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EFFICACY UNDER SECTION 3(d): AN ANALYSIS THROUGH THE LENS OF INDIAN JUDICIARY

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CERTIFICATE

This is to certify that Ms. Divya Elizabeth Sebastian, REG NO: LM0321012, has submitted her Dissertation titled "EFFICACY UNDER SECTION 3(d): AN ANALYSIS THROUGH THE LENS OF INDIAN JUDICIARY" in partial fulfilment of the requirement for the award of the Degree of Master of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bona fide and genuine.

Dr Liji Samuel

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Date: 30.07.2022

Place: Ernakulam

DECLARATION

I declare that this Dissertation titled "EFFICACY UNDER SECTION 3(d): AN ANALYSIS THROUGH THE LENS OF INDIAN JUDICIARY" is researched and submitted by me to the National University of Advanced Legal Studies, Kochi, in partial fulfilment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Dr Liji Samuel, Associate Professor and is an original, bona fide and legitimate work. It has been pursued for academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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LIST OF ABBREVIATIONS

AIR: All India Reporter

DIPP: Department of Industrial Policy & Promotion

DPSP: Directive Principle of State Policy

DSB: Dispute Settlement Body

DSS: Dispute Settlement System

EMR: Exclusive Marketing Right

EPO: European Patent Office

EU: European Union

GATT: General Agreement on Tariffs and Trade

GoM: Group of Ministers

IPAB: Intellectual Property Appellate Board

IPR: Intellectual Property Right

LDC: Least Developed Countries

Mad. HC: Madras High Court

MIPR: Manupatra Intellectual Property Reports

MLJ: Madras Law Journal

MNC: Multinational Corporation

MoU: Memorandum of Understanding

NGO: Non-governmental Organisation

OD: Once a day

PCT: Patent Co-operation Treaty

SC: Supreme Court

TPRB: Trade Policy Review Body

TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights

TSM: Teaching Suggestion Motivation

UK: United Kingdom

UM: Utility Model

UOI: Union of India

US: United States of America

USIBC: US India Business Council

WIPO: World Intellectual Property Organization

WP: Writ Petition

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CHAPTER I
INTRODUCTION

1.1. INTRODUCTION

The 2005 amendment to the Patent Act,1970, has made some radical changes to the patent law regime in India.[1] It introduced the concept of product patents in India.[2] Much of the amendments were made to make the Indian law consistent with the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS")[3] since India is a signatory to the TRIPS.

Insertion of Section 3(d)[4] is vital to the pharmaceutical sector. From the provision's wording, it can be inferred that clause(d) of Section 3 explicitly covers chemical substances.[5] The issues pertaining to Section 3(d) that were raised before the Indian courts majorly dealt with the patentability of pharmaceuticals. The provision is worded negative and provides for "what does not qualify as patent". This provision grabbed much attention in the famous *Novartis v. Union of India case*[6] ("Novartis case"). The case involved the question of granting the patent for a drug, *Glivec*, used in cancer treatment.[7] The patent application was filed in 1998 under the mailbox system. However, it was only taken into consideration after the 2005 Amendment. The Madras Patent office rejected the application. The Madras High Court has rightfully analysed and upheld the constitutionality of Section 3(d).[8] The Madras High Court narrowly interpreted the requirement of "enhancement of efficacy" as the requirement of therapeutic efficacy.[9] On appeal, the matter came up before the Intellectual Property Appellate Board ("IPAB"), Chennai.[10] It was followed by the 2013 Supreme Court

[1] The Patents (Amendment) Act,2005, No. 15, Act of Parliament, 2005 (India).
[2] *Id.*
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade organisation, Annex 1C. [hereinafter TRIPS]
[4] The Patents (Amendment) Act,2005, § 3, No. 15, Act of Parliament, 2005 (India).
[5] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[6] AIR 2013 SC 1311.
[7] Novartis AG v. Union of India, AIR 2013 SC 1311.
[8] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[9] *Id.*
[10] Novartis AG v. Union of India, MIPR 2009 (2) 345.

("SC") judgment in which the issue was finally settled.[11] The SC, too, ruled against the granting of the patent.[12] Many discussions and debates have happened regarding the various interpretations made by the courts. One of the main discussion points is quantifying the "test of efficacy" under Section 3(d).[13] The courts, in their judgments, have adopted a narrow interpretation of the efficacy that is limited to therapeutic efficacy.

1.2. SCOPE OF STUDY

The research work aims to explore Section 3(d), the Patent Act,1970,[14] in accordance with judicial pronouncements and international agreements. The research work examines the qualifications for "efficacy" in the Indian patent law regime. The 2013 judgment of the apex court in *Novartis AG v. Union of India*[15] was among the first few cases that challenged Section 3(d).[16] In this case, the Court limited the definition of efficacy to "therapeutic efficacy".[17] Much of the research is based on this particular judgment's context and explores the subsequent decisions. The research work analyses the constitutionality of Section 3(d)[18] and its compatibility with the TRIPS Agreement. Similar provisions in other countries are also compared with. The narrow definition of "enhancement of efficacy" adopted by the SC[19] is analysed in the Indian patent law regime context.

1.3. RESEARCH PROBLEM

Patenting of pharmaceuticals is a highly contested topic across the world. There does not exist a single answer to this issue. The approaches adopted by countries vary across the globe. In the Indian scenario, the much-contested provision is Section 3(d), the Patents Act,1970. The provision provided for the "test of efficacy". The issue with the provision is that the term "efficacy" is nowhere defined in this context. The legislature has wholly left the interpretation of the term with the judiciary. The jurisprudence of

[11] Novartis AG v. Union of India, AIR 2013 SC 1311.
[12] *Id.*
[13] The Patents Act, 1970,*Supa* note 5, at § 3(d).
[14] *Id.*
[15] AIR 2013 SC 1311.
[16] Novartis AG v. Union of India, AIR 2013 SC 1311.
[17] *Id.*
[18] The Patents Act, 1970, *Supa* note 5, at § 3(d).
[19] Novartis AG v. Union of India, AIR 2013 SC 1311.

Section 3(d) is still evolving. The proper interpretation of Section 3(d) is crucial for the pharmaceutical sector and the public. So far, the courts have narrowly interpreted the term "efficacy". There is a need to analyse whether the narrow interpretation is suitable for the Indian scenario.

1.4. OBJECTIVES

1. To explore the rationale and significance of Section 3(d), Patent Act,1970, in the Indian pharmaceutical sector in protecting public health.

2. To analyse Section 3(d) and its compliance with TRIPS.

3. To identify the significance of the Novartis v. Union of India (SC, 2013) in the Indian pharmaceutical sector.

4. To analyse the interpretation of Section 3(d) by Indian courts.

5. To analyse the interpretation of "efficacy" in Section 3(d) by Indian courts.

1.5. RESEARCH QUESTIONS

1. What is the role of S.3(d) in the Indian patent-pharmaceutical law regime?

2. Is Sec.3(d) in compliance with the TRIPS?

3. Does Sec.3(d) serve the purpose of preventing the evergreening of patents?

4. What is the scope of "enhanced efficacy" as deliberated in the *Novartis case*?

5. Has the Indian courts reached a specific criterion for measuring the requirement of "enhanced efficacy"?

1.6. HYPOTHESIS

India being a welfare state, the law should always be interpreted in favour of the public interest. The Indian courts have narrowly interpreted "enhancement of efficacy" under Section 3(d), the Patents Act, 1970,[20] as "therapeutic efficacy".

[20] The Patents Act, 1970, *Supa* note 5, at § 3(d).

1.7. METHODOLOGY

The research methodology used in this research work is the doctrinal method. The primary sources include various international agreements, national legislations and articles that deal with patent law. The secondary sources include journal articles, white papers, books, and commentary on legislation.

