SRYAHWA PUBLICATIONS

Journal of Law and Judicial System
ISSN: 2637-5893 | Volume 7, Issue 1, 2024
https://doi.org/10.22259/2637-5893.0701002

REVIEW ARTICLE

A Comparative Study of Patent Laws in India and the United States of America

Komanduri S, Murty[1], Jeevarathnam Daniel Mehat[2]

[1]*Alma Jones Professor of Social Justice Fort Valley State University, USA.*
[2]*Georgia Public Schools, USA.*

Received: 30 August 2024 Accepted: 17 September 2024 Published: 25 September 2024

Corresponding Author: Komanduri S, Murty, Alma Jones Professor of Social Justice Fort Valley State University, USA.

Abstract

This paper examines the evolution of patent systems in India and the United States, with specific reference to changes pertaining to pharmaceuticals, to assess how both the nations have adopted changes overtime to protect intellectual property while simultaneously protecting public interest, i.e., affordable health care. The analysis suggests that the patent laws of both the countries stayed within the standards established by international patent regime; and, that they reflect the interests specific to their utilizations of intellectual property. India utilized its opportunities to adjust its patent law to suit its needs at various stages of development and benefited from those opportunities. Likewise, the United States has reached a level of technological predominance because of the utilization of its opportunities as an industrialized economy.

Keywords: Patent Laws, Trips, Wto, Wipo, Pharmaceuticals.

1. Introduction

Recent years have shown an unprecedented increase in drug prices, far greater than what is necessary to sustain the R&D efforts of the industry. Cancer drug prices have doubled in the US in the last decade, averaging US $5,000 to US $10,000[1] a month. Prices of new cancer medications continue to rise faster than public and private spending on health care, creating challenges even for health systems and individuals even in high-income countries. The profit-motive contributes for pharmaceutical company neglect of key public health issues. Pharmaceutical companies are reluctant to invest in the development of medicines for people with limited or no purchasing power. Not-for-profit drug development organizations are working to fill gaps in drug development for certain neglected diseases, but they struggle with securing funding for their R&D activities.[2] This paper examines the evolution of patent systems in India and the United States, with specific reference to changes pharmaceutical patents, to assess how both the nations have adopted changes overtime to protect intellectual property while simultaneously protecting public interest, i.e., affordable health care.

2. The Indian Patents Act 1970

"Patent" refers to an exclusive right granted to one who invents any new, useful and non-obvious process, machine, article of manufacture, or composition of matter, or any new and useful improvements, and claims that right in a formal patent application.

It is a set of exclusive rights granted by a state to an inventor or their assignee for a limited period of time in exchange of public disclosure of an invention.

[1]Tito Fojo and Christine Grady, "How much is life worth: cetuximab, non-small cell lung cancer, and the $440 billion question," Journal of the National Cancer Institute 101, no. 15 (2009):1044-1048, doi: 10.1093/jnci/djp177, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2724853/
[2]10 Policy Cures, G-Finder, Neglected Disease Research and Development: Emerging Trends. By Mary Moran, Javier Guzman, Nick Chapman, Lisette Abela-Oversteegen, Christine Whittall, Rachel Howard, Penny Farrel, Dale Halliday, and Catherine Hirst. Sydney, Australia. Policy Cures, 2014, http://policycures.org/gfinder. Html#linkthree

Citation: Komanduri S, Murty A Comparative Study of Patent Laws in India and the United States of America. Journal of Law and Judicial System. 2024;7(1): 11-19

©The Author(s) 2024. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

The Patents Act was enacted by the Parliament of India in 1970 in pursuance of its powers under Entry 49 of the List I of Schedule VII. Entry 49 reads, "Patens, inventions, and designs; copyright; trademarks and merchandise marks." The Act was passed on September 19, 1970, as Act 39 of 1970. It aimed to: (1) encourage scientific research, new technology and industrial progress; (2) grant exclusive privilege to own, use, or sell the method of the product for the limited period for the purpose of stimulating new inventions of commercial utility; and, (3) ensure more effectively that patent rights ae worked to the detriment of the consumer or to the prejudice of trade or the industrial development of the country. Thus, the act is kept in line with the development of technological capability in India, coupled with the need for integrating intellectual property system with international practices and intellectual property regimes.

