

The Benefits and Barriers of Patenting: How Academicians and Researchers Can use their IP to Improve Research Outcomes: An Indian Perspective

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ABSTRACT

Patent protection is the exclusive rights to protect the invention which forbid the manufacture, use, distribution or trade of the invention by others unless they get permission from the patentee. Patent is granted to those inventions which are novel, inventive and have industrial or commercial applications. In India patenting is governed under the law "Indian patents act 1970". Recently India has become one of the top pioneers in filing of patents compared to other countries. One of the main reasons is the strong enforcement of Intellectual Property Rights (IPR) which plays pivotal role in motivating researchers so as to improve their research outcomes and enhance economic development. With the several developments in various fields, India is mainly focusing on R&D sectors to encourage researchers by dissemination of knowledge and information about benefits of patenting. This article mainly highlights the benefits and also the barriers of patenting and how a researchers can make use of their intellectual properties to improve research outcomes. We also concentrate on the status of patent filing and also to investigate the problems faced by researchers while patenting their inventions and analyze significant efforts taken by Indian patent office.

Key words: Patent, Types, Intellectual Property Rights, Indian patent office, Patent Laws.

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INTRODUCTION

A patent is a form of protection approved by the patent office which is granted for an invention, given to the person or a company which had applied for the patent. This means that a patented invention, process or design cannot be commercially made or it cannot be used or distributed and cannot be imported or sold by others without the permission of the patentee. In India, the patent protection is available for inventions or patents regarding both the products as well as for processes. From the year 2005, the protection period for a patent in India in all fields, including the field of pharmaceuticals, has been extended to twenty years from its date of registration.¹ After the completion of twenty years of the period, all the information regarding

the product becomes a part of the public domain.²

The word patent originates from a Latin word *patentem* which means "open" or "lying open". The word patent generally refers to the privileges approved to anyone who discovers any innovative or valuable, and novel method, instrument, an object of production, work or material. The patents are a part of "Intellectual Property Rights".³ The "World Intellectual Property Organization" (WIPO) defines patent as "an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem".^{4,5} The "World Intellectual Property Organization" (WIPO) was launched in 1970. This is an international



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organization which is committed to helping the creators and owners of intellectual property so that their rights are protected worldwide.⁶

A “Patentee” is the one who has applied and received the patent, having all the authority over his/her invention. “Patent protection” is the exclusive rights of the owner to protect the invention which forbid the manufacture, use, distribution, or trade of the invention by others, unless they get the permission from the patentee. Hence, a patent gives protection to the patentee, giving the control over their invention or product for a pre-specified period, after which it has to be disclosed completely.^{7,8} The initial phase in getting a “patent” is to submit a “patent application”. The application should contain the “title” as well as the “technical field” of the invention.⁹ Furthermore, an outline describing the invention and its specifications should be written in a comprehensible manner, and enough information should be provided for an average person in that field to understand, operate and manufacture that invention. Therefore, such explanations are usually followed by other illustrations like pictures, sketches, diagrams and charts that will explain the invention in a detailed manner. Along with this, various “claims” are contained, that will further enhance the protection offered by the patent.¹⁰

Benefits of patenting

- **Encouragement to Innovators:** “Patents” encourage the patentee by giving them proper credit for their innovation and help them to earn by marketing their invention. This will increase their chances for further innovation, thereby improving the quality of human life. Efficient Intellectual Property (IP) Systems can assist in getting more investment and also help in improving the technology market, thereby accelerating innovation and entrepreneurship. Further, it promotes more investment in research and development and increases collaboration among Universities and other firms.¹¹
- **Promotion of Unique Inventions and Works of Art:** An Efficient IP system will be able to provide more time to implement the innovator’s creations and ideas to expand his/her business or startup company before other firms copy it. In exchange for the patent protection, the patentee has an obligation to publicly disclose all the information about the invention to further enrich the collective knowledge in the world. Thus, the vital information obtained inspires other researchers as well as innovators in continuing to invent unique products and other works of art.
- **Entry Barriers:** A well- documented “patent” gives the patentee the “right” to hinder others from copying that invention in the countries which have approved his /her patent. The different barriers will further strengthen the protection of the product thereby shielding it from potential threats of other rival companies. Some of the important barriers are trade secrets, trademarks, exclusive rights and market shares.
- **Patent Infringement:** We can also look for products that are infringing your patent. Detecting infringement can play an important role in achieving a higher monetary return. There are two options available if someone infringes your patent. One will be to license your patent to the infringer, and the other is to file an infringement suit against the infringer.
- **Donating a Patent:** On the off chance that you need to be thoughtful and liberal, giving your patent to any association, which can be a foundation or little level association, will be the best choice. This may likewise lessen your assessment liabilities.

