Himachal Pradesh National Law University, Shimla (India)

Journal Articles HPNLU Journal of IPIR

Volume: I (2024)

IPR And Growing Pharmaceutical Sector: Revisiting The Development Of Patent Law In India

D Akshay Kumar & S. Divya

This article can be downloaded from:
https://hpnlu.ac.in/journal-level-2.aspx?ref-id=32

ISSN: XXXX-XXXX

Recommended Citation:

D Akshay Kumar & S. Divya, IPR And Growing Pharmaceutical Sector: Revisiting The Development Of Patent Law In India, I HPNLU IPIR. 133 (2024)

Contents

IPR AND GROWING PHARMACEUTICALS SECTOR: Revisiting the development of Patent laws in India

D Akshay Kumar[1] & Divya S.[2]

Abstract

Since the inception of World Trade Organization in 1995, the TRIPS agreement subsequently being put into effect, pharmaceuticals have been covered by broad and strict intellectual property rights (IPR) protection. Drug discovery and economical access to generic medications are so closely related that neither would be possible without the other. Since India's independence, health has been a major problem, and even now, with the emergence of the Trade-Related Aspects of Intellectual Property Rights, it continues to impede the growth of the economy. In India, the pharmaceutical industry is significant to society and has the potential to be harmful to the country's growing economy and development. The handling of intellectual property rights is one of the key features of the new international economic system (IPRS). The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has members who are particularly concerned about how it would affect their economy. The provisions of the Agreement that deal with the problem of access to novel pharmacological discoveries are of special relevance. TRIPS places a strong emphasis on an intellectual property rights framework, in which IP holders of the innovations can impose access restrictions for business needs. Due to rising costs of medicines and other healthcare innovations, low-income consumers in developing nations may be unable to afford life-saving drugs and technology. Of course, monopolistic positions can only be allowed to the extent that exploitative economic practices are permitted. Lack of requisite financial resources often acts as a hurdle in the path of access to various IP's which in turn affects the R&D activities. The critics mainly focused on what exactly patents are, how they have evolved globally, and how product patents have gradually extended throughout India. The article focuses upon the value of pharmaceutical patents to society and the economy as the main topic of discussion. India is a developing country; therefore, it must balance the needs of its citizens for simple access to healthcare patents, especially those that are sold at exorbitant prices. First, there is a tension between the right to health and the principle of granting patents,

[1] Research Scholar, The National University of Advanced Legal Studies, Kochi.
[2] Student, National University of Advanced Legal Studies, Kochi.

particularly in the pharmaceutical sector, which calls for critical consideration of these two fundamental challenges in the Indian pharmaceutical industry. In the current climate, we hardly see justice being done to the right to health, which is protected by Article 21 of the Indian Constitution as one of the most crucial and significant Fundamental Rights. Exorbitant prices make life-saving medications inaccessible to the public due to monopolistic approach in the market. India should modify its Patent Policy for Pharmaceutical products in the international market or stick with the practice that is supportive of more people having access to life-saving pharmaceuticals at much more reasonable and inexpensive costs. This is a far greater problem than protecting the rights and interests of the general public or those of the commercial sector.

Keywords

TRIPS Agreement, Pharmaceuticals industry, World Trade Organization, Novelty, Innovations.

INTRODUCTION

Intellectual property (IP) is an intangible asset created by the human mind or intellect, and it is crucial for preventing mimicking the existing intellectual work of others. In a way, IP inherently possesses a trust factor from any observer's point of view. The pharmaceutical industry faces high risks of embezzlement, and patents, in fact, protect its creators and their innovation rights. The Patent Act of 1970 marked a significant growth in IP rights after independence, with the introduction of a process patent policy and the introduction of the home-grown generic sector. However, interstate rivalry led to changes in the statutes. The World Trade Organization (WTO) and the Trade-Related Intellectual Property Rights (TRIPS) Agreement in 1995 required compliance from nation-states. India had to make two significant revisions to comply with the TRIPS agreement, including extending the patentable scope to include "essentially non-biological processes" and bacteria, and increasing the patent term from 10 to 20 years. These changes were implemented as of January 1st, 2000, but only the latter one was implemented as of 2005.