3. TRIPS Agreement and Resulting Changes in Intellectual Property Rights in India

Intellectual property rights given to one over creations of their minds. It gives creator an exclusive right over use of his/her creation for a certain period of time. An international agreement on Trade-Related Aspects of Intellectual Property Right is administrated by the World Trade Organization (WTO) that sets minimum standards for many forms of intellectual property regulation. Its objectives are to: (1) reduce distortions and impediments to international trade and take into account the need to promote competent as well as adequate protection of intellectual property rights; (2) ensure that measure and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade; (3) reduce tensions by reaching strengthened commitment to resolve disputes on trade-related intellectual property issues through multilateral procedures; and, (5) to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (WIPO) (Dhar & Joseph, 2019; Parmar 2023). Table 1 shows the comparison of how intellectual property rights are protected in India before and after the TRIPS Amendment:

3.1 Indian Patents Act Amendments and Key Features

The government of India appointed Justice N. Rajagopal Ayyangar Committee to examine the question of revision of the Patent Law to advise government regarding changes warranted in 1957. The two-part report of the committee report was submitted in September 1959. First part dealt with general aspects of the patent law and the second part gave detailed note on several clauses of the lapsed bill of 1953. The first part also dealt with the evils of the patent system and solutions with recommendation in regard to law. Major changes recommended by this report were incorporated into the Patent Bill of 1965, which was introduced in the Lok Sabha on September 21, 1965, but it lapsed. In 1967, an amendment bill was introduced which was referred to a Joint Parliamentary Committee and on final recommendation of the Committee, the Patent Act 1970 was passed, and it came into enforcement in April 1972. This Act was later replaced with Patent (Amendment) Act 1999, and it was enforced from January 1, 1995. The second amendment to the Patents Act 1970 was made through the Patent (Amendment) Act 2001, and it was enforced from May 2003. The third amendment to Parent Act 1970 was introduced as Patent (Amendment) Act 2005 (Act 15 of 2005) on April 4, 2005, and it came into enforcement retroactively from January 1, 2005 (Singh 2005; WIPO, 2023:249-255). The salient features of the Indian Patent (Amendment) Act 2005 are: (1) extension of product patents to all field of technology including food, drugs, chemical and

Table 1. *Intellectual Property Rights in India Before and After TRIPS Amendment*

Intellectual Property Rights Before TRIPS	Intellectual Property Rights After TRIPS
Patent Act 1970	Patent Act 1970 as amended in 1999, 2002, & 2005
Copyright Act 1957	Copyright Act 1957 as amended in 1994 & 1999
Design Act 1911	Design Act 2000
Trade & Merchandise Marks Act 1958	Trade Mark Act 1999
For protection of undisclosed information, there is no legislation, but usually handled by Contract Act 1872	National Innovation Act 2008
No provision for Geographical indication	GI of Good (Registration & Protection) Act 1999
No provision for protection of lay out design of semiconductor IC	Semi-conductor Integrated Circuit Layout Design Act, known as Act 2000
No provision for protection of New Plant Varieties	Protection of Plant Varieties & Farmers' Right Act 2001

microorganisms; (2) deletion of provisions relating to Extensive Marketing Rights (EMRs); (3) introduction of a provision for enabling grant of compulsory license (CL) for export medicines to countries which have insufficient or no manufacturing capacity to meet emergent public health situations; (4) modification in the provisions relating to opposition procedures with a view to streamlining the system by having both pre-grant and post-grant opposition in the Patent Office; (5) strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies; and, (6) rationalization of provisions relating to time-lines with a view to introducing flexibility and reducing the processing time for patent application (Singh 2005).

3.2 Criteria for Patentability

The general criteria for patentability under the Indian Patent (Amendment) Act 2005 are: (1) New/ Innovative inventions—invention means any new process or product involving inventive steps and utility. And new invention means any invention or technology which has not published or use in the country elsewhere in the world before the date of filing of patent application. (2) Non-obviousness—means feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to person skilled in the art. (3) Industrial applicability—means invention must be capable of being useful in an industry.

