Available online on 15 Mar, 2025 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Intellectual Property Rights

Lakshmi Priya Manda*

Northeastern University, College of Professional Studies, Boston, Massachusetts, USA-02115

Abstract

A novel drug's development necessitates extensive study in chemistry, production, controls, preclinical science, and clinical trials. Drug reviewers in regulatory agencies around the world bear the responsibility of evaluating whether the research data support the safety, effectiveness and quality control of a new drug product to serve the public health. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing and labelling of pharmaceutical products. This article examines the drug clearance procedure in various nations, including the United States and India. A drug product must be examined for safety and efficacy in people before it can be licensed for import or production of a new medicine. A company's regulatory affairs department is critical in adhering to the laws, regulations, and standards established by many countries' regulatory agencies. The purpose of this article is to compare the drug approval processes in the United States, India, and all data on drug patents granted in the previous years and the current year.

Keywords: Intellectual property rights, Patents; FDA; ANDA; Pharmaceutical Products; US Patent Act; TRIPS; Patent Cooperation Treaty (PCT)

Article Info: Received 27 Sep 2024; Review Completed 11 Dec 2024; Accepted 14 Jan 2025

Cite this article as:
Manda LP. Intellectual Property Rights. Int. J. Drug Reg. Affairs [Internet]. 2025 Mar 15 [cited 2025 Mar 15]; 13(1):1-5. Available from:
http://ijdra.com/index.php/journal/article/view/713

DOI: https://doi.org/10.22270/ijdra.v13i1.713
*Corresponding author

1. Introduction

Any original, authorised creation of the human race, such as art, writings, inventions, and research, is protected by intellectual property rights. Intellectual property rights are legal privileges given to an originator or developer to protect their work for a predetermined period of time. PR is a powerful tool for protecting an IPR creator's investments of time, money, and effort since it grants the creator an exclusive right to use his creation for a long period of time. IPR promotes healthy competition, industrial advancement, and financial prosperity as a result, which helps a nation's finances. (1)

Refers to a group of discrete intellectual property rights that can be utilised to protect different components of a creative work for several purposes:

- Copyrights
- Patents
- Trademarks
- Protection of IC layout design
- Geographical indications and
- Protection of concealed information
- Registered (industrial) design

1.1 Rationale of patents

Patents issued help to recognise the IP form that appears in invention. Patents are issued for innovations that meet the criteria for originality and versatility underneath the strict inspection and appeal processes established in the Indian Patent Act, 1970. (2)

To protect IPR that is covered by their preview, the most of countries have national frameworks in place. With the exception of copyrights, the protection offered to the inventor or author in a country (like India) or a region (like the European Union) is restricted to the territory for which protection is requested and is not valid in other countries or regions.

a) For instance, a patent issued in India is only good for India and not the USA. therefore, if the patent agent successfully describes and asserts the invention, the inventor or his assignee will have a monopoly.

b) The resulting patent would grant the patent owner an exclusive market if the patent agent accurately defined and claimed the invention in the patent specification produced. (3)

The patentee has two options for exercising his exclusivity: either by using his own marketing channels or by granting a third party a licence.

2. Patents history

2.1 United states:

The United States Constitution, which was initially established on September 17, 1787, included a guarantee safeguarding intellectual property. Article I, Section 8, has the stipulation:

The Patent Act of 1790 served as the first federal patent statute in the United States. The bill was titled "An Act to Encourage the Progress of Useful Arts." The federal act, like the state statutes, granted patent holders a 14-year window of exclusivity to use their ideas without the possibility of an extension. This was deemed inadequate by many inventors who prefer longer protection periods for their ideas. (4)

The first patent was granted on 13th July of 1836. All former patent numbers were retroactively given the suffix "X" by the Patent Office in 1836. Prior to this, patents were identified by numbers rather than names and dates. The renumbering resulted in Patent 1 becoming Patent 1X. In 1790, the First US Patent Act of the US Constitution was written. The first US Patent, with the serial number X000001 (visible to the right), was issued on July 31, 1790. The patent was granted by George Washington, the president. Samuel Hopkins of Pittsford, Vermont, was awarded the patent for "producing pot ash and pearl ash by novel machinery and process."(5)