1.8. REVIEW OF LITERATURE

The research has depended on the primary resources, including the Constitution of India, the Patent Act 1970, the TRIPS Agreement, and various legislations and case laws. The research has also relied on secondary resources, books, and commentaries to understand the subject and analyse the multiple topics properly. The research extensively depends upon electronic resources like online databases and websites for gathering resources.

1. *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*[21]- The article analyses the *Novartis* judgment of the High Court of Madras on the constitutionality and TRIPS compatibility of Section 3(d), Patents Act,1970. It focuses on making a clear distinction between the pharmaceuticals that are eligible to be patented and not eligible to be patented. The article also provides specific suggestions to be made to the contested provision and even calls for the amendment of the requirement.
2. *Indian pharmaceutical patent prosecution: The changing role of Section 3(d)*[22]- This paper examines changes in the use of the provision using a new data source, the patent office's first examination reports. The paper argues that there has been a significant increase in the use of Section 3(d) over time, including on the central claims of patent applications. However, it is still used in conjunction with other types of patentability objections. The paper provides that there has been a significant increase in the use of the provision against primary patent applications, which goes against the provision's intent, raising concerns about potential overuse.

[21] Shamnad Basheer & T. Prashant Reddy. *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d).* 5 SCRIPTed. 232, (2008).
[22] Sampat BN & Shadlen KC , *Indian pharmaceutical patent prosecution: The changing role of Section 3(d)*, 13(4) PLoS ONE, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0194714.

3. *Trials and TRIPS-ulations: Indian Patent law and Novartis AG v. Union of India*[23]- The article begins with an in-depth analysis of the evolution of patent laws in India. To be effective, India's patent law must be clear and consistent. The 2005 Amendment and Section 3(d) injected significant confusion into Indian patent law. India is an interesting case study since its massive population is gradually changing into a global force. Its enormous generic pharmaceuticals business, which provides drugs to both developing and developed countries throughout the world, is also beginning to be able to exploit India's trained workforce. The consequences of a country's patent system on local businesses and public health are apparent. India should proceed cautiously in making decisions that would change India's generally conservative approach to patent policy. More substantial intellectual property rights, such as novel use patents or patents on recognised chemical derivatives, may assist India's pharmaceutical industries by promoting innovative research and development.
4. *Is Section 3(d) Consistent with TRIPS?*[24]- This article examines how various policy regimes worldwide evaluate inventions and analyses Indian rules in this light. Well-drafted and scientific legislation to apply the inventive step criterion might prevent the majority of the issues presented by Section 3(d) of the Indian Patents Act, which is consistent with the Trade-Related Aspects of Intellectual Property Rights Agreement.
5. *Whose interest ? Independent India's patent law and policy*[25]- The article traces the history of the Indian patent law regime since the British era. It delves into a detailed discussion on the various committee reports and the measures adopted by the Government of India to protect the national interests. The article argues that the operation of the patent legislation as a decision-making process has not harmed foreign patent holders, even though the administration through which applications are handled leaves much to be desired. However, foreign patent holders grasped the system and learnt how to continue their dispute courts under

[23] Linda L. Lee, *Trials and TRIPS-Ulations: Indian Patent Law and Novartis AG v. Union of India*. 23 BERKELEY TECH. L.J., 281 (2008).
[24] Carlos M Correa, *Is Section 3(d) Consistent with TRIPS?* 48 Economic and Political Weekly, 49–52 (2013).
[25] Rajeev Dhavan, Lindsay Harris & Gopal Jain, *Whose interest ? Independent India's Patent Law And Policy*, 32 Journal of the Indian Law Institute, 429–77 (1990).

the protection of interim injunctive relief in the Patent Act 1970. Previously, it was considered and presented as a declaration of socialist ideology.

6. *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*[26]- The article briefly discusses the amendments to the Patent Act, 1970, after India became a signatory to the TRIPS in 1995. It focuses on the various flexibilities that have been incorporated into the Indian legislation that has been provided under the TRIPS Agreement to its member states.
7. *Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India*[27]- The article summarises Indian patent law as it applies to pharmaceuticals, discusses the issues the law is now experiencing and recommends some alternative approaches India may desire to take. Various points raised during the Novartis case are also addressed. It concludes that, while the Indian SC's decision in the Novartis case may benefit the developing world and those in need of inexpensive pharmaceuticals, it ultimately marks a missed opportunity for the Court to clarify section 3(d), which would stimulate international investment and spur growth and innovation in the local pharmaceutical and biotech sectors.
8. *IP strategies and policies for and against evergreening*[28]- This research examines the phenomena of evergreening. It addresses various forms of evergreening techniques along with basic models. The paper discusses the consequences of the management of counter strategies and innovation and intellectual property legislation.
9. *May your drug price be evergreen*[29]- This article investigates how evergreening activity may contribute to the problem. The author examines every incident in which a company added a new patent or exclusivity from 2005 to 2015. The findings represent a surprising shift from the traditional pharmaceutical intellectual property protection view. Instead of developing new drugs,

[26] 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).
[27] William J. Bennett, *Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India*, 13 WASH. U. GLOBAL STUD. L. REV. 535 (2014).
[28] Ove Granstrand &Frank Tietze, *IP strategies and policies for and against evergreening*. 1 Centre for Technology Management working paper series (2015).
[29] Robin Feldman. *May your drug price be evergreen*, 5 Journal of Law and the Biosciences, 590–647 (2018).

pharmaceutical companies recycle and repurpose old ones. Specifically, seventy-eight per cent of the drugs related to new patents were not novel drugs but existing ones, and the trend of extending protection is most noticeable among blockbuster drugs. Once a company begins to prolong protection, it tends to return to the well, with the majority adding more than one extension and fifty per cent being serial violators. The situation is becoming worse with time.

10. *"Ducking" TRIPS in India: A saga involving Novartis and the legality of Section 3(d)*[30]- The article analyses the various issues raised before the High Court of Madras in *Novartis v. Union of India*. The article infers into the righteousness of the Court in reaching its decision on each issue that was considered. It also analyses the entire history of the Novartis patent application till the conclusion of the High Court of Madras.
11. *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d)*[31]- The article is based on the judgment of the SC of India in *Novartis AG v. Union of India* in 2013. It makes the following claims: Section 3(d) of the 2005 Amendment to the Indian Patents Act is not consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the World Trade Organization's (WTO) minimal criteria for intellectual property protection, according to the Indian SC's interpretation. Regardless of TRIPS compliance, requiring efficacy for secondary patents under Section 3(d) may assist India in striking a better balance between pharmaceutical innovation and India's public health concerns than stringent TRIPS compliance. A broad interpretation of Section 3(d)'s enhanced efficacy requirement would be the most compatible with Section 3(d)'s claimed objective of preventing patenting minor alterations to the prior art, although imperfectly. A definition of efficacy as therapeutic efficacy generates an unprincipled distinction between "therapeutic" and other "efficacy" that does not conform with patent law theory but may benefit India's public health goals. As India's underlying objective for Section 3(d) is incompatible with patent law theory, India should make the

[30] Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
[31] Dorothy Du, *Novartis Ag v. Union of India: "Evergreening," Trips, and "Enhanced Efficacy" Under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).

actual aim of Section 3(d) plain and argue that it should not have been compelled to comply with TRIPS by 2005 completely. Novartis is an example of a pharmaceutical product that would meet the more important requirement of enhanced efficacy but would fail the narrower requirement of "enhanced therapeutic efficacy" despite a considerable improvement over the prior art.

