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ON THE TOPIC

STRENGTHENING PATENT PROTECTION AND PATENTABILITY CRITERIA FOR PHARMACEUTICAL INNOVATION IN INDIA

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CERTIFICATE

This is to certify that Ms. SARIKA S (Reg. No. LM0223012) has prepared and submitted the dissertation titled " STRENGTHENING PATENT PROTECTION AND PATENTABILITY CRITERIA FOR PHARMACEUTICAL INNOVATION IN INDIA " in partial fulfilment of the requirement for the award of the Degree of Master of Laws in International Trade Law, to the National University of Advanced Legal Studies, Kochi, under my guidance and supervision. It is also affirmed that the dissertation he submitted is original, bona fide, and genuine.

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I, SARIKA, S (Reg. No. LM10555), pursuing Master in International Trade Law, do hereby declare that the Dissertation titled 'STRENGTHENING PATENT PROTECTION AND PATENTABILITY CRITERIA FOR PHARMACEUTICAL INNOVATION IN INDIA', submitted for the award of L.L.M Degree in the National University of Advanced Legal Studies, Kochi, during the academic year 2023-2024 is my original, bona fide and legitimate research work, carried out under the guidance and supervision of Dr. Ambily P. This work has not formed the basis for the award of any degree, diploma, or fellowship either in this university or other similar institutions of higher learning.

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SARIKA S

LIST OF ABBREVIATIONS

- R&D : Research and Development
- TRIPS : Trade-Related Aspects of Intellectual Property Rights
- WTO : World Trade Organization
- PCT : Patent Cooperation Treaty
- GATT : General Agreement on Tariffs and Trade
- IP : Intellectual Property
- USPTO : United States Patent and Trademark Office
- AIA : America Invents Act
- EPO : European Patent Office
- EPC : European Patent Convention
- USC : United States Code
- PHOSITA : Person Having Ordinary Skill in The Art
- JPO : Japan Patent Office
- MNC : Multinational Corporation
- PPPDNA : Public Private Partnership for Development of New Drugs and Diagnostics
- BRCA : Breast Cancer gene (specifically BRCA1 and BRCA2)
- STEM : Science, Technology, Engineering, and Mathematics
- SDG : Sustainable Development Goals
- IPR : Intellectual Property Rights
- US : United States
- WHO : World Health Organization
- IR : International Relations
- NMR : Nuclear Magnetic Resonance
- BPCIA : Biologics Price Competition and Innovation Act
- FTC : Federal Trade Commission
- UNDP : United Nations Development Programme
- AZT : Azidothymidine (also known as Zidovudine, an antiretroviral medication)

- JHIV : Journal of HIV (Hypothetical, as JHIV is not a standard abbreviation)
- IPAB : Intellectual Property Appellate Board
- OPPI : Organization of Pharmaceutical Producers of India
- CL : Compulsory Licensing
- DIPP : Department of Industrial Policy and Promotion (India)
- MSME : Micro, Small, and Medium Enterprises
- AIPL : Alliance for Intellectual Property Law
- IPO : Intellectual Property Office
- FER : First Examination Report
- NCE : New Chemical Entity
- NME : New Molecular Entity
- VCLT : Vienna Convention on the Law of Treaties
- WIPO ` : World Intellectual Property Organization

TABLE OF CASES

CASE	CITATION
Novartis AG v. Union of India	AIR 2013 SC 1311
Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979)	AIR 1982 SC 1444
Cipla Ltd. v. F Hoffmann-La Roche Ltd. (2015)	DLT 391; 2015 (61) PTC 1 (Del)
Diamond v. Chakrabarty (1980)	U.S. 303 (1980)
Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012)	U.S. 66 (2012)
Bilski v. Kappos (2010)	561 U.S. 593 (2010)

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CHAPTER – 1

INTRODUCTION

1.1 INTRODUCTION

In the pharmaceutical sector, patent protection is an essential component that fosters innovation and the creation of novel medications. This legal protection gives innovators the sole right to stop anyone from creating, utilising, or commercialising their innovation for a predetermined amount of time. Since the research and development (R&D) of new drugs requires a significant commitment of time, resources, and financial capital, the importance of patents in this industry cannot be understated. Patents encourage the continuous growth of medical science, which results in the invention of life-saving and life-enhancing pharmaceuticals by guaranteeing inventors a return on their investment. Additionally, pharmaceutical patents are essential for maintaining a balance between the interests of many parties, including as patients, healthcare providers, generic producers, and inventors. To establish a just and efficient patent system that fosters innovation while defending the interests of public health, national regulations and international agreements like the Trade-Related Aspects of Intellectual Property Rights (TRIPS) must carefully manage these obstacles[1].

Innovation is the driving force behind development, especially in fields like pharmaceuticals, which are vital to people's health and welfare. Because they give inventors the only right to their inventions, encourage investment in research and development (R&D), and promote technological growth, patents are essential to innovation. However, the standards for what constitutes a patentable innovation have come under fire, particularly in high-stakes sectors like the pharmaceutical industry. This examination is prompted by worries that loose patentability requirements could result in the issuance of patents for insignificant or incremental discoveries, thus inhibiting real innovation and encouraging anti-competitive behaviour.

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[1]Keith E. Maskus, "Patent Protection and Access to New Drugs in Developing Countries", Journal: World Trade Review, Volume: 1, Issue 2, Year: 2002, Pages: 131-151, DOI: 10.1017/S1474745602001068

The fundamental aspect of patentability rules is their function as innovators' gatekeepers. These rules, which usually include elements like novelty, non-obviousness, and industrial applicability, are meant to guarantee that patents are only given out for innovations that constitute substantial improvements over the state of the art. Stricter standards like these are essential for maintaining market competition, guaranteeing access to reasonably priced medications, and defending the rights of legitimate innovators.

The study makes the case that more stringent regulations on what qualifies as a patented invention with an emphasis on significant innovation can effectively safeguard true innovation while reducing anti-competitive behaviour. The main research question is whether the pharmaceutical business in particular, needs these strict regulations. Because of the industry's special traits—long development cycles, large R&D expenses, and major ramifications for public health—it is critical to provide strong patentability criteria in order to strike a balance between societal benefits and innovation incentives.

India, which is known around the world as a centre for pharmaceutical research and production, is essential to the availability and affordability of medications everywhere. Over time, the nation's patent laws have changed dramatically, especially in light of its obligations under international accords like the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Prior to these modifications, India only permitted pharmaceutical process patents, which greatly aided in its reputation as the "pharmacy of the developing world," providing impoverished nations with affordable generic medications[2].

However, India's patent environment experienced a paradigm shift in 2005 with the introduction of product patents in accordance with TRIPS. This modification attempted to maintain access to reasonably priced medications while also encouraging homegrown innovation. Notwithstanding these revisions, there are still issues with how patentability standards should be interpreted and applied, particularly with regard to what constitutes non-obviousness and inventiveness in the context of

[2]Ilse de Groot, Thomas Pogge, "The Pharmaceutical Industry and the Developing World: Access, Innovation and Global Health", Palgrave Macmillan,2015

pharmaceuticals. The legal landscape pertaining to pharmaceutical patents in India has been profoundly influenced by significant court rulings that have both clarified and occasionally questioned accepted conventions. Reaffirming the nation's position on patentability, the Supreme Court of India's 2013 ruling in Novartis AG v. Union of India[3] highlighted the need for inventions to show improved efficacy and therapeutic benefits in order to be eligible for patent protection. The decision demonstrated India's dedication to striking a balance between the incentives for innovation and the needs of public health, making sure that patents are only given for inventions that actually improve patient care and treatment options.

The pharmaceutical sector is changing quickly due to market forces and scientific discoveries, making strong patentability rules more and more necessary. The goal of this study is to further the conversation in India regarding patent law and policy by promoting a sensible strategy that fosters innovation and guarantees fair access to necessary medications. The objective of this research is to investigate the present state of pharmaceutical patents in India and identify opportunities for enhancement. The findings should contribute to evidence-based policymaking and the development of a sustainable innovation ecosystem in the healthcare sector.

1.2 RESEARCH PROBLEM

In the pharmaceutical industry, where patents play a critical role in protecting investments and encouraging the development of new drugs, a consistent approach in applying the criteria can prevent the proliferation of "evergreening" practices. The inconsistent application of existing criteria leads to numerous challenges on granted patents and consequently, raises the number of disputes on pharmaceutical patents. This causes a high volume of litigation and detrimentally affects the availability of medicines in the market. Inconsistent application of criteria results in creating barriers and hindrances in developing new medicines and treatment methods which in turn affects the research, development and trade of pharmaceutical products in the domestic sector.

[3]AIR 2013 SC 1311

1.3 RESEARCH QUESTIONS

1. What are the key challenges faced by the pharmaceutical industry regarding patent practices?
2. What are the significant issues related to "evergreening" and the accumulation of patent disputes?
3. What are the potential benefits of implementing stricter patentability guidelines in the pharmaceutical industry, particularly focusing on fostering innovation and preventing anti-competitive practices?
4. How far the existing laws promote innovation in pharmaceutical products and to what extent?

1.4 OBJECTIVES OF THE RESEARCH

1. To assess the strengths and weaknesses of the existing criteria for what constitutes a patentable invention in the pharmaceutical sector, focusing on their ability to protect genuine innovation.
2. Identify and analyse the practices of "evergreening" in the pharmaceutical industry and their impact on competition and access to medications.
3. Examine the causes and consequences of the accumulation of patent disputes in the pharmaceutical sector, with a focus on the burden on the judiciary and legal costs for companies.
4. Assess the potential effects of implementing stricter patentability guidelines on innovation dynamics, R&D investments, and patient access to medications in the pharmaceutical sector.
5. There are no substantial guidelines governing the approval of arbitrary drug patents.

1.5 LITERATURE REVIEW

1. **Jagashety R Bharatesh (2004)**[4]. His research study, “A Critical Study on the law pertaining to Drugs and Their Patenting, the problems involved in its

[4]Jagashety R Bharatesh (2004), Acritical study on law pertaining to Drugs and their Patenting, the problrms incolved in its application in India in the context of World Legal Regime, thesis banglore university 2004

Application in India in the Context of World Legal Regime "mainly covers the requirement for more flexibility in the TRIPS Agreement to meet the needs of specific country and its provision.

2. **Henry G Grabowski and John M Vernon**, in this paper, "Substitution laws and innovation in the pharmaceutical industry", mainly cover IP Protection in the development of new drug products. It also analyses the characteristics of R&D costs and returns in the pharmaceutical Industry[5].

3. **WTO** on 'TRIPS and pharmaceutical patents[6]**',** which mainly covers the philosophy and basic patent rights, The TRIPS agreement's introduction of product patents in India in 2005 led to a shift in focus by Indian pharmaceutical companies from process research to product research. This change, required by TRIPS, made it more difficult for Indian companies to develop generic versions of patented drugs, raising concerns about access to affordable medicines. India has utilised TRIPS flexibilities and judicial interventions to balance intellectual property protection with public health needs, impacting the strategic orientation and global competitiveness of the Indian pharmaceutical industry.

4. **Tain M Cockburn,** in a Research paper 'Intellectual Property Rights and Pharmaceuticals: challenges and opportunities for economic research[7]' describes the pharmaceutical industry as highly knowledge-intensive and sensitive to intellectual property rights. Research is needed to understand the complex dynamics between IPRs, regulations, and the global industry.

5. **Office of the Controller General of Patents, Designs and Trademarks** in a research paper 'Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals[8]' This covers the the guidelines for patent examination in

[5]Henry G Grabowski and John M Vernon, Substitution laws and innovation in the pharmaceutical industry, law and contemporary problems 43-66
[6]TRIPS and pharmaceutical patents, wto.org (last visited march 10th)
[7]Intellectual property rights and pharmaceuticals: challenges and
Opportunities for economic research iain m. Cockburn, the economics on intellectual property
[8]Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, https://www.ipindia.gov.in/(last visited march 10th)

India are supplemental to existing practices and procedures. They aim to achieve uniform standards of patent examination and grant. The guidelines include illustrations but are not exhaustive. Examiners are advised to examine applications on a case-by-case basis and follow the Patents Act and Rules if there is any conflict. The guidelines are dynamic and will be updated as needed.

1.6 HYPOTHESIS OF THE RESEARCH

The existing regulatory mechanisms in patent legislation governing pharmaceutical products impose legal and procedural barriers that delay and hinder the research and development of new medicines.

1.7 RESEARCH METHODOLOGY

The research methodology used in this study is mainly doctrinal. Both the primary and secondary sources were used in this thesis. The Primary source covers, In India, the legal framework governing pharmaceutical patents, including the Patents Act of 1970, which underwent significant amendments to align with international standards, particularly the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement—patentability Criteria on Innovation and Competition in the Pharmaceutical Sector. However, with the introduction of the new patent regime, India also transitioned to recognising product patents in compliance with TRIPS obligations. The amendments to the Patents Act aimed to balance the interests of inventors and the public, ensuring access to essential medications while protecting intellectual property rights. Specific provisions within the Patents Act address issues such as compulsory licensing, the term of patents, and safeguards against abuse of patent rights. Additionally, guidelines for the examination of patent applications in the field of pharmaceuticals provide detailed procedures for assessing novelty, inventive steps, industrial applicability, and other aspects crucial for pharmaceutical patenting in India. The secondary sources such as articles, books, data, case laws etc. All these are noted on the basis of the latest versions, which already have proper citations. The data collected, i.e., primary and secondary, have helped the researcher test the hypothesis and answer the research question raised in this research. The Blue Books unique

system of citation in writing has been used for ages by legal researchers, students, lawyers, scholars, judges, and other legal professionals. As the legal profession changes rapidly, the bluebook maintains a systematic and uniform standard of citations to inform communities of the importance of information and the sources and the legal authorities upon which they rely in their research work. The researchers have followed a bluebook: A uniform style of citation, Harvard law review association 20th edition standards in the citation for this thesis.

1.8 LIMITATION OF THE RESEARCH

The research focusing on patent protection in the pharmaceutical industry, where the regulatory frameworks can create ambiguities and inconsistencies in interpretation, which may delay the approval process; the dynamic nature of policy and regulatory changes in India's pharmaceutical sector hinder findings outdated or less applicable overtime, necessitating ongoing monitoring and updates. The focus on India regulatory environment may limit the generalizability of findings to other countries with different systems and regulations.

1.9 OVERVIEW OF CHAPTERS

The entire research work has been divided into 5 chapters,

Chapter 1 INTRODUCTION: The first chapter of the research includes an overview of the research, including the significance of the research, objectives of the research, hypothesis of research, method of research, and limitations of research. This Chapter also talks about the methodology and the citation style adopted by the researcher. It also gives the overall idea relating to subsequent chapters. The researcher has tried to give a basic understanding of pharmaceutical patents in this chapter. Moreover, to understand the problem in depth, the researcher reviewed literature in this regard from various sources. Important books, articles, and reports that the researcher has reviewed are mentioned in this chapter. While reviewing the literature, several questions were raised in the minds of the researcher to which answers were sought.

Based on this chapter, the researcher framed the research questions and began the journey ahead to seek answers.

Chapter 2 Evolution of Patent Law in the Pharmaceutical Sector**.** The second chapter covers the Historical development of patent laws relevant to pharmaceuticals, including TRIPS compliance and Indian legislative changes. Impact of international agreements on India's patent regime. Patentability Criteria in Pharmaceutical Industry. Analysis of current patentability criteria: novelty, inventive step (non-obviousness), industrial applicability, and enhanced efficacy. Comparative review of patentability standards across jurisdictions. Role of patents in fostering innovation in the pharmaceutical sector. Case studies illustrate the impact of patentability standards on R&D investments and innovation quality.

Chapter 3 Evaluation of current Patentability guidelines. Assessment of existing criteria and their effectiveness in the pharmaceutical industry. Identification of strengths, weaknesses, and areas for improvement. Impact of Stringent Guidelines on Pharmaceutical Innovation. Analysis of how more stringent patentability guidelines could influence innovation dynamics, R&D investments, and patient access to medicines. Exploration of the relationship between patentability standards and anti-competitive behaviours (e.g., evergreening, pay-for-delay). Case studies and legal analyses of relevant practices in the pharmaceutical sector.

Chapter 4 Impact of Patentability Criteria on Innovation and Competition in the Pharmaceutical Sector, Analysis of practices such as patent evergreening, pay-for-delay agreements, and market exclusivity strategies. Legal and policy responses to mitigate the impact of anti-competitive behaviours on market competition. Economic models and analyses on the impact of patentability criteria on drug pricing, market competition, and consumer welfare. Case studies of landmark legal disputes involving patentability and competition law in pharmaceuticals. Discussion of the regulatory challenges associated with implementing and enforcing patentability criteria in pharmaceuticals. Impact assessment of proposed policy interventions on innovation and competition. Development of actionable recommendations for policymakers, regulatory bodies, and industry stakeholders to refine patentability criteria. Strategies to promote genuine innovation while addressing concerns related to anti-competitive practices.

Chapter 5 Conclusion, Recapitulation of research objectives and hypotheses. Highlighting major contributions to knowledge and policy implications. Reflection on limitations encountered during the study. Recommendations for future research to address unresolved questions and emerging issues in pharmaceutical patent law.

CHAPTER - 2

EVOLUTION OF PATENT LAW IN THE PHARMACEUTICAL SECTOR

2.1 INTRODUCTION

India's patent law history has been influenced by its historical setting, which includes colonial control, independence, and following economic policies. During the British colonial administration, India's patent laws primarily supported the interests of foreign corporations, particularly those in the pharmaceutical industry. This trend continued after independence, pushing the Indian government to pass revolutionary legislation aimed at promoting domestic innovation and economic growth. These efforts culminated in the India Patents Act of 1970, a historic piece of legislation that altered the country's attitude to intellectual property.

The India Patents Act of 1970, passed after much debate and influenced by expert opinions, imposed significant restrictions on patent rights, particularly in medicines, by limiting patentability to procedures rather than products. This strategy sought to avoid monopolies, strengthen local manufacturing capabilities, and address public health issues. Pharmaceutical goods were expressly excluded from patent protection, whereas processes were granted patents for a limited time, with provisions for compulsory licensing after three years.

India's entrance to the World Trade Organization (WTO) in 1995 needed additional changes to align its patent laws with international norms, particularly the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement[9]. The Patents Act of 1999 provided a framework for product patenting in pharmaceuticals and a mailbox system for pending patent applications during a transition period. By 2005, India had completely implemented TRIPS, extending patent protection to

[9] V. K. Unni, Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health, 25 Pac.McGeorge Global Bus. & Dev. L.J. 323 (2012).
Available at: https://scholarlycommons.pacific.edu/globe/vol25/iss1/12

pharmaceutical items and introducing additional compulsory licensing rules to ensure public access to vital medications.

International treaties such as the Paris Convention and the Patent Cooperation Treaty (PCT) have played critical roles in creating India's patent system. These agreements encourage harmonisation, expedite international patent filings, and foster global trade and technical exchange while considering India's national interests and developmental priorities.

