	Request for withdrawal	Any time before the grant of Patent	Sec 11B(4), Rule 26
19.	Upon receipt of the Request for examination, the Controller refers the Application to the Examiner	Ordinarily within one month from the date of publication or request for examination, whichever is later	Rule 24B(2)(i)
20.	Time within which Examiner makes report to Controller	Ordinarily within one month but not exceeding three months from the date of such reference	Rule 24B(2)(ii)
21.	Controller disposes off the report of Examiner	Ordinarily within one month from the date of receipt of report	Rule 24B(2)(iii)
22.	First Examination Report (FER) sent by the Controller to applicant	Ordinarily within six months from request for examination or publication, whichever is later	Rule 24B(3)
23.	Time for complying with all requirements imposed by the Act	Twelve months from the date of issuance of the FER	Rule 24B(4)
24.	Time, after publication, before expiry of which no patent is granted	Six months from the date of publication	Rule 55(1A)
25.	Pre-grant opposition	Any time before the grant of patent	Section 25(1)
26.	Reply statement and evidence (pre-grant opposition)	Three months from the date of notice of the Controller	Rule 55(4)
27.	Decision by Controller upon pre-grant opposition	Ordinarily within one month from completion of the proceeding	Rule 55(6)
28.	Notice of Opposition (post-grant opposition)	One year from the date of publication of grant of patent	Section 25(2)
29.	Reply statement by patentee	Two months from receipt of opponent‘s written statement	Rule 58(1)
30.	Reply evidence by opponent	One month from date of delivery of patentee‘s reply statement	Rule 59
31.	Opposition Board submits report	Three months from the date on which documents were forwarded to Board	Rule 56(4)
32.	Periodical review of secrecy directions	Every six months	Section 36(1)
33.	Controller disposes permission for filing abroad	Ordinarily within twenty one days from such request	Section 39 Rule 71
34.	Time after which no permission required for filing abroad	Six weeks after filing the application in India, where no direction for secrecy in present	Section 39(1)
35.	First renewal fee	In respect of third year, before the expiry of second year	Rule 80(1)
36.	Payment of first renewal fee, where patent has been granted after the expiry of two years from date of filing	Three months from the date of recorded in Register of Patents	Section 142(4)
37.	Extension in time for payment of renewal fee, where patent has been granted after expiry of two years from date of filing	Extendable at the most by six Months	Section 142(4)
38.	Time for payment of the renewal fee	Before the expiry of the nth year from date of patent in respect of the (n+1) th year	Rule 80(1)
39.	Extension in time for payment of renewal fee	Maximum six months	Rule 80(1)
40.	Application for restoration of patent	Eighteen months from the date on which the Patent ceased to have effect	Section 60
41.	Request for hearing by an applicant for restoration, where prima facie case has not been made out	One month from date of intimation by the Controller	Rule 84(2)
42.	Notice of Opposition against restoration	Two months from the date of publication of application for restoration	Rule 85(1)
43.	Payment of the unpaid renewal fee and additional fee when restoration Allowed	One month from date of order	Rule 86(1)
44.	Notice of Opposition against an offer to surrender a patent	Three months from the date of publication of offer	Rule 87(2)
45.	Notice of Opposition against application for post-grant amendment	Three months from the date of publication of such application	Section 146(2), Rule 131 (2)
46.	Furnishing information relating to working of patent in respect of the calendar year	Three months from the end of each year	Section 146(2), Rule 131 (2)
47.	Furnishing information relating to working of patent, upon notice of Controller	Two months from the date of notice.	Section 146(1)

Differentiating Features[9]

Following are the major differentiating features between U.S., Asian and European Patent Systems:

Major Differences between U.S., Asian and European Patent Systems

Patent systems' features	United States (USPTO)	Asian	Europe
Patents granted on the basis of first-to-file?	No	Yes	Yes
Filing permitted in any Language?	Yes	No	No, but accepts English, French, German, or any Official language of member state of European patent convention
Are patent applications Published?	No, kept secret until patent is granted	Yes, 18 months after filing/ priority date	Yes, 18 months after filing, priority date
Can patent examination be deferred?	No	Yes, for 7 years after filing	Yes, for 6 months after 18-month publication
Patent term	20 years from filing	20 years from date of publication for purposes of opposition, but not more than 20 years from filing†	20 years from filing
Grace period (amount oftime inventors have tofile patent applicationsafter their inventionshave been made public)	1 Year with no restrictions on disclosure by inventor	1 Year with restricteddisclosure permitted	1 Year with restricteddisclosure permitted
Pre-grant opposition?	No	Yes	No
Compulsory licensing	Only for national security	Yes	Laws of member states control
Legal systems	Common law	Civil	Civil/UK common law
Patent commissioners	Political appointee	Professional bureaucrat	Professional bureaucrat
Patent documents	Public good	Copyrighted	Varies
Formality	• Less stringent • Reviewed by clerks and examiners	• Extremely stringent • Reviewed by clerks (not Examiners)	Reviewed by clerks and examiners
Pendency after examination Requested	19.6 months	28 months	24.8 months
Backlog	About 1 year	About 5-6 years	Less than 9 months
Number of Applications (1993)	174,743	366,486	56,966
Patents granted (1993)	98,344	88,400	36,667