1.9. CHAPTERISATION

CHAPTER 1: INTRODUCTION

The introductory chapter gives a basic framework within which the research is conducted. It denotes the study's objectives, the research problem, the research question, and the hypothesis to be tested. The literature review is also included in this chapter. A brief idea about the contents of all the subsequent chapters is also laid down.

CHAPTER 2: ANALYSIS OF SECTION 3(d) IN THE CONTEXT OF TRIPS

The chapter focuses on the formulation and evolution of Section 3(d) from a TRIPS perspective and analyses the compatibility between the two. The enactment of Section 3(d) into the patents Act, 1970 was under the flexibility provided under TRIPS. Since it was tailor-made for the Indian law, not all nations, specifically the United States, were not happy with India enacting such a law. Even though not the same, certain other countries also have national laws similar to Section 3(d). Tracing the history of WTO and TRIPS is crucial since India is a signatory to these international agreements. This implies that national laws should not be a violation of international agreements. This points toward the pivotal role of WTO and TRIPS in shaping the Indian patent law regime.

CHAPTER 3: SECTION 3(d) & THE INDIAN PATENT LAW REGIME

The chapter is entirely dedicated to perusing the legal and policy history of the Indian patent law regime. The history of patent law in India commenced before its independence. The British laws heavily influenced the patent law in India, as the British implemented the first legislation on patents in 1856 in India. The Indian legislation is built upon the Constitution of India. The constitutionality of intellectual property rights

arises from Article 300. It recognises intellectual property as property. Only in 1972 was exclusive legislation on patents enacted in India. The Ayyangar Committee Report is the substratum upon which the Indian patent law regime is built. After that, the various ingredients of Section 3(d) are analysed in detail in comparison with provisions in other jurisdictions.

CHAPTER 4: THE INTERPRETATION OF SECTION 3(d) BY THE INDIAN COURTS: NARROW OR WIDE?

This chapter is dedicated to analysing the interpretation of Section 3(d) by Indian courts through its decisions. The interpretation of Section 3(d) by the SC was in the case of *Novartis v. Union of India* (2013). The chapter analyses the fundamental issues the courts have dealt with while analysing the provision. The other decisions by different Indian courts post-*Novartis decision* are also briefly explored.

CHAPTER 5: CONCLUSIONS & SUGGESTIONS

The final chapter concludes the research work findings based upon the court's interpretation in its decisions.

CHAPTER II

TRIPS AND SECTION 3(d)

2.1. INTRODUCTION

The TRIPS Agreement[32] has played a crucial role in the development and the enactment of Section 3(d), the Patents Act,1970.[33] Therefore understanding the brief history of WTO and TRIPS is essential in understanding the underlying objective of the provision. Since the research questions involve the patentability of pharmaceuticals, a brief description of the characteristics of intellectual property, particularly that of patents, is also briefly discussed. TRIPS remains to be the international authority regulating the protection of intellectual properties across different countries. The signatory nations of the TRIPS have modelled their intellectual property laws per the TRIPS requirements. The amendment of Section 3(d) stems from the requirement under the TRIPS. More specifically, the provision can be regarded as adopting flexibility under TRIPS.

Even though the patent is a territorial right, the United States has expressed their dislike of adding Section 3(d) to the Indian Patent law.[34] The reasons for the displeasure of the United States are also mentioned and analysed.[35] One among the uniqueness of Section 3(d) is that there does not exist an exact parallel provision elsewhere in the world. However, there do exist a few similar requirements across different countries.[36] The chapter further discusses identical conditions in other jurisdictions and their benefits. The chapter dwells on the evolution of Section 3(d) based upon the TRIPS and analyses the provisions according to the TRIPS requirements.

[32] TRIPS Agreement, *supra* note 3
[33] Patents Act, *Supa* note 5, at § 3(d).
[34] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, THE SPECIAL 301 REP. (2014), https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.
[35] *Id.*
[36] Arora S & Chaturvedi R, *Section 3(d): Implications and key concerns for pharmaceutical sector*, 21(1) Journal of Intellectual Property Rights, 16-26, (2016).

2.2. HISTORY OF TRIPS

On 1 January 1995, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into being.[37] It can be regarded as the most extensively drafted multilateral agreement on intellectual property.[38] Intellectual Property Rights (IPR) denote the rights granted to any person in connection with the creations of their mind.[39] Granting intellectual property rights enables the creator to enjoy the exclusive rights that come with the recognition as intellectual property for a limited period. Each nation individually does the granting of the status of IPR.[40] Therefore, the rights granted by being an intellectual property are available only within the nation's territorial boundaries that have granted the right. The World Trade Organisation categorises intellectual property rights into two broad categories: copyright and rights related to copyright and industrial property.[41] Under the category of copyrights and rights related to copyrights, the rights of authors of artistic and literary works (which includes computer programmes, books, films, musical compositions, sculptures, writings and paintings) for at least 50 years from the date of death of the author.[42] The rights of the performers (actors, musicians and singers), broadcasting organisations and producers are also protected by virtue of the copyright protection.[43] The intention behind copyright protection and related rights is to incentivize and guerdon the creative piece of work.[44]

Industrial property includes two further categorisations. This distinction is mainly based on their purpose.[45] Industrial designs, Patents and trade secrets fall under a similar category in which protection of the industrial property is for the encouragement of design, innovation and the development of technology.[46] It incentivises further technological development and research. The other category consists of geographical

[37] TRIPS Agreement, *Supra* note 3
[38] TRIPS — Trade-Related Aspects of Intellectual Property Rights, WTO. https://www.wto.org/english/tratop_e/trips_e/trips_e.htm.
[39] WTO, *What are intellectual property rights*? https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.
[40] WTO, *Intellectual property: protection and enforcement*. https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.
[41] WTO, *Supra* note 40.
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] WTO, *What are intellectual property rights?* https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.

indications and trademarks.[47] The protection of these distinctive signs aims to protect the customers' interests by making them capable of making informed choices between the numerous goods and services available in the market and of establishing fair market competition.[48]

One of the objectives behind granting IPR protection is to stimulate technological innovation and creative work and to enable the benefits to reach the public, thereby promoting cultural, social and economic welfare. It serves the social purpose of encouraging and rewarding creative work. Specifically, in the case of patents, the articulation of the rights is in such a way as to incentivise the research and development by availing protection for innovations as a result of investment in the research and development.

From an economic point of view, the absence of proper regulations and IP protection makes it difficult for the creators of the intellectual property to monetise their creation or extract financial returns.[49] Also, most of these creations and innovations are characterised by public good features. Therefore, non-regulation of them will lead to the non-exclusion of their consumption. Along with that, it has to be ensured that the use of an invention or work by a person does not lead to the deprivation of any other person from using the same work in the absence of any other legal restraints. It is undeniable that from the perspective of society, there is always a risk of market failure, as this may lead to underinvestment in instances of socially beneficial innovative and creative work.

Nevertheless, the IP system allows for the creation of products and technology development in response to the demand, allowing market-driven decentralised decision making. The territorial nature of Intellectual Property Rights forms part of their fundamental nature.[50] The principle of territoriality is of great significance in the intellectual property rights regime.[51] The concept of territoriality enables the respective

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[47] WTO, *What are intellectual property rights?* https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm.
[48] *Id.*
[49] WTO, *The Economics of Trips* https://www.wto.org/english/tratop_e/trips_e/trips_econprimer1_e.pdf.
[50] Marko Schauwecker, *Extraterritoriality in Patent Law: A Comparative Analysis of Extraterritorial Application of Patent Law*, Stanford Law School, https://law.stanford.edu/projects/extraterritoriality-in-patent-law-a-comparative-analysis-of-extraterritorial-application-of-patent-law/.
[51] Slobodan Markovic, *Global Administrative Crisis of the Patent System* ,2007 Annals FAC. L. BELGRADE INT'l ED. 50 (2007).

nations to tailor-make their respective intellectual property laws and regulations to meet the nation's individual needs to boost their development in economic and technological fields.[52] In analysing the role of IPR as a public policy tool, the objective is to balance the interests of the users and the rights holders by subjecting them to numerous exceptions and limitations as intellectual property rights are not absolute and unlimited.[53] Effective implementation of the system satisfying its objectives and balancing the competing public policy interests by way of the defined scope of patentable subject matter and limited term of protection in addition to the exceptions and limitations are relevant.