WHY PATENTS MATTER - REASONS

A patent is an intellectual property granted to an individual or group for a unique development that offers a better way to accomplish something or a new, specialized solution against any problem with intellectual inventions. It grants the holder exclusive rights to prevent others

from using the protected invention, allowing them to recover development expenses and generate interest in promoting it. Patents are crucial for R&D investment and financial growth. Organizations must implement a critical approach to maximize the chances of getting a patent while minimizing acquisition expenses.[3] Patents offer various benefits, including business progress and expansion for specific companies, mainly when multiple rivals or a dominant player are in the market.

TYPES OF INDIAN PHARMACEUTICAL PATENTS

India's pharmaceutical industry is crucial globally due to its strong generic basis, offering low-cost and high-quality medications. This positions pharmaceutical patenting in a strong position to address public health issues and provide affordable medical supplies. Pharmaceutical companies in India can protect their ideas from unauthorized commercial use by obtaining patent rights for their procedures or products as categorized by the Indian Patent Office.

i) Formulation And Composition Patents

Patent claims for a medication class or formulation technique used in multiple pharmaceutical products. Generic businesses can use the same active ingredient in different formulations, as active ingredients are not covered by patents based on formulation. Composition claims include active ingredients and excipients approved for use in pharmaceutical products.[4]

ii) Drug Compound Patents

Markush-type claims are patents that allow functionally equivalent chemical entities in therapeutic molecules, creating rights over a wide spectrum without prior experimentation or testing. These patents protect a company's product by preventing other pharmaceutical companies from synthesizing, manufacturing, or exploiting the drug until the patents expire.[5]

iii) Synergistic Combination

[3] Aishl Rathore, *An Insight into Indian Pharmaceutical Sector*, 356, SAGE PUBLICATIONS, 2018.
[4] Intellectual Property India, *Guidelines for Examination of Patent Applications in The Field of Pharmaceuticals* 9 2014.
[5] *Id.*

Patent drug synergy combines drugs to enhance their effects, with new treatment combinations secured for new active ingredients. However, some nations may reject combination patents without evidence of a new and non-obvious synergistic effect. [6]

iv) Technology Patents

These patents are based on actual processes. It is used to solve certain technological issues, i.e., issues with stability and solubility.[7]

v) Polymorph Patents

Polymorphs exist in amorphous solids and crystalline varieties with varying characteristics. They are discovered through regular testing for medication creation and are often produced to lower impurities or increase compound stability.[8]

vi) Biotechnology Patents

The science of biotechnology includes using living things and biological processes to create ingredients for medicinal goods. These patents have a variety of immunological, medicinal, and diagnostic devices.[9]

vii) Process Patents

These patents protect a unique and inventive process for producing a precise good. No such statements are made regarding the merchandise.[10]

IMPORTANT COMPONENTS OF THE PATENTS ACT, 1970

I. The invention is defined under Section 2(j)

II. Things that are not patentable are listed in Section 3, and they include

1. Unnecessary invention
2. Inventions that are against public health and morals
3. Simply discovered
4. Admixtures
5. Simple rearranging, etc.
6. Creation involving atomic energy

The law restricts product patents for chemical foods and medicines, requiring royalties and licensing. It imposes a fourteen-year time frame for chemical food and drugs,

[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*

considering business interests and avoiding import monopolies on occasion of any conflicts.

PATENTING OF PHARMACEUTICALS AND INDIAN PATENT LAWS

The Indian pharmaceutical industry has 60 therapeutic categories and 60,000 generic drugs, and a strong generic foundation developed under the former patent legislation. The industry has gained international recognition as a cost-effective manufacturer of high-standard and high-quality pharmaceutical items, making 1.5 billion dollars in export sales annually. However, there was no product patent system in place for drugs and medicines at that time, and only procedures used for food, remedies, medicines, or compounds produced through chemical processes were eligible for patenting in pharmaceuticals. Indian law does not currently grant therapeutic products patent protection. The New Patents Act of 1970 made agrochemicals and pharmaceuticals ineligible for patents, reducing India's reliance on imports and promoting the development of a domestic pharmaceutical industry. This led to the development of expertise in reverse engineering of drugs that are patentable as products in the industrialized world but unprotectable in India. The Indian patent law ruling in the Novartis case is an essential win for communities' access to cost-effective treatments in developing countries. It affects the capacity of people experiencing poverty to obtain medications. However, this strategy is also anti-competitive, as it would enable multinational companies to eliminate generic manufacturers' competition and demand excessive prices for their unique drugs. As a result, many essential treatments will no longer be accessible to the general population in developing countries, thereby negatively affecting public interest.