India's patentability criteria, impacted by significant court interpretations and legislative reforms, prioritise fundamental principles such as novelty, non-obviousness, utility, and improved efficacy in pharmaceutical inventions. These criteria ensure that pharmaceutical patents encourage genuine innovation while discouraging methods such as evergreening, which seeks to extend monopolies by modest alterations[10].

The evolution of India's patent laws demonstrates a careful balance between fostering innovation, safeguarding public health interests, and meeting international obligations. The country's patent regime is evolving in response to global standards and internal imperatives, defining its place in the dynamic global intellectual property landscape[11].

2.2 THE COMMITMENT OF INDIA TOWARDS INTERNATIONAL FRAMEWORK

2.2.1 The Paris Industrial Property Convention

The first multilateral agreement in the field of patents is the Paris Convention, which was concluded in 1883 and subsequently amended in 1900, 1911, 1925, 1934, 1956,

[10] An International Guide to Patent Case Management for Judges, https://www.wipo.int/patent-judicial-guide/en/full-guide/india
[11] INTELLECTUAL PROPERTY RIGHTS IN INDIA, Prepared by Smt. Rachna Sharma, Additional Director (23034591) and Smt. Seema Jain, Deputy Director of Lok Sabha Secretariat under the supervision of Smt. Kalpana Sharma, Joint Secretary and Smt. Anita Khanna, Director.

1967, and 1993. An unprecedented expansion of commerce across national boundaries occurred during the 19th century, which required close international cooperation in a variety of economic matters, including patents. A critical connection between the economic and political subsystems of nations was established by the patent system. During this period, the significance of patents in the context of inventive activities was increasingly recognised. At the same time, there was an increasing demand for robust patent protection from manufacturers and inventors, which was being met with opposition from proponents of free trade[12].

By 1873, situations had improved for those who advocated for patents. It was a significant milestone in the establishment of an international mechanism for intellectual property protection that the international exhibition in Austria that year represented. The Vienna Exhibition was a catalyst for the Paris Convention's conclusion in 1883, as manufacturers were hesitant to participate due to concerns about the misappropriation of their ideas. The international patent system was institutionalised by this convention, which also underscored the global imperative to safeguard intangible assets. Although it was initially signed by a limited number of countries, it established the fundamental principles of international patent protection, including the right of priority, national treatment, and common regulations.

Major advanced countries, as well as Brazil and Tunisia from the developing world, comprised the initial signatories. Many developing countries, which had either enacted or inherited patent laws, joined the Convention after World War II. In the 1990s, membership increased significantly, primarily due to the TRIPS Agreement, which integrated the substantive legal provisions of the Paris Convention without requiring membership. Most of the 164 countries that were parties to the Paris Convention by January 2002 were developing nations. Nevertheless, some contend that the Convention, which was conceived by and for established countries, poses a disadvantage to developing nations. Although these concerns are valid, the Convention permits a significant degree of flexibility in national laws with respect to compulsory licensing, patentability, and opposition procedures[13].

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[12] wipo.int/treaties/en/ip/paris/summary_paris.html (last viisted may 30th)
[13] abounaja.com/blogs/paris-convention-of-1883(last visited april 30th)

2.2.2 The Patent Cooperation Treaty (PCT)

The challenge of filing multiple applications in various countries within the timeframe prescribed by the Paris Convention and to reduce duplication of effort by national patent offices were the primary objectives of the Patent Cooperation Treaty (PCT), which was established in 1970 and amended in 1979 and 1984. The Patent Cooperation Treaty (PCT) simplifies pre-patent granting procedures and conditions, including filing, search, and examination. This enables a single application, international prior art search, and international publication. Additionally, it stipulates an optional international preliminary examination.

The PCT experienced a surge in membership during the 1990s, particularly among developing countries, as a result of the advantages it provides to patent offices and applicants. Nationals or residents of member states have the ability to submit international patent applications to their national patent offices and receive international prior art search reports, resulting in substantial cost savings. The burden on national offices in developing countries, which frequently lack the requisite resources, is alleviated by the availability of prior art searches, international publications, and examination facilities. The PCT also endeavours to facilitate economic development in developing countries by offering technical assistance and accessible technological information.

The Patent Cooperation Treaty (PCT)[14] is widely regarded as the most sophisticated mechanism for international cooperation in the field of patents since the Paris Convention. Although it does not issue patents, it simplifies the process of obtaining national patents in numerous countries by means of an international and national phase. The national phase consists of final patent granting procedures by national and regional offices, while the international phase involves centralised filing, searching, and optional preliminary examination. Separate national or regional applications in designated countries are equivalent to a single international application under the PCT.

[14] wipo.int/treaties/en/registration/pct/summary_pct.html (last visited may 15th)

2.2.3 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

In Marrakech, Morocco, on April 15, 1994, the TRIPS Agreement was signed and became effective on January 1, 1995, as a component of the WTO regime[15]. Intellectual property was not incorporated into multilateral trade agreements prior to TRIPS. During the Uruguay Round, developed countries, which were headed by the United States and Japan, endeavored to integrate intellectual property protection into the General Agreement on Tariffs and Trade (GATT). This endeavour was successful, the TRIPS Agreement being the consequence, despite the strong opposition from developing countries[16].

The TRIPS Agreement was designed to enhance the protection of intellectual property (IP) for business communities in industrialised countries, which were experiencing substantial economic losses as a result of counterfeiting and piracy. Additionally, it endeavoured to rectify the deficiencies of current intellectual property conventions, which were devoid of effective enforcement mechanisms. TRIPS implemented an efficient dispute resolution mechanism that permits trade retaliation against nations that violate its regulations. By establishing minimum standards, expanding patent protection, and guaranteeing effective enforcement of rights, the agreement seeks to harmonise the protection of intellectual property rights.

Although some contend that TRIPS imposes stringent requirements that favour rights holders and restrict the ability of states to customise their own patent regimes, others believe that it allows for national policies that prioritise public interest, promote foreign direct investment, and foster local innovation. TRIPS also addresses the misuse of patent rights and public interest concerns. TRIPS do not pursue or attain global harmonisation of domestic patent laws despite its promotion of uniformity in patent law[17].

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[15]wipo.int/wipolex/en/text/305907(last visited june 20th)
[16]Uruguay Round TRIPs: A Bibliographic Essay Authors William M. Walker
[17]Revisiting the TRIPS negotiations: Genesis and structure of this book image of Revisiting the TRIPS negotiations: Genesis and structure of this book Authors: Antony Taubman and Jayashree Watal Source: The Making of the TRIPS Agreement, pp 3-13, Publication Date: October 2015, https://doi.org/10.30875/6e3b37c3-en

2.3 PATENTABILITY CRITERIA IN THE PHARMACEUTICAL INDUSTRY

To qualify for a patent in India, an invention must meet specific criteria and fall within the category of patentable inventions. Novelty, non-obviousness, and utility comprise the three primary criteria for patentability. Several prerequisites must be satisfied for an invention to be patented, which also serve as the fundamental principles of Indian patent law.

Initially, an invention must be novel, which means that it cannot have been foreseen by a prior publication and must not be in the public domain. A 'new invention' is defined as an invention that has not been previously published, as per Section 2(l) of the Patents (Amendment) Act, 2005. This principle of novelty was emphasised in the cases of Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979)[18] and Gopal Glass Works Ltd. v. Assistant Controller of Patents (2005)[19], which emphasised that an invention must be both new and original.

Secondly, an invention must possess an inventive step, as defined in Section 2(1)(j) of the Indian Patents Act, 1970. This implies that the invention should not be readily apparent to an individual with expertise in the pertinent discipline. In the case of Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979)[20], the concept of an inventive step was further developed. The case outlined four tests for obviousness: identifying the inventive step in prior use or knowledge, distinguishing between the subject matter and the invention, observing these differences, and ensuring a degree of inventiveness.

The third requirement is that the invention must be practical and capable of industrial application, as outlined in the case of Cipla Ltd. v. F Hoffmann-La Roche Ltd. (2015)[21]. In order to qualify for a patent, an invention must have a commercial application, as mere utility is insufficient. Indian Vacuum Brake Co. Ltd. E.S. Luard (1925) also addressed this requirement of utility, stating that utility must be more than abstract usefulness.

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[18]main.sci.gov.in/jonew/judis/4915.pdf
[19]indiankanoon.org/doc/599281/
[20]wipo.int/wipolex/en/judgments/details/2012(last visited june 17th)
[21]Wipo.org(last visited june 17th)

Fourth, a criterion was introduced to ensure that new forms of known substances demonstrate a significant improvement in efficacy, particularly in the context of pharmaceutical inventions. This requirement is especially pertinent considering Section 3(d) of the Indian Patents Act, which is designed to prevent the practice of "evergreening" in the pharmaceutical industry. Evergreening is the process of making minor modifications to extend the patent life of existing medications. In the seminal case Novartis AG v. Union of India (2013), this provision was interpreted to emphasise that a novel form of a known substance must demonstrate a substantial improvement in therapeutic efficacy in order to qualify for a patent. This criterion guarantees that patents are issued solely for genuine advancements, thereby fostering innovation and preventing unjustified monopolies in the pharmaceutical sector.

In addition to these criteria, certain inventions are explicitly non-patentable under Sections 3 and 4 of the Indian Patents Act of 1970. These encompass inventions that are frivolous or fabricated, those that violate public morality or pose a threat to human, animal, or plant life, simple scientific principles, new substances or known devices arranged differently, methods of agriculture or horticulture, and processes related to medical, therapeutic, or surgical treatment. Additionally, inventions that are founded on traditional knowledge duplication, mathematical algorithms, artistic works, information presentations, and business methods are excluded[22].

2.4 COMPARATIVE REVIEW OF PATENTABILITY STANDARDS ACROSS JURISDICTIONS[23]

Although there are common foundational principles such as novelty, inventive step (or non-obviousness), and industrial applicability (or utility), patentability standards differ across jurisdictions. The standards of the United States, European Union, Japan, and India are the focus of this comparative review.

[22] unctad.org/system/files/official-document/ictsd-idrc2006d2_en.pdf
[23] uspto.gov/patents/basics/international-protection/patent-cooperation-treaty(last visited june 24th)

2.4.1 Inclusion of Novelty

Under 35 U.S.C. S102, the United States Patent and Trademark Office (USPTO)[24] necessitates unequivocal novelty. An invention is not considered novel if it has been disclosed in prior art, which includes any public knowledge, use, publication, or patent application prior to the filing date of the patent application. The United States has transitioned to a "first to file" system under the America Invents Act (AIA), which is more in accordance with international standards. Novelty is required by the European Patent Office (EPO)[25] in accordance with Article 54 of the European Patent Convention (EPC). An invention is deemed novel if it is not a component of the state of the art, which encompasses all information that was made available to the public by any means prior to the filing date. The EPO also considers prior art that was disclosed in other European patent applications that were filed prior to the patent in question but were published after the filing date[26]. The Japan Patent Office (JPO) adheres to comparable standards, necessitating absolute novelty in accordance with Article 29(1) of the Japanese Patent Act. Any prior public disclosure, regardless of its location or method of occurrence, may be considered prior art. An invention in India must not have been anticipated by a prior publication, as stipulated in Section 2(l) of the Patents (Amendment) Act, 2005. India adheres to a novelty requirement that is relatively stringent, like the absolute novelty standard. An invention is rendered unpatentable if it has been publicly disclosed anywhere in the world[27].

2.4.2 Inventive Step (Non-Obviousness)

In the United States, under 35 U.S.C. S103, an invention must not be obvious to a person having ordinary skill in the art (PHOSITA) at the time of the invention. The Graham v. John Deere Co. (1966) framework considers the scope and content of prior art, differences between the prior art and claims, and the level of ordinary skill in the pertinent art[28]. In the European Union, Article 56 of the EPC requires an inventive step, meaning the invention must not be obvious to a person skilled in the art. The EPO uses the “problem-solution approach” to assess the inventive step, focusing on

[24] uspto.gov/ip-policy/patent-policy/patent-cooperation-treaty(last visited june 24th)
[25] See supra n 34
[26] See supra n 35
[27] Chittaranjan Andrade and Nilesh Shah (2005) by N Shah · 2010 · Cited by 38
[28] 35 U.S.C. S 103

the technical problem the invention addresses and whether the solution was obvious based on prior art. In Japan, Article 29(2) of the Japanese Patent Act stipulates that an invention must have an inventive step, meaning it must not be easily conceived by a person skilled in the art. The JPO evaluates the inventive step using a similar approach to the EPO, considering the differences between the invention and prior art and the technical problem addressed. In India, Section 2(1)(j) and (ja) of the Indian Patents Act define an inventive step as a feature that makes the invention not obvious to a person skilled in the art. Indian courts, such as in Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries (1979)[29], have reiterated the need for an inventive step, considering the prior art and the technical advancement.

2.4.3 Industrial Applicability (Utility)

In the United States, under 35 U.S.C. S 101, an invention must be useful, meaning it must have a specific, substantial, and credible utility. This requirement is relatively straightforward and typically easy to satisfy[30]. In the European Union[31], Article 57 of the EPC requires an invention to be susceptible to industrial application, meaning it can be made or used in any kind of industry. This includes agriculture and is broadly interpreted. In Japan[32] the JPO mandates industrial applicability under Article 29(1) of the Japanese Patent Act. The invention must be capable of being used in industry, which is broadly defined and generally easy to meet. In India, Section 2(1)(j) of the Indian Patents Act requires that an invention must be capable of industrial application, meaning it must be useful and have practical applicability. The standard is similar to that of the EU and Japan.

2.4.4 Enhanced Efficacy

The United States, Japan, and the European Union In these jurisdictions, the concept of enhanced efficacy is not a distinct criterion; however, certain aspects of it may be regarded as inventive steps and novelty. For instance, in pharmaceutical patents, enhanced efficacy may serve as evidence of an inventive step. In India, Section 3(d)

[29] AIR 1982 SC 1444
[30] 35 U.S.C. S101
[31] Treaty on the Functioning of the European Union (TFEU): Article 57
[32] Japanese Patent Act: Article 29(1)

of the Indian Patents Act is specifically designed to address pharmaceutical patents, which are concerned with enhanced efficacy. It prevents the patenting of new forms of known substances unless they exhibit a substantial improvement in efficacy. The Novartis AG v. Union of India (2013) case, a landmark case, upheld this provision, establishing that in order to be patentable, novel forms of known drugs must demonstrate increased therapeutic efficacy. The objective of this rigorous requirement is to prevent "evergreening" and guarantee authentic advancements in drug development.

2.5 EVOLUTION OF INDIAN PATENT LAWS

India passed its first patent legislation in 1856, during British control, which lasted until the country's independence in 1947. Patent regulations were changed several times during the colonial period, but medicinal products were always patentable. The majority of patents granted during this period went to foreigners, resulting in a pharmaceutical sector dominated by multinational companies (MNCs) with little participation from domestic firms at the time of independence[33].

Following independence in 1947, the Indian government began developing new patent laws to encourage the growth of an indigenous pharmaceutical industry. This preparation took 25 years and culminated in the passing of the India Patents Act of 1970, which went into force in 1972 after extensive expert studies and parliamentary deliberations. Section 83 of the India Patents Act of 1970 placed significant restrictions on patent rights to encourage local development and commercial production in India. The new legislation prohibits the patenting of pharmaceuticals. Instead, firms were allowed to patent only one method of making a treatment, preventing monopolisation of all drug production processes. Furthermore, the duration of pharmaceutical process patents was reduced to five years from patent issue or seven years from application filing date, whichever was shorter, as contrast to the 14-year term for other patents. Furthermore, the Act incorporates broad "compulsory licensing" provisions for pharmaceutical process patents, designating patents as "licenses of right" within three years of award and allowing anybody to use

[33] A “Calibrated Approach”:Pharmaceutical FDI and theEvolution of IndianPatent LawWeb version:August 2007Authors:KatherineConnor Lintonand NicholasCorrad

the patented technology in exchange for a royalty. Thus, while pharmaceutical products were not protected, pharmaceutical processes were for a maximum of five years, with mandatory licensing beginning three years later.

In January 1995, India became a founding member of the World Trade Organization (WTO), subscribing to the terms of the WTO's intellectual property accord, Trade-Related Aspects of Intellectual Property Rights. As a poor country that did not initially allow for pharmaceutical product patenting when TRIPS went into effect, India was granted a 10-year transition time until January 2005 to create pharmaceutical patent protections (TRIPS Art. 65.4). During the transition phase, India was required to provide a "mailbox" facility for filing applications and allocating filing dates. TRIPS also required that "exclusive marketing rights"—the sole right to commercialise an invention for a set term—be awarded for specific postal applications filed during the transition period (TRIPS Art. 70.8(a) and 70.9). Following the United States' WTO case, which was resolved against India, India complied with these provisions by the Patents Act of 1999.

In 2002, India modified its patent legislation to include the TRIPS-mandated 20-year patent length for all inventions, which would apply to pharmaceutical patents after the end of the transition period. These amendments included new compulsory license provisions, allowing a compulsory license application three years after a patent is granted if the "reasonable requirements of the public" regarding the invention are not met, if the invention is not available at an affordable price, or if the invention is not being manufactured in India (India Patents Act 2005, S84). The law also allows for immediate compulsory licensing in cases of government notification of a public health crisis, public non-commercial use, or export to countries with insufficient manufacturing capacity to address public health issues (India Patents Act 2005, Section 92-A). Indian law has some of the largest compulsory licensing provisions in the world, which has raised worries among international pharmaceutical corporations, even though no forced licenses have been requested or awarded under the new law to date[34].

[34] patent laws and their service for ip rights jul 13, 2022 intellectual property rights saumya kumar singh and prashant shivam

The completion of the transition period in January 2005 marked a major step in India's execution of its TRIPS commitments, as did the necessary revision to its law to give patent protection for pharmaceutical items. According to Indian industry and government representatives, the country is now pursuing a "calibrated approach" to intellectual property protection, balancing concerns about public health, access to medicine, and domestic industry. Despite its focus on internal challenges, India has built an intellectual property law that matches international norms.

2.6 TRIPS COMPLIANCE AND INDIAN LEGISLATIVE CHANGES

The TRIPS Agreement mandates that member nations grant patents for any inventions, regardless of whether they are commodities or processes, in all technological fields, if they satisfy the standard criteria of industrial usefulness, creativity, and novelty. It also stipulates that patents and rights should be accessible regardless of the location of the invention and whether the items are imported or produced locally (Article 27.1).

The basic criterion of patentability allows for three allowed exceptions. First, inventions that violate public order or morals, such as those that endanger human, animal, or plant life or harm the environment, can be excluded. This exclusion only applies if commercial exploitation of the innovation is likewise prohibited and required to maintain public order or morals (Article 27.2). Second, members may exclude diagnostic, therapeutic, and surgical procedures for treating humans and animals from patentability (Article 27.3(a)). Third, plants and animals other than microorganisms, as well as the biological processes that produce them, might be omitted. Countries that exclude plant varieties must, however, offer an appropriate sui generis system of protection, which will be reviewed four years after the agreement enters into force (Article 27.3 (b))[35].