At the international level, the World Trade Organisation (WTO) remains the institutional and legal foundation for the administration and development of trade relations.[54] It was established by way of the Marrakesh Agreement, which was enacted on 1 January 1995.[55] A total of 164 nations are members of it.[56] The objective of WTO is to ensure fair and equitable standards for carrying out international trade and employing trade and investment to help raise living standards.[57] Before the establishment of WTO, the General Agreement on Tariffs and Trade (GATT) regulated the international trade scenario.[58] The trade regulations were mainly pursued under the various trade rounds undertaken to strengthen the regulations. The Uruguay Round was the most comprehensive of all the trade rounds. The eighth round of trade negotiations, popularly known as the Uruguay round, was launched in 1986 and was concluded in 1994.[59] The Uruguay round witnessed the development of extending trade to services and intellectual property.[60] This reflected the emerging importance and their increasing share in international trades. The creation of the WTO was an essential contribution of the Uruguay rounds.[61] The formation of the organisation was intended for the

[52] *Id.*
[53] Alexander Peukert, *Territoriality and Extraterritoriality in Intellectual Property Law. Beyond Territoriality: Transnational Legal Authority in an Age of Globalization*, Queen Mary Studies in International Law, Brill Academic Publishing, Leiden/Boston, 189-228 (2012).
[54] CRAIG VANGRASSTEK, THE HISTORY AND FUTURE OF THE WORLD TRADE ORGANIZATION (WTO 2013).
[55] Marrakesh Agreement Establishing the World Trade Organization, Apr.15, 1994, 1867 U.N.T.S. 154 [hereinafter Marrakesh Agreement].
[56] *Id.*
[57] CRAIG VANGRASSTEK, *Supra* note 54.
[58] *Id.*
[59] THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, (Jayashree Watal & Antony Taubman eds., WTO 2015).
[60] *Id.*
[61] CRAIG VANGRASSTEK, *Supra* note 54.

administration of the agreements.[62] The GATT, 1994 and the TRIPS Agreements are annexed to the WTO agreement.[63] Therefore, these documents do not have a separate legal existence outside the realm of the WTO Agreement. The previous GATT, or the GATT, 1947, consists of numerous provisions relating to intellectual property.[64]

The Uruguay round was preceded by the Tokyo Round of multilateral trade negotiations, which lasted from 1973 to 1979.[65] After that, many have argued for the need to include intellectual property aspects. This resulted in the formation of a negotiating group on "Trade-Related Aspects Of Intellectual Property Rights" (TRIPS) in 1986 to protect and promote intellectual property rights.[66] Further, in 1989 the group attained a full mandate to discuss TRIPS in the mid-term review of the overall Uruguay Round.[67] This decision of 1989 is regarded as the cornerstone of the present structure of the TRIPS Agreement.[68] During 1989 and 1990, prominent players, the European Union, Japan, Switzerland, the United States and a group of fourteen developing countries submitted their proposals.[69] Based on these proposals, a text was prepared, and negotiations were carried on based upon this text. Although certain aspects, including the language of the text, were agreed upon, specific other issues relating to copyrights, patents and transition period were not agreed upon. Towards 1991, much progress was made regarding patent provisions dealing with compulsory licensing, test data protection, exhaustion of rights, exceptions to patentability and transition periods.[70] In 1991 during the tenure of Arthur Dunkel as the Director General of the GATT, the Draft Final Act, famously known as the "Dunkel text", was released.[71] In the Final Act of 1993, the limiting scope of compulsory licensing of semi-conductor technology (Article 31(c)) and the text on the moratorium on so-called "non-violation

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[62] THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, *Supra* note 59.
[63] CRAIG VANGRASSTEK, *Supra* note 54.
[64] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].
[65] The Tokyo Round negotiations (1973-1979) resulted in anti-dumping agreements, government procurement, technical trade barriers, and other non-tariff measures known as "codes."
[66] GRAEME B. DINWOODIE AND ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME (Oxford Scholarship Online 2012).
[67] *Id.*
[68] THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, *Supra* note 59.
[69] *Id.*
[70] *Id.*
[71] Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Dunkel Draft), excerpts pertaining to TRIPS (1991).

complaints" in dispute settlement cases (Article 64.2 and Article 64.3) were added in addition to the Draft Final Act,1991.[72]

2.3. WTO AND TRIPS

The TRIPS Agreement forms an intrinsic part of the WTO Agreement and is binding on all members. The Marrakesh Agreement,[73] regarded as the establishing document of the WTO, contains the TRIPS Agreement in its Annex 1C.[74] The TRIPS Council was headed with the duty of administration of the TRIPS Agreement.[75] In order to make the member states quickly adapt to these new rules and regulations, the WTO members were allowed transition periods.[76] The General Council forms the second tier in the WTO structure and is headed by the Ministerial Conference.[77] The WTO General Council includes representatives from all member nations and meets around five times annually.[78] In situations where the Ministerial Conference is not in session, the General Council is empowered to adopt decisions on behalf of the conference.[79] The authority over the Trade Negotiations Committee is also vested with the General Council.[80] The General Council consists of three sectoral councils, including the TRIPS Council.[81] The other two sectoral councils are the Council for Trade in Services and the Council for Trade in Goods. The Dispute Settlement Body (DSB) and the Trade Policy Review Body (TPRB) consist of the General Council and distinct chairpersons. The DSB deals with all sorts of disputes relating to the Trips Agreement. The Trade Policy Review Body is authorised to conduct trade policy reviews as required by the Trade Policy

[72] THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, *Supra* note 59.
[73] Marrakesh Agreement, *Supra* note 55
[74] *Id.*
[75] TRIPS, art. 68.
[76] TRIPS, art. 65.
[77] WTO, *Whose WTO is it anyway? understanding the WTO: the organization.* https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm#:~:text=Second%20level%3A%20General%20Council%20in%20three%20guises&text=The%20General%20Council%20acts%20on,to%20analyse%20members'%20trade%20policies.
[78] WTO, *The WTO General Council*, https://www.wto.org/english/thewto_e/gcounc_e/gcounc_e.htm.
[79] *Id.*
[80] WTO, *Supra* note 77.
[81] WTO, *TRIPS — Trade-Related Aspects of Intellectual Property Rights,* https://www.wto.org/english/tratop_e/trips_e/trips_e.htm.

Review Mechanism of the WTO Agreement.[82] The WTO Agreement acts as a master agreement for the TRIPS Agreement and the other trade-related agreements.