2.2 India:

In order to provide the nation's impoverished with greater access to affordable medications, the Indira Gandhi administration enacted the Indian Patents Act in the early 1970s. To put it another way, India would provide patents to the production method rather than to specific pharmaceuticals. As a result, Indian pharmaceutical firms may produce the same medication in several methods (this is otherwise known as reverse engineering).(6)

It became apparent that India's patent strategy could no longer safeguard domestic consumers as it sought to expand its global market share. The necessary legislation to update the Indian Patents Act to comply with TRIPS was supposed to be tabled during the 2004 winter session of Parliament; instead, on December 26, 2004, an ordinance was passed, and it went into effect on January 1, 2005. This amended the Indian Patents Act, and on March 22 and 23, 2005, respectively, the Lok Sabha and Rajya Sabha passed the Patents (Amendment) Bill as a result of this amendment to the ordinance. On April 5, 2005, the President's signature made the measure an Act of Parliament.(7)

3. Pharmaceutical patent regulation in united states:

Intellectual property protection in the pharmaceutical industry:

The pharmaceutical sector contains two types of intellectual property protection for pharmaceutical ideas that are comparable but unique. However, the FDA offers newly approved medicines the opportunity to disallow competing medicines. This is a practice known as regulatory exclusivity

A successful patent grant requires demonstration of three elements:

- Usefulness (the invention accomplishes its intended purposes)
- Novelty (the invention was not publicly known before the patent applicant invented it)
- Non-obviousness (the invention is not an obvious development to an expert in the invention's field)

At any point during a drug's development, a patent can be requested and granted. Secondary patents are those that add new features to or enhance drugs that already have a patent on them. a single drug may be protected by more than 100 patents. (8)

3.1 Economic justification of patents

Patents are a regulatory tool that can be used to address knowledge-based innovation results that are not effective. In industries where research and development expenses are significant, the cost of developing a new product is substantial. Additionally, competitors who did not contribute to the initial costs but are now eligible for the profits can readily copy the new product. Patents allow the business that developed the new product to temporarily prevent rivals from capturing future profits. Patents are publicly accessible documents that include extensive details on the nature of the invention. This promotes the public sharing of scientific findings while avoiding financial penalties, which fosters further innovation.

Not to mention, you can "rent" patents by paying royalties. They can be purchased or sold as well. This offers competing businesses the opportunity to create products that would otherwise violate patent rights, so long as a contract is in place with the patent owners. Patents do not guarantee an innovator a successful monopoly.(9)

3.2 Financial analysis of patents in the pharmaceutical industry

Assuredly, there are enormous expenses involved in bringing new pharmaceuticals to market, however published figures might differ greatly from one another. They can be misleading indicators of the financial health of a pharmaceutical company because these charges are highly volatile and prone to risk. However, drugs covered by patents are shielded from competition and price regulations for about 20 years, providing patent holders the sole monopoly. But someone has to pay for the ongoing research needed to create better and newer medicines, and unhappily the required funding is not small. Without patents, some pharmaceutical companies wouldn't spend money on their own research, preferring to wait for someone else to discover the drug and obtain a licence permission.(10)

3.3 Previous reforms of pharmaceutical patents

The Drug Price Competition and Patent Term Restoration Act of 1984, along with the America Invents Act of 2011 (commonly known as the Leahy-Smith America Invents

Act or AIA), are foundational laws that significantly impacted patent regulation and shaped future modifications to patent law.(11)

One of the major outcomes of the 1984 legislation was the creation of the Abbreviated New Drug Application (ANDA), which streamlined the FDA approval process for generic drugs. Unlike new drug applications, ANDAs do not require generic drug manufacturers to demonstrate safety and efficacy through clinical trials. Instead, they must show that their generic product is bioequivalent to the reference brand-name drug, meaning that the active ingredient performs in a similar way in the body. To prove this, manufacturers conduct bioavailability studies, where blood samples from patients are analyzed to ensure that the levels of the drug in the bloodstream closely match those of the brand-name counterpart. (12)

When submitting an ANDA, generic manufacturers must also certify one of four patent statuses:

- The proposed generic drug does not infringe on any existing patents.
- The patents related to the reference drug have expired.
- The generic will not be marketed until all relevant patents have expired.
- The generic manufacturer believes the patents are either invalid or irrelevant to the drug in question.