Patent Law in India

The Government of India (Allocation of Business) Rules, 1962, which oversees the division of work among different Ministries/Departments of the Government of India, has outlined the legal framework for IPRs in India and the associated Administrative Ministries. The Government of India has enacted several IPR-related legislation to establish a legal framework for the protection of intellectual property rights in India. Some of these laws were passed before the WTO was established, while others were passed after January 1, 1995. In addition, several of these laws have been changed to reconcile them with India’s commitments under the TRIPS (“Trade-Related Aspects of Intellectual Property Rights”) agreement. There is no single ministry in charge of all IPR laws. The Department of Industrial Policy and Promotion, which is an administrative ministry under the Ministry of Commerce and Industry, is in charge of IPRs relating to trademarks, industrial designs, patents, and geographical indications.¹²⁻¹⁶ Because it is difficult to forecast the reach of existing rules in a rapidly developing and dynamic knowledge sector, legislative modifications may be necessary from time to time. The legal framework could potentially be used to improve the administration and enforcement of IPR rules by increasing transparency and efficiency.^{17,18} The patent system in India is governed by the Patent Act, 1970 and the patent rules came into effect from 20th April 1972 onwards. Consequently the 1970 patent

rule was modified successfully on 1st January 1995, and the 1972 patent act was modified successfully on 2nd June 1999.¹² Following the example is shown by Germany of granting only “process patents” (Countries like Japan, Brazil, Austria, Netherlands, Czechoslovakia, Mexico, Hungary, Norway, Russia and Poland were later followed.¹³ The act on patents 1970 was sanctioned on the recommendations of the Commission that India should be placed along with other 50 nations, previous-TRIPS that excused “pharmaceuticals” from “product patent protection”.^{14,15} Also, it was necessary to reject product patents, particularly for drugs or food items, as they need to be made accessible to the general public at an ostensible cost and can't be permitted to be controlled by any single organization. As they have to be made available to the society at a nominal cost and cannot be allowed to be controlled by any single company.¹⁶⁻¹⁸

The conditions for the grant of patent license are

Novelty -means that the new innovation should not be available in any other country or the paper should not be published anywhere else before patent application is filed.

- Inventiveness – the invention should have skill involved in it or having economic significance
- Commercial use- the invention must have commercial use.¹⁹

The inventions that are not patentable in India

- a) Invention which is against natural law
- b) Any invention which produces harmful effect to animal or human life or plant.
- c) Any discovery related to scientific principle and abstract theory.
- d) Technique used in agriculture
- e) Method or any method in medicinal or other care of human beings
- g) Topography of integrated circuits

The “invention” falling within subsection (1) of the Atomic Energy Act, 1962 (33 of 1962) are not patentable under section 4 of the act.

Patent system in India over the years

The patent system in India has been advancing ever since its implication. In India the patent system has seen tremendous amendments and taking into consideration the pharmaceutical and research field. The following Figure indicates the developments made in Indian Patenting system over the years.²⁰

Amendment of patent rules in India

The “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement was adopted at the World

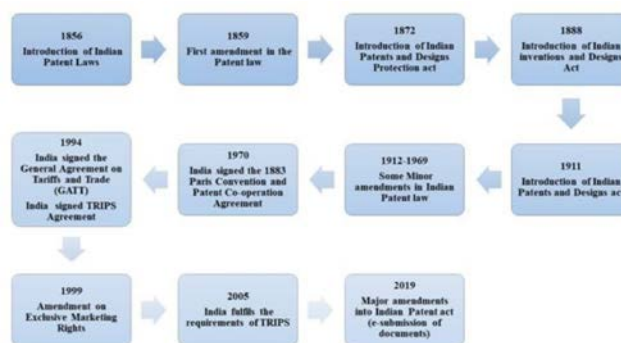


Figure 1: Indian patent system over the years.