The TRIPS Agreement provides for a comprehensive multilateral agreement exclusively on intellectual property. The document contains provisions on the application of the dispute settlement mechanism provided under WTO,[83] enforcement and administration of IPRs,[84] different IPRs[85] and standards for protecting the IPRs.[86] The Uruguay round directives largely influence the Preamble of the TRIPS Agreement. The reading together of Article 7,[87] Article 8[88] and the Preamble provides the spectrum of objectives, principles and general goals of the TRIPS Agreement. The objectives focus on balancing the interests of the rights holder and the user. The establishment of intellectual property protection was not solely to foster technological innovations. It parallelly upholds the more significant social interests in enhancing the economic and social welfare by transferring and disseminating technologies to balance the rights and obligations so that both the producers and the users benefit. Article 8, dealing with "Principles", provides for the right exercised by the states to enact specific rules and regulations to prevent the abuse of intellectual property rights and protect its interests in public health and other social interests.[89] These rules and regulations adopted by the states should align with the provisions under the TRIPS Agreement. The preamble provides for the fundamental objective behind having the document.[90] It provides for endorsing the adequate and effective protection of intellectual property rights, curtailing impediments and distortions to international trade and ensuring that the numerous measures and procedures for implementing intellectual property rights do not cause impediments to lawful trade.[91] It is provided in the Doha Declaration on the TRIPS Agreement and Public Health, 2001[92] that "*in applying the customary rules of*

[82] Trade Policy Review Mechanism,1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 3, 1869 U.N.T.S. 480.
[83] TRIPS, art. 64.
[84] TRIPS, Part III- Enforcement of Intellectual Property Rights.
[85] TRIPS, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights.
[86] TRIPS, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights.
[87] TRIPS, art.7.
[88] TRIPS, art. 8.
[89] TRIPS, art. 8.
[90] TRIPS, Preamble.
[91] TRIPS, Preamble.
[92] DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH WTO (2001).

interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."[93]

The following discussion pertains to the brief introduction to the different parts of the TRIPS Agreement. The basic principles and the general provisions of the TRIPS Agreement are provided under Part I of the TRIPS Agreement.[94] It also provides for the relationship and implication of other international intellectual property conventions, including the Paris Convention's provisions.[95] Part II lays down the minimum standards of protection that are to be ensured by the WTO member nations in case of different categories of intellectual properties, including copyright, geographical indication, layout designs of integrated circuits, industrial designs, patents, trademarks and undisclosed information including test data and trade secrets.[96] The provisions dealing with controlling anti-competitive practices in contractual licenses are also provided under this part.[97] The WTO member nations, in addition to the TRIPS Agreement, are also required to comply with the provisions of the Berne Convention[98] and the Paris Convention[99] with exemption to moral rights. The Berne Convention and the Paris Convention are the major conventions under the World Intellectual Property Organization (WIPO).[100] The TRIPS Agreement contains specific provisions in addition to the provision under the two conventions administered under the WIPO. Therefore, the TRIPS Agreement is also referred to as the "Paris-plus" and "Berne-plus" agreements.[101] In order to ensure that the member nations do not move away from the existing obligations under the Berne Convention, Paris Convention, and Rome Convention, Article 2.2[102] has been added to the TRIPS Agreement as a saving clause.

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https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?DataSource=Cat&query=@Symbol=%22WT/MIN(01)/DEC/2%22%20OR%20@Symbol=%22WT/MIN(01)/DEC/2/*%22&Language=English&Context=ScriptedSearches&languageUIChanged=true.

93 *Id.*

94 TRIPS, PART I, General Provisions and Basic Principles.

95 Paris Convention for the Protection of Industrial Property, 1883.

96 TRIPS, PART II, Standards Concerning the Availability, Scope and Use of Intellectual Property Rights.

97 TRIPS, § 8, art. 40.

98 Berne Convention for the Protection of Literary and Artistic Works, 1886.

99 Paris Convention for the Protection of Industrial Property, 1883.

100 Convention Establishing the World Intellectual Property Organization, https://www.wipo.int/treaties/en/convention/.

101 WTO, Overview: the TRIPS Agreement. https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

102 TRIPS, art. 2.2.

Part III exclusively deals with the enforcement of intellectual property rights.[103] In general, it provides the principles applicable to intellectual property enforcement procedures, precisely domestic procedures and the remedies for intellectual property rights enforcement.[104] Various provisions on administrative and civil procedures and remedies,[105] criminal procedures,[106] provisional measures and special requirements needed under border measures are also laid down.[107] The effective enforcement of the rights of the right holder provides for the need for procedures, remedies and safeguards. Part IV of the TRIPS Agreement is about administering intellectual property rights.[108] The administrative structure involves rules regarding the accession and upkeeping of intellectual property rights, specifically regarding the application process for obtaining intellectual property rights, procedures for reviews and available appeals. The dispute prevention and settlement mechanism are dealt with under Part V of the TRIPS Agreement and are contingent upon the WTO dispute settlement mechanism.[109] A significant proportion of the prevention mechanism deals with the transparency mechanism of intellectual property laws and their enforcement.[110] The provisions dealing with technical cooperation,[111] technology transfer and transition periods are listed in Part VI of the TRIPS Agreement. General issues and institutional arrangements fall within the purview of Part VII of the TRIPS Agreement.[112]

2.4. TRANSITION PERIOD

India joined the WTO in 1995, solidifying its position as a dependable trading partner in the global market. However, the benefits of WTO participation come at a cost, specifically the acceptance of TRIPS. TRIPS represented the culmination of rich nations' attempts to get better intellectual property protection overseas, particularly in developing countries.[113] It aimed to enhance global IP regime harmonisation by

[103] TRIPS, Part III- Enforcement of intellectual property rights.
[104] TRIPS, Part III- Enforcement of intellectual property rights, § 1, art. 41.
[105] TRIPS, Part III- Enforcement of intellectual property rights, § 2, art. 42.
[106] TRIPS, Part III- Enforcement of intellectual property rights, § 5, art. 61.
[107] TRIPS, Part III- Enforcement of intellectual property rights, § 4.
[108] TRIPS, Part IV.
[109] TRIPS, Part V.
[110] TRIPS, Part V, art. 63.
[111] TRIPS, Part VI, art. 67.
[112] TRIPS, Part VII.
[113] Wei Shi. *Intellectual property in the global trading system: EU-China perspective.* Springer Science & Business Media(2008).

establishing minimum requirements for all WTO members.[114] WTO members might officially accuse other WTO members of breaking TRIPS rules by filing a case against them in the WTO's DSB.[115] Although the TRIPS commitments benefitted industrialised nations, developing countries such as India were forced to accept the conditions of the agreement to be admitted to the WTO. Nonetheless, developing countries were given transition periods to bring themselves into TRIPS compliance, while the least developed countries (LDC) were given even more time.[116]

The TRIPS Agreement provides a one-year transition period for developed countries to comply with their legislation and practices. Developing countries and countries transitioning from a centrally planned to a market economy would have a five-year transition period,[117] while the least-developed countries would have an 11-year transition period.[118] Developing countries that do not currently provide product patent protection have up to ten years to implement such protection.[119] In the case of pharmaceutical and agricultural chemical products, however, they must accept patent applications from the start of the transition period.[120] This is the Swiss equivalent of "pipeline protection," which applies to applications filed after January 1, 1995.[121] Though the patent does not have to be granted until the end of this period, the invention's novelty is preserved as of the filing date. Suppose the relevant pharmaceutical or agricultural chemical product is approved for marketing during the transition period. In that case, the developing country must grant the product exclusive marketing rights for five years or until a product patent is granted, whichever comes first.[122]

The TRIPS Agreement provides developing countries with a general transition period of five years to implement all of the Agreement's provisions.[123] It also provides for a five-year transition period for developing countries that do not currently provide for

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[114] Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Calif. L. Rev. 1571 (2009).
[115] TRIPS, art. 64.
[116] TRIPS, arts. 65,66.
[117] TRIPS, art. 65.
[118] TRIPS, art. 66.
[119] TRIPS, art. 65, cl. 5.
[120] TRIPS, Part VII, art. 70, cl. 8.
[121] THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, *Supra* note 59.
[122] TRIPS, § 7, art. 39.
[123] TRIPS, art. 65, cl. 2.