3.3 Non-Patentable Subject Matter

Indian Patent (Amendment) Act 2005 identified two categories of non-patentable subject matter in Sections 3 and 4, as follows:

Section3: Those which are not inventions. They include:

a. An invention which is frivolous, or which claims anything obvious contrary to well established natural laws.

b. An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

c. The mere discovery of scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature.

d. The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or mere discovery of any new property or news use for known substance or of the mere use of known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

   Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

e. A substance obtained by mere admixture resulting only in the aggression of properties of components thereof or a process for producing such substance.

f. The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.

g. A method of agriculture or horticulture.

h. Any process for the medical, surgical, curative, prophylactic (diagnostic therapeutic) or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

i. Plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

j. A mathematical or business method or a computer programme per se or algorithms.

k. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television production.

l. A mere scheme or rule or method of performing mental act or method of playing game.

m. A presentation of information.

n. Topography of integrated circuits.

o. an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Section 4: Inventions relating to atomic energy. No patent shall be granted in respect of an invention relating to atomic energy falling within subsection (1) of section 20 of the Atomic Energy Act, 1962 (Act 33 of 1962).

3.4 Changes Pertaining to Pharmaceuticals

Table 2 shows a comparison of changes between the Indian Patent Act before and after 2005, directly related to pharmaceuticals. The table shows that some additional provisions like compulsory licensing, Bolar, are parallel import are added, a few provisions like "Licenses of Rights" were removed, patent term was increased from 7 to 10 years, and section 3(d) is expanded with explanation in Patent (Amendment) Act 2005.

Table 2. *Changes in Pharmaceutical Patent Provisions, Before & After 2005*

S. No.	Before January 1, 2005	After January 1, 2005
1	Regarded as Patent Act 1970	Regarded as Patent (Amendment) Act, 2005
2	Only process patent was allowed on pharmaceutical/ chemical inventions [S5(1)]	Product patent is allowed [omission of section 5]
3	Term of process patent for pharmaceutical/chemical process was 7 years from filing of complete specification.	Term for all kinds of patent for pharmaceutical/chemicals are 20 years from the date of filing of either provisional/complete specification [section 53]
4	New use/new property of known drug is not patentable [section 3(d)]	Enlargement of section 3(d) with explanation.
5	Provision for endorsement of "Licenses of Rights" for patented pharmaceutical/chemical processes after 3 years of grant over and above of "compulsory licensing."	Provision for endorsement of "License of Rights" is removed but provision for "compulsory licensing" is continued.
6	No provision for "compulsory licensing for export of medicine to foreign country in emergency."	Provision for "compulsory licensing for export of medicine to foreign country in emergency." [section 92 A]
7	In case of infringement proceedings, burden of proof lies on patent owner.	It is responsibility of the infringer to produce proof that he is not infringing [section 104A]
8	No "Bolar" provision	"Bolar" provision for rapid entry of generics after expiration of patent term [section 107A(a)]
9	No provision for "parallel import"	Provision for "parallel import" [section 107A(b)]

4. Patent System in the United States

The first U.S. Patent, numbered X000001 was granted on July 31, 1790, by Thomas Jefferson to Samuel Hopkins, for "making of post ash and pearl ash by a new apparatus and process." (U.S. Congress, 1790; Maxey, 1998). On July 13, 1836, Patent 1 was granted. All old patents were relished with X's, and the first patent became Patent 1X. Patent law was amended in 1839 to provide a grace period of two years to use the patent. The 1861 amendment of patent law included some important amendments, such as nomination of three chief examiners to hear patent application, but it had been rejected at least twice. In 1887, the U.S. joined the Paris Convention. By 1911, approximately one million patents were granted. Plant Patent Act was established in 1930 to allow asexual, manmade plants to receive patents, and it was amended in 1954 to include seeds, mutants and hybrids. U.S. Patent Office was renamed "U.S. Patent and Trademark Office," (USPTO) in 1975, which opened patent museum in 1995. First official publication of U.S. Patent Application was made available in 2001. In 2005, the U.S. Congress introduced major reforms, including a switch to first-to-file system. On September 16, 2011, the *America Invents Act* was signed into law, which provided for "the first inventor to file" standard to align with other nations' intellectual property standards (Dobyns, 1994; USPTO, 2024).