Trade Organization in 1994 due to rising globalization of the pharmaceutical industries as well as to prevent the complexity of IPR systems prevailing in each country. “The Patents Act”, 1970 has been amended three times in the years 1999²¹ 2002 and 2005 to conform to the TRIPS. In the year 2002, its modification redefined as “invention” consisting of being “novel” also of being “capable of industrial application” or with any new “inventive step”. In the year 2005, India was affiliated to TRIPS requirements; therefore, procedure and patents which are approved these days will be valid for twenty years from the date of filing of patent.²²⁻²⁴ Most recent amendment to the patents act was in the year 2019 which mainly focused on submission of documents electronically.

Post TRIPS Agreement impact on Indian pharmaceutical industry

Indian pharmaceutical industry has been expanding immensely and has achieved self-sufficiency. Since the 1980's India has become one of the major drug exporters. This made industries successful and were able to concentrate on research and development in order to develop generic drugs, which the industries acquired through patent protection regime of patents act 1970. During the mid-1900's the Indian pharmaceutical industry had to face tremendous challenges due to world trade organization's agreement on trade-related intellectual property rights (TRIPS agreement).²⁵

However, in 2005 India amended the patents act 1970 to comply with the TRIPS Agreement.²⁶ This introduced product patents for chemical products, drug and food and the term for patent expiry was increased to 20 years. Post TRIPS agreement implementation, changed the favorable conditions enjoyed by the Indian pharmaceutical generic companies due to the introduction of product patent for drugs. At the beginning, post TRIPS agreement implementation created panic throughout the pharmaceutical industry

and a hike in drug prices. But slowly they copped up with new changes and involved in continuous R and D.

Types of Patents

A person or a company can file for different types of patents:

- **Matter patent:** A patent granted for any chemical molecule for diagnostic purposes or the treatment of any diseases.
- **Use patent:** These are patents given for other uses of a known drug, to treat or prevent a different disease condition.
- **Process patent:** A Patent which is granted for different processes for creating a compound or any other substance is called “process patent”.
- **Formulation patent:** “Formulation patents” are granted for novel drug delivery systems and different derivatives of a branded drug, for example, novel formulations and controlled-release formulations of the drugs having higher therapeutic benefits.
- **Compulsory License:** A “compulsory license” is required for any persons interested, other than the patentee, to make the patented item to meet the public requirement. The requirements for obtaining a compulsory license should be met to get the approval of the Government.²⁷ The provisions for a compulsory license are laid out in “Section 84 of the Patents Act”, 1970. It expresses that following three years from the date of the publication of a patent, any individual/organization can document a demand to the Controller contending that the required conditions of the community have not been fulfilled or that the drug is not manufactured in sufficient quantity or sold at a sensible cost. Thus he/she can file a request to obtain a compulsory license to produce and distribute that drug or product.²⁸ India started granting product patents after amendments in the Patents Act in 2005. After that, only a few requests have been filed for grant of the compulsory license.²⁹

Patent Searching

The most important factor before filing any patent in India is the thorough patent search. For this purpose, the Indian patent office in 2012 introduced a database “IPAIRS” (Indian Patent Information Retrieval System) that helps in accessing patent information.³⁰ Later in 2015, a updated version of IPAIRS called “InPASS” (Indian patent advanced search system) was introduced that allows a full text search of all Indian patent applications and Indian Patents.³¹

Process of patent filing in India

The Office of the Controller General of Patents, Designs, and Trade Marks is in charge of Intellectual Property in India (CGPDTM). This is a government of India subordinate office that administers Indian patent, design, trade mark, and geographical indications law. The ministry suggested nodal officers to deal with enforcement concerns in order to ensure adequate coordination between stakeholders and enforcement agencies in the topic of patent laws enforcement. In India patent office is situated in Chennai (Territorial Jurisdiction includes Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Pondichery, Lakshadweep), Mumbai (Territorial Jurisdiction includes Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhatisgarh, Daman and Diu, Dadra and Nagar Havel), Delhi (Territorial Jurisdiction includes Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttanchal, NCT of Delhi, Chandigarh) and Kolkata (Rest of India) where the patents can be filed.³²

The steps involved in patent filing in India

1. Check if your invention is patentable
2. Patent Search and Drafting
3. Patent Filing
4. Publication of the Application.
5. Examining the patent application
6. Decision to grant patent
7. Grant of Patent.