INDIA'S LAW OF PATENTS

India's patent rights were first made accessible in 1856, and the Indian Patent Act of 1970 was passed in 1970. The Act protects inventions that meet novelty, usefulness, and non-obviousness standards.[11] However, it does not cover horticultural or agricultural techniques, medicinal, surgical, preventative, therapeutic, diagnostic, or other therapies for humans or animals. Patents are only granted for the method of manufacture, not the substances themselves, in medicines, food items, prescriptions, treatments, and chemically produced products.[12] Though the Patent and Designs Act of 1911 established

[11] The Patents Act, 1970, S.3(d).
[12] *Id.*

a patent system in India, the 1970 Act made it impossible for medicines and agricultural chemicals to get patent protection. This expulsion was aimed at reducing India's reliance on foreign drug imports and developing an independent domestic pharmaceutical industry.[13] The Act also limited patent protection for molecules that are the end result of chemical processes, as well as basic admixtures. The pharmaceutical industry suffered greatly due to lacking product patent protection for medicines and agrochemicals.[14] This led to the development of reverse engineering of medications, which can be patented in the developed world but not in India. The Act also includes preventive measures to increase access to medications and prevent misuse of patent rights. A person in India who actively exploits the patent invention may seek the patentee to authorize the issuance of a license. The Patent Act of 1970 contributed to India's admission into the global patent system.[15]

THE PHARMACY SECTOR AND PATENT LAW

The pharmaceutical sector requires substantial expenditures and high expertise, making it crucial for companies to obtain patent rights to preserve their ideas. Patents promote innovation and protect investments in research and development. However, the patentability of pharmaceutical concepts has been debated due to legal concerns, particularly in India. The Indian Patent Office allows for additional materials or experimental research to support the invention's therapeutic effectiveness. Section 3(d) of the Patents Act of 1970 applies to pharmaceutical inventions, excluding using known methods, equipment, or devices without generating a new product or employing a new reactant. The Indian Patent Laws also prohibit the straightforward combination of two or more materials without inventive faculties, but the subject matter is considered patentable if the interplay between these factors results in unique or improved results[16]. In medicine,

[13] He, J. *Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?* INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA. ARCIALA SERIES ON INTELLECTUAL ASSETS AND LAW IN ASIA 2019 (*Accessed* on June 12, 2023).

[14] Chandra Nath Saha, *Intellectual Property Rights: An Overview and Implications In Pharmaceutical Industry* 2 J ADV PHARM TECHNOL RES 88 2011.

[15]MONDAQ *License of Rights In Patents* (April 10, 2018) *available at* https://www.mondaq.com/india/patent/690290/licens e-of-rights-in-patents (Last visited June 13, 2023).

[16] Soumya Shankar, *Importance Of Intellectual Property Laws*, 278, (EXCEL BOOKS, 2015).

composition claims typically refer to treatment techniques, but equipment or devices used in medicine, therapy, or diagnosis may qualify for patent protection.

ROLES OF PATENTS IN THE PHARMACEUTICAL INDUSTRIES

The pharmaceutical industry has experienced steady growth due to innovation and patent rights, resulting in a wealth reservoir for R&D and market share. Early adopters relied on patent protection, as developing new treatments requires significant financial and time commitment. The TRIPS-adopted global patent protection framework has benefited the pharmaceutical business, encouraging innovation and R&D spending. It paved the way for acquisitions and contract-based research with multinational corporations,[17] such as Ranbaxy's acquisition by Daiichi Sankyo and Sun Pharma's repurchase of Ranbaxy.

a. Patent grants ownership of medications, enabling innovation, scientific reputation, competitive edge, and control over production and quality from suppliers.
b. Manufacturers control market pricing, resulting in high return on investment and commercialization, enabling significant profit margins.
c. The patentee has a monopoly and exclusive rights with regard to the economically viable patented product, which strengthens their position and market share and makes them a significant player in the market.
d. The pharmaceutical businesses are able to sell or licence the patented medicine and generate cash either individually or jointly.
e. Patent protection helps advance medicine and improve quality in countries with high medicine costs. Thailand and India's non-patent pharmaceutical businesses aim to secure a preference for antiretroviral drugs from the Global Fund for AIDS, Tuberculosis, and Malaria by requesting a profit.