product patents in any field of technology to extend product patents to those fields of technology.[124] However, in the case of pharmaceutical and agrochemical products, the TRIPS Agreement requires that product patent applications be accepted as of the date of the agreement.[125] Suppose those products are granted patents and marketing approval in another country, and the patent owner wishes to introduce them into the Indian market. In that case, he should be granted exclusive marketing rights for five years or until his pending patent application in India is approved or rejected, whichever comes first.[126]

The introduction of liberalised trade policies has exposed countries to the global market. Large-scale industrialization is the key to economic development, necessitating the transfer of technology, know-how, and cultural promotion. Intellectual property rights also provide significant impetus to research and development. Intellectual property rights, which have significant commercial value in this context, play a critical role in economic development. While protecting intellectual property, a balance must be struck between allowing foreign investment and preserving indigenous industry. A patent, copyright, or trademark registered in one country is only valid in that country.[127] As a result, protection for those outside the country's borders must be obtained in each country separately.[128] In order to be effective in an increasingly global economy, inventors must frequently secure patent rights in multiple jurisdictions. Despite the existence of international agreements such as the Paris Convention,[129] PCT,[130] and TRIPS Agreement,[131] attorneys are required to address multiple substantive patent laws and granting procedures. The ratification of the TRIPS Agreement by almost all countries worldwide has resulted in the harmonisation of intellectual property rights. Intellectual property laws make creative endeavours financially feasible and potentially

[124] TRIPS, art. 65, cl. 4.
[125] TRIPS, art. 70, cl. 8(a).
[126] TRIPS, art. 70, cl. 9.
[127] Emmanuel Kolawole Oke, *Territoriality in Intellectual Property Law: Examining the Tension between Securing Societal Goals and Treating Intellectual Property as an Investment Asset*. 15(2) SCRIPTed. (2018). https://script-ed.org/article/territoriality-in-intellectual-property-law-examining-the-tension-between-securing-societal-goals-and-treating-intellectual-property-as-an-investment-asset/#:~:text=According%20to%20the%20principle%20of,of%20technological%20and%20economic%20development.
[128] *Id.*
[129] Paris Convention for the Protection of Industrial Property, 1883.
[130] The Patent Cooperation Treaty, 1970.
[131] The TRIPS Agreement, 1995.

rewarding.[132] They provide significant impetus for research and development. Apart from the benefits, intellectual property has some drawbacks, such as monopoly pricing during the protection period. Legislators should address these concerns and work to minimise such disadvantages. Countries around the world should modify their intellectual property laws to meet the needs of society and the global economy. Countries should pursue adequate intellectual property protection in the complex game of trade diplomacy.

2.5. TRIPS FLEXIBILITIES

TRIPS contains detailed requirements. Patents must be issued for inventions in all branches of technology, with just a few exemptions,[133] and must be valid for at least twenty years.[134] On the other hand, several additional standards are broadly defined, and governments have had some leeway in establishing the specific outlines of the TRIPS requirements.

The TRIPS Agreement has provided some leeway for countries to take public interest measures, such as those to protect public health. TRIPS flexibility allows the government to fine-tune the protection provided to achieve social goals. The developing world's concerns about pharmaceutical patents have been clarified and heightened by the 2001 Doha Declaration on TRIPS and Public Health and the 2003 decision[135] allowing countries that cannot manufacture their medicines to import pharmaceuticals manufactured under the compulsory licence. The Doha Declaration states that TRIPS should be interpreted and implemented to support WTO Members' rights to protect public health and, in particular, to promote universal access to medicines.[136] The Declaration addresses issues concerning pharmaceutical patent implementation.[137] The Doha Declaration represents a significant step forward in recognising that introducing patents in the health sector significantly impact drug access.

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[132] The TRIPS Agreement, 1995.
[133] TRIPS, at arts. 27.1, 27.2, 27.3.
[134] TRIPS, at art. 33.
[135] Decision of the General Council of 30 August 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WTO. https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
[136] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].
[137] Declaration on the TRIPS agreement and public health (2001).

The Doha Declaration acknowledged that the TRIPS Agreement does not preclude Members from taking public health precautions.[138] At Doha, WTO members also reaffirmed each member's right to fully implement the Agreement's provisions that provide flexibility for protecting public health and, in particular, promoting "access to medicines for all."[139]

Some governments were uncertain about how these TRIPS flexibilities would be interpreted and how far their right to use them would be respected. The Doha Ministerial Conference in November 2001 settled much of this. In the central Doha Ministerial Declaration, WTO member governments emphasised the importance of implementing and interpreting the TRIPS Agreement to support public health by promoting access to existing medicines and developing new medicines. As a result, they adopted a separate TRIPS and Public Health Declaration. They agreed that the TRIPS Agreement does not and should not preclude members from taking public health measures. They emphasised a country's ability to use TRIPS Agreement flexibilities, such as compulsory licencing and parallel importing, and agreed to extend pharmaceutical patent exemptions for LDCs until 2016.

Several such flexibilities are available to developing countries to address some of the negative consequences of pharmaceutical patents. The main flexibilities are obligatory licencing, Parallel importation, Patentable subject matter provisions, Research exception, Data security provisions, Competition and anti-competitive behaviour control and Bolar Provision. TRIPS fundamentally altered the role of international trade law in promoting and enforcing intellectual property protection globally. The developing countries were given till 2005 to comply with the agreement's conditions. TRIPS-compliant Indian patent legislation has been revised multiple times. The Indian Patents Act was amended in 2005 to align with global patenting regulations for pharmaceutical and agrochemical goods.[140] Before the Patents Act amendment, the Indian patent system allowed for a process patent. This limitation made it easier to work around innovations. On January 1, 2005, India introduced pharmaceutical product patent protection.

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[138] Declaration on the TRIPS agreement and public health (2001). ¶ 17-19.
[139] *Id.*
[140] The Patents (Amendment) Act, 2005, *Supra* note 1.

By simply eliminating Section 5 of the Patents Act in the 2005 Amendments to the Patents Act, India authorized product patents for medicines.[141] Despite the reintroduction of product patents, the 2005 Amendments included a slew of access-friendly regulatory levers, or "TRIPS flexibilities," that the Indian generics sector could use to invalidate brand-name patents and get generics to market.[142] Some of the approaches were self-evident—compulsory licencing, for example, had already garnered much attention as a vital instrument for expanding access—but others made inventive use of procedural restrictions in the patent approval process.[143] For example, the 2005 Amendments expanded the procedural options for challenging patents while limiting the ability to get injunctive remedies for patent infringement. They also imposed bans on several licencing terms that patent-based corporations may otherwise attempt to impose. The TRIPS flexibility provided under Section 3(d), better described as the anti-evergreening provision, has developed as a significant legal battlefield, attracting international attention. The provision excludes any novel form of a known substance that lacks "efficacy" over and above that of the known substance from the patentable subject matter.[144] The TRIPS Agreement includes some leeway in how TRIPS obligations are carried out. These are the results of Article 1.1 of the agreement, which states that WTO members might use innovative ways to incorporate into their national laws and put into practice specific TRIPS Agreement elements that have been stated but not defined.[145] Thus, Section 3(d) of the Patents Act of 1970 evolved, which is nothing more than an exercise of liberty granted to all TRIPS member nations. Section 3(d) was added to the Indian patent law regime through the 2005 Amendment to the Patent Act, 1970. The provision plays a significant role in the Indian patent law regime, as it provides for subject matters that are not qualified to be patentable. The quintessence of adding Section 3(d) to the Patent Act 1970 was to prevent the phenomenon of "evergreening" of patents in India. This is not a blanket bar on the patentability of improvements or new additions. Pharmaceutical derivatives can be

[141] The Patents (Amendment) Act, 2005, *Supra* note 1.
[142] Jodie Liu. *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act*. 56(1) HARV INTL LJ (2015).
[143] Amy Kapczynski, Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector, 97 CALIF. L. REV. 1571 (2009).
[144] The Patents Act,1970, § 3(d).
[145] TRIPS, at art. 1.1

patented if significantly enhanced efficacy can be demonstrated. This test of enhanced efficacy is provided under Section 3(d).