Product patents must grant exclusive rights to create, use, offer for sale, sell, and import the product. Process patent protection must include items obtained directly from the process. Patent owners have the right to assign or transfer their patents, as

[35] impact of trips over indian patent regime vis avis indian pharmaceutical industry, 2013 gjls vol.1, no.1

well as enter into licensing agreements (Article 28). Members may accept limited exceptions to these exclusive rights if they do not interfere with the patent's usual utilisation and do not unfairly harm the patent owner's legitimate interests, taking into account third-party interests (Article 30). The period of protection must not expire before 20 years from the filing date (Article 33).
Patent applicants must describe their invention clearly and completely enough for a skilled person to carry it out, and they may be asked to indicate the inventor's best manner of conducting the invention (Article 29.1). If a patent covers a process for obtaining a product, judicial authorities may require the defendant to demonstrate that their process is distinct from the patented one, if specific factors indicate that the protected process was most likely used (Article34).

Compulsory licensing and government use without the right holder's authorisation are permitted but subject to limitations that preserve the right holder's legitimate interests. These conditions, outlined in Article 31, generally entail an attempt to secure a voluntary license on reasonable terms within a reasonable time, adequate remuneration for the license, and the possibility of judicial or independent review of judgments by a higher authority. These conditions are reduced if compulsory licenses address practices that have been legally determined to be anti-competitive. These requirements must be interpreted in connection with Article 27.1, which requires non-discriminatory enjoyment of patent rights in the sphere of technology regardless of whether the items are imported or manufactured domestically.

2.7 ROLE OF PATENTS IN FOSTERING INNOVATION IN THE PHARMACEUTICAL SECTOR

The global pharmaceutical industry is renowned for its high research intensity, with innovative firms typically designating approximately 15% of their sales turnover to research and development (R&D). Conversely, the Indian pharmaceutical industry maintained an R&D intensity of less than 2% as a percentage of sales turnover until the early 2000s. In 1973, the Hathi Committee report from 1975 observed that the intensity of research and development was a mere 1.1%. This low R&D intensity can be attributed to the fact that Indian companies prioritise the development of

non-infringing processes and the manufacturing of generics rather than investing in the development of novel drugs, which necessitates substantial financial commitments. The Patents Act of 1970, which permitted process patents, permitted Indian companies to manufacture and distribute patented pharmaceuticals through alternative processes without violating patent rights. Nevertheless, beginning in 2000-01, the intensity of R&D began to increase as a result of changes in government policy toward the private sector and the introduction of new incentive mechanisms, such as product patent rights[36].

Promoting the discovery of novel drugs in pharmaceutical patents necessitates the establishment of an environment that safeguards intellectual property rights and encourages research and development (R&D) investment. This method promotes innovation by enabling pharmaceutical companies to recoup their investments through exclusivity rights. Pharmaceutical patents are essential in this process, as they provide companies with transient monopolies over their inventions, which encourages them to invest in expensive research and development endeavours. In addition, patent protection motivates organisations to disclose their innovations to the public, thereby augmenting the general corpus of scientific knowledge. This disclosure enables other researchers to expand upon their existing discoveries, thereby facilitating the advancement of drug development. Additionally, the patent system ensures that the interests of innovators and the public are balanced by incorporating provisions for compulsory licensing in situations where access to essential pharmaceuticals is at risk. This guarantees the availability of novel drugs while also compensating innovators for their contributions.

To advance technology, it is necessary to cultivate an environment that is conducive to innovation and development in all sectors. Substantial investments in research and development (R&D) are among the most effective strategies, which comprise technology development and basic and applied research. Strong intellectual property rights (IPR) protection fosters innovation by safeguarding inventions and offering incentives for investment in research and development. The collaborative resolution of intricate challenges is achieved through Public-Private Partnerships (PPPs), which

[36] sagaciousresearch.com/contact-us/(last visited june20th)

leverage a combination of resources and expertise. A skilled workforce is essential for the implementation of new technologies, and education and skill development in STEM disciplines prepare one for this purpose. Innovation is facilitated by regulatory frameworks that are both clear and supportive while adhering to ethical and safety standards. Establishing innovation clusters and ecosystems promotes collaboration among researchers, entrepreneurs, and policymakers, thereby expediting the development and commercialisation of technology. The promotion of innovations that address global challenges such as climate change and healthcare is facilitated by aligning advancements with the Sustainable Development Goals (SDGs). Finally, innovation is stimulated by international collaboration, which effectively addresses shared global challenges by combining a variety of resources and expertise. Collectively, these strategies propel economic expansion, enhance quality of life, and advance global sustainable development objectives.

It is essential to attract investment and talent to promote technological advancements and innovation. To encourage investment in research and development (R&D) infrastructure, governments and organisations can provide attractive incentives, including tax exemptions, grants, and subsidies. The establishment of innovation centres or clusters, which facilitate collaboration among established companies, researchers, and start-ups, is also crucial for the attraction of talent. Additionally, building a favourable regulatory environment and offering access to trained labour through education and training programs increases desirability. Nations frequently engage in global competition by emphasising their dedication to innovation and providing stable legal frameworks that safeguard intellectual property rights (IPR). These rights are indispensable for investors who are interested in generating long-term returns on their innovations.

The process of technology transfer and collaboration between public and private entities is simplified by the establishment of mechanisms that facilitate licensing and collaboration. This can be accomplished through technology licensing offices in academic institutions and research organisations, which handle intellectual property and negotiate license agreements. The process is streamlined by the standardisation of agreements and the reduction of bureaucratic obstacles, which promotes the efficient dissemination and commercialisation of knowledge. Local and international

collaboration platforms facilitate the exchange of resources, expertise, and risks, thereby expediting innovation cycles. Joint ventures and public-private partnerships (PPPs) are examples of collaborative models that employ complementary capabilities to develop and commercialise technologies more effectively.

Market competition is essential for maintaining a balance between consumer benefits and innovation incentives. Regulatory bodies are essential in the enforcement of fair competition practices and the prevention of monopolistic behaviours that could stifle innovation. Antitrust laws and competition policies are intended to cultivate innovation by establishing a level playing field in which multiple participants can flourish, thereby promoting healthy competition. At the same time, the safeguarding of intellectual property rights guarantees that innovators are motivated to allocate resources to research and development without worrying about imminent emulation. Ensuring that competition benefits consumers by promoting affordability and access to innovative products and services while also encouraging innovation throughIPRprotection.

Addressing the tension between assuring broad access to essential technologies and medicines and incentivising innovation through IPR protection is essential for balancing public access and innovation. Guarantee that critical innovations, particularly in healthcare and essential technologies, are accessible to the public at reasonable prices; governments frequently implement mechanisms such as compulsory licensing and patent pools. Encouragement of open innovation models, which involve the open exchange of knowledge and collaboration between researchers and companies, can also broaden the availability of innovations. Furthermore, regulatory pathways such as the expedited approval of essential medicines during public health emergencies are designed to strike a balance between the need to promptly address societal requirements and the promotion of innovation. Sustainable development and societal well-being are ultimately facilitated by policies that prioritise transparency, affordability, and equitable access to innovations.

Case laws that demonstrate the influence of patentability standards on the quality of innovation and R&D investments:

Diamond v. Chakrabarty (1980), In 1980, the US Supreme Court upheld the Court of Customs and Patent Appeals' decision to grant a patent for Pseudomonas putida, a genetically modified bacterium capable of degrading crude oil. Ananda Mohan Chakrabarty developed this bacterium to address oil pollution issues. Chakrabarty's patent application included claims about the bacterium's production method, inoculum, and bacterium itself. The patent examiner denied the bacterium claims, arguing that microorganisms are natural products and not patentable under Section 101. The Supreme Court classified Chakrabarty's bacterium as a "manufacture" or "composition of matter" under Section 101, setting a precedent for the patentability of genetically modified organisms. [37].

Mayo Collaborative Services v. Prometheus Laboratories, Inc. was a US Supreme Court case that ruled that patents involving natural laws and phenomena are only patentable if they incorporate inventive concepts that surpass standard practices. The case focused on Prometheus Laboratories' patents for optimising drug efficacy by correlating metabolite levels with therapeutic outcomes. The Supreme Court emphasised that adding common steps to natural laws does not make them patentable, maintaining the exclusivity of basic scientific principles and encouraging new ideas. The USPTO issued revised guidelines on subject matter eligibility in response to the case, introducing a structured three-step inquiry to determine whether patent applications involve natural laws, phenomena, or abstract ideas. [38].

Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)**,** The U.S. Supreme Court ruled in the Association for Molecular Pathology v. Myriad Genetics case that isolated naturally occurring genes are not eligible for patent protection, but synthetically created composite DNA (cDNA) is. The case involved Myriad Genetics, Inc., which isolated two human genes linked to increased breast and ovarian cancer risks. The Association for Molecular Pathology argued that these patents were invalid under 35 U.S.C. S101, stating they did not contain a patentable invention. The Supreme Court maintained the patent ineligibility of isolated DNA, recognising it as a

[37] Diamond v. Chakrabarty, 447 U.S. 303 (1980) Prepared by UNCTAD's Intellectual Property Unit http://supreme.justia.com/cases/federal/us/447/303/case.html

[38] The case is Mayo Collaborative Services, et al. v. Prometheus Laboratories, Inc. (Supreme Court of the United States, 566 U.S., 2012). Prepared by the Intellectual Property Unit of UNCTAD http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf

naturally occurring product. However, cDNA synthesis was determined to be patent-eligible due to its synthetic nature. The decision established the current U.S. approach to patent eligibility for natural substances and phenomena, emphasising the need for inventions involving natural elements to exhibit significant synthetic manipulation or inventive applications.[39].

In Bilski v. Kappos, the U.S. Supreme Court upheld the Federal Circuit's rejection of a patent application for an energy market hedging strategy in 2010. The application, submitted by Bernard L. Bilski and Rand Warsaw, required consumers to pay a fixed price based on their historical energy consumption. The patent examiner declined all claims, stating the invention was abstract and addressed only mathematical problems. The Board of Patent Appeals and Interferences affirmed the rejection, stating the application focused on mental processes without transforming physical matter. The Supreme Court revised the Federal Circuit's decision in 2010 regarding process patentability and the exemption of business methods from patent eligibility. The court ruled that the machine-or-transformation test was insufficient for determining process patent eligibility, particularly in the Information Age, and that the doctrine of noscitur a sociis was not suitable for defining "process" under S100(b), which encompasses methods as part of the definition of process[40].

Alice Corp. v. CLS Bank International [41]was a 2014 US Supreme Court ruling that a computer-implemented scheme for mitigating settlement risk was patentable. The case centred on whether the claims were directed to patent-eligible subject matter under 35 U.S.C. S. Alice Corp. owned patents for a computerised trading platform, while CLS Bank International contested the patents, arguing they merely implemented an abstract concept using generic computer technology without innovative features. The Supreme Court unanimously upheld the Federal Circuit's judgment, determining that the claims related to an abstract concept and routine computer functions. The ruling emphasised the importance of preventing patents from

[39] Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al., 569 U.S.12-398 (13 June 2013)
Prepared by UNCTAD's Intellectual Property Unit
http://supreme.justia.com/cases/federal/us/569/12-398/
[40] 561 U.S. 593 (2010)
[41] 573 U.S. 208 (2014)

pre-empting fundamental concepts and ideas, particularly in software and business methods.

2.8 CONCLUSION

The development of Indian patent laws has been influenced by historical, economic, and international factors. The 1970 Patents Act promoted local industry, while the TRIPS Agreement in 1995 required reforms to ensure global standards and public health protection. The 2005 Patents Act expanded patent protection to pharmaceutical products and introduced rigorous criteria to prevent exploitation and ensure affordable medicines. Despite criticism, India's patent regime maintains a balance between domestic priorities and international obligations. Patentability standards in the United States, European Union, Japan, and India share fundamental principles, including novelty and inventive steps.

Section 3(d) of the Patents Act[42] is the only legal framework in India that specifically addresses the concept of enhanced efficacy, which is particularly relevant in pharmaceutical patenting. The Patents Act specifically designed this provision to address "evergreening[43]," ensuring that patent protection only extends to new forms of known substances that demonstrate a substantial improvement in efficacy. The objective of such a stringent requirement is to strike a balance between public health considerations and innovation incentives.

Patents are crucial in high-cost sectors like pharmaceuticals, as they encourage innovation and recoup R&D costs. Patent law's adaptability, as demonstrated by landmark cases, balances innovation and monopolistic practices. Harmonising patent laws across jurisdictions could enhance global innovation and technological advancement, particularly in information technology and biotechnology. This fosters R&D investment, intellectual property rights, and equitable competition.

[42] unctad.org/system/files/official-document/ictsd-idrc2006d2_en.pdf
[43] wipo.int/patent-judicial-guide/en/full-guide/india(last visted june 24th)

CHAPTER 3

IMPACT OF STRINGENT GUIDELINES ON PHARMACEUTICAL INNOVATION.

3.1 INTRODUCTION

Patentability guidelines are essential in the pharmaceutical industry, as they are the foundation for promoting innovation by allocating exclusive rights based on criteria such as novelty, non-obviousness, and industrial applicability. These guidelines ensure the recognition of innovative medicines and therapies for their scientific advancements, which in turn encourages investment in research and development (R&D) and facilitates ongoing improvements in medical treatments. Nevertheless, a thorough evaluation is required to evaluate the efficacy of these criteria in addressing public health priorities and navigating industry-specific challenges.

In essence, patent law's novelty requirements prevent the granting of protection to inventions already disclosed in the prior art, thereby preserving the integrity of patent systems and preventing trivial advancements. In contrast, non-obviousness criteria require that inventions be less apparent to skilled practitioners, which is especially difficult in complex disciplines such as biotechnology, where interpretation can be subjective. In the meantime, industrial applicability ensures that inventions have practical utility, which is widely defined in the pharmaceutical industry to include therapeutic and diagnostic applications. This encourages investments in critical medical advancements[44].

Despite the benefits, evergreening, a practice in which minor modifications to existing medicines extend patent protection, is a significant obstacle for the pharmaceutical sector. This practice delays the market entry of more affordable generic alternatives. Furthermore, the intricacy of patent litigation creates obstacles for smaller innovators and generic manufacturers who wish to challenge patents, thereby affecting market dynamics and healthcare accessibility. Continuous assessment and potential reforms

[44] GUIDELINES ON PATENTABILITY ANDACCESS TO MEDICINES,,Germán Velásquez(2014)

specifically designed to accommodate the distinctive dynamics of pharmaceutical innovation are necessary to address these intricacies. Key strategies for streamlining regulatory frameworks and ensuring equitable global access to essential pharmaceuticals include promoting international harmonisation of patent laws, expediting reviews for generics and biosimilars, and increasing transparency in patent filings. It is essential to collaborate among a variety of stakeholders, including pharmaceutical entities, regulatory bodies, healthcare providers, and advocacy organisations, to develop policies that effectively address public health imperatives and promote innovation.

This introduction takes a close look at the current rules for patentability in the pharmaceutical industry. It focuses on the good points, the bad points, and possible ways to make things better in the future so that everyone can get new medicines and new ideas for healthcare around the world.

3.2 EVALUATION OF CURRENT PATENTABILITY GUIDELINES.

The Guidelines for the Examination of Pharmaceutical Patents, developed by the World Health Organization (WHO), serve as a reference for drafting internal procedure manuals for national intellectual property offices to assess the patentability of chemical-pharmaceutical inventions. It is a common practice for patent offices worldwide to guide their examiners through patentability guidelines, which detail the application of patent law in specific circumstances. These guidelines set the level of patentability requirements that examiners use to evaluate patents, ensuring consistent and thorough assessments[45].

The introduction of the WHO guidelines highlights the significant role of the pharmaceutical sector within the patent system. Thousands of applications submit to protect variations of existing products, manufacturing processes, or, when allowed second indications for known pharmaceutical products, despite the annual approval of only a small and decreasing number of new chemical entities. Patents grant exclusive rights for the production, sale, and use of the patented material, thereby limiting competition and maintaining higher prices compared to a competitive market with generic medicines. Given the profound impact that patents can have on competition,

[45] . ipindia.gov.in/(last visited june 24th)

prices, and access to medicines, the criteria for examining and granting pharmaceutical patents are critically important for public health policies. The guidelines aim to provide a series of general principles for the examination of common types of pharmaceutical patents. They address growing concerns about the proliferation of patents that protect minor variants and, in some cases, obvious modifications of existing medicines and processes. This includes changes to drug formulations, salts, esters, ethers, isomers, polymorphs of existing molecules, and combinations with other active substances.

These guidelines aim to grant patents in the pharmaceutical sector only for genuine innovations, thereby promoting medical science advancement and public accessibility to essential medicines. Strict scrutiny of patents can reveal that many, despite not being invalid, serve to prevent generic competition, thereby reducing access to medicines. These guidelines acknowledge the importance of subsequent pharmaceutical innovations in certain cases but aim to enhance the capacity of patent offices, regulatory authorities, public health agencies, and civil society to evaluate and implement necessary measures. In cases where patent requests and claims do not merit the monopolistic reward that a patent grants, we act in accordance with national legislation to protect public health.

The guidelines aim to support national patent offices by providing a rational analysis of pharmaceutical patents based on the proper implementation of patentability requirements. They do not propose a new condition for patentability but rather emphasise the consideration of specific factors related to innovation in pharmaceutical products when applying the common requirements of novelty, inventiveness, and industrial applicability (utility)[46].

Patentability criteria in the pharmaceutical business are critical in ensuring that ideas eligible for patent protection meet high standards of novelty, non-obviousness, and industrial applicability. These criteria provide important incentives for innovation by awarding inventors exclusive rights, allowing them to recoup their R&D costs, and encouraging continual breakthroughs in medical therapies. However, rigorous

[46] Wipo.org (last visited June 23rd)

examination is required to determine the effectiveness of these criteria in attaining their intended aims and addressing sector-specific problems.

Industrial applicability requires that an invention be practicable for use in industry, which is broadly defined in pharmaceuticals as therapeutic or diagnostic applications. This criterion promotes investment in novel medications and medical technologies. Patents granted for inventions with speculative or minimal industrial relevance raise concerns about the proliferation of patents that may not convert into major clinical advantages.

Despite their relevance, existing patentability standards face hurdles in the pharmaceutical sector, including potential abuses such as evergreening, in which modest adjustments extend patent protection and postpone generic market entry. Furthermore, complex and costly patent litigation creates barriers for smaller innovators and generic manufacturers who challenge problematic patents, reducing market competitiveness and access to affordable medications. Addressing these difficulties necessitates continual examination and future adjustments adapted to the pharmaceutical industry's specific characteristics. Future directions could include increasing openness in patent filings, speeding up review processes for generics and biosimilars, and unifying international patent laws to streamline rules and promote worldwide access to critical medications. Collaboration among stakeholders, such as pharmaceutical companies, regulators, healthcare providers, and patient advocacy organisations, will be critical in developing regulations that foster innovation while assuring equal access to healthcare developments.