A robust patent protection statute and court precedent prevent potential patent infringements in pharmaceutical developments. This helps reduce litigation costs and allows pharmaceutical companies to modify their patent conflicts. However, pharmaceutical firms face obstacles such as the "ever-greening" approach, which involves making minimal modifications to their products to re-secure patent rights. This strategy

[17] Amit Aggarwal *Importance Of Establishing A Patent Regime In Pharmaceutical Industry* THE ECONOMIC TIMES (January 9, 2020) *available at* https://health.economictimes.indiatimes.com/news/pharma/importance-of-establishing-a-patent-regime-in-pharmaceutical-industry/73084962 (last visited on June 18, 2023).

can lead to a monopoly and spur patent lawsuits. Generic pharmaceutical businesses exploit patent gaps, negatively impacting revenue and the development of new treatments.[18] Additionally, patent protections can create an uncontrolled market for buying and selling patents between innovators and patients. Pre-grant resistance from third parties can also challenge the validity of inventions, constricting the pharmaceutical industry's expansion.[19] A sound patent system is crucial for economic development, but debates surrounding patent protection impact overall economic growth.

DRUG PATENTS, BUSINESS AGREEMENTS AND SECTION 3(D)

The General Agreement on Tariffs and Trade (GATT) did not include protecting intellectual property. However, the Uruguay Round of the World Trade Organization (WTO) and its agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) mandated that all nations, except the "Least Developed Countries," follow pharmaceutical patents. However, member nations failed to enable pharmaceutical patents in the beginning of 1995, leading to the TRIPS agreement. India, one of the most opposed nations during the Uruguay Round, was the most affected by the agreement.

India's legislation was modified in 1999, 2002, and 2005 to consider all of TRIPS' requirements and create specific adjustments. A system of Exclusive Selling Rights (EMRs) was developed during the transition period, and India delayed the patented status of medicinal products until 2005. The country was the only nation to suffer the entire transition amount, starting receiving applications in the mail in 1999.[20]

2005 India inserted Section 3(d), severely limiting secondary patents. Most secondary patents are not eligible for patenting, as they are often not considered innovations. The authors of Section 3(d)[21] took a moderate stance in favor of allowing secondary patents

[18] Manoj Poonia and Surbhi Bhardwaj, *Importance of Patents in Pharmaceutical Industry*, *available at*: http://www.pharmabiz.com/ArticleDetails.aspx?aid=92383&sid=21 (last visited on June 13, 2023).
[19] CALIFORNIA REVIEW MANAGEMENT *Patents and The Pharmaceutical Industry* (May 26, 2017) *available at*: https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/ (last visited on June 18, 2023).
[20] B Dhar and R K Joseph *'The Challenges, Opportunities And Performance Of The Indian Pharmaceutical Industry.*
Post-Trips INNOVATION, ECONOMIC DEVELOPMENT, AND INTELLECTUAL PROPERTY IN INDIA AND CHINA. ARCIALA SERIES ON INTELLECTUAL ASSETS AND LAW IN ASIA 2019 (*Accessed* on June 19, 2023).
[21] The Patents Act 1970, S. 3(d).

due to the current medication has undergone significant changes. Debates over lengthening the patent during the Uruguay Round discussions led to establishing of the TRIPS agreement. The committee advised against this as it might promote R&D activity to produce more novel compounds. Section 3 (d) effectively fortifies against the "evergreening" patent, allowing companies to maintain their market share even after their initial patents expire. A case examining the viability of section 3 (d) came to light when Novartis filed a petition opposing the patent claim's competition. The case involved Novartis, a pharmaceutical company, which filed a patent application for the blood cancer medication Glivec in India in 1998.

The Indian Patents Act of 1970 was amended to make Section 3(d) incompatible with Articles 1 (1) and 27 of the TRIPS Agreement. The Supreme Court of India rejected Novartis' claim of violating Section 3(d) due to its vagueness, arbitrariness, and violation of Article 14 of the Indian Constitution. The High Court of India disapproved of certain aspects of the country's revision while adhering to the TRIPS agreement. The court argued that Article 7 of the TRIPS Agreement provides enough room for a member country to comply with its obligations under the agreement. The court ruled that phase 3 requirements no longer violated Article 14 of the Indian Constitution.[22] The Indian Supreme Court analyzed the medicine Novartis sought a patent for, determining whether it was a "novel product" that differed from competition and made the invention "not evident to a persons versed in the art." The court ruled that the medicine was invalid because it did not adhere to section 3 (d) rules and did not pass the test for innovation and inventiveness.