Evergreening of patents can be regarded as a market strategy used to extend the already granted patent term that is about to terminate in a particular territorial jurisdiction by getting new patents to hang on to the royalties generated from them.[146] Robin Feldman has defined evergreening as the practice of artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period.[147]

Most definitions of evergreening are very generic. A definition of evergreening based on Intellectual property is, *"IP based evergreening is the business strategy to extend the duration of the effective protection derived or derivable from a portfolio of IPRs in order to increase the appropriability of an innovation or a set of business-related innovations or technologies."*[148]

Unlike the United States of America, which is a country experiencing a market-driven economy, India is not so. In adopting new rules and regulations, the interests of the public play a predominant role in the decision-making process due to the welfare nature of the country. Moreover, Article 27.1 under the TRIPS Agreement requires WTO Members to provide patent protection for all inventions in all domains of technology.[149] The provision, as mentioned earlier, in addition to stating the criterion of patent eligibility, provides considerable freedom in that it does not define the parameters of novelty, inventiveness, and industrial application, allowing WTO members to select how these should be read and implemented.[150] There are two categories of pharmaceutical innovations: major and minor. New compounds are infrequent, yet thousands of pharmaceutical patents are awarded each year, raising concerns about the number of patents that may be granted for modest alterations.[151] As is evident, most of such minor alterations would be based on a novel use of an existing pharmaceutical product. The TRIPS agreement does not preclude nations from refusing patentability of

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[146] *Supra* note 142.
[147] *Supra* note 29.
[148] Ove Granstrand & Frank Tietze, *IP strategies and policies for and against evergreening* (Centre for Technology Management working paper series. April 2015) https://www.ifm.eng.cam.ac.uk/uploads/Research/CTM/working_paper/2015-01-Granstrand-Tietze.pdf
[149] TRIPS Art. 27.1.
[150] Sisule F. Musungu & Cecilia Oh, *Study on The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* WTO (2006). http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.
[151] FICCI's POSITION ON SECTION 3(d) OF THE PATENTS ACT, 1970, FICCI

new uses due to a lack of originality, inventive step, or industrial application.[152] Countries can choose whether or not to enable patentability for new purposes. In 2002, the IPR Commission suggested that developing nations remove diagnostic, therapeutic, and surgical procedures from patentability and innovative applications of recognised items to facilitate access to medicines.[153]

It is worth noting that Article 7 of the TRIPS agreement requires member nations to guarantee Intellectual Property protection so that producers and consumers of technological knowledge benefit mutually, which promotes social and economic wellbeing.[154] It is also crucial to note that Article 8 of the TRIPS Agreement warns member states that practical steps must be taken to preserve public health and nutrition and ensure that rights holders do not exploit intellectual property rights in developing or amending their laws.[155] The essence of the issue is that monopolies should not be awarded to innovations that are not "genuinely inventive enough", which, if granted protection, would impede or be highly detrimental to societal and economic benefit. In terms of pharmaceuticals, the system should ensure timely access to essential medicines at affordable prices for the general public by preventing or controlling the abuse of patent protection by extending such monopolies to frivolous pharmaceutical inventions, thereby benefiting the general population at large.

In harmony with the TRIPS principles, India enacted Section 3(d),[156] which assures that patent protection is granted solely to meritorious inventions rather than frivolous ones, thereby curbing patent abuse.

2.6. PATENTABLE SUBJECT MATTER

Article 27 of the TRIPS Agreement[157] states that subject to the exclusions specified in the TRIPS Agreement, patents shall be accessible for all inventions, whether products or processes, in all sectors of technology.[158] However, Article 27 does not specify what constitutes an invention. Because the agreement does not define an invention, nations

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[152] *Id.*
[153] COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, Chapter 2: Health, at 29.(2002) http://www.iprcommission.org/papers/pdfs/final_report/Ch2final.pdf.
[154] TRIPS, art. 7.
[155] TRIPS, art. 8.
[156] Patents Act,1970, § 3(d).
[157] TRIPS, art. 27.
[158] *Id.*

have the flexibility to restrict the extent of the idea of innovation under their national laws in order to exclude new uses from patentability.[159]

Governments may refuse to grant patents for three reasons related to public health:

(i) inventions whose commercial exploitation should be prevented in order to protect human, animal, or plant life or health;

(ii) diagnostic, therapeutic, and surgical methods for treating humans or animals; and

(iii) specific plant and animal inventions.[160]

The TRIPS Agreement allows the Member States to exclude diagnostic, medicinal, and surgical treatments for people or animals.[161] A medical treatment technique for sickness is not a patentable subject matter under the Indian Patents Act.[162] Though there are significant discrepancies in the legal position in different jurisdictions, a procedure consisting of the use of a known substance for medical treatment of a human being has often been determined not to be a patent-eligible subject matter.[163] Many courts worldwide have ruled that a procedure for medical treatment of humans is not a valid topic for a patent monopoly.[164] In order to group the three kinds of patentability exceptions in Article 53(a),[165] (b),[166] and (c) EPC,[167] EPC 2000 added treatment and diagnostic procedures to the exceptions to patentability.[168]

2.7. SECTION 3(d) & TRIPS

The aim of India's Section 3(d) is not a radical departure from traditional international standards to control the patenting of derivatives and new uses. According to TRIPS Article 27.1, "patents shall be available for any inventions, whether goods or processes, in all disciplines of technology, provided that they are new, involve an inventive step, and are suitable for industrial application."[169] The three criteria for patentability—

[159] ELIZABETH VERKEY, LAW OF PATENTS., Lucknow Eastern Book Company 569 (2d ed.2012).
[160] TRIPS, art. 27.3.
[161] ELIZABETH VERKEY, *Supra* note 159.
[162] Patents Act,1970, § 3(i).
[163] ELIZABETH VERKEY, *Supra* note 159 at 569.
[164] *Id.* 569.
[165] The European Patent Convention, art. 53(a).
[166] The European Patent Convention, art. 53(b).
[167] The European Patent Convention, art. 53(c).
[168] The European Patent Convention, 10th ed.(2000).
[169] TRIPS, art. 27.1.

novelty, inventive step, and industrial applicability—are laid forth in this clause, which requires member nations to grant product and process patents in all areas of technology.[170] The terms "inventive step" and "industrial application" are equivalent to the American ideas of "non-obviousness" and "utility."[171]

In order to meet the requirements of Article 27.1, the 2005 Amendment extended product patent protection to pharmaceutical substances.[172] TRIPS does not define the terms "novelty," "inventive step," or "industrial application" therefore, it can be argued that member nations have a great deal of latitude in determining whether something qualifies as these three things.[173] One viewpoint holds that Section 3(d) codifies the non-obviousness criteria for pharmaceutical drugs, making them acceptable under TRIPS.[174] Under TRIPS, India has little leeway in determining the subject matter that qualifies for patent protection but more leeway in altering the inventive step standard to fine-tune its patent regime.[175]

In order to effectively achieve the goal of encouraging innovation, India's patent law must be transparent and trustworthy. There is a great deal of confusion in Indian patent law due to the 2005 Amendment and Section 3(d).[176] Therefore, India must exercise caution when interpreting Section 3(d). As an illustration, even if Section 3(d) prohibitions on patenting derivatives of known substances have variants in other patent regimes, the issue arises from the lack of clarity regarding how the Indian patent office

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[170] TRIPS, art. 27.1.