3.2.1 Guidelines for the Examination of Pharmaceutical Patents

The rules for reviewing pharmaceutical patents establish a thorough framework for determining the legality and merit of patent claims in the industry. They provide insights into typical types of claims and their treatment in various jurisdictions, with a focus on enhancing public health and access to medicines. Below, we look at specific suggestions for two common categories of claims: formulations and compositions and active ingredient combinations[47].

[47] Guidelines issued by leading patent office's such as the USPTO, EPO, and Japan Patent Office (JPO)

- New formulations and compositions should be considered evident in the past, especially when combining a single active component with known or unknown carriers or excipients. However, if a new formulation solves a challenging problem or addresses a long-standing need, such as dramatically decreasing side effects or offering a major advantage over existing medicines, it may be patentable. This exception is granted when the new formulation offers an unexpected benefit, such as addressing complex or chronic problems.
- Combinations of known active substances can be patented with a novel synergistic impact, provided they demonstrate a greater effect than the sum of its parts. The patent application must include thorough biological testing and detailed disclosure to ensure transparency. The guidelines aim to balance incentivising genuine innovation with preventing patent system prolongation of market exclusivity. They discourage extending patent protection for minor improvements, promoting early generic drug market entry and competition. Limiting unjustified patent extensions can increase the availability of affordable pharmaceuticals.
- Dosage claims, which describe specific amounts or schedules for administering a pharmacological medication, do not constitute inventions in countries where medical treatment procedures are not patentable. These claims are often used in clinical trials and standard medical practice but do not meet the inventive step requirement for patentability. Some governments prohibit dosage claims from patent eligibility, allowing healthcare practitioners to prescribe the most effective treatment without legal constraints or additional costs. This allows for faster release of generic drugs when the original patent expires, reducing prescription costs and increasing patient access to key drugs. Patent protection for novel dosages could result in extended exclusivity periods, limiting affordability, especially in poor and middle-income nations. Patent offices should provide explicit standards for evaluating dosage claims, emphasising tangible proof of innovation and inventive inventiveness. Proper training of examiners is essential to ensure consistency and impartiality in the patent examination process, benefiting both applicants and the public.
- Salts, ethers, esters, and other forms of existing pharmaceutical medicines should not be considered patentable unless they show significant, unexpected advantages over existing forms. These changes are chemical alterations to

active pharmaceutical ingredients (APIs) used to enhance a drug's solubility, stability, or absorption. However, many of these changes produce incremental gains rather than significant advances, lacking the inventive step required for patent protection. A global consensus is promoting significant inventions for patentability, preventing the monopolisation of small alterations. This approach contributes to a balanced pharmaceutical market and encourages the development of new medicines. Prohibiting patents on novel salts, ethers, esters, and other forms accelerates the release of generic copies of medications, reducing healthcare affordability and accessibility. In unusual cases, applicants must include precise experimental evidence and comprehensive analysis in their patent specifications. Patent offices should develop explicit criteria for analysing claims involving salts, ethers, esters, and other forms, emphasising the importance of demonstrating unanticipated advantages and providing specific training for examiners.

- Polymorphism is an inherent property of matter in a solid state, and patenting the active ingredient and its polymorphs can prolong protection. Polymorphs are distinct crystalline structures of a single chemical molecule, resulting in differences in physical characteristics. Obtaining patents for different polymorphs of a substance can lead to "evergreening," which hinders the introduction of generic medications and increases drug prices. However, patent protection may not be available for polymorphs themselves but for the original and creative methods used to produce them. Examining applications for polymorphs requires careful analysis to evaluate if they provide significant advantages compared to existing forms. Examining methods for obtaining polymorphs should prioritise originality and lack of obviousness.
- Markush Claims[48]: Patent offices should limit claims to a specific range of chemicals, such as fusion points, infrared absorption spectrum, or nuclear magnetic resonance, obtained through authentic testing and experimentation. This information should allow replication of each embodiment of the invention. However, claims with restricted boundaries may be approved if sufficient evidence can be provided to show that substituting any member within the same family class will result in the same outcome. Markush claims,

[48] Grunwald, G. D. (2013). "Markush claims in chemical and pharmaceutical patent practice." Chemical Reviews,

which encompass a wide spectrum of structurally interconnected molecules, can hinder competition and creativity by granting excessively broad patent rights. Patent offices should assess these claims thoroughly to ensure they are adequately substantiated by empirical evidence.

- Selection patents are awarded when a specific group of chemicals or compositions has been made public, highlighting a unique feature or benefit. They must be novel and not previously disclosed and demonstrate creative advancement. The selected components must provide an unexpected benefit or address a specific issue. If the selected subset demonstrates a notable enhancement in attributes, it can justify the patentability. Patent offices should rigorously examine patent applications to maintain the quality of patents and encourage true breakthroughs in medicines by only granting patents for inventive and non-obvious options.
- Pharmaceutical procedures that are neither new nor evident, regardless of their novelty or inventiveness, should not be eligible for patent protection. To be eligible, a process must be new and demonstrate inventiveness, not just a modification of an existing technique. Patent offices evaluate whether the claimed procedure is a substantial technological development compared to current methods, requiring comprehensive disclosures to prove it is not a simple modification of existing techniques. This ensures only creative methods receive protection, encouraging pharmaceutical companies to focus on developing innovative methodologies rather than less innovative approaches.
- Patents for single enantiomers of racemic mixtures are typically not granted if both enantiomers are already recognised. Instead, novel and inventive procedures for obtaining enantiomers may be eligible for protection. Enantiomers are molecular entities with the same chemical formula but differ in spatial arrangement, resulting in mirror-image isomers. Patenting one enantiomer alone lacks innovation, so innovative methods of separating or obtaining individual enantiomers can be granted.
- Active metabolites of medications should not be considered independent entities from the active substance they form. Patents should only be granted for products with an atypical, unpredictable impact and must have adequate support from the specifications. Prodrugs are inert substances that undergo

metabolic transformation into active pharmaceutical agents, engineering themselves to enhance drug absorption, minimise negative effects, or optimise transportation. Patent applications must provide a detailed description of the prodrug, demonstrate an unforeseen therapeutic impact, and contain adequate empirical evidence to substantiate assertions on its effectiveness, safety, and distinctive advantages. Patent offices should set strict rules for active metabolites and prodrugs to balance encouraging real pharmaceutical innovation and preventing patents from being extended without a good reason. This would promote a competitive market and enhance the availability of inexpensive medications[49].

- Treatment procedures, including surgical procedures, diagnostic methodologies, and preventive strategies, should not be eligible for patents if they require industrial applicability. Legal systems often prohibit patenting these procedures due to their lack of practical usefulness. This raises ethical concerns as it could impede access to vital medical treatments and limit healthcare professionals' effectiveness. Patent offices classify treatment methods as non-patentable, ensuring everyone has access to essential therapies. This encourages pharmaceutical companies and researchers to focus on developing innovative pharmaceuticals and medical devices, fostering innovation in healthcare.
- Patent offices can reject claims for the utilization of recognised pharmaceutical products, including secondary indications, due to a lack of innovation and industrial applicability. This can restrict monopolies on existing treatments, promote competition, and provide affordable medications. Rejecting patents for new uses of established products that lack innovation or industrial applicability can lead to the development of novel treatments that can significantly improve healthcare.

[49] Guidelines issued by leading patent office's such as the USPTO, EPO, and Japan Patent Office (JPO)

- The World Health Organization (WHO) has stopped organising workshops for patent examiners due to the widespread acceptance of WHO guidelines. Countries like Mercosur, Egypt, India, and Ecuador have adopted the guidelines, while Egypt has unofficially adopted them. The South Centre provides ongoing support through seminars and educational initiatives, ensuring that patent examiners and policymakers understand and execute these guidelines. The South Centre organised seminars in Mumbai, Chennai, Kolkata, and New Delhi in August 2014.

3.2.2 The Case of India

India's President ratified a modification to the patent legislation on April 4, 2005, bringing it in line with the TRIPS Agreement. India, along with a small number of emerging World Trade Organization (WTO) countries, took advantage of a ten-year transition period (1995–2005) to delay the process of obtaining patents for pharmaceutical products as required by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) regulations. The TRIPS Agreement does not provide a clear and explicit definition for the three requirements of patentability: originality, inventiveness, and industrial applicability. This grants governments the freedom to interpret and establish these standards in a flexible manner. In response to this, the new Indian Patent Act has explicit provisions.

Firstly, the term "inventive step" is defined as a notable technological advancement or economic significance that renders an invention unobvious to a person with expertise in the field. The Act also tries to stop "evergreening" by not letting patents be issued for basic discoveries, like new forms of existing chemicals that don't make them work better, new properties or uses for known substances or just using old methods.

In 2005, India incorporated these measures into its intellectual property legislation, earning it the nickname "pharmacy of the Third World." In March 2012, the Indian Patent Office granted Natco Pharma a compulsory license[50] for Bayer's patented

[50]Rai, A. K., & Reichman, J. H. (2009). Compulsory Licensing of Pharmaceuticals Through the Lens of Innovation Theory. In R. Dreyfuss, H. First, D. L. Zimmerman, & A. K. Rai (Eds.), Working within the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society (pp. 253-300). Oxford University Press. doi:10.1093/acprof /9780195340677.003.0011

anti-cancer medication "sorafenibtosylate" (sold as "Nexavar"). The purpose of this move was to reduce expenses and enhance the availability of the medication, which Bayer had set at a price of USD 5,600 per patient per month without revealing its research and development costs.

In April 2013, India's Supreme Court denied Novartis' patent application for the anti-cancer medicine Gleevec following a lengthy legal dispute lasting seven years. Novartis challenged India's Section 3(d) of the Patent Act, which complies with TRIPS criteria, by claiming that it obstructed the process of obtaining patents for modest modifications to existing compounds. The court's judgment was crucial, prioritising public health above business interests.

Novartis' history in India exemplifies the worldwide consequences of such actions. Despite patents protecting Gleevec in more than 40 countries, India's opposition to evergreening sets a model for other nations seeking to ensure the affordable availability of medications for poor populations.

In 2012, The Indian generics industry had the capacity to sustain the production and exportation of this and other pharmaceuticals at significantly lower costs, thereby providing advantages to individuals and healthcare systems around the world.

The Indian Patent Office is currently in the last phase of amending its standards for the examination of pharmaceutical items. We anticipate the approval of these revised guidelines before the year ends. The amended guidelines bear many resemblances to those put forth by the World Health Organization (WHO), demonstrating shared concepts focused on guaranteeing equitable availability of medications.

Novartis challenged the Indian patent office's decision to reject their patent application for the cancer medication Gleevec (imatinib mesylate). Novartis contended that the beta-crystalline form of imatinib mesylate represented a novel and superior iteration of the medication. The Supreme Court affirmed the denial of Novartis' patent application pursuant to Section 3(d) of the Indian Patents Act. According to Section 3(d), in order for a new version of a known substance to be eligible for a patent, it must show a higher level of effectiveness compared to the

known drug. It was decided by the Court that Novartis did not provide enough proof to show that the beta-crystalline form of imatinib mesylate was a much more effective medicine than the already-known chemical. Merely enhancing attributes such as bioavailability did not suffice to meet the increased effectiveness criteria. The Court emphasised that the purpose of Section 3(d) was to prohibit "evergreening," the strategy of acquiring fresh patents for minor alterations to existing pharmaceuticals in order to prolong the patent monopoly. The verdict received widespread acclaim for upholding India's commitment to maintaining a balance between patent protection and allowing inexpensive access to medicines, particularly for developing nations. The verdict set a significant standard for the interpretation of patentability criteria. The verdict dealt a significant blow to Novartis but also confirmed that India has the authority to customise its patent rules in order to address public health requirements while staying within the permissible boundaries defined by international trade agreements such as TRIPS [51].

3.3 THE INFLUENCE OF RIGOROUS STANDARDS ON INNOVATION WITHIN THE PHARMACEUTICAL SECTOR

The current patentability standards in the pharmaceutical industry provide significant benefits that promote innovation and safeguard genuine advances in medical treatments. For starters, these requirements encourage significant investment in research and development (R&D)[52] by awarding inventors exclusive rights and supporting continual innovation. Secondly, they enforce stringent novelty requirements, guaranteeing the patent protection of only truly original innovations, thereby halting the proliferation of patents for minor modifications. Third, the criteria encourage industrial applicability by requiring inventions to demonstrate practical utility in healthcare settings, which directs research toward relevant clinical applications[53].

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[51] Federal Trade Commission v. Actavis, Inc., 570 U.S. 136 (2013

[52] Grabowski, H., & Vernon, J. (2000). "Return on investment in pharmaceutical research and development: a review of the literature." Journal of Health Economics, 19(5), 855-881. doi:10.1016/S0167-6296(00)00074-4. This review discusses how regulatory factors, including patentability criteria, influence pharmaceutical R&D investments and innovation.

[53] Mullin, T. (2011). "The pharmaceutical patent landscape." Nature Reviews Drug Discovery, 10(1), 87-88. doi:10.1038/nrd3374. This article provides insights into how stricter patentability criteria impact innovation strategies within pharmaceutical companies.

However, these strengths come with significant challenges. One important drawback is the subjective character of non-obviousness standards, which leads to inconsistent application and ambiguity in patent decisions, especially in complicated domains such as biotechnology and pharmacology. Another concern is the potential for abuse, such as evergreening, in which firms extend patent protection through modest alterations or trivial improvements, delaying the market introduction of generic alternatives and restricting competition. Furthermore, the difficulties and high costs associated with patent litigation impose hurdles on smaller inventors and generic manufacturers, influencing market dynamics and access to cheap medications.

We can identify numerous areas for improvement to overcome these issues and increase the effectiveness of patentability criteria in the pharmaceutical industry; improving clarity and transparency in patent filings and examination procedures is critical for reducing confusion. Clearer standards for patentable ideas and transparent review processes can limit strategic patenting techniques, giving inventors and generic manufacturers more certainty and creating a stable environment for investment and innovation. Clear standards and objective criteria for determining non-obviousness are required to ensure the validity of patentability criteria. A more stringent approach would prevent patents for minor innovations that do not significantly expand scientific knowledge or help patients, hence favouring true innovation.

Addressing evergreening techniques necessitates a closer inspection of patent applications for incremental improvements, as well as the timely entry of generic and biosimilar pharmaceuticals into the market. These policies encourage fair competition, prohibit monopolistic activities, and improve the worldwide cost and availability of important medicines. Encouraging worldwide harmonisation of patent laws and regulatory standards can simplify processes and decrease duplication across borders. Harmonisation makes patent application and approval processes more efficient for global pharmaceutical businesses, encourages collaboration among regulatory authorities, and guarantees that innovative medications reach patients worldwide successfully.

By addressing these areas for improvement, stakeholders can improve the efficiency

of patentability criteria in the pharmaceutical business, stimulating innovation and providing equal access to healthcare developments around the world.

In the pharmaceutical industry, the rigorous criteria for patentability are designed to acknowledge true innovation by guaranteeing that patents are only awarded to innovations that demonstrate substantial progress compared to existing technology. These rules provide rigorous criteria for originality, lack of obviousness, and practical utility, incentivising pharmaceutical corporations to allocate resources towards innovative research and development (R&D) endeavours that result in revolutionary cures. The focus on significant innovation fosters a competitive atmosphere that encourages enterprises to actively seek out breakthroughs that solve unfulfilled medical requirements and improve patient results.

These principles direct pharmaceutical companies to engage in research and development that produces valuable medications with significant therapeutic advantages. By requiring compelling evidence of effectiveness, safety, and clinical significance, they discourage investments in small alterations or "me-too" medications that have only limited therapeutic benefits. Prioritising this approach allocates resources towards breakthroughs that have the potential to significantly enhance healthcare, thereby enhancing the overall quality of newly released pharmaceuticals on the market.

In addition, strict criteria for patentability are crucial in preventing anti-competitive behaviours within the pharmaceutical sector, such as the practice of patent evergreening. These guidelines effectively reduce the chances of corporations obtaining patent protection for minor adjustments or negligible breakthroughs by implementing strict standards for patent approval, which involve thorough evaluations of non-obviousness and novelty. The existence of regulatory monitoring promotes equitable competition by allowing generic and biosimilar producers to enter the market sooner with cost-effective alternatives, thereby improving the worldwide availability of medications.

Stringent guidelines in the pharmaceutical sector, while establishing precise criteria for patentability, also create difficulties and motivations for innovation. Companies must successfully navigate intricate regulatory frameworks and provide compelling

evidence of significant scientific progress in order to get patent protection. The strict regulations in place motivate pharmaceutical companies to invest in state-of-the-art technologies, partner with academic institutions and investigate new therapeutic approaches that fulfil rigorous patentability standards. Incentives such as exclusive rights and market recognition for truly unique products motivate companies to explore ground-breaking discoveries in drug development that can transform patient care and generate economic growth.

The strict criteria for determining the eligibility of pharmaceutical patents have a significant impact on fostering innovation. These requirements encourage the development of genuine innovations, prioritise high-value research, discourage anti-competitive behaviours, and provide incentives for enterprises to overcome regulatory obstacles. These principles are crucial for achieving a balance between encouraging innovation and meeting the greater social objectives of improving healthcare accessibility and cost.

3.3.1 Innovation, R&D Investments, and Patient Access to Medications

Anticipated strict criteria for patentability are likely to alter the dynamics of innovation by increasing the minimum requirements for what can be considered a patented invention. These rules encourage pharmaceutical companies to focus on significant developments in technology rather than making little enhancements or creating treatments that are similar to existing ones. This transformation has the potential to cultivate a culture of innovation, wherein corporations allocate resources towards pioneering research to tackle unaddressed medical needs and create treatments with significant therapeutic advantages. Nevertheless, rigorous regulations may also pose difficulties by amplifying the intricacy and expenses related to obtaining patents, thus deterring investment in more daring research and development endeavours.

More stringent patentability requirements could have a major influence on R&D investments. Companies may allocate resources towards projects that are more probable to fulfil these requirements, such as medicines that exhibit evident effectiveness, safety, and distinctive mechanisms of action. By prioritising high-value research and development, there is a possibility of accelerating the creation of

ground-breaking medications that can revolutionise patient treatment. However, due to increased uncertainty and regulatory obstacles, strict requirements may redirect resources from exploratory research and early-stage innovation. Smaller organisations and start-ups, especially, may have more challenges in negotiating the strict patent environment, which could impact their capacity to obtain finance and compete with larger pharmaceutical giants.