THE ROLE OF PATENTS IN DRUG DEVELOPMENT[10]

Under a patent system, an inventor is entitled to a limited monopoly for a period of time, typically 20 years. This exclusivity may permit high prices and, consequently, an increased economic return that serves as an incentive to develop new products. The system has worked quite effectively in the pharmaceutical area, where the incentives deriving from exclusivity have resulted in important new drugs. The first generation of patients pays a higher price than subsequent generations, which provides compensation for the large research costs involved in developing a new drug. When the patent expires, the price normally falls as generic competitors enter the market.

Even though this approach has been extremely successful in the developed world, it does not generally work for products for which the main market is limited to the developing world. The total magnitude of the market in the developing world for products for HIV, malaria, TB, or less widespread diseases is likely to be too small to provide an adequate incentive for the private sector. This fact, together with the fact that patents are likely to result in higher prices, has raised important concerns in the developing world.

The Drug Access Debate

This agreement requires the members of the WTO, which include nearly all major trading nations, to live up to defined standards of intellectual property protection. TRIPS was part of a much broader international trade package negotiated during the Uruguay Round, one of a series of international trade negotiations that The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) entered into force on January 1, 1995.

The pharmaceutical industry's concern was that a number of developing nations had made deliberate decisions to deny patent protection to pharmaceutical products and to grant protection only to processes for producing pharmaceuticals. These nations believed that inexpensive access to pharmaceutical products was so important that these products should not be patented. In its 1970 patent law, for example, India excluded pharmaceuticals from product patent protection, effectively choosing to provide low-cost pharmaceuticals for its people at the expense of eliminating incentives to create new products. This law was one of the reasons the Indian generic pharmaceutical industry was able to evolve to make and market copies of drugs that were still on patent in wealthier nations. Another concern for the pharmaceutical industry arose from the compulsory license process, a legal process available in some nations to authorize the use of a patented technology under some circumstances even over the patent holder's objection. In practice, compulsory licenses are rarely granted but are instead used as a threat to negotiate lower prices for the technology or pharmaceutical involved.

The United States was determined to change these laws and in TRIPS achieved important requirements for expanding patent protection. The most important TRIPS provision relevant to pharmaceuticals is article 27, which includes a requirement that "patents shall be available for any inventions, whether products or processes, in all fields of technology." (U.K. Commission on Intellectual Property Rights 2002). The clear intent of this language was to prohibit exclusions of pharmaceutical products as in the Indian law. Article 31 established careful procedural limitations on when a nation could grant a compulsory license. Because of these transitional provisions, developing nations were not generally required to provide product patents on pharmaceuticals until January 1, 2005 (a date that has since been extended to 2016 for the least developed countries).

During the years following the entry into force of TRIPS, a substantial and bitter debate over access to pharmaceutical products

in developing countries focused largely on access to antiretroviral agents for HIV patients in Sub-Saharan Africa. A group of nongovernmental organizations argued that patents on these drugs in the developing world raise the prices of the products necessary to help such patients survive. The research-based pharmaceutical industry countered that many of the relevant products are not covered by patents in the nations involved and that the problem is not patents but the inadequacy of the countries medical infrastructure.

An area of convergence has begun to emerge in relation to differential pricing: prices should be lower in developing nations than in developed nations, permitting pharmaceutical firms to recover their research expenditures in the developed world while making products available at near marginal production cost to the poor in the developing world. This differential pricing is justified because potential sales in poor nations are so small that the market provides only a minimal incentive: total sales in the poorest nations account for only about 1 percent of global pharmaceutical sales. The research-based pharmaceutical industry would prefer to achieve this differential pricing by means of a donation program or simply by charging different prices. Critics would prefer that the patent monopoly not be available to raise prices in the developing world, thereby opening up markets to local generic producers.