Patent can be filed through 4 forms (form 1, 2, 3 and 5) which will be sent to the respective patent office.

- Form 1:** this form contains name of the applicant and inventor s is given. The application will also contain information regarding whether it is filed as convention or Patent cooperation treaty (PCT) form.
- Form 2:-** this form will contain full descriptive information regarding the invention or work for which the patent is being filed.
- Form 3:-** this form is concerned with whether the invention is filed in any foreign country or not.
- Form 5:-** it's a declaration from of inventorship. Declaration means here both the inventors and applicant are true persons involved in this work.³²

The Figure 2 shows steps involved in the Patent filing procedure in India.³³

Publication: After the application form is filed the applicant must publish a journal which will contain the name, address, abstract and invention procedure to the respective patent office. This should be done

within 18 months from the date of filing to patent office. Immediately after this step, patent application will be open for public inspection. However, before the publication it will not be available for the public.

Examination: The application form, claims all of those forwarded by the applicant gets examined. A First Examination report will be published after testing of the reports which will be sent to the respective patent office or his agent, with statement to any objection for which the applicant has to reply within 6 months. An extension of 6 months will be provided to applicant in case he fails to report or reply.

Opposition to Patent: The next step after first examination report is that the patent office searches if there is any same type of patent in their offices in order to ensure that the applied patent is valid and there are no claims of this work or invention already in the past.

Grant of License: If the patent office is satisfied and the application meets with all the criteria then the patent is issued which is valid for 20 years.³³

Status of patenting in India

Patents affect medicines availability and affordability, as it stops generic manufacture and makes monopolistic high costs of medicines. Pre-grant oppositions act as a mechanism to prevent granting of wrongful patents. It will also make a conflict between patent rights and also rights to health.^{34,35} Table 1 shows the trends in Patenting in India for the last six years.³⁶ During 2016-17, the number of patent applications examined increased by 72.2%, the number of grant of patents increased by 55.3% and disposal of applications increased by 37.7%, as compared to 2015-16. Domestic filing of Patents applications was 29.2% in 2016-17 as compared to 28% in the previous year, thereby showing 1.2% increase as compared to 2015-16. During 2017-18, the number of patent applications examined tremendously increased to more than double the applications examined in the previous year, whereas, number of grant of patents increased by 32.5% and as compared to 2016-17. Domestic filing of patents applications in 2017-18

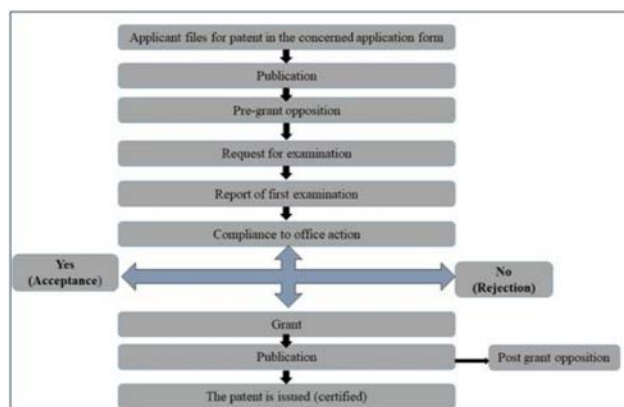


Figure 2: Patent filing procedure in India.

has also increased to 32.5% as compared to 29.2% in 2016-17.³⁶

Initiatives taken by Indian patent office to improve access to the applicants

To strengthen Intellectual Property administration in the country, the Government of India has taken necessary steps to set up a favorable environment for the protection of IP Rights. The National Intellectual Property Rights Policy was launched by the Government of India on 12th May 2016 for the management and administration of Intellectual Property Rights. The patent office has taken necessary steps to accomplish the country's economic and industrial development objectives by providing stable Intellectual Property systems in the country. Patent Rules 2003 have been revised with effect from sixteenth May 2016 to disentangle patent systems and finish IT enablement in working.³⁷

The following improvements have been brought about in the functioning of Patent Office by Patents (Amendment) Rules, 2016:

- Small entity and the startup have been introduced in the rules, and a reduced official fee has been provided in comparison with the large entities.