When implementing stricter patentability criteria, it is important to consider how they will affect the availability of medicines for patients. These rules should strive to encourage real innovation and prevent unfair tactics like extending patents indefinitely. However, they must also find a balance between promoting innovation and ensuring that inexpensive treatments are available in a timely manner. Tighter regulations could expedite the entrance of generic and biosimilar medications onto the market by restricting patent protection for insignificant adjustments or minimal enhancements. The presence of competition among pharmaceutical companies has the potential to decrease prices and improve accessibility for patients. On the other hand, strict regulations could cause a delay in the release of innovative treatments into the market, particularly if companies face long periods of patent assessment or have difficulty meeting more rigorous patentability standards.

The Court determined that a biosimilar applicant's obligation to provide its application and manufacturing information to the brand-name producer, as mandated by the Biologics Price Competition and Innovation Act (BPCIA)[54], cannot be enforced through a court order under federal law. The remedy explicitly stated in the Biologics Price Competition and Innovation Act (BPCIA) is the only recourse available. Nevertheless, the Court acknowledged the potential for a state-law injunction to be utilised in order to enforce this requirement. The Court referred the matter back to the Federal Circuit for further determination. According to the Court's ruling, the BPCIA allows a company seeking to produce a biosimilar to inform the brand-name manufacturer about its plans to sell the product before gaining FDA approval. Compliance with this notice requirement is obligatory. The situation emerged when Sandoz, a maker of biosimilars, notified Amgen in July 2014 that the FDA was evaluating Sandoz's request to sell a biosimilar version of Amgen's medication,

[54] Biologics Price Competition and Innovation Act (BPCIA) - This legislation establishes the framework for the approval of biosimilar and interchangeable biological products in the United States.

Neupogen. Amgen filed a lawsuit against Sandoz, accusing them of violating the Biologics Price Competition and Innovation Act (BPCIA). The Supreme Court's unanimous ruling partially invalidated, partially overturned, and sent the case back to the Federal Circuit for additional procedures in accordance with its judgment[55].

Dealing with the legislative and business issues related to stricter patentability criteria is a complicated task. These principles aim to protect intellectual property rights and promote innovation while also impacting worldwide attempts to achieve regulatory harmonisation. Differences in the criteria for granting patents in different countries may have an effect on global trade, the capacity to enter markets, and the approaches taken to develop new pharmaceutical products. By implementing collaborative activities to synchronise patent rules and simplify regulatory processes, it is possible to alleviate some of these problems. This will result in a more unified global pharmaceutical market that is advantageous for both inventors and patients. Implementing more rigorous patentability criteria has the potential to boost innovation by encouraging greater investment in research and development and preventing unfair competition.

However, it is crucial to strike a careful balance to guarantee that everyone has fair access to novel treatments. To effectively deal with these factors, it is important to have continuous discussions among various parties involved, such as pharmaceutical companies, regulatory agencies, healthcare providers, and patient advocacy groups. This will help to maximise the benefits of strict patentability criteria while also protecting patient interests and promoting public health outcomes.

3.4 EXPLORATION OF THE RELATIONSHIP BETWEEN PATENTABILITY STANDARDS AND ANTI-COMPETITIVE BEHAVIOURS.

3.4.1 Evergreening strategies

Pharmaceutical corporations frequently utilise "evergreening" tactics to prolong the patent protection and exclusive market rights of their products beyond the initial patent duration. This entails acquiring additional patents for minor alterations to current medications, such as novel formulations, doses, or combinations that provide

[55] Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017)

very slight therapeutic enhancements. These evergreening strategies allow firms to maintain high prices while postponing the entry of generic competitors, which can have a significant impact on patient access and affordability. To tackle this problem, there have been suggestions to implement stricter criteria for patentability.

Before granting new patents, these criteria would require pharmaceutical advancements to demonstrate significant improvements in effectiveness, safety, or patient well-being. By deterring baseless patent claims for insignificant alterations, such norms can facilitate the early introduction of generic alternatives and enhance the affordability of drugs for patients. The objective of this method is to achieve a more optimal equilibrium between encouraging authentic innovation and guaranteeing the prompt availability of inexpensive medications[56].

3.4.2 Pay-for-delay agreements[57]

Pay-for-delay agreements involve brand-name drug makers compensating generic competitors to postpone the release of cheaper equivalents, prolonging the exclusivity of the brand-name drug and delaying competition in the market. These agreements sometimes entail providing financial compensation to generic medication manufacturers in return for delaying their introduction into the market, thereby maintaining the ability of brand-name drugs to charge monopolistic prices.

Strict patentability criteria can assist in reducing pay-for-delay schemes by restricting the length and extent of patent protection. More precise standards for granting patents decrease the motivation for well-known corporations to participate in anti-competitive agreements, promoting fair competition and ensuring that affordable generic products are promptly available to customers.
Nevertheless, the presence of rivalry among brand-name pharmaceuticals is unlikely to result in a decrease in the list prices of already established brand-name drugs in the same category. Barriers include physicians' reluctance to prescribe the most economically efficient therapies due to their limited expertise, payers' inability to

[56] Hemphill, C. S., & Sampat, B. N. (2012). Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. Journal of Health Economics, 31(2), 327-339. doi:10.1016/j.jhealeco.2011.10.004
[57] FTC v. Actavis

compare different manufacturers during drug price negotiations, and mismatched incentives for pharmacy benefits managers (PBMs) to accept exorbitant list prices[58].

The introduction of a small number of generic competitors has the potential to reduce drug prices by over 30%, and the subsequent entry of more generic competitors can result in much larger price reductions. Enhancing the accessibility of cost-effective medications relies on facilitating increased competition among generic drug manufacturers through efficient approval procedures and restricting anti-competitive behaviours.

The Supreme Court said that the rule of reason analysis can be used to look for antitrust violations in reverse payment settlements. These are agreements where brand-name drug companies pay generic drug companies to delay the release of cheaper versions of their products. The Court dismissed the "scope of the patent" examination, which had previously protected such settlements from antitrust disputes, along with the FTC's suggested "quick look" regulation of presumed unlawfulness. However, the Court determined that the FTC is required to demonstrate its antitrust case using the conventional rule of reason framework. This framework allows defendants to present explanations for the reverse payment, such as avoidance of litigation expenses or fair value of services. The Court's ruling sparked the initiation or reinstatement of over 30 distinct antitrust lawsuits, all challenging reverse payment agreements as anti-competitive. The Federal Trade Commission (FTC) has successfully resolved cases by imposing restrictions on reverse payment arrangements that impede the entry of generic drugs into the market. However, these settlements allow certain payment types that are considered unlikely to disrupt competition. The FTC v. Actavis case was a significant finding that brought reverse payment settlements under antitrust investigation with the goal of fostering more competition among generic drugs and ensuring the inexpensive availability of medications[59].

3.4.2.1 Stringent Patentability Guidelines

Rigorous patentability criteria are essential to reducing pay-for-delay schemes by restricting the length and extent of patent protection. More precise standards for

[58] European Commission Decision in Lundbeck (Case AT.39226)
[59] Federal Trade Commission v. Actavis, Inc., 570 U.S. 136 (2013

granting patents decrease the motivation for well-known corporations to participate in anti-competitive agreements, promoting equitable competition and guaranteeing prompt access to affordable generic products for consumers. The introduction of a small number of generic competitors has the potential to reduce drug prices by over 30%, and the subsequent entry of more generic competitors can result in much larger price reductions. Enhancing generic competitiveness by simplifying approval procedures and restricting anti-competitive behaviours is vital for enhancing the availability of cost-effective medications. Establishing uniform standards for patent examination at an international level and enhancing global competition regulations can promote consistent criteria for evaluating patents, ease equitable market entry for generic drugs, and foster innovation by ensuring a fair and equal competitive environment for pharmaceutical businesses. This helps to reduce inequalities in healthcare access and promotes the sustainability of healthcare systems by ensuring that affordable pharmaceuticals are available internationally in a timely manner.

3.4.3 Product Hopping

Patent evergreening has been noted by critics of the pharmaceutical industry's present patenting methods to be combined with "product hopping." Product hopping is the practice of a brand switching doctors, pharmacists, and consumers to a newer version of the same (or similar) drug with later-expiring patents by using its present dominating market position. This happens when the patents on an older branded drug are expiring. Put differently, the brand makes customers "hop" from one product to another. For instance, the product may have an extended-release form, a new dosage (such as going from twice daily to once daily), a different administration route (such as switching from capsules to tablets or tablets to film strips), or a chemical modification (such as switching to an alternate enantiomer). To persuade physicians, insurers, and patients to move to the new version, there may be a marketing campaign, discounts, and rebates along with the changeover; in certain situations, the older version may no longer be produced. 435 Product switching typically manifests itself in one of two ways: either a "soft switch," in which the brand offers the new version of the product alongside the original, or a "hard switch," in which the company pulls the original from the market.436 A hard changeover is exemplified by the Abbott Laboratories v. Teva Pharmaceuticals USA, Inc. case. 8 Abbott made

modifications to TriCor, a medication used to treat excessive triglycerides and cholesterol, in that situation. Abbott is accused of reducing the dosage of the medication, converting it from a capsule to a tablet, discontinuing the sale of capsules, repurchasing pharmacy supplies of capsules, and designating capsules as "obsolete" in the national drug database. 43 per cent. Following the development of generic alternatives to the reformulation, Abbott is accused of reducing the drug's potency once again, discontinuing sales of the original tablets, and redesignating the old pills as "obsolete." There was a purported soft switch in Schneiderman v. Actavis PLC. Actavis created Namenda IR (IR) there, a medication taken twice a day to treat Alzheimer's disease. Actavis allegedly tried to persuade physicians and patients to convert from IR to XR by introducing Namenda R (R), a once-daily form of the medication, while the IR patents were about to expire and generics were getting ready to hit the market. [60] While the generic versions might have been used in place of IR, they could not have been used in place of the new XR product due to the dosage variations (10 mg in IR and 28 mg in XR). At first, XR and IR were offered jointly on the market. Actavis allegedly stopped selling IR during that time and "invested significant financial resources in promoting XR to physicians, caregivers, patients, and pharmacists. “Actavis also provided rebates to ensure that patients did not have to pay greater copayments for XR than IR and offered XR at a discount, making it significantly less expensive than IR[61] Actavis allegedly executed a hard switch by declaring it will end IR and trying to prevent Medicare health insurance from covering IR, after it became apparent that the soft switch would only convert thirty per cent of IR consumers to XR[62]

3.4.3 Patent Thickets

Some pharmaceutical manufacturers have been accused of creating "patent thickets" in order to shield their goods from competition. There are two slightly different uses for this term, both involving things that have a large number of patents covering them. Initially, a patent thicket might characterise a scenario when several parties had

[60]This term was coined by Professor Herbert Hovenkamp in the early 2000s. See Alan Devlin, Exclusionary Strategies in the Hatch-Waxman Contexz, 2007 MIcH. ST. L. REV. 631, 658 (2007) (citing HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.5 (2002)).
[61]Carrier & Shadowen, supra note 370, at 192, 437 432 F. Supp. 2d 408 (D. Del. 2006). 438 /d. at 415.
[62]Id. at 647

overlapping patent rights for a single product, meaning that a "possible manufacturer needs to discuss license agreements with every patent holder to introduce a product into the market without violating any patents."[63] In this way, patent thickets create concerns about inefficient technological exploitation since many patent owners lead to higher transaction costs and coordination issues[64]. Secondly, the phrase can also refer to the practice of an incumbent manufacturer accumulating a significant number of patents for a single product, with the aim of discouraging competitors from entering the market or making it excessively expensive and hazardous for them to do so. When critics allude to the patent "thickets" that shield pharmaceutical items, they usually mean this second meaning.

3.5 CONCLUSION

To summarise, the evaluation of existing patentability criteria in the pharmaceutical industry emphasises their essential function in fostering innovation while ensuring the equitable availability of pharmaceuticals. The criteria of novelty, non-obviousness, and industrial applicability are essential for upholding the integrity of patent systems. They reward genuine scientific advancements and prevent the issuance of frivolous patents. However, there are still difficulties, particularly when it comes to implementing these standards in rapidly developing areas like biotechnology, as well as issues over techniques like evergreening.

To tackle these issues, continuous adjustments are necessary. Essential measures include enhancing openness in patent filings, accelerating the approval processes for generic and biosimilar medications, and aligning worldwide patent rules. These initiatives not only promote competition in the market but also improve access to innovative therapies, especially in underprivileged areas.

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[63]Stu Woolman et al., Evidence of Patent Thickets in Complex Biopharmaceutical Technologies, 53 IDEA: INTELL. PROP. L. REV. 1, 2 (2013); Carl Shapiro, Navigating the Patent Thicker: Cross Licenses, Patent Pools, and Standard-Setting, 1 INNOVATION POL'Y & ECoN, 119, 119 (2001). 476 See Gavin D. George, What Is Hiding in the Bushes?

[64]eBay's Effect on Holdout Behavior in Patent Thickets, 13 MICH. TELECOMM. & TECH. L. REv. 557, 558-60 (2007) (summarizing the economic literature); see generally Shapiro. supra note 475; Michael A. Heller & Rebecca Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCi. 698, 698 (1998).

Moreover, it is crucial to cooperate and coordinate among various stakeholders, such as pharmaceutical companies, regulatory agencies, healthcare providers, and patient advocacy groups. This collaboration is essential for developing policies that successfully strike a balance between promoting continuous innovation and addressing public health requirements. To guarantee that patents continue to drive significant breakthroughs in pharmaceutical research and healthcare delivery, governments should align patentability criteria with the changing landscape. This will also help to maintain affordable access to vital medicines on a global scale.

CHAPTER- 4

IMPACT OF PATENTABILITY CRITERIA ON INNOVATION AND COMPETITION IN THE PHARMACEUTICAL

4.1 INTRODUCTION

Effective patent protection is widely acknowledged as being essential to promoting pharmaceutical innovation, especially in light of the high expenses and dangers associated with creating new medications and winning regulatory approval. This protection supports the drawn-out and costly process of turning laboratory discoveries into safe, effective therapies, in addition to providing incentives for early discoveries. The financial incentives required for innovation would be undermined if generic competitors lacked patent protection, as they could readily undercut prices once regulatory approval is obtained.

The difference between "primary patents" which cover novel chemical entities and "secondary patents, which cover follow-on developments including novel applications, formulations, or combinations of already-approved medications, has, however, come up in recent times. While primary patents are important, some contend that secondary patents might be discouraged since they could have a greater negative impact on society than a positive one. They argue that these patents frequently cover small-scale breakthroughs that might not require the same degree of exclusivity as medications that are the first of their kind.

In response, more stringent criteria for assessing secondary pharmaceutical patents are suggested by guidelines like those issued by the United Nations Development Programme (UNDP). These recommendations support stricter standards for patentability, which may restrict the range of inventions in the pharmaceutical industry that are covered by patents. For example, they advise against patenting inventions such as polymorphs, enantiomers, and specific combination goods unless there are special conditions that warrant it.

Defenders of secondary patents contend that despite these obstacles, these inventions continue to advance medicine and should be protected when necessary. They include instances of secondary patents that have successfully resisted legal challenges, proving their legitimacy and significance in the advancement of medical technology.

In the future, the discussion will focus on finding the ideal compromise between providing widespread access to necessary medications and encouraging innovation through patent protection. This conversation is essential to developing policies that both effectively meet the demands of global health and encourage continued pharmaceutical innovation.

Guidelines that contest the patentability of pharmaceutical innovations underscore the significance of subsequent innovations in the field. According to these criteria, some innovations—such as novel medical applications, product combinations, and formulations—might not be eligible for patent protection. Still, these kinds of inventions frequently become vital in introducing novel therapies to the market. Drugs like Evista (raloxifene) for osteoporosis and AZT (zidovudine) for HIV, for example, were developed and made accessible with the help of secondary patents. These patents support continuous research and guarantee ongoing advancements in medication efficacy and safety, enhancing the accessibility of healthcare around the world.

4.2 ISSUES CONCERNING SECTION 3(D) IN THE INDIAN PATENTS ACT IN 2006

The pharmaceutical company Novartis was denied a patent for the B-crystalline form of Imatinib mesylate by the Assistant Controller of Patents and Designs. The reason given was that the claimed form was not patentable under Section 3(d) of the Indian Patents Act, lacked innovation, and was obvious. Later, in 2009, the IPAB upheld the Assistant Controller's ruling, and in 2013, the Supreme Court did the same[65].

According to the Organization of Pharmaceutical Producers of India (OPPI), Article 27 of the TRIPS agreement is incompatible with Section 3(d) of the Indian Patents Act. The non-discrimination principle outlined in Article 27 is allegedly violated by

[65] http://indiankanoon.org/doc/1352538/(last visited june 24th)

Section 3(d), which places extra barriers to patentability on discoveries that are particularly related to drugs or chemical compounds. Furthermore, according to OPPI, TRIPS Article 27 offers a non-extendable list of topics that member nations may choose to exclude from patentability; however, the topics that are prohibited from patentability under Section 3(d), or novel forms of known substances, fall outside of this list.

4.2.1 India's Compulsory Licensing Process

The first compulsory license (CL) for patents in India was released in 2012 by the Controller of Patents. With patent number 215758, Natco Pharma Ltd. received the CL. Bayer Corporation is the recipient of the patent for the medication Sorafenib tosylate, which is marketed under the Nexavar brand. This medication is recommended for the treatment of hepatocellular carcinoma (liver cancer) and renal cell carcinoma (kidney cancer).

Bayer appealed this ruling in turn to the Bombay High Court, the Intellectual Property Appellate Board (IPAB), and ultimately the Supreme Court. The Supreme Court ended the case's legal processes in December 2014 by upholding Natco's obligatory license.

The Indian government has promoted compulsory licensing in its "National Manufacturing Policy" as a mechanism to effectuate technology transfer in certain sectors, according to reports from the United States International Trade Commission and the Office of the United States Trade Representative. This suggests that the government is using compulsory licensing merely as a tool to achieve its industrial policy goals rather than for the purpose of protecting the public health of the nation.

SA In her testimony before the U.S. House of Representatives, Teresa, the Deputy Under Secretary of Commerce for Intellectual Property and the Deputy Director of the United States Patent & Trademark Office (USPTO), claimed that the compulsory license granted by India in the Naxavar case violated the TRIPS agreements. Singham, Managing Director of Babson Global's Competitiveness and Enterprise Development Project in the United States, questioned the requirement for compulsory licensing in

India by declaring that compulsory licenses cannot be utilised as a market mechanism or as a replacement for antitrust laws, as stipulated in the Indian Patents Act. Singham went on to say that India could face a dispute settlement lawsuit at the WTO for improperly managing forced licensing in the Naxavar issue[66].