Movement toward agreement on differential pricing was reflected in the Doha Declaration on TRIPS agreement and public health, reached at a November 2001 WTO meeting of trade ministers. This declaration affirmed that TRIPS "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (TRIPS, paragraph 4, 2001). The new agreement covered products needed to address public health problems recognized in the Doha Declaration, but the United States feared that it would be expanded to a variety of other products and was unwilling to accept it. Finally, a compromise was reached in August 2003. This agreement represents a step forward for access and will certainly place pressure on the research-based pharmaceutical industry to provide products in the developing world at low prices. It leaves several important problems only partly resolved, however. One is the need to prevent importation of the low-priced products into the developed world. Such imports would cut into the patent-protected market and affect incentives to develop new products. A second is political backlash. When the general public becomes aware that a product is available to the poor in a developing nation at a price far below that which patients in developed nations must pay, the political backlash for the pharmaceutical industry in the developed world may be severe.

The Research Tool Issue

Another important problem arises from the changing nature of medical research and of patenting practice. This is the research tool problem: many of the basic tools used in medical research are now themselves patented. For example, the research use of certain genetically modified mice is patented in the United States, as are the uses of many gene sequences and protein crystal coordinates. In the case of the malaria antigen merozoite surface protein 1, some 39 patent families cover various aspects of the protein (U.K. Commission on Intellectual Property Rights 2002).

Such patents can significantly complicate research and make it more expensive. Each one that might affect a particular research program requires legal analysis to determine whether it is valid and actually applies to the planned research program. If relevant, a license must be sought or the research program must be redesigned. The more patents are involved, the greater the likelihood that a patent holder will refuse to grant a license or will demand an exorbitant sum. Even though Walsh, Arora, and Cohen's (2003) study finds no cases of research programs being cancelled midstream because of this problem, it finds many cases of efforts to avoid the problem by, for example, modifying the research; conducting the research offshore in locations where the relevant patents are not in force; or, in some cases, simply ignoring the patent.

Regulatory and Liability Issues

Developing and registering new products are generally lengthy and complicated processes which are regulated both at the national level and, in some circumstances, at the international level. The role of the regulatory system extends beyond the launch of a new product to manufacturing and compliance standards and to post marketing surveillance for clinical effects and potential untoward outcomes. For products that are intended to be deployed in global markets, manufacturers have to comply with regulatory requirements in the country of origin as well as the requirements of each country where the product may be marketed. One exception is the mutual recognition systems used currently by European Union countries (Pignatti, Boone, and Moulon 2004). The situation may be different for products intended for use only in developing countries; however, for legal and liability reasons, manufacturers in developed countries have refrained from working with two different sets of regulatory requirements.

The best example for illustrating this process is the FDA (2004). Over the years, FDA regulations have developed into a clear pathway. The process is initiated through an application by the manufacturer and a step-by-step approach toward licensing. The agency gets involved in every phase of the development process and approves in advance the experimental design, assays, and endpoints for clinical trials. After it has collected all the information, the agency examines the materials submitted and reaches a decision. The FDA process extends through regulating and approving marketing materials and post licensing collection of efficacy data and information about possible side effects.

The FDA approval process differs somewhat for pharmaceutical products and vaccines. One of the main differences is the obligation of vaccine manufacturers to prepare materials for use in phase 3 trials in the final and approved production facility. This requirement means that the firm must invest in completing the manufacturing plant well ahead of launching a specific product, a process that can take three to six years. The regulatory process for vaccines also dictates batch release for every batch ready for deployment in the marketplace. This part of the regulatory process, although it ensures quality control, adds to costs and to the timeline.

In 1996, the European Union adopted a centralized procedure for applications and approvals through the European Medicines Evaluation Agency and through a mutual recognition process (Pignatti, Boone, and Moulon 2004). In many ways, the procedure parallels the FDA process, with several differences reflecting the fact that the European Union consists of many countries, each with a country-based process that remains as an alternative or an addition to the community wide process. The International Conference on Harmonization of Technical Requirements for Regulation of Pharmaceuticals for Human Use was established to achieve coordination of the process of drug development between industry, Japan, the United States, and the European Union (Abraham and Reed 2002; Ohno 2002). The conference's activities have improved understanding of the regulatory process and reduced duplication.

In contrast, the absence of a unified or harmonized approach to product registration and approval at the global level adds multiple layers of complexity. National systems consist of complex processes with differing thresholds and interpretations and with changing requirements in addition to differing Global Manufacturing Program standards and enforcement. A number of recent attempts have been made to resolve the issue. First among these is the World Health Organization's effort to expand its prequalification system, to develop technical standards earlier in the approval process, and to expand the availability of reference reagents for international calibration (Milstien and Belgharbi 2004). These efforts aim at injecting a higher level of quality control and transparency into the global regulatory system. The effort may have the potential to provide a global process that transcends national borders. Such a process should provide a simplified, systematic, and disciplined system that would reduce costs and speed up market access for new products.