Year	2012-13	2013-14	2014-15	2015-16	2016-17	2017-2018
Filed	43,674	42,951	42,763	46,904	45,444	47,854
Examined	12,268	18,615	22,631	16,851	28,967	60,330
Granted	4,126	4,227	5,978	6,326	9,847	13,045
Disposal	9,027	11,411	14,316	21,987	30,271	47,695

Source: Data obtained from annual report 2017-18; The Office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications, India.³⁵

- Expedited examination of patent applications filed by startups and the applicants selecting Indian Patent Office as ISA/IPEA for their PCT applications,
- International searching authority and international preliminary examination authority has been established
- If the candidate isn't keen on seeking after the examination of his application filed for a patent, then the applicant can withdraw his claim before the issuance of the First Examination Report with a refund of fees paid.
- Introduced dynamic stock and flow utility which provides real-time status of Patent applications.
- Nowadays all the patent office locations are provided with Video-conferencing or audio-visual communication devices facility so that the applicant can approach the patent office through this facility and also a reduction in the fees for sequence listings
- The patent agents must file an online application to speed up digitization and processing of patent applications. From 1st January 2016, Unique Numbering System for Patent Applications and Requests for Examination was introduced for the auto-allocation of requests for examination of patent applications
- From 1st April 2016, the procedure of issuance patent grant certificates was fully automated. The First Examination Reports and certificates are transmitted to the applicant through registered email, and same can be printed by the applicant.
- Recently, to rationalize the search system, "Indian Patent Advanced Search System (InPASS) A login-free online public search facilities for patents have been implemented.³⁷⁻³⁹
- **Huge time needed for invention/innovation:** It takes a lot of time in developing, undergoing approval for clinical trials and manufacture of new drug molecules. Thus, improvement of productivity in the R&D departments, along with accelerating the development of novel molecules which will be beneficial to the common people, should be one of the top priorities in the Pharmaceutical sector.^{41,42}
- **High capital investment:** As more financing is required, the allotment of sufficient funding by the Government as well as by other Pharmaceutical companies should be done to finance the research in different institutions and to encourage and promote innovations.⁴³
- **Shortage of qualified professionals:** There is a lack of qualified personnel which hinder the rate of progress of novel inventions and technological development. The Pharmaceutical Industries can incorporate more research activities by increasing the expenditure in the Research and Development areas and provide sufficient funding to encourage and train more researchers.⁴⁴ The sophisticated Research Centers should be established, and proper training should be given to increase the number of adequately trained researchers and related personnel.⁴⁵

Future Opportunities in Research

Currently pharmaceutical industries are gaining a lot of sustainability by various organizations, consumers and policy makers. India has various organizations that promote research like Department of Biotechnology (DBT), Department of Science and Technology (DST) and Council for Scientific and Industrial research etc., thereby giving opportunities to research activities. The Council for Scientific and Industrial Research (CSIR) is one of the main organization that promotes research field in India and making it one of the top organization in India through which patent application is filed. In 2005, after India implemented TRIPS agreement "CSIR" has emerged as a global competitor by mainly focusing on novel inventions and being at a forefront in intellectual property generation in India. With the various organizations providing awards, fellowships and grants to researchers thus making it possible to broaden the scope of research in general public.⁴⁶

Recommendations

- Even where there are innovations, does the patent system influence the access to those innovations?
- Is the patent system accurately recognizing genuine inventions?