The Office of the United States Trade Representative and the United States International Trade Commission have released reports criticising India's current patent opposition provision. According to reports, the present patent opposition process in India burdens patent applicants and delays the issuance of patents excessively. Regarding the information and undertaking of overseas applications, as stipulated in Section 8 of the Indian Patents Act, the Organization of Pharmaceutical Producers of India (OPPI) provided comments. OPPI claims that this rule unfairly singles out foreign patent applicants and is overly onerous. In addition, the punishment for breaking this section—that is, the patent being revoked—is severe as compared to other nations

4.2.2 Steps to improve India's patent and intellectual property laws

On April 23, 2015, India's Prime Minister Narendra Modi opened the inaugural "Global Exhibition on Services" in New Delhi. In his inaugural address, the prime minister stated that the nation's intellectual property rights (IPR) system is being strengthened by the administration. He went on to say that "if we can convince the world about the robustness of our IPR, there is a huge scope for our creative industry to flourish"[67].

The Indian government's Department of Industrial Policy and Promotion (DIPP) published a press release in 2015 outlining several steps the government had taken to strengthen the nation's IP environment in order to support the "Make in India" initiative. The government has modernised IP administration, made information easily accessible through the patent office website, provided e-filing facilities and fee rebates for MSMEs, ratified the Madrid Protocol, implemented IPR awareness campaigns; and had India recognised by WIPO as an international search and preliminary examining authority.

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[66] Froman MBG; Office of the United States Trade Representative. 2014

[67] Indian express. Com, creating conductive mechanism for service growth (last visited june 24th)

The initial draft of the "National IPR Policy" was published in 2014 by the Department of Industrial Policy and Promotion (DIPP)[68], Government of India. The draft placed a strong emphasis on the necessity of enacting new legislation on utility model patents, sometimes known as "petty patents," which are currently unavailable in India but have been effectively used in many other nations. Utility models permit the patenting of innovations that meet the requirements for patentability under the present Patents Act, even though they may not be new, practical, or inventive in their own right. Micro, Small, and Medium-Sized Enterprises (MSMEs) and businesses operating in the unorganised/informal sectors can greatly benefit from utility models. Despite making up roughly 45% of the manufacturing output overall, MSMEs have relatively little intellectual property. The draft also underlined how important it is to improve India's enforcement and adjudicatory systems, as well as to modernise and fortify IP management.

4.2.3 Expedited review of patents

There isn't currently a choice in India for expedited patent examination. The provision for faster patent examination in India has been proposed to be added to the Draft Patent (Amendment) Rules, 2015. The invention must be manufactured in India at the time of patent filing, or the patent applicant must begin manufacturing the invention within two years of the patent grant, according to the proposed guidelines, in order for a request for expedited examination to be granted. The proposed rules for expedited examination have, however, been criticized by various organisations, viz. American Intellectual Property Law Association (AIPL), Sinapse and Intellectual Property Owners Association (IPO) on different grounds, including:

- The condition of manufacturing the invention in India is discriminatory, as in the Natco vs. Bayer case, the Bombay High Court and the IPAB have clarified that the requirement of working on a patent could be satisfied even by importing the patented product if the patentee could satisfy that the patented product could not be manufactured in India.

[68] Dipp.nic.com intellectual property initiatives to drive (last visited june 24th)

- In the case of pharmaceutical inventions, where regulatory approvals may take several years, commitment to commencing manufacture within 2 years from the patent grant seems unrealistic[69].
- In accordance with the proposed regulations, when submitting a request for an expedited examination, the applicant must provide evidence of the funding and facilities needed to manufacture the invention. Nevertheless, it would be exceedingly difficult for small-scale businesses, start-ups, and individual inventors to secure the funding and facilities needed at the time of patent filing.
- For natural individuals (Rs. 50,000 for e-filing; Rs. 55,000 for physical filing) and small-scale industries (Rs. 1,25,000 for e-filing; Rs. 1,37,500 for physical filing), the accelerated examination charge is exceptionally high and non-refundable.
- The Controller may grant a restricted quantity of requests for accelerated review each year.

4.2.3 Complete provisional specification

A "techno-legal" document known as a patent specification explains the technical details of an invention in a way that complies with legal standards. When submitting an ordinary patent application, the applicant may choose to file the complete or provisional specification.

However, the only thing that will be looked at is the entire specified application. Only a complete specification needs to be submitted with a convention application or a PCT application. The provisions of the Patents Act pertaining to complete and provisional specifications are explained in Sections 9 and 10, respectively.

Temporary Specification: Usually, early in the research process, a provisional specification is produced; once the invention is fully developed, the complete specification is filed. In a provisional specification, an abstract and claims are not necessary. The tentative specification may not be changed in any way. The applicant receives a patent application number and a "priority right" over any other person's patent application for the same or nearly identical invention being developed

[69] Wipo.org(last visited June 23rd)

concurrently in a different region of the world upon filing a provisional specification. A comprehensive specification is a necessary document for a patent to be granted. It needs to be submitted no later than a year after the provisional specification was filed. Improvements related to the topic of the temporary application might be included. A fair basis for the full specification to assert precedence over any provisional specification must be found in the provisional specification[70].

4.2.4 Analysing the Patent Application

The patent office will only review an application for examination if the request is filed within 48 months of the original filing date. The application is examined by a patent examiner designated by the controller of patents, who then sends the controller the "First Examination Report" (FER). The examiner may ask the applicant or his representative to provide further information, respond to questions, present a defence for any opposition presented under section 25(1), or alter the application, 73 2.1.13, during the examination. objection to patents. Even though the patent office carefully reviews all patent applications before granting patent rights to patent holders, defective or low-quality patents may occasionally be issued in error. Opposition measures are included in the patenting system to guarantee the quality of the issued patents.

4.2.5 Compulsory license u/s 84

After three years have passed since the date of the patent grant, an interested party may be granted a compulsory license on the grounds that the following conditions have not been met: (a) the public's reasonable requirements regarding the patented invention have not been met; (b) the patented invention is not reasonably affordable for the general public; or (c) the patented invention is not worked in the territory of India[71].

A list of circumstances is provided in Section 84(7) of the Patents Act, and if any of them apply, the reasonable requirements of the public will be deemed to have not been met. These situations include: (a) the patent holder refuses to grant a license, which harms trade, industry, or commercial activities in India; (b) the patent holder

[70] OPPI Indian pharmaceutical challenges ,. indiaoppi.com
[71] http://pindia.nic.in/ipoNew/compulsory_License_12032012.pdf

imposes unjustifiable conditions upon the grant of licenses, which are detrimental to the development of trade and industry in India; or the demand for the patented article is not met. (c) The patent holder establishes requirements for the exclusive grant back, prohibits contesting the patent's validity, or uses coercive package licensing (d) The patented innovation is not fully or adequately implemented on a commercial scale in India in a way that is reasonably practical; (e) The patent article's importation from outside prevents the invention from being implemented on a commercial scale in India[72].

A "reasonably affordable price" may be determined by the Controller by taking into consideration a number of variables, including the purchasing power of Indian consumers and end users, the cost of production, the accessibility and affordability of any product substitutes, etc.

4.2.6 specialised courts for intellectual property and patents

Indian law does not establish courts with a focus on intellectual property or patents. Only challenges pertaining to intellectual property rights are heard by the Intellectual Property Challenges Board (IPAB), a specialised administrative tribunal whose authority is restricted to appeals against judgments made by the Patent and Trademark offices. IPAB is not able to decide cases of infringement. “The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015" (The Commercial Courts Act) was passed by the Indian government on December 31, 2015.4. New district-level business Courts and Commercial Divisions in every High Court have been established in accordance with the Act to hear only "commercial disputes". The Commercial Appellate Division of the relevant High Court is where one may file an appeal against a decision made by the Commercial Court or Commercial Division. IPRs such as patents, trademarks, copyrights, designs, geographical indications, domain names, and semiconductor integrated circuits are included in the category of commercial conflicts. However, these disagreements must involve more than Rs. 1 crore[73].

[72] Ibid., at 37
[73] Manual of Patent Office Practice and Procedure, chapter 03.02

4.3 PROMOTING SIGNIFICANT INNOVATION IN PHARMACEUTICAL PATENTING: THE IMPERATIVE FOR ENHANCED GUIDELINES

Robust innovation largely depends on stricter patentability requirements, especially when it comes to new versions of recognised chemicals that exhibit demonstrably greater efficacy. The patent system forces pharmaceutical businesses to concentrate on creating truly innovative and therapeutically superior drugs by imposing strict requirements on novelty and inventive steps. By Limiting the number of patents granted to innovations that truly improve therapeutic outcomes, this strategy forces the industry to focus more on research and development than on little tweaks meant to prolong market exclusivity.

Stricter regulations effectively prevent anti-competitive tactics like "evergreening," in which pharmaceutical companies modify already-approved treatments only slightly in order to prolong their patent life without providing meaningful advances. The rules lessen the potential of firms to maintain monopolies beyond the original patent term by prohibiting the patenting of incremental improvements that do not offer significant therapeutic benefits. Tighter regulations also lessen the formation of patent thickets, which are collections of patents centred around a single product. This lowers legal and regulatory obstacles for generic manufacturers and promotes a more competitive market.

The timely introduction of generic pharmaceuticals onto the market is made possible by preventing evergreening and lowering patent thickets. Because of the increasing competition from generics, prescription prices are usually lowered, allowing consumers to purchase needed drugs. Access to essential therapies can be hampered by high drug costs in resource-constrained healthcare systems, yet the availability of less expensive generics can greatly enhance public health outcomes. The rules assist in striking a compromise between the necessity of incentivising pharmaceutical innovation and the necessity of guaranteeing access to reasonably priced drugs by guaranteeing that patents are only awarded for noteworthy improvements.

Tighter patent regulations can greatly lower the quantity of pointless patent applications and the ensuing litigation, which will lighten the load on the courts.

There are fewer legal challenges and oppositions when patents are exclusively awarded for significant and clearly inventive developments. Patent disputes can be resolved more quickly as a result of the court's ability to concentrate on truly contentious matters and the streamlining of legal procedures. Therefore, the overall efficacy and efficiency of the legal system in managing pharmaceutical patent cases can be improved by a more precise and stringent patent framework.

One prominent example of how strict patentability requirements have been implemented well is found in Section 3(d) of the Patents Act in India. This clause effectively prohibits the patenting of incremental modifications without appreciable advantages by requiring the showing of improved efficacy before new versions of recognised chemicals can be granted patent protection. The legitimacy of Section 3(d) was maintained by the Supreme Court in the Novartis v. Union of India case, highlighting the significance of making sure that patent protection is only provided for truly new and beneficial innovations. This case demonstrates how strict patentability requirements can be effectively put into practice to encourage real innovation and stop anti-competitive behaviour [74].

Tighter criteria for patentability ensure that the system supports society's need for reasonably priced and efficient medications rather than just the profit margins of pharmaceutical corporations, which helps to better align the patent system with the interests of the general public. These principles improve the credibility of the patent system and its capacity to strike a balance between the need for accessible healthcare and innovation incentives by giving priority to true innovation over small changes. Maintaining the legitimacy and efficacy of the patent system in promoting innovation and public health depends on this alignment with the public interest.

Ensuring uniform implementation of strict requirements across many jurisdictions and preventing forum shopping need international cooperation and harmonisation of patentability standards. Furthermore, sufficient resources and training should be given to patent offices so they can perform exhaustive searches for previous art and rigorous exams. Public health advocates are among the stakeholders who can be included in the policy-making process to guarantee that the guidelines take into account a range

[74] Mueller, J. M. (2007). "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation." University of Pittsburgh Law Review, 68(3), 491-641. Available at: University of Pittsburgh School of Law

of requirements and viewpoints. These steps can contribute to the development of a fair and efficient pharmaceutical patent system that encourages real innovation and guarantees access to reasonably priced[75].

Implementing more stringent patent guidelines in the pharmaceutical industry offers numerous benefits, including fostering genuine innovation, preventing anti-competitive practices, enhancing access to affordable medications, and reducing the judicial burden. By guaranteeing that patents are only granted for noteworthy innovation[76]s, these rules foster a fair and equitable marketplace that rewards genuine innovators while allowing for healthy competition. To create a strong and just pharmaceutical patent system that serves the public interest, policymakers, industry stakeholders, and international organisations must move decisively to adopt and execute stronger patentability standards.

4.4 COMPREHENSIVE STRATEGIES FOR ADDRESSING PATENT ISSUES IN THE PHARMACEUTICAL SECTOR

A thorough and multifaceted strategy is needed to address the issues raised by evergreening techniques and the growing number of patent disputes in the pharmaceutical sector. This strategy includes bolstering the standards for patentability, encouraging pre- and post-grant opposition procedures, utilising TRIPS flexibilities, investigating substitute incentive schemes, fortifying the enforcement of competition law, and improving the ability and effectiveness of the legal system.

Improving the criterion for patentability is the first step towards solving patent issues. Particularly for pharmaceutical patents, it is imperative to precisely define and rigorously enforce the criteria of novelty, inventive step, and industrial applicability. This guarantees that patent protection is only given to truly inventive and useful inventions. Section 3(d) of the Indian Patents Act[77] serves as an example for the introduction of measures that should be implemented globally to prohibit the

[75]Kumar, R. (2015). "A Critical Analysis of Section 3(d) of the Indian Patents Act." Journal of Intellectual Property Rights, 20(4), 289-297. Available at: National Institute of Science Communication and Information Resources

[76]Shanti Kumar, Dr. Nitin Shukla, Tanushree Sangal, "Evergreening of Patents and the Indian Patent Law" available at Social Science Research Network on the following link: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1420003

[77] An International Guide to Patent Case Management for Judges, wipo.org

patenting of small alterations of existing compounds unless they show significant increases in efficacy. Additionally, patent offices need to be given enough time and resources to perform exhaustive prior art searches. The integrity of the patent system is preserved by this preventive mechanism, which stops the issuing of invalid patents[78].

The use of pre-and post-grant opposition methods is essential to a strong patent system. These procedures give interested parties the ability to contest pharmaceutical patents' validity both before and after they are granted. These processes improve the review of patent applications by permitting the submission of previous art and proof of lack of novelty or inventive step during the examination process. In order to ensure that conflicts are resolved in a timely manner, it is imperative that efforts be made to streamline opposition procedures and make them more effective and less time-consuming.

Essential flexibilities provided by the TRIPS Agreement can be used to protect public health and advance access to necessary medications. Compulsory licensing and parallel imports are two strategies that nations can employ to guarantee the cost-effectiveness of patented medications, particularly in times of public health emergency. One of the most important tools in promoting public health is the granting of compulsory licenses for medications when they are not available at acceptable prices. Furthermore, the Bolar exception (early working) makes it easier for generic medications to enter the market promptly when their patents expire, which encourages competition and lower prices.

To achieve a balance between promoting pharmaceutical innovation and guaranteeing accessibility, it is imperative to investigate different incentive schemes. Novel methods such as prize monies, milestone awards, and advance market pledges encourage medication research without sacrificing price. Patent pools and open-source drug discovery are two examples of open innovation methods that encourage cooperation and hasten the creation of novel therapies, especially for underdiagnosed illnesses.

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[78] Protecting Your Intellectual Property with Patent Alternatives,Oct. 3, 2007There are myriad methods for protecting innovation and intellectual property.Tom Colson

Roche sued Cipla[79] in India for patent infringement related to its lung cancer drug Erlotinib (Tarceva). The case centred on the validity and enforceability of Roche's patent and whether Cipla's generic version infringed upon it. It also highlighted challenges in enforcing pharmaceutical patents in India's evolving legal landscape. The Delhi High Court ruled in favour of Roche, finding Cipla liable for patent infringement. This case highlighted the complexities of enforcing pharmaceutical patents in emerging markets and the legal standards for patent validity and infringement.

Enforcing competition rules strictly is essential to stop evergreening's anti-competitive actions. Procedures such as product hopping and pay-for-delay settlements must be looked into and dealt with very away. Fair competition and consumer interests are protected by fining or resolving pharmaceutical businesses that are deemed to be abusing their dominating position through strategic patenting.

For the purpose of effectively enforcing patent rights and resolving disputes, it is imperative to improve judicial competence and efficiency in processing patent issues. It is essential that judges participate in specialised training programs on patent law and the evaluation of pharmaceutical inventions. The creation of specialised courts or tribunals for intellectual property allows for the quicker resolution of complicated patent matters. Promoting the use of alternative dispute resolution procedures like arbitration and mediation relieves the load on established judicial systems and expedites the settlement of conflicts.

The difficulties presented by evergreening techniques and patent disputes in the pharmaceutical sector can be successfully resolved by putting into practice a combination of these strategies that are suited to the unique requirements and environments of each nation. These programs find a compromise between safeguarding the interests of public health, guaranteeing access to reasonably priced medications, and encouraging true innovation. In order to achieve both societal objectives for affordable and efficient pharmaceutical treatments and to promote innovation, a strong and equitable patent system is essential.

[79] Roche Products Inc. v. Cipla Ltd., CS (OS) No. 89/2008, Delhi High Court, Judgment dated September 7, 2012. Available at: Indian Kanoon

4.4.1 Strategic Patenting by Pharmaceutical Companies

Authorities overseeing competition must act sooner rather than later in response to pharmaceutical corporations' strategic patenting. It seeks to draw their notice to the negative consequences of strategic patenting. In particular, it will refute the conventional wisdom of the pharmaceutical industry's originators, who hold that competition law's meddling in patenting procedures will lessen their motivation to develop. However, in addition to the more obvious detrimental impact of high medicine prices, which has been extensively discussed in the literature, strategic patenting also impedes dynamic competition by impeding innovation. Crucially, it will be clarified that the evaluation of this practice's impact should not only concentrate on innovators' innovations but also adopt a broader market viewpoint by analysing its impact on generic businesses' subsequent innovations. The last point is frequently disregarded. In addition to outlining the current theory of strategic patenting, which views this conduct as legal, the article will make arguments in favour of competition law involvement. Consequently, this will create an avenue for competition authorities to look into this practice and stop its negative impact on innovation and consumer welfare. Furthermore, while patent law may offer certain tools to combat strategic patenting, such as increasing the threshold for pharmaceutical follow-on innovations to be patentable, these instruments might not always be useful.

The intricate structure of the pharmaceutical industry will be covered initially, with a particular emphasis on the two main participants for the purposes of this article: originators and generic corporations. It will define the term "strategic patenting" and delve more into the patenting strategies used by pharmaceutical companies. The paper will next make the case that the latter tactic undermines the goals of patent and competition laws by undermining the incentives of both original and generic companies to develop, so stifling competition. Lastly, it will go over the current theory of strategic patenting, which views this practice as legal, and make the case that, in order to mitigate its detrimental impacts, it should be closely examined in accordance with competition law regulations.