4.1 U.S. Code of Patent Law

Title 35 of the United States Code is a title of U.S. Code regarding patent law. The following sections of Title 35 govern all aspects of patent law in the U.S. (JUSTIA. 2018).

Section 101: Inventions Patentable—Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Section 102: Conditions of Patentability; Novelty and Loss of Right to a Patent—A person shall be entitled to a patent unless: (a) invention was known or used by others in this country, or patented or described in printed publication in this or a foreign country, before invention thereof by the applicant, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year to the date of application, or (c) he has abandoned the invention, or (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of application in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in U.S., or (e) the invention was described in an application for patent, published under section 122(b), by another filed in U.S. before invention by the applicant, or (f) he did not himself invent subject matter sought to be patented.

Section 103. Conditions for Patentability; Non-obvious Subject Matter—A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the rt to which said subject matter pertains.

4.2 Changes Pertaining to Pharmaceuticals

(1) Patent Term and Adjustment—the terms of certain patents may be subject to extension or adjustment under 35 USC Sec.134(b). This results from certain types of delays which may occur while in application pending. Pharmaceutical patent term is 20 years from date of filing. (2) The patent term can be extended (35 USC 156)—single extension of term up to five years may be granted as a result of delays in the first marketing of a product due to regulatory review. (3) The extension of term may be obtained if patent relates (a) to active ingredient of human or animal drug product or combination of this, medical device, food additive or color additive, (b) to methods of manufacturing or approved use of such products, and (c) product is subject to regulation under the Food, Drugs and Cosmetics Act. (4) Bolar provision (35 USC 271 (e)(1))—it not be an act of infringement to make, use, offer to sell, or sell within the U.S. or import into U.S. a patented invention. (5) Patent Term Adjustment (PTA) is a process carried out by USPTO for adding day-for-day credits to the normal 20-year term from filing of a patent based on delay in prosecution, which include (a) failure of the Office to take certain actions within specific time frames set forth in 35 USC 154(b)(1)(A); (b) failure of the Office to issue a patent within three years of the actual filing date of the application as set forth in 35 USC 154(b)(1)(B); (c) other conditions set forth in 35 USC 154(b)(1)(C) that includes delays due to interference proceeding 35 USC 135(a), secrecy orders under 35 USC 181, or successful appellate review (Hoag, 2024).

4.3 Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) of 1984 provides patent holders on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining Food and Drug Administration (FDA) approval. According to this Act, a generic pharma company can work on patented invention to speed up faster entry of generics as soon as patent get expired. In return, Innovator Company get five years exclusivity after FDA approval and generics cannot challenge at that time. Any generics who challenge innovator after fiver years and try to invalidate its parent, get 180 days market exclusivity—Para IV certification (Thomas, 2016).

Abbreviated New Drug Application (ANDA) is for generic duplicate of an approved New Drug Application (NDA) product. ANDA contains data that, when submitted to FDA's Center for Drug Evaluation and Research, office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. There are four types of ANDAS: Para I—filing for the launch of generic drug is made when innovator has not made the required information in the Orange book; Para II—filing is made when the drug is already off patent; Para III—filing is made when the applicant does not have any plans to sell the generic drug until the original drug is off patent; and, Para IV—filing for the launch of generic drug is made when applicant believes its product or use of its product doesn't infringe on innovator's patents or where applicant believes such patents are not valid (Thomas, 2016).

5. Difference Between the U.S. Patent System and Indian Patent System

There are striking differences between the U.S. and Indian Patent Systems as shown in Table 3. Some of

those major differences are: (1) the patentable subject matter in the U.S. Patent Act is illustrative in nature in the sense that it defines what is patentable in U.S., whereas the Indian Patents Act defines what is not patentable subject matter; (2) the U.S. Patent Act allows a discovery of process, machine, manufacture or composition of matter to be patented, provided it meets the criteria of novelty, utility and non-obviousness; but, under Indian Patent Act, the mere discovery of a new and useful process or product is not patentable; (3) plants, unlike in India, are patentable in the U.S.; (4) provisions for Patent Term Adjustment, Patent Term Extension, and Option to opt-out of the publication are available in the U.S. Patent Act, whereas no such provisions exist in Indian Patent Act; (5) there is no special court to decide matters of patent infringement in India, and appeals from the decision of Indian Patent Office lie at the Intellectual Property Appellate Board, which is a specialized quasi-judicial body with certain powers of a High Court, whereas in the United States the Federal Circuit court is specialized to deal with appeals related with patent disputes; and above all, (5) Indian Patent Law does not allow extension of patent on minor cosmetic changes in the product (evergreening), but on the other hand, U.S. Patents Act allow such extension, because of which the drug prices there are so high. This evergreening provision alone spurred some conflict between the two nations.