This process has not only accelerated the introduction of lower-cost generic medications to the market but also fostered legal battles over patent validity, as generic manufacturers frequently challenge brand-name patents to gain earlier market entry. These patent certification categories, particularly the fourth option (known as a Paragraph IV certification), have led to significant litigation between brand-name and generic drug companies.

Table 1. Patents granted for drugs during last 6 years and current year (13)

S.no	Title	Patent grant date	Patent no
1	STILBENE BASED COMPOUNDS AS HDAC INHIBITORS	05-04-2016	272490
2	“A LENTIVIRAL VECTOR-BASED VACCINE	12-04-2016	272595
3	NOVEL 11B-HYDROXYANDROST-4-ENE-3-ONES	19-04-2016	272676
4	“MODIFIED ERYTHROPOIETIN”	25-04-2016	272749
5	A READY TO DRINK LIQUID FOR ALZHEIMER PATIENTS	06-05-2016	272979
6	"HYDROXYAPATITE-TARGETING MULTIARM POLYMERS AND CONJUGATES MADE THEREFROM	31-05-2016	273340
7	DICLOFENAC GEL	21-06-2016	273641
8	INTERLEUKIN-13 ANTIBODY COMPOSITION"	28-06-2016	273776
9	"NANOPARTICULATE FORMULATION FOR ORAL DELIVERY O F COENZYME Q10	23-01-2017	279439
10	(R)-6-METHOXY ALKYL EXEMESTANE COMPOUNDS AND RELATED METHOD OF USE	25-01-2017	279563

Table 1. Total Patents granted for drugs

S.No	Patents granted years	Total number of patents
1	2022	12
2	2021	25
3	2020	29
4	2019	26
5	2018	26
6	2017	37
7	2016	22

4. Pharmaceutical patent regulation in India

The patent system in India underwent significant modifications after the country accepted the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement in 1995. The first modification in this series was the Patents Act in 1999, which offered pipeline protection before the country granted product patents for inventions with a pharmacological basis.

Beginning on January 1, 1995, it established the procedures for submitting mailbox applications for product patents in the industries of pharmaceuticals and agrochemicals, and it started the granting of Exclusive Marketing Rights (EMRs) on those patents. India also amended the Patents Act, 1970 with the passage of the Patents (Amendment) Act of 2002 in order to comply with the second set of TRIPS standards.

The third set of changes to patent law was made with the introduction of the Patents (Amendment) Act, 2005. The Indian Patents Act of 1970, which provides patent protection for pharmaceutical products and drugs, was updated in 2005. In accordance with Section 3(d) of the Patents Act of 1970, the use of a known process alone is not recognised as distinguishing it from the use of a known substance and is not entitled to patent protection.(14)

4.1 Scope of protection of patent

In India, pharmaceutical products, including medications, biological products, and medical equipment, are eligible for both product and process patents.

A patent offers the following rights to the patentee (15):

- The exclusive right to bar anyone from creating, using, offering for sale, selling, or importing that product into India when a product is the subject of the patent.
- When a process is the focus of a patent, the owner has the sole authority to bar anyone from using the process in India as well as from using, offering for sale, selling, or importing the product obtained directly through the technique for those reasons.

When two or more persons are identified as the grantee or proprietor of a patent, each such person (or such person's agent) shall be entitled to the above rights, unless otherwise agreed in writing. However, a co-grantee of a patent is not allowed to licence or assign the invention unless both parties consent to it.

A complete specification contains the following:

- a title that adequately conveys the invention's related subject matter.
- An explanation of the invention, drawings, a model, or a sample (if necessary).
- Full and detailed description of the invention, its mechanism of action or intended use
- disclosure of the most effective way to implement the invention that the applicant is aware of and for which the applicant is eligible for protection
- A claim outlining the invention's boundaries, together with an abstract outlining the invention's technical details.
- The applicant must deposit the biological material to an international organisation if the specification refers to a biological substance that cannot be adequately described using language and is not readily available to the public.