4.4.2 The Pharmaceutical Industry's Innovation and Generic Competition

The complexity of the pharmaceutical sector is unlike any other. It is typified by stringent state control and, on occasion, by the conflicting interests of society and the pharmaceutical industry. In addition, a number of parties are involved, including the original creators,[80] marketing authorisation organisations, generic businesses, physicians, pharmacies, and patients. All of these contribute to the long and intricate process of turning a chemical component into a reasonably priced, useful medication that is subsequently administered, filled, and swallowed. The two major actors in these intricate interactions play vital roles. On the one hand, innovators are crucial to the advancement of medicine and its benefits to society. Conversely, generic drug businesses help society by providing less expensive versions of the original manufacturers' medications, which lowers drug costs and makes it easier for people to get access to reasonably priced medications. The advantages to society are maximised when the interests of these two parties are balanced and new and improved medications, as well as timely access to generic drugs, are provided. But society suffers if the odds go in favour of one of the players because there won't be enough access to either novel or reasonably priced medications. Thus, proper incentives and protections are needed for both generic competition and pharmaceutical innovation.

Furthermore, there is a continuous exchange of information between these two components of the pharmaceutical sector, and their influence is significant. The pharmaceutical sector is mostly driven by innovation in the field, with originators holding a significant role. The lengthy and intricate process of developing new drugs entails large financial outlays as well as high commercial risk[81]. It is also heavily controlled, requiring originators to get specific permission from a specified governmental entity in order to market a medicine, among other things. These marketing authorisations are only given to the inventors of the drug if they can demonstrate its safety and efficacy, which usually necessitates extensive and costly clinical research[82].

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[80]European Commission (2009a, b, c), p. 9 (“‘Originator company’ is defined as a company that sells originators, while an ‘originator’ is defined as a novel drug that was under patent protection when launched onto the market”).
[81]UNCTAD (2015), p. 3
[82]European Commission (2009a, b, c), pp. 7–8

Pharmaceutical firms greatly depend on the exclusivity provided by intellectual property rights, particularly patents, to safeguard their substantial efforts and investments[83]. With the use of a patent, a pharmaceutical business can enjoy market exclusivity and set a monopolistic price for its products for a period of 20 years. Strong patent protection, according to inventors, is necessary both to recover investments and to encourage them to make more innovative products[84]. However, after this kind of patent protection ends, other businesses might create generic versions of branded medications and begin to fight the original manufacturer for market share.

The three main stages of the drug development process are as follows: (i) the R&D stage, which concludes with the introduction of a drug onto the market; (ii) the time between the introduction of a drug and its patent expiration; and (iii) the phase following the patent expiration, during which generics may be introduced to the market. This information was provided by the European Commission in its Sector Inquiry Report[85]. In order to recover their R&D costs and turn a profit prior to the onset of generic competition, originators aim to maximise their revenue from the product during the second stage, which is the period following the drug's debut. During this phase, pharmaceutical corporations also want to extend their exclusive market access.

To counter the threat of generic competition, pharmaceutical companies have increasingly depended on the strategic application of the patent system in recent years. The term "life cycle management" is frequently used by those who invented and supported these methods. One crucial component of any life cycle management strategy, for instance, is to extend patent protection beyond the primary patent term for as long as feasible by submitting secondary patents that are successful in keeping generics off the market, as stated by Burdon and Sloper[86]. Critics have labelled the process as "evergreening," nevertheless, since it effectively evergreens a product's exclusivity and patent protection[87]. Bansal et al., for example, define evergreening as

[83]See e.g. Roin (2009), p. 545
[84]European Commission (2009a, b, c), para. 253, citing EFPIA ("Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation").
[85]European Commission (2009a, b, c), para. 128
[86]Burdon and Sloper (2003), p. 227
[87]Ho (2015), p. 314; Myers (2008), p. 774

"various methods by which patent owners exploit the law and related regulatory procedures to prolong their intellectual property monopoly, especially over extremely profitable 'blockbuster' pharmaceuticals, by filing cleverly disguised patents on an already patent-protected invention soon before the 'parent' patent expires.

The European Commission discovered during its investigation into the pharmaceutical industry that the value of a drug has a significant impact on the number of patents granted and pending applications.

Even when generic manufacturers are aware that their products would only legitimately infringe upon a small number of a huge portfolio of patents, the more intricate the web of secondary patents, the more challenging it is for them to develop their generic versions[88]. Even with this knowledge, it is impossible to predict with certainty whether this will be the case prior to the introduction of a generic and, consequently, whether the generic business will face injunctions that prohibit the sale of their generic products[89]. Because of this, originators benefit greatly from this strategy, significantly reducing the legal and commercial certainty surrounding generics' potential to enter the market[90].

4.4.3 analysis of strategic practices in the pharmaceutical sector

So-called patent "evergreening" is the practice of filing for new patents on secondary features of a particular product as earlier patents expire, thereby extending patent exclusivity past the original twenty-year term. Later-filed patents may delay or prevent entry by competitors, thereby allowing the brand-name drug manufacturer (the brand) to continue charging high prices.

Generic drug manufacturers allege that as patents on a particular product expire, brand manufacturers may attempt to introduce and switch the market to a new, similar product covered by a later-expiring patent, a process known as "product hopping" or "product switching." This practice takes two forms: a "hard switch," where the older product is removed from the market, and a "soft switch," where the older product is kept on the market with the new product. In either case, the brand will focus its

[88] Ibid., p. 7
[89] Ibid
[90] Ibid.; Abud et al. (2015), p. 2; Ho (2015), p. 314.

marketing on the new product in order to limit the market for any generic versions of the old product.

Generic and biosimilar companies also allege that the brands create "patent thickets" by filing numerous patents on the same product. These thickets allegedly prevent generics from entering the market due to the risk of infringement and the high cost of patent litigation.

Litigation often results when a generic or biosimilar manufacturer attempts to enter the market with a less expensive version of a branded pharmaceutical. Core issues usually include whether the brand's patents are valid and whether the generic or biosimilar product infringes those patents.

Rather than litigate these issues to judgment, however, the parties will often settle. Such settlements may involve the brand paying the generic or biosimilar to stay out of the market- referred to as "reverse payment" or "pay-for-delay" settlements. These settlements are allegedly anticompetitive because they allow the brand to continue to charge high prices without risking the invalidation of its patent, thus unjustifiably benefiting the settling companies at the expense of the consumer.

4.5 THE IMPACT OF EVERGREENING ON PHARMACEUTICAL PATENTS: CHALLENGES AND IMPLICATIONS

For research and development to continue advancing, every creative and clever endeavour requires the dissemination of knowledge throughout the intellectual spectrum. This exact goal is achieved by the full disclosure requirement for patents. The patent rights become public property after the 20-year period from the date of issuance and are open for use by everyone without additional study or improvement. Nonetheless, there are attempts to unfairly extend this monopoly by securing patents for minor or unimportant changes made to the innovation[91]. The term "evergreening" refers to the practice of perpetually extending a patent monopoly. When it comes to pharmaceuticals and drugs, the practice is highly common. In order to maintain their current monopoly over the drug, the patent holder aims to prolong patent protection

[91]Shanti Kumar, Dr. Nitin Shukla, Tanushree Sangal, "Evergreening of Patents and the Indian Patent Law" available at Social Science Research Network on the following link: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1420003

for drug derivatives made from small and unimportant alterations at the time of or even before the patent expires. Evergreening is the result of original manufacturers attempting to "Stockpile" patent protection by securing independent patents covering several features of a single product. These patents can cover any part of the product, including the manufacturing process, the colour of the tablet, and even a molecule that is created by the patient's body after drug ingestion and metabolism. The term "evergreening of patents" traditionally describes the practice of a patent holder trying to obtain multiple and/or cumulative patents covering distinct aspects of a single invention, applied for at key junctures to extend the patent protection beyond the 20-year statute of limitations and stifle generic competition.[92] Evergreening is a very fitting term for the obvious business strategy used by forward-thinking pharmaceutical corporations to add bells and whistles to their products long after the initial patent for such products has expired[93].

To put it simply, the practice of "evergreening" abuses the intellectual property rights awarded to innovative businesses by placing older medications or slight modifications of such medications under patent protection and enabling these businesses to charge exorbitant prices for their necessary medications based on the fact that they have invested a significant amount of money in research and development. In order to gain access to the patent subject matter, generic manufacturers are forced to either wait for the patent period to expire or engage in commercial negotiations with the innovator businesses. Moreover, it manifestly violates the spirit of the policy on competition. Pharmaceutical corporations would concentrate on making little changes to their products and obtaining patents if evergreening were permitted. They would limit their attention to small-scale technologies that have great potential but little risk. It would go against the whole philosophy of intellectual property protection, which encourages innovation to promote wider societal interest and to make society more knowledgeable—both scientifically and technologically—by discouraging risky and laborious R&D efforts, which would be detrimental to the progressive development of science. This would have a negative impact on the millions of people in the third

[92]Michelangelo Temmerman, "The TRIPS Agreement, the Evergreening of Patents and Access to Medicines: Novartis v. India" NCCR Trade Working Paper No. 2008/16, Swiss National Centre of Competence in Research, July 29,2008. Available at www.nccr-trade.org
[93]BINNIE, on behalf of the majority, Supreme Court of Canada, Apotex Inc., and AstraZeneca v. Canada (Minister of Health and Attorney General of Canada), 3 November 2006, 2006 SCC 49, at 39.

world who cannot afford the expensive medications, making them less accessible to those who need them most.

When a product is evergreened through patent methods, the original manufacturer just adds new patents to it, whether they are justified or not, and regardless of whether the product needs to be improved. This so-called "evergreening" effectively prevents rivals and the generic medication business from producing or using any inventions or innovations related to the patent's subject matter, even after the 20-year period has passed. Competitors and the generic industry are deterred from attempting to develop beyond the scope of the current patent due to the high costs and delays involved with litigation. The original manufacturer will create what is euphemistically referred to as "life-cycle management plans" in order to evergreen its products. These plans consist of a variety of tactics, including patent techniques, that are intended to prevent or postpone the release of a generic product onto the market. Pharmaceutical firms use the complexities of patent prosecution procedures to create "bulletproof" patent portfolios cantered upon multimillion-dollar medication compounds. For a given basic innovation, several patents are typically obtained covering a range of inventive aspects, some of which are occasionally useless, without drawing objections to double patenting. By building a portfolio of patents centred around a fundamental idea, "Evergreening" serves as a patent prosecution and management approach that allows for the extension of patent terms. The child's parents can focus on any of the numerous supplementary creative aspects. The European Generic Medicines Association states that during the 1980s, only a small number of a drug's properties—primary uses, processes and intermediates, bulk forms, simple formulations, and composition of matter—were eligible for patent protection. But in the 1990s, the list quickly grew to include patents on other topics, such as (i) a wide range of applications; (ii) treatment methods; (iii) mechanisms of action; (iv) packaging; (v) delivery profiles; (vi) dosage regimen; (vii) dosage range; (viii) dosage route; (ix) combinations; (x) screening methods; (xi) chemistry methods; (x) biological target; and (xi) field of use[94].

As a result, "evergreening" a patent is fully legal in the majority of nations, and the technique is used just like any other business tactic. Many nations, especially those in

[94]anice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation," 68 University of Pittsburgh Law Review (2007), 491

the West, which had previously been beneficiaries of the absence of a patent system but were now strongly lobbying for its introduction, saw a significant transformation in their industries from generic to innovative. This was made possible by the TRIPs Agreement. The responsibilities of developing nations concerning intellectual property have undergone a significant transformation since the World Trade Organization entered the market and adopted its Agreement on the Trade-Related Aspects of Intellectual Property Rights. While flexibility does not change, developing countries have been required since 2005 to grant patents only for new, inventive, and commercially viable inventions; this obligation applies to all inventions, regardless of their location, technology domain, or domestic or foreign production.

The scope of patentability was limited by elaborating on required phrases, such as creative step and novel invention, in accordance with modifications prepared by the Ministry of Business and Industry and approved by the Parliament. Pharmaceutical substances that involve one or more innovative steps will now be eligible for patent protection. The question of whether a pharmaceutical chemical would be classified as a New Chemical Entity (NCE) or a New Medical Entity (NME) was brought up in the parliament. The question of whether restricting the patent to a New Chemical Entity or New Medical Entity, including one or more innovative steps, would be TRIPS compliant was referred to a Technical Expert Committee. The Expert Committee established to investigate these issues, led by Dr R.A. Mashelkar, submitted its report and recommended that every effort be made to provide drugs at affordable prices as well as to prevent the grant of frivolous patents and "ever-greening." In addition, another issue was raised regarding whether it would be TRIPS-compatible to exclude microorganisms from patenting. The Committee further argued that in order to completely limit the risk of awarding bogus patents, the Indian Patent Office should utilise comprehensive rules while reviewing patent applications in the pharmaceutical industry. The Committee further noted that only new drug delivery methods should be eligible for process patents and platform technologies that can be used to increase drug utilisation, patient compliance, and convenience.

4.5.1 Restrictions on India's Ever-Greening: Modifications to the 1970 Patent Act[95]

The Indian Patents (Amendment) Act 2005 aims to prevent evergreening by tightening patentability requirements for small-scale pharmaceutical developments. Section 3(d) excludes minor modifications to existing medications from patent protection unless they improve their efficacy and value. It also forbids the new use of prescribed drugs. The term "new invention" is defined as a novel technique or invention that has not been published elsewhere and has not become public domain. Patent holders face difficulty in securing patents for minor or unimportant modifications to their prior patents. The term "inventive step" refers to elements of an invention that include technological advancement relative to prior art and render the invention not immediately apparent. Small adjustments made to name previous patents will not be accepted.

India vs. Novartis[96] is a case that highlights the challenges in patent law and the need for developing countries to maximise access to medications within the TRIPS Agreement. The case involves Swiss company Novartis AG, which filed a patent application for Imatinib Mesylate, an anti-cancer medication used to treat chronic myeloid leukaemia. The Controller of Patents denied the Gleevec patent in 2006 due to Indian patent law's stricter requirements for novel, inventive drugs.

Novartis filed a lawsuit against Indian pharmaceutical companies, including Medihaux International, Ranbaxy Laboratories, Adarsh Pharma, and Cipla Limited, to prevent them from producing, importing, selling, or distributing the drug. The Madras High Court rejected Novartis' argument that there should be guidelines for determining enhanced efficacy, stating that the term "significant" was legitimate and that there are materials built into Indian patent law that would control and guide the Patent Controller's discretion.

In 2004, the Bombay High Court denied an injunction against Meher Pharma and others for producing, marketing, and exporting their anti-cancer medication under the "B-crystalline form of imatinib Mesylate salt" under the brand name Veenat. The

[95]Husain, N. (2010). "Preventing 'Evergreening' of Pharmaceutical Patents: A Case Study of India's Section 3(d)." Journal of Generic Medicines, 7(3), 217-227. Available at: SAGE Journals
[96]Novartis AG v. Union of India & Others, (2013) 6 SCC 1. Available at: Supreme Court of India

Supreme Court of India rejected Novartis' patent request for Glivec, as the compound did not satisfy the test of novelty or inventiveness required by Indian law.

The verdict is seen as a victory for India and the developing world, providing a huge impetus to the generic drug industry without the fear of exorbitant patent litigation. The Supreme Court's decision will ensure that drug companies will not be able to practice "ever-greening" of patents in India, making many medicines beyond the reach of the poor and common masses.

4.6 ADDRESSING ANTI-COMPETITIVE BEHAVIORS: LEGAL AND POLICY STRATEGIES TO PROTECT MARKET COMPETITION

India's Patents Act, particularly Section 3(d), aims to balance innovation incentives and access by restricting the patentability of minor modifications to known substances unless they show significant efficacy improvements. This helps prevent "evergreening" tactics that delay generic competition. Effective use of pre-grant and post-grant opposition procedures can further curb patent abuse. Regulation of natural monopolies is also important, as many pharmaceutical markets exhibit characteristics of natural monopolies. Governments may need to regulate prices and access to ensure consumers are protected from the negative effects of lack of competition. International cooperation between competition authorities can help address cross-border anti-competitive practices in the pharmaceutical sector, such as collusion or abuse of dominance. By implementing these legal and policy measures, governments can work to maintain competitive, innovative, and consumer-friendly pharmaceutical markets.

In India, mechanisms to limit secondary patents are crucial in balancing pharmaceutical innovation with public health access. These mechanisms primarily focus on stringent patentability criteria, patent examination guidelines, and collaborative examination processes. India's approach to limiting secondary patents emphasises preventive measures through stringent patentability criteria and robust examination guidelines. However, the efficacy of mechanisms aimed at limiting secondary patents, particularly through Section 3(d) of the Patents Act, has been scrutinised with mixed results. Efforts to strengthen scrutiny processes, ensure

consistent application of patentability criteria, and possibly amend the provisions to clarify exclusions could enhance its effectiveness in preventing unwarranted patent extensions and promoting genuine innovation in the pharmaceutical sector.

AstraZeneca was accused by the European Commission of abusing its dominant market position by engaging in practices to delay generic competition for its ulcer drug Losec (omeprazole). AstraZeneca was alleged to have misled patent offices and courts and engaged in litigation settlements that delayed the entry of generic competitors. The Commission argued that these actions constituted unfair competition and violated EU competition law. The European Court of First Instance upheld the Commission's decision, ruling that AstraZeneca had abused its dominant position. This decision underscored the importance of competition law in preventing anti-competitive practices that hinder market entry of generics[97].

4.7 BALANCING INNOVATION INCENTIVES WITH PUBLIC HEALTH CONSIDERATIONS

Patentability criteria, such as novelty, non-obviousness, and utility, are crucial in incentivising pharmaceutical firms to invest in research and development for new drugs. These criteria ensure that only genuinely innovative drugs receive patent protection, fostering the development of novel therapies that address unmet medical needs. Patent expiration and generic entry stimulate market competition, leading to price reductions and increased affordability. Policies that balance patent exclusivity with generic competition, such as Bolar exemptions, enhance consumer welfare by promoting price competition among manufacturers. Patentability criteria also impact access to medicines, particularly in developing countries. Stricter criteria can expedite generic market entry, enhancing the affordability and availability of essential medications. Optimal patentability criteria strike a critical balance, encouraging innovation while preserving competitive markets. This balance is essential for promoting continuous pharmaceutical innovation, ensuring fair pricing, and enhancing consumer welfare.

[97] Hancher, L., & Sauter, W. (2010). "AstraZeneca and EU Competition Law: Thin Evidence, Narrow Law." European Law Review, 35(3), 603-615. Available at: ResearchGate

Balancing innovation incentives with public health considerations in the pharmaceutical sector requires a multifaceted approach that integrates targeted patent policies, flexible competition laws, international collaboration, transparency, tailored incentives, evidence-based policy development, and value-based pricing strategies. Patents play a major role in enabling pharmaceutical companies to charge higher prices for their drugs, as they allow them to exclude others from making, using, or selling the patented invention for a specified period, typically around 20 years. High costs and lengthy timelines associated with pharmaceutical R&D and regulatory approval also contribute to higher drug prices. However, some argue that the link between R&D costs and drug prices is not as direct as claimed, with pharmaceutical companies engaging in "strategic patenting" practices that extend market exclusivity and delay generic competition, even in the absence of significant new innovation.