THE MODIFICATIONS MADE BY THE AMENDMENT AND THEIR EFFECTS

The Indian Patents Amendment aimed to raise patentability threshold in accordance with TRIPS and impact the pharmaceutical industry and access to medicines in India.[23]

A. New Invention Defined

The Amendment to the Act introduces a controversial definition of a circular and redundant new invention. The Act already has a definition of invention that outlines

[22] The Constitution of India, Art 14.

[23] Section 3(k) excluded a computer programme per se from the scope of patentability, the pre-grant opposition has been widened and provisions for post-grant opposition have been introduced. *See* Shamnad Basheer, *India's Tryst With TRIPS: The Patents (Amendment) Act, 2005*, 1 IJLT 19 (2005).

the requirements for a valid patent using the word "new." The amendment's vagueness complicates interpretation and leaves a gap in the law. Additionally, the Act does not adhere to the same requirement of innovation, as its S.25 outlines the grounds for opposing patents. This discrepancy prevents rival patent applicants from effectively contesting a patent if the innovation is used or known outside India. The amendment was deemed to be passed in lieu of the January 1, 2005 deadline, despite the hastily published Ordinance.[24]

B. Inventive Step

The modified section aims to increase patentability by requiring an innovative step to be unobvious to ordinary experts in the field. It includes additional requirements for economic relevance and technical advancement. The goal is to advance technology to a higher level for issuance with monopoly privileges. However, the non-obviousness test has been criticized due to its complexity. The added terms of technical advancement and economic significance reiterate the prerequisites of non-obviousness and industrial application.[25] The modified phrases increase uncertainty, allowing patent officers to interpret terms without explicitly stated time periods, and raising the likelihood of needless litigation.

C. The Maligned Section 3(d)

Section 3(d) of the Indian Patent Act is a controversial section that aims to prevent stockpiling intellectual protection by granting twenty-year patents on multiple aspects of a single product, known as the ever-greening phenomenon. The amendment adds several non-patentable items, including using any known process, machine, or apparatus unless it produces a new product or uses at least one new reactant. However, the amendment raises ambiguous and obscure phrases, such as the meaning of the phrase "improvement of the known effectiveness" and the concept of efficacy. The Madras High Court's decision in the Novartis case used a narrow concept of efficacy, which excluded the bioavailability of various derived compounds from its purview.[26] This interpretation excluded other forms of increased efficiency in

[24] In order to meet the deadline stipulated in the TRIPS agreement, the Patents (Amendment Bill), 2003 was passed by a Presidential Ordinance [Patents (Amendment) Ordinance, 2004]. The Amendment was published in the Gazette of India on April 1, 2005 with retrospective effect from January 1, 2005.

[25] K M Gopakumar & Tahir Amin, *Patents (Amendment) Bill 2005: A Critique*, 40 EPW 1503-1505. (April 9, 2005).

[26] *See Consumer Education and Resource Centre* v. *Union of India* AIR 1955 SC 636, *State of Punjab and Others* v. *Mohinder Singh* AIR 1997 SC 1225.

producing and making the drug available to the general public, such as heat stability, humidity resistance, side effects, toxicity, and dosage.

The judiciary's interpretation of efficacy as medicinal efficacy is naive, as this clause applies to various substances outside medicines, such as food, agri-products, and other chemicals. The Indian government's public health policy initiatives depend on the availability of new patentable pharmaceutical formulations with improved efficacy, such as those with lower production costs or more bioavailable derivatives of the original patent-protected drug.

D. Bolar Provisions

The Bolar Exception, an international principle, allows research and development work without patent infringement. The 2005 Act recognizes this exception in Section 107A and includes importation, aiding the generic industry in opposing frivolous patents.

E. Parallel imports

Parallel imports allow importing patented drugs from legally permitted sources without violating patent rights. However, this clause is subject to exhausting patent holders' rights after the first sale. The 2005 amendment's compromise between intellectual property protection, public health concerns, and national security was unsuccessful, limiting pharmaceutical patentability and tipped the balance in favour of the public health lobby, damaging the product patent regime's effectiveness.[27]

THE NEED FOR PUBLIC HEALTH AND ACCESS TO ESSENTIAL MEDICATIONS

The new patent regime in India may limit access to life-saving medications, particularly for developing countries like India. This is due to expanding affordable medication access and providing incentives for new therapeutic items. Monopoly rights granted to corporations can lead to increased drug costs. [28] Opponents argue that this policy does not adversely affect the right of developing and least-developed countries to access essential medicines at affordable prices. They also argue that a product patent regime in India could lead to "ever-greening" strategies, prolonging patent benefits by filing new patents over processes, dosage forms, or administration methods, potentially delaying the release of patented medications into the public domain. The Indian Drug Manufacturer's Association (IDMA) opposed the proposed

[27] Prabhu Ram, *India's New "TRIPS- Complaint" Patent Regime: Between Drug Patents and the Right to Health*, 5 CM-KENT J. INTELL. PROP. 195, 204 (2005-2006).