Additionally, when Indian government issued its first compulsory license, it became an eyesore for multinational drug companies and the U.S. issued Report 301. Under Section 301 of Trade Act of 1974, the United States Trade Representative (USTR) issues an Annual Report in which the countries that could not protect intellectual property rights of the U.S. companies are identified and threatened. In this report the U.S. claimed that India needs to modify its IP rules and regulations, specifically on compulsory licensing and Section 3(d), while placing India on the 'Priority Watch List' along with other countries like Algeria, China, Pakistan, etc.[3], which is USTR's worst classification.[4]

Table 3. *Comparison Between the U.S. and Indian Patent Systems*

S. No.	Parameter	The U.S. System	Indian System
1	Patent Act	35 US Code • 4 part • 37 chapters • 376 sections [e.g., 35 USC 101]	Patent (Amendment Act) 2005 • 23 chapters • 163 sections [e.g., Section 3(d)]
2	Rule of Patent Right	"First to Invent"	"First to File"
3	Scope of Patent Act	Covers • Utility Patent • Plant Patent, & • Design Patent	Covers • Utility Patent (Other two are covered by separate Act)
4	Criteria for patentability	Any invention or discovery which is novel, non-obvious & possess industrial utility [35 USC 102, 103, 112]	Any invention which is novel, non-obvious & possess industrial utility [U/s2(1)(j)]
5	Specific restrictions on the patentability of patentability of polymorphs/ new forms in the governing law/ rules	No specific restrictions	Under section 3(d), to be patentable a new form of the known substance must show enhanced efficacy as compared to the existing substance
6	Non-patentable subject matter	Everything is patentable, if it meets the criteria in no. 4 above	Certain inventions are not patentable [U/s 3&4]
7	New use of existing drug	Patentable [35 USC 101]	Non-patentable [U/s 3(d)]

[3] Michael B.G. Froman, 2015 Special 301 Report. Washington D.C.: Executive Office of the United States Trade Representative, 2015, at p.3. Available at: https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf

[4] Amanpreet Kaur and Rekha Chaturvedi, Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma, Journal of Intellectual Property Rights 20:279-287, 2015, at p.281. Available at http://docs.manupatra.in/newsline/articles/Upload/3FB94432-F6A8-44FD-8D4B-2-EC49FABC703.pdf

8	Mere discovery	Allows a discovery of process, machine, manufacture or composition of matter to be patented if it satisfies the criteria of novelty, utility and non-obvious	Mere discovery of new and useful process or product is not patentable. [U/s 3(d)]
9	New plant varieties	Patentable [35 USC 161]	Protected by "Sui Generics" system
10	Transgenic animals	Patentable [Transgenic mice]	Not patentable [u/s 3(i)(j)]
11	Term of Patent	20 years from date of non-provisional filing [34 USC 154(3)]	20 years from filing of either provisional or complete specification [U/s 53, U/s 7(4)]
12	Provision for Patent Term Adjustment (PTA)	Yes. For each day delay by USPTO after 3 years [35 USC 154.b.2]	No such provision.
13	Provision for Patent Term Extension (PTE)	Yes. For each day delay by USPTO after 3 years; and, for delay during regulatory approval of new drugs by FDA [35 USC 155, 156]	No such provision.
14	Option to opt-out of the publication	Yes.	No.
15	Provision for compulsory licensing	No such provision	Available under certain grounds to work on patented invention in India [U/s 84]
16	Provision for compulsory license to export medicines to other countries	No such provision	Available to export medication in case of extreme emergency to any foreign country [U/s 92A]
17	Provision for parallel import	No such provision	Available [U/s107A(b)]
18	Bolar provision	Available [35 USC 271€(1)	Available [U/s 107A(a)]
19	Requirement for reporting of working of patents	No.	Yes (in Form-27)
20	Penalty on failure to comply	Not applicable.	Failure to furnish the information is punishable with fine up to 10-lakh rupees; knowingly furnishing false information is punishable with imprisonment up to six months, or with fine, or both.
21	Member of PPH?[5]	Yes.	No.
22	Member of PCT?[6]	Yes. Since January 24, 1978.	Yes. Since December 7, 1998.
23	IP/patent specialized courts	The Federal Circuit court is specialized to deal with appeals related with patent disputes.	No such specialized courts.