The issue of liability in relation to harm to individuals receiving pharmaceutical products has been extremely significant in US product development. It is entirely appropriate for those developing new products to be sued if they are negligent in their research or product development, but in some cases pharmaceutical firms have been sued for side effects of drugs that may have been unforeseeable or may not even have been the result of the product. This type of liability can be a barrier to product development. Although perhaps a less serious concern since the 1993 Daubert v. Merrell Dow Pharmaceuticals lawsuit in the United States, a case that has been interpreted to restrict the presentation to juries of evidence determined not to be "scientific," the issue is still significant. It may also be part of the reason the US vaccine industry has shrunk significantly, and it has certainly affected the direction of investment, pushing it away, for example, from products such as vaccines that are used in one or a few doses in healthy people toward products used repetitively by those who already have a chronic disease (Institute of Medicine 2004). It, thus, provides pressure directly contrary to public health priorities, which emphasize prevention and, therefore, the use of vaccines.

Problematic Issues in Patent Documentation[11]

A major problem in our country is the enormous delay in the processing of patent applications. It is obvious that the implementation of the Intellectual Property regime can be effective only if we have a very good support structure. Around 10,000 patents are being filed; hardly 2000 patents are being issued. There is a proposal to recruit more examiners, but unless we modernize our system there will perpetually be a backlog. Record management too is quite poor in the patent offices and digitization has not been completed. The position is no better in respect of trademarks. A delay of 3 to 5 years for registration is normal. The modernization of the offices and the improvement of the systems do not brook delay. An IP Appellate Board is also required to be set up under the trademarks act to hear appeals against the decisions of the Registrar of Trademarks. Only after the Board is set up, can the notification operationalising the Geographical Indication Act and Rules be issued. In our country there is a negative perception about the IPR Agreement because of the vigorous campaign that the Agreement would have an adverse impact on the prices of drugs and pharmaceuticals. A strengthened IPR regime may not be disadvantageous to our country, especially if the basic concern regarding accessibility to essential drugs is taken care of. The prospect of securing a good share of world trade is also much better in pharmaceuticals, since it is a knowledge-based industry. Implementation and enforcement of IPR will also encourage investment in the country.

Recommendations

Pharmaceutical companies must focus on R & D so that they can get their product patent and capture a large market. Indian Govt. and other regulatory bodies can play a significant role in determining the success of drug discovery research in India. The govt. should give more tax deductions for expenses related to research and development. Since, electronic filing is being made mandatory. This requires a good knowledge of computers. This e-filing system should be made easier. Another thing is that the process of getting product patent is quite long. It should be made shorter. It is the proposed movement of document and approval procedures in digital form (CII, 2002). The date of filing with the patent office should be accepted as the date of filing with the foreign patent office. But as more and more companies are also filing overseas, the paperwork is piling up and threatening to overwhelm everyone. If all of this can be done on-line, it will be unnecessary to send all of this documentation through the mails and considerable savings can be achieved. All patent office's check to see if an application represents a novel invention. This means that all patent offices have to have patent disclosure information, technical journals, specialist reference books and more, from all over the world. Many developing countries find it very difficult to assemble and stock the references they need. If all of this could be put on-line, such countries could simply access the industrialized countries' databases. Companies also have to go through the literature and check all of the patent information to make sure that the same invention has not already been patented elsewhere before they file a patent application. All of the world's patent offices would put their patent information up on their websites. It would vastly simplify such searches because everything could be done on-line. In addition, it would be to the patent offices' benefit, since they could switch from paper to computer processing.

Computerization would also have many other advantages:

1. Information Disclosure

Just as the Patenting office grants an inventor exclusive rights to an invention, it also imposes an obligation to make the technology and other information public. The Patenting office Web site has been called one of the Government's best. It is imperative that the patenting office is not just a place that grants exclusive rights, but that it is also a gathering place for technological information and a cyber office with a vast database that researchers can use. Indeed, it is essential that this database work to promote technological development as well as research and development around the globe. Today's patent procedures were formalized over 40 years ago. Yet companies and the economy in general are obviously very different now from what they were then. Business practices are different, as are documentation techniques. Computers have come into general use and telecommunications modalities are radically different. Even corporate ethics and accountability are different.

2. Reforming Patent Administrations

It is imperative that the patenting office continues working to enhance customer satisfaction for the people who file patent applications. Procedures need to be made more transparent and be more open and accountable. In the examination area, for example, the process should be speeded up and provisions made for holding hearings outside the big cities, and even by using teleconferencing. Likewise, it might be good to establish a system of circuit arbitrators for appeal examinations.

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