Barriers faced by the researchers while registering intellectual property rights

Although researchers have various facilities for patent filing, but there are certain difficulties that arise due to the complex system of patent filing. The barriers faced by the researchers while registering intellectual property rights are as follows

- **Research and Development facility:** Currently there is a lack of Research and Development infrastructure as well as facilities in India. More investment in R&D sector is required for the development of novel drugs and products. Also, patented drugs can be manufactured on a contract basis. The research to patent novel formulations and new uses for the current drugs can be carried out while giving importance to quality standards.⁴⁰

- Are patents becoming a necessary ingredient of equitable access to new medicinal products or are patents becoming obstructions to equitable access?
 - How the pre-grant opposition system can be used widely and effectively to prevent wrongful patents?
 - Are patents on medicines and medical technology being granted to legitimate inventions of value to society or are they also being granted on relatively trivial developments and obvious extensions of known substances or technologies?
 - There is a need for the improved awareness and understanding of patentability criteria in India among researchers to reinforce the judicious application of patents.
1. Expand an open and transparent system of filing patent applications; scrutinizing the applications, publishing the First Examination Report (FER), checking the amendments in the patent applications after the FER, and grant or reject patent applications based on compelling evidence will improvise the scrutiny and inquisitorial efficiency of the patent system.
 2. Giving careful consideration to how patent applications are inspected and allowed and whether the provisions of the patent law are being taken after, as an essential public health tool
 3. Prevent patent candidates from recording patent applications that contain superfluous Markush claims.
 4. Pre-grant oppositions can be enhanced if the “published patent applications” and the layout contain all the critical data, including the International Nonproprietary Name, utilization of the compound for the treatment of particular diseases.
 5. Revise the strategy and practice around pre-grant oppositions to take into consideration a period bound becoming aware of the issue, after the pre-grant opposition is documented.
 6. Re-take at the terms of the Patents Act and roll out important improvements that would help in the advancement of well-being of the overall population and to give access to all drugs at an affordable price.

CONCLUSION

Patenting has gained a lot of importance owing to the protection it provides for new inventions. Indian patent system is ever growing since its first introduction. Pharmaceutical field has seen a lot of developments and

growth in terms of research field due to the increased knowledge of patent. The major reforms of Indian patent system in 2005 allowed the growth of patent activity in India. Although post TRIPS agreement caused a decline in pharmaceutical industry patent filing due to the introduction of “Product patent”, which led to immense panic at the beginning but slowly the Indian pharmaceutical industries coped up with the changes and involved in further R&D work. Pharmaceutical industry should manifest more towards their R&D sectors to enhance more patent filing in the future. The government of India has taken the necessary measures to ensure that more importance has been given to R&D sectors. A constant effort is put forth by Indian patent office to create awareness amongst the research scholars, general public and various organizations about the patenting and its benefits. They also nurture cooperation at international level and enhanced the awareness amongst the general public by making the knowledge and information transparent, accessible and understandable to them. Thus, Indian patent system is exemplary and with its strong enforcements enable a balance of interest between common man and inventors, making it thrive more towards the path of development.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

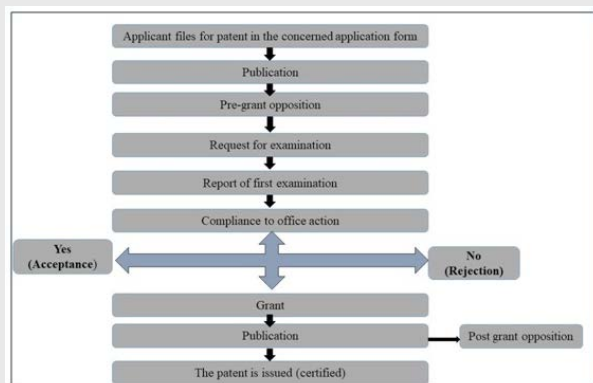
CSIR: Council for Scientific and Industrial Research; **DBT:** Department of Biotechnology; **DST:** Department of Science and Technology; **FER:** First Examination Report; **InPASS:** Indian Patent Advanced Search System; **IPR:** Intellectual Property Rights; **PCT:** Patent cooperation treaty; **TRIPS:** Trade-Related Aspects of Intellectual Property Rights; **WIPO:** World Intellectual Property Organization.

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PICTORIAL ABSTRACT



SUMMARY

We look at the relationship between patenting from the pharmaceutical sector and economic growth of the country. How Academicians and researchers from the pharmaceutical sector can make use of their IP to improve research outcomes. We also find that the significant efforts taken by the Indian Patent Office to improve access to the applicants for patenting.

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