Despite the foregoing differences there are also some similarities between the patent systems of the U.S. and India. For example: (1) Both are contracting nations of PCT; (2) Like the U.S., duty of candor (Section 8 requirement) is an uncompromising requirement in India; and, (3) A patent is granted on a single incentive concept in both India and the U.S.

6. Patent Marking in the U.S. and India

Patent marking is the method of adding notices; e.g., "Patent Pending," "Pat. 1,234" etc. on patent owner's products to notify others that such products are either patented or a patent application has been filed on them. In the United States, failure to comply with patent marking requirement could be expensive,

[5]PPH stands for Patent Prosecution Highway, which is a cooperative program between USPTO and participating foreign patent offices to expedite the allowance of patent applications that previously received favorable rulings.

[6]PCT stands for the Patent Cooperation Treaty. It is an international patent law treaty, signed initially by 18 contracting states on June 19, 1970; i.e., on the last day of the Washington Diplomatic Conference on Patent Cooperation Treaty. The Treaty was subsequently amended in 1979, and modified in 1984 and 2001. Any contracting state to the Paris Convention for the Protection of Industrial Property can become a member of the PCT. As of March 16, 2017, there were 152 contracting states to the PCT (see for a complete list, https://www.wipo.int/pct/en/pct_contracting_states.html). Major advantages of PCT procedure (also called international procedure) are to allow new ventures more time to locate strategic partnerships, funding, and markets, before their technology becomes public.

because the patent owner, without proper patent marking, would be ineligible to recover damages for infringement under Section 35 USC 287. The patent marking can be physical or virtual marking The patent statute applies only to articles and not process or method claims. Likewise, Section 111 of India Patent Act 1970 also specified about the need for valid marking (i.e., one that include the number of the patent) as deemed notice to the public, but innocent infringers have a chance being excused from liability for damages. Thus, although both nations have statutes on patent marking and limited liability of damages, they differ in their approach. In U.S., section 25 USC 287 requires the patentee to mark the product, whereas in India section 111 of the Act does not. As a result, in American judicial system, when the patentee files an infringement suit, the patentee is required to prove that his products were properly marked before he could claim damages pertaining to that timeframe. However, section 111 of the Act in India, contemplates lack of marking as *defense* in an action of infringement. Thus, the initial burden of proof in India is on defendant to prove that he did not have knowledge. In other words, the defendants are required to prove that the patented products were not or improperly marked. At best, the patentee would be directed to establish another way of making aware of the existence of patent, such as a public notice or cease and desist letter. On the whole, section 111 of the Act is under-utilized in India, although a patent marking is in place.[7]

7. Conclusion

The foregoing analysis and comparison of patent laws in the United States and India suggest that the patent laws of both the countries are within the standards established by international patent regime; and, that they reflect the interests specific to their utilizations of intellectual property.

That is, India utilized its opportunities to adjust its patent law to suit its needs at various stages of development and benefited from those opportunities. Likewise, the United States has reached a level of technological predominance because of the utilization of its opportunities as an industrialized economy. Therefore, judging India by its experience under the TRIPS Agreement and beyond amounts to denying it from availing the opportunity that it is entitled to.