There are three routes through which an application can be filed before the Indian Patent Office:

- Regular application.
- Application of convention.
- Application for the National Phase of the Patent Cooperation Treaty (PCT).

5. Conclusion

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. A patent is the granting of a property right by a sovereign authority to an inventor. This grant provides the inventor exclusive rights to the patented process, design, or invention for a designated period in exchange for a comprehensive disclosure of the invention.

The Patent Act of 1790 served as the first federal patent statute in the United States. The first patent was granted on 13th July of 1836. In order to provide the nation's impoverished with greater access to affordable medications, the Indira Gandhi administration enacted the Indian Patents Act in the early 1970s. At any point during a drug's development, a patent can be requested and granted. Patents are publicly accessible documents that include extensive details on the nature of the invention.

There are enormous expenses involved in bringing new pharmaceuticals to market, however published figures might differ greatly from one another. The Drug Price Competition and Patent Term Restoration Act of 1984 and the America Invents Act of 2011 (often referred to as the Leahy-Smith America Invents Act or AIA) are two key pieces of legislation that laid the groundwork for future patent modifications. The legislation instituted the shortened FDA approval process for generic drugs known as the Abbreviated New Drug Application (ANDA).

The Indian Patents Act of 1970, which provides patent protection for pharmaceutical products and drugs, was updated in 2005.

Acknowledgements

I would like to express my sincere gratitude to the editorial team and reviewers of International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Reference

1. Singh R. Law relating to intellectual property (A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case-Law and much more). Edition 2, Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd.; 2004
2. The Geographical Indications of Goods (registration and protection) Act, 1999 along with Geographical Indications

of Goods (registration and protection) Rules 2002. India. New Delhi: Universal Law Publishing Co. Ltd; 2004.
3. The Patents Act, 1970 as amended by Patents (amendment) Act 2005. New Delhi: Commercial Law Publisher (India) Private Ltd; 2005.
4. Federal Trade Commission. Generic drug entry prior to patent expiration [Internet]. US:FTC; 2002 [cited 2008 Jun 14] Available from: http://www.ft c.gov
5. Eaton, Jonathan, Kortum S. Trade in ideas: Patenting and productivity in the OECD', NBER Working Paper No. 5049, NBER: Boston and Washington, D.C; 1995.
6. Singh R. Law relating to intellectual property (A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case-Law and much more). Edition 2, Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd.; 2004
7. History of Patent System, India: Intellectual Property India, Ministry of Commerce and Industry; c2004-2008 [Internet]. India: ipindia; 2024 Mar 07 [cited 2008 Apr 02]. Available from: https://ipindia.gov.in/Patents/history_of_indian_patent_system
8. Lexchin J. Intellectual property rights and the Canadian pharmaceutical marketplace: Where do we go from here? Int J Health Serve.2005; 35:237-56.
9. Shivashankar M, Mani D, Mandal BK. An overview on intellectual property rights in pharmaceutical and biotechnology industries. J Chem Pharm Res. 2011; 3(2):753-61
10. Musungu SF, Villanueva S, Blasetti R. Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks. Geneva: South Centre; 2004 Apr.
11. Edenshaw A. Asian perspectives on post-TRIPS issues in intellectual property. J World Intellect Prop. 2005; 8:211–2.
12. The Patents Act, 1970 as amended by Patents (amendment) Act 2005. New Delhi: Commercial Law Publisher (India) Private Ltd; 2005.
13. Central Drugs Standard Control Organization. List of Approved New Drugs [Internet]. India: CDSCO; 2025 [cited 2008 Apr 02]. Available from: https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/
14. Correa C. Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries, Third World Network 1999 [Internet]. twnside [cited 2008 Apr 02]. Available from: www.twnside.org.sg/title/foster.htm
15. IPO Intellectual property handbook. WIPO Publication no. 489 (E) ISBN 978-92-805-1291-5. Second Edition Reprinted. Geneva, Switzerland: World Intellectual Property Organization; 2004.