Implementing and enforcing effective patentability criteria poses significant regulatory challenges, leading to inconsistent application by patent examiners and pharmaceutical companies exploiting loopholes in the patent system. Policymakers have proposed reforms to address these issues, such as implementing a "one-and-done" patent policy, simplifying the patent process, increasing transparency, and collaborating examination processes that involve health regulatory agencies. However, these interventions face resistance from industry and require coordination between different government agencies.

The Bolar exemption[98] refers to legislative provisions that allow generic drug manufacturers to conduct preparatory work to obtain marketing approval before the expiration of patents covering the original drugs. This exemption facilitates early entry of generics into the market after patent expiry. Cases in various jurisdictions, including the United States (Roche v. Bolar)[99] and Europe, have clarified the scope and applicability of Bolar exemptions. These cases often involve disputes over the permissible activities of generic manufacturers during the patent term of originator drugs. The rulings have affirmed the importance of balancing patent rights with public health interests, enabling timely market entry of affordable generic medicines upon patent expiration.

[98] Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984). Available at: Justia
[99] See supra n 32

Merck sued Sigma[100] Pharmaceuticals in Australia over a patent covering an antiviral drug, Penciclovir. The case involved disputes over the validity of Merck's patent and whether Sigma's generic version infringed upon it. It tested the legal principles surrounding patent validity and the scope of protection in the pharmaceutical sector. The Australian Federal Court initially ruled in favour of Merck, finding Sigma liable for patent infringement. This case highlighted the application of patent law to pharmaceutical innovations and the need for clarity in defining patent boundaries.

4.8 CONCLUSION

Section 3(d) of the Indian patent laws has demonstrated considerable efficacy in reducing the number of secondary patents, especially those that are thought to be "evergreening" patents—that is, patents that prolong market exclusivity without providing appreciable additional therapeutic advantages.

There are obstacles in the way of implementing Section 3(d), including different interpretations by patent examiners and applicants' capacity to circumvent its provisions. This has led to situations where patents awarded in India under Section 3(d) may not have been accepted in countries with more stringent patentability requirements, casting doubt on the law's ability to prevent unjustified market monopoly.

In order to improve Section 3(d) mechanisms' effectiveness, the following are necessary: enhancing the examination of patent applications to guarantee strict adherence to the requirements for patentability. Making unclear clauses in Section 3(d) clearer in order to reduce loopholes and stop deliberate patenting. To adjust policies based on actual data, these mechanisms should be regularly monitored and their effects evaluated. Legislators must strike a balance between providing incentives for true innovation and limiting secondary patents, which is essential to preventing the abuse of patent rights. Secondary patents are crucial to the progression of medicine because they frequently lead to little improvements that enhance therapeutic efficacy, safety, and patient outcomes. Although Section 3(d) addresses secondary patents in India, there are still issues to be resolved and alignment with the larger policy goals of

[100] Merck & Co., Inc. v. Sigma Pharmaceuticals (Australia) Pty Ltd, [1999] FCA 1724; (1999) 92 FCR 114. Available at: AustLII

encouraging innovation and guaranteeing cheap access to medications is needed for it to be effective. A balanced approach that meets public health imperatives and innovation incentives in the pharmaceutical sector would require ongoing enforcement and improvement of these systems.

Chapter - 5

CONCLUSION

5.1 INTRODUCTION

The important dual goals of protecting patentability standards and encouraging innovation in the pharmaceutical industry are the driving forces behind India's strict laws governing pharmaceutical patents. These rules are essential in guaranteeing that patent protection is granted to only real inventions that satisfy strict requirements for novelty, non-obviousness, and industrial application. Indian patent law seeks to prohibit patents from being granted for minor adjustments or incremental improvements that do not substantially advance medical science or technology by upholding strict requirements.

Nevertheless, despite these well-meaning laws, it is still difficult to effectively execute and enforce them. The intended impact of strict patent restrictions may be undermined by inefficiencies in the enforcement procedures, such as long litigation proceedings, delays in patent examinations, and difficulties in interpretation. These inefficiencies not only increase the length of time it takes to grant patents but also fuel legal ambiguities and disputes, which can discourage funding for R&D.

Furthermore, the introduction of novel medications and treatments onto the market may be delayed as a direct result of the delayed approval of pharmaceutical patents. Consequently, this postponement could restrict patients' access to novel treatments and potentially life-saving drugs. Such delays can have major public health consequences in a dynamic healthcare environment where quick breakthroughs are essential, especially for patients who are waiting for therapies for serious and life-threatening illnesses.

In addition, ineffective patent enforcement could have unexpected consequences, including monopolistic behaviour and market distortions that further stifle competition and drive up the cost of medications. This may have a negative impact on

healthcare systems, especially in underdeveloped nations where access to reasonably priced medications is already a major problem.

To tackle these obstacles, a diverse strategy is needed. To improve the efficacy of pharmaceutical patent regulations in India, it is imperative to fortify the capabilities and assets of patent offices, augment transparency in the procedures of patent examination, and foster systems for the prompt settlement of patent disputes. Furthermore, it is essential to create a balanced intellectual property ecosystem that promotes innovation and medication accessibility in order to guarantee that strict patent laws accomplish their intended goals without inadvertently creating obstacles to the timely and affordable release of new pharmaceutical products. strict laws controlling pharmaceutical patents in India are essential to upholding high standards of patentability and encouraging creativity, but their effectiveness depends heavily on effective enforcement. India can ensure that patients in need have timely access to novel therapies while simultaneously better-leveraging innovation in the pharmaceutical sector by tackling enforcement issues and advocating for a balanced approach to intellectual property rights.

5.2 RESEARCH ANALYSIS

The pharmaceutical industry operates within a complex framework of patent laws and regulations aimed at balancing innovation incentives with public health priorities. This research aims to critically analyse key challenges faced by the industry, explore the potential benefits of stricter patentability guidelines, and propose improvements to the patenting process. The objectives include assessing existing criteria for patentable inventions, examining practices like "evergreening," and evaluating the impact of patent disputes and guidelines on innovation and accessibility. The pharmaceutical industry encounters several challenges related to patent practices: Pharmaceutical companies often employ strategies to extend market exclusivity beyond the original patent term through minor modifications or reformulations of existing drugs. This practice, known as evergreening, can delay generic competition and maintain higher drug prices, thereby impacting access to affordable medications.: The accumulation of patent disputes, including infringement lawsuits and challenges to patent validity,

adds complexity and uncertainty to the pharmaceutical landscape. These disputes not only tie up judicial resources but also escalate legal costs for companies, diverting resources away from innovation and drug development.

Implementing stricter patentability guidelines in the pharmaceutical industry could yield several benefits, such as Fostering Genuine Innovation. Stricter guidelines would enhance scrutiny on patent applications, ensuring that only truly novel and non-obvious inventions receive patent protection. This focus on genuine innovation encourages pharmaceutical companies to invest in research and development (R&D) that leads to significant therapeutic advancements. Clearer and more stringent guidelines can help mitigate practices like evergreening, where companies seek to extend market exclusivity without substantial therapeutic benefits. By preventing anti-competitive practices, stricter guidelines promote a competitive market environment that benefits consumers through lower drug prices and increased access to medicines.

To promote innovation and ensure access to affordable medications, improvements to the pharmaceutical patenting process should be considered. Evaluating and potentially revising existing criteria to better reflect the evolving nature of pharmaceutical innovation can strengthen patentability standards. This includes assessing the balance between rewarding innovation and preventing the grant of patents for minor modifications that do not offer significant clinical benefits. Developing efficient mechanisms for resolving patent disputes, such as specialised patent courts or expedited procedures, can reduce the burden on the judiciary and minimise legal costs for pharmaceutical companies. This enables quicker market entry for generic drugs and enhances competition. Enhancing transparency in the patent examination process and fostering public participation can improve accountability and trust in the patent system. Stakeholder engagement ensures that patent policies reflect broader societal interests, including patient access to essential medicines.

5.3 ADVANTAGES "STRINGENT GUIDELINES FOR PATENTABILITY"[101]

Stricter rules assist in avoiding the abuse of patent laws to retain market exclusivity beyond what is justified by true innovation by restricting patents to inventions that truly improve patient care[102].

Improved patentability requirements encourage the prompt introduction of generic medications following patent expiration, which increases competition in the pharmaceutical industry. In order to reduce prescription costs and increase patient accessibility, generic competition is essential. When patents are limited to substantial innovations, generic producers have an easier time breaking into the market once the original patent expires. Both original manufacturer and generic manufacturer innovation is encouraged by this competition, which results in more affordable treatment alternatives. Stricter patentability rules encourage competition and prevent artificial market monopolies, which helps increase access to pharmaceuticals, especially for underserved patient populations and lower-income nations. In order to guarantee that patients may take advantage of the most recent medical advancements without facing financial obstacles, affordable access to critical medicines is crucial for public health outcomes.

The goal of patent systems is to achieve a balance between promoting public health objectives and rewarding innovation. Tighter standards for patentability ensure that only innovations that truly advance science are eligible for patents, which helps maintain this balance. This methodology advances medical knowledge in support of larger societal objectives while guaranteeing that healthcare systems can afford to treat individuals in need.

Stricter patentability requirements in the pharmaceutical sector can encourage a more inventive and dynamic business. Stricter regulations encourage competition, enhance drug access, and support sustainable healthcare systems around the world by restricting evergreening activities and limiting patent protection to significant

[101] European Patent Office (EPO). (n.d.). Guidelines for Examination in the European Patent Office. Retrieved from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/index.html
[102] Matthews, D., & Begg, A. (2012). Patent Law Essentials: A Concise Guide (3rd ed.). Federation Press.

innovations. This strategy improves public health and scientific advancement while fortifying the integrity and efficacy of patent systems, which in turn helps patients and healthcare providers.

Simplifying examination processes, guaranteeing thorough prior art searches, and improving patent decision openness are all necessary to improve the pharmaceutical patenting process. This can lessen the number of faulty or irrational patents, which will minimise patent disputes and lighten the load on the courts.

5.4 KEY FINDINGS

Because of current administrative bottlenecks that cause delays in patent approvals, efforts to improve the pharmaceutical industry's patent application processes are essential since they ultimately influence patients' timely access to novel medications. It is imperative to establish specialist divisions for patent examination that possess knowledge in both pharmaceutical research and patent law. This specialisation guarantees that patent applications are thoroughly reviewed by experts who understand the intricacies of drug development. Continuous training initiatives are similarly important for patent examiners since they improve their knowledge of pharmaceutical developments and legal requirements, allowing for thorough but efficient evaluations. The patent application review process can be greatly accelerated by giving priority to patent applications for important medical discoveries or cures for uncommon diseases, indicating the pressing healthcare needs these innovations address.

Building confidence and accountability in the patent awarding process requires transparency. Encouraging policies and procedures for providing input helps to improve the standard and equity of patent judgments. Cooperation and standardisation of patent examination procedures are beneficial on a global scale, allowing for the quick recognition of patents across borders and stimulating innovation and access to medications. Through discussions and feedback systems, the public and stakeholders are brought into the patent examination process, providing insightful viewpoints and bolstering the legitimacy and societal acceptance of patent decisions. In addition, providing rewards for superior patent applications encourages careful planning and

filing, producing copious amounts of information and proof of invention that speed up evaluations and decision-making. All of these projects are meant to increase the effectiveness and efficiency of patent systems in fostering pharmaceutical innovation and swiftly satisfying healthcare demands.

5.5 SUGGESTIONS

A number of crucial tactics can be used to improve the efficacy and efficiency of patent application procedures in the pharmaceutical industry. First, filing and processing can be streamlined by utilising digital platforms and automated systems, which will shorten administrative bottlenecks and speed up initial evaluations. Specialising divisions within patent offices handling pharmaceutical patents, manned by specialists in pharmaceutical research and patent law, guarantee thorough but expeditious review of applications. Assessment capabilities can be further enhanced by ongoing training programs for patent examiners that concentrate on pharmaceutical developments and regulatory norms.

It would be beneficial to provide prioritisation procedures for patent applications pertaining to rare illness therapies or important medical advancements in order to expedite the evaluation of inventions that have a major impact on public health. Working together, patent offices, pharmaceutical companies, academic institutions, and healthcare practitioners can expedite application evaluations and offer insights into state-of-the-art advances. Ensuring fairness and quality assurance in the patent granting process requires transparency, coupled with well-defined norms and accountability procedures.

It is crucial to conduct regular assessments of patent examination procedures that take stakeholder input into account in order to find and apply improvements that preserve system integrity. By facilitating faster global recognition of patents through international cooperation to unify patent examination standards, pharmaceutical innovation is supported on a larger scale. Public participation in hearings and consultations increases legitimacy and transparency while providing insightful viewpoints on how patent decisions affect society.

Last but not least, rewarding superior patent applications with complete information and proof of innovation promotes careful planning and speeds up evaluations. All of these steps work together to streamline the patenting process, guaranteeing prompt access to cutting-edge medications while maintaining exacting standards of assessment and responsibility.

In conclusion, pharmaceutical corporations gain from increased judicial capacity, but the public's need for access to reasonably priced drugs is also served. Effective patent dispute settlement promotes competition by allowing generic medications to enter the market sooner, which lowers prescription costs and increases access to healthcare. To support a well-balanced pharmaceutical market, funding for specialised IP courts and judge training programs is important. Governments may encourage innovation and guarantee that patients have access to reasonably priced pharmaceuticals by accelerating the resolution of patent disputes, cutting down on litigation expenses, and improving legal clarity. These programs support the development of a regulatory environment that promotes equitable competition, safeguards intellectual property rights, and improves public health outcomes.

Ensuring timely and efficient patent grants in the pharmaceutical sector is crucial for facilitating timely access to innovative medicines, which are essential for treating diseases and improving public health outcomes. The process of granting patents must strike a delicate balance between expediency and rigorous scrutiny to uphold the integrity of patent rights while preventing abuses such as "evergreening."

Prompt patent grants enable pharmaceutical innovators to secure exclusivity for their inventions, thereby incentivising substantial investments in research and development (R&D). This incentivisation drives continuous innovation in medical science, leading to the discovery of new therapies that address unmet medical needs and improve patient outcomes. Moreover, timely patent grants foster a competitive marketplace where innovators can recoup their investments and fund future R&D endeavours.

However, the expedited patent granting process must not compromise on the quality and thoroughness of patent examination. Effective scrutiny ensures that patents are

granted only for inventions that genuinely contribute to scientific progress and patient care rather than for trivial modifications or minor advancements. Rigorous evaluation of patent applications, including assessments of novelty, non-obviousness, and industrial applicability, is essential to uphold the integrity of the patent system and prevent monopolistic practices that could hinder access to affordable medicines.

The efficient and effective grant of patents in the pharmaceutical industry is pivotal for promoting innovation, improving healthcare outcomes, and fostering economic growth. By streamlining the patent-granting process without compromising on scrutiny, governments and regulatory bodies can support a vibrant ecosystem where innovative medicines reach patients swiftly while ensuring that patent rights are granted responsibly and ethically. This approach not only benefits pharmaceutical innovators but also facilitates broader access to transformative treatments that address global health challenges.

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Appendix

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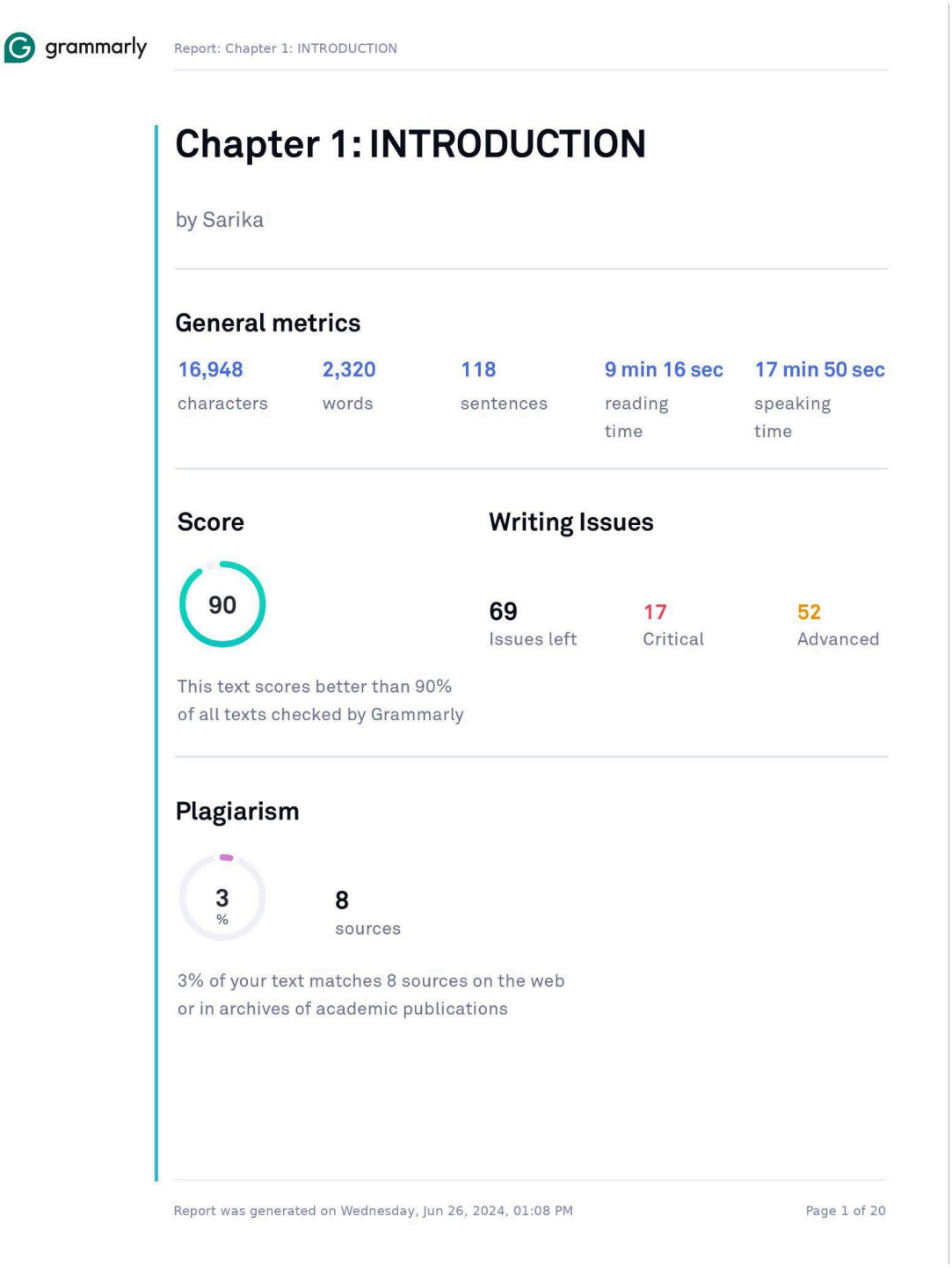

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