[28] Jean Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, INNOVATION POLICY AND THE ECONOMY 3 2002 4.

amendment to the patent regime, fearing negative effects on the drug industry and consumers. However, the Indian pharmaceutical sector has thrived on reverse-engineering since 1970, with mandatory licencing being the world's most extensive system. A stronger patent policy was needed to encourage creative drug manufacturing operations, rather than using reverse engineering. The amendment has increased access to medicine by allowing foreign and Indian research to be shared, leading to increased investment in research and development, collaboration, and mergers. The average price increase for pharmaceuticals over the past decade has been around 7%, while the increase for drugs not subject to price regulation has been only 1%. This shift in Indian companies and implementing preventative measures like mandatory licensing and stem price control measures have led to increased access to various medications since 2005.[29]

SYSTEM FOR COMPULSORY LICENSING

The Indian patent act enforces the compulsory licensing system for patented inventions, which can only be approved three years after delivery. The system is consistent with the TRIPS Agreement, as the Doha Declaration states. The mandatory primary license was recognized as part of the Post TRIPS procedure in the *Bayer v. Naco* case, where Bayer Corporation's American subsidiary, Natco Pharma Ltd, produced an anti-cancer drug at a low price.[30] The Controller of Patents granted a non-exclusive CL to Natco Pharma Ltd, ensuring the medicine was made available to the general population at an affordable price. The Office also mandated Natco Pharma Ltd to pay Bayer AG 6% of the medication's online revenue.

WORLDWIDE DEVELOPMENTS

Before the World Trade Organization (WTO), GATT was responsible for overseeing trade affairs and aimed to encourage trade by limiting or abolishing protectionist practices. India and other developing nations, such as Brazil, Thailand, and Argentina, initially resisted joining TRIPS, but eventually agreed to be members in the late 1980s. The TRIPS agreement protects pharmaceutical products, with India being a major producer of generic medications. However, compliance could negatively impact India's pharma and public health sectors. Introducing

[29] Padmashree Gehl Sampath, *Economic Aspects Of Access To Medicines After 2005: Product Patent Protection And Emerging Firm Strategies In The Indian Pharmaceutical Industry*, UNITED NATIONS UNIVERSITY-INSTITUTE FOR NEW TECHNOLOGIES (UNU-INTECH) *available at* http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf (Last accessed on June 22, 2023).
[30] *Bayer* v. *Natco* 2012 7 SCC 729.

product patents increased drug costs, leaving only 30% of the population with affordable treatment. The Doha Declaration in 2002 introduced innovation criteria, increased patent terms, and increased scrutiny of patentability.

The WTO included a clause in the TRIPS agreement stating that developing nations, including India, have 5 years to modify their intellectual property laws to comply with TRIPS. Countries that do not grant product patents are given an additional 5 years but must offer EMRS if another WTO nation issued a patent after 1995.

India used the 10-year window to its advantage, and the third and final amendment, passed in 2005, introduced new features in food, drugs, and pharmaceuticals. The amendment raised the definition of "invention" and made pharmaceutical material patentable.[31] Section 92A demands compulsory licencing in generic medications to nations needing them due to scarcity of medicines or no manufacture of medicines to address public health. Pre-grant opposition occurs before the patent is granted, and post-grant opposition occurs after the patent is granted.[32]

CONCLUSION

India recognizes the importance of intellectual property (IP) protection and has taken steps to uphold its TRIPS responsibilities. The country's IP legal system is on pace with other wealthy countries, and it is preparing for adequate IPR protection and enforcement. India's economy is expanding rapidly, and it is aiming to be a pro-IP, knowledge-driven economy with a new National IPR Policy and a tagline, "Creative India" or "Innovative India" Rapid digitalization and the introduction of GST are expected to promote development further.

[31] The Patents Act, 1970, S. 84(1).
[32] The Patents Act, 1970, S. 92A(1).