8. References

1. Dhar, Biswajit & Joseph, Reiji K. (2019). The Challenges, Opportunities and Performance of the Indian Pharmaceutical Industry Post-TRIPS. In: Liu, KC., Racherla, U.S. (eds) *Innovation, Economic Development, and Intellectual Property in India and China*. ARCIALA Series on Intellectual Assets and Law in Asia. Springer, Singapore. https://doi.org/10.1007/978-981-13-8102-7_13
2. Dobyns, Kenneth (1994). *The Patent Office Pony: A History of the Early Patent Office.* Fredericksburg, VA: Sergeant Kirkland's Press.
3. Fojo, Tito & Grady, Christine (2009). How much is life worth: cetuximab, non-small cell lung cancer, and the $440 billion question. *Journal of the National Cancer Institute* 101(15):1044-1048. doi: 10.1093/jnci/djp177
4. Froman, Michael B.G. (2015). *2015 Special 301 Report.* Washington D.C.: Executive Office of the United States Trade Representative. https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf
5. Gopalakrishnan, Tarun & Ramanujan, Adarsh (2011). *Patent marking in the U.S. and India—A comparison.* New Delhi, India: Lakshmikumaran & Sridharan Company. https://www.lakshmisri.com/Uploads/MediaTypes/Documents/L&SWeb_IPR_Article_Patent_Marking.pdf
6. Hoag, Foley (2024, August 27). Patent Term Adjustment and ODP: USPTO Defends Federal Circuit's Cellect Decision. *JDSUPRA. https://www.jdsupra.com/legalnews/patent-term-adjustment-and-odp-uspto-9373976/*
7. JUSTIA (2018). U.S. Code Title 35 – Patents. https://law.justia.com/codes/us/2018/title-35/
8. Kaur, Amanpreet & Chaturvedi, Rekha (2015). Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma, *Journal of Intellectual Property Rights* 20:279-287. http://docs.manupatra.in/newsline/articles/Upload/3FB94432-F6A8-44FD-8D4B-2EC49FABC703.pdf
9. Maxey, David W. (1998). Samuel Hopkins, The Holder of the First U.S. Patent. *Pennsylvania Magazine of History and Biography* 122:3-37. https://journals.psu.edu/pmhb/article/view/45216/44937
10. Moran, Mary, Guzman, Javier, Chapman, Nick, Abela-Oversteegen, Lisette, Whittall, Christine, Howard, Rachel, Farrel, Penny, Halliday, Dale, & Hirst, Catherine (2014). *Neglected Disease Research and Development: Emerging Trends*. Sydney, Australia: Policy Cures. https://www.policycures.

[7]Tarun Gopalakrishnan and Adarsh Ramanujan, Patent marking in the U.S. and India—A comparison, New Delhi, India: Lakshmikumaran & Sridharan Company, 2011. Available at: https://www.lakshmisri.com/Uploads/MediaTypes/Documents/L&SWeb_IPR_Article_Patent_Marking.pdf

org/wp-content/uploads/2022/11/Y7-GFINDER-full-report-web-.pdf

11. Parmar, Shyam (2023, June 19). TRIPS Agreement and Its Effect on Intellectual Property Laws in India: An Analysis. *Parker & Parker.* https://www.parkerip.com/blog/trips-agreement-and-its-effect-on-intellectual-property-laws-in-india/#:~:text=The%20TRIPS%20Agreement%20has%20significantly%20influenced%20intellectual%20property,copyright%20protection%2C%20trademark%20regulations%2C%20and%20access%20to%20medicines.
12. Singh, Manisha (2005, January 12). Major Amendments in the Indian Patents Law. *Mondaq.* https://www.mondaq.com/india/patent/30369/major-amendments-in-the-indian-patents-law
13. Thomas, John R. (2016, September 28). *The Hatch-Waxman Act: A Primer.* Washington, D.C.: Congressional Research Service. https://crsreports.congress.gov/product/pdf/R/R44643/3
14. U.S. Congress (1790). *Patent Act of 1790. https://fraser.stlouisfed.org/title/patent-act-1790-5734*
15. U.S.P.T.O. (2024). *Patent Milestones. https://www.uspto.gov/patents/milestones#:~:text=U.S.%20patent%20no.%201%20was%20granted%20to%20Senator,numbering%20system%20are%20now%20known%20as%20the%20X-patents.*
16. WIPO (n.d.). The PCT now has 157 Contracting States. Geneva: Switzerland. https://www.wipo.int/pct/en/pct_contracting_states.html
17. WIPO (2023). *An International Guide to Patent Case Management for Judges.* Geneva: Switzerland. https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1079-en-an-international-guide-to-patent-case-management-for-judges.pdf