[171] UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, 359-61 (2005). Provides, that "inventive step" and "capable of industrial application" is synonymous with "non-obvious" and "useful."

[172] The Patents (Amendment) Act,2005.

[173] Many academic scholars and non-governmental organisations share this viewpoint. While member countries are required to use those three criteria, the WTO Dispute Settlement Board (DSB) has never addressed how member countries must do so. The Dispute Settlement Board (DSB) ruled in one of the few WTO disputes involving Article 27 that member countries can establish different rules for certain product areas as long as the variations serve legitimate interests. UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, 358-61 (2005).

[174] Shamnad Basheer, *India Patent Act Faces TRIPS Challenge*, Spicy IP, http://spicyipindia.blogspot.com/2006/09/indian-patent-act-faces-trips.html (last visited Jul. 29, 2022).

[175] One early position voiced by academics when TRIPS was promulgated was that the WTO should be more deferential to developing countries in terms of inventive step than subject matter issues: *See* Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 282-304 (1997).
The subject of admissible non-obviousness requirements under TRIPS, on the other hand, is hotly disputed on both sides. According to some critics, the most difficult issue in international intellectual property harmonisation is non-obviousness: *See* J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL.11.

[176] *Supra* note 23.

and judiciary will interpret the term "improved efficacy." The word "efficacy" is not defined in the 2005 Amendment. The Indian Manual of Patent Practice and Procedure (MPPP), a publication of the Indian Patent Office, does not define it either.[177] Even though TRIPS outlines the very minimum in terms of IP protection, it is questionable whether or not member nations must go above and beyond.[178] However, a robust patent system could be advantageous for India and should act as a motivator for technological advancement. Compared to many other developing nations, India has a higher level of technological development, and an increasing number of its domestic pharmaceutical firms are conducting unique research.[179] For instance, a system that recognises new use patents might be advantageous to some local enterprises with the technological competence to develop novel medical uses. While Section 3(d) seeks to eliminate frivolous patents, incremental inventions frequently contain significant innovation.[180] In particular, patents in the pharmaceutical business rarely incorporate new chemical entities but relatively incremental improvements over past inventions. Suppose the non-obviousness requirement is set so high that it effectively prohibits the patentability of most incremental pharmaceutical breakthroughs. In that case, the regulation may violate TRIPS[181] and damage the Indian pharmaceutical industry in the long run by failing to offer adequate incentives for R&D.

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[177] INDIAN PATENT OFFICE, MANUAL OF PATENT PRACTICE AND PROCEDURE (2005). http://patentoffice.nic.in/ipr/patent/manual-2052005.pdf

[178] Shamnad Basheer, *Novartis Patent Dispute: Of Spins and Empty Rhetoric*, Spicy IP. http://spicyipindia.blogspot.com/2007/08/novartis-patent-dispute-ofspins-and.html (last visited Jul. 29, 2022).

[179] Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT'L ECON. L. 77,(2005).

[180] Shamnad Basheer, a renowned analyst on India's intellectual property policy, holds this perspective. He founded the Spicy IP blog. In response to the Novartis litigation, the Indian government commissioned a committee of specialists known as the "Mashelkar Committee" to opine on whether recent changes to India's patent law were TRIPS compliant. Basheer was commissioned by the Intellectual Property Institute (IPI), an English think tank, to produce a document for submission to the Mashelkar Committee. Both Basheer and the final Mashelkar Committee Report argue that restricting pharmaceutical patents to "new chemical entities" would be in violation of TRIPS. It should be noted, however, that the Mashelkar Committee Report does not directly address Section 3. (d). The Mashelkar Committee Report was eventually withdrawn in response to charges that it copied from Basheer. Basheer claims on his blog that these allegations are false. *See Deconstructing the Mashelkar Committee Report Controversy: Part I*.SPICY IP.

[181] Article 27.1 would be violated if India's non obviousness standards were so stringent that an innovation would need an "inventive leap" rather than an "inventive step."
Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, (1997).

2.8. RESPONSE OF THE UNITED STATES

Since 1998, the United States has designated India as a priority watch list nation owing to poor protection and unequal market access for US personnel engaged in intellectual property protection.[182] These countries require heightened awareness and attention. They are classified as having severe intellectual property rights problems by US trade representatives.[183] One of the primary issues of concern to US pharmaceutical businesses is Section 3(d) of the Patents Act, which bans patent issuance to incremental innovation unless therapeutic efficacy increases. [184] This restriction prevents large pharmaceutical businesses from gaining a total monopoly.[185] In India, no Utility Model (UM) law is in place to safeguard incremental advances.[186] The US administration attempted to impose unilateral action to put pressure on nations on the priority watch list to strengthen IPR protection beyond TRIPS.[187]

In 2009, the USIBC (US India Business Council) published a study advocating incremental innovation.[188] According to the report's findings, Section 3(d) of the Indian Patents Act hinders research and development.[189] This eventually inhibits foreign direct investment (FDI) into India, which is desperately required to improve the Indian economy. Section 3(d) also fails to identify and measure therapeutic efficacy. According to Fyan (2014),[190] Section 3(d) is vague and does not clearly instruct pharma patent applicants as to which incremental improvements to the art are patentable and which are not because efficacy is not specified.[191]

The patentability requirements in India and the United States are substantially different, with India restricting patenting of previously known drugs that have not dramatically

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[182] Shalini Arora & Rekha Chaturvedi, *Section 3(d):Implications and Key Concerns For Pharmaceutical Sector*. NISCAIR-CSIR, India (2016).
[183] *Id.*
[184] SPECIAL 301 REPORT, *Supra* note 34.
[185] *Id.*
[186] Shalini Arora & Rekha Chaturvedi, *Supra* note 182.
[187] MSF, Persistent us attacks on India's patent law & generic competition (2015). https://msfaccess.org/us-attacks-indias-patent-law (last visited Aug. 2,2022)
[188] U.S-INDIA BUSINESS COUNCIL, THE VALUE OF INCREMENTAL PHARMACEUTICAL INNOVATION(2009), http://www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReport Final.pdf (last visited Jul. 29, 2022).
[189] *Id.*
[190] Fyan S, *Pharmaceutical patent protection and Section 3(d): A comparative look at India and the U.S*, 15 Virginia Journal of law & Technology, 198-226, (2010).
[191] *Id.*

improved efficacy. Several patent applications for antiviral and cancer drugs have been denied to prevent evergreening and the proliferation of identical products on the market. This would also avoid monopoly pricing by US firms. While US patent law favours patent grants for new forms, new uses, or combinations of existing compositions, they have lower levels of patentability criteria than Indian patent law. Because of the lower patentability standards, the United States multiplies the patent quantity to block generics from accessing the market. Because the expense of R&D for medication development is relatively high, pharmaceutical corporations in the United States are focused on maintaining monopolies and generating massive profits. At the same time, while business creation is the Multinational Corporation (MNC) mantra, it has impacted access to medication. To address such difficulties, India is a welcoming place for MNCs seeking to work on producing cost-effective quality drugs and providing various development solutions.

2.9. SIMILAR PROVISIONS IN OTHER COUNTRIES

Other countries have provisions similar to Section 3(d). Patent legislation in several countries is comparable to Section 3 of the Indian Patent Act (d). Countries in the Asia-Pacific area are also considering implementing a comparable provision of Section 3(d) to patent only breakthrough drug inventions. The Philippines has already amended its law on the same lines to toughen the patentability standards. Brazil's Patent Office issued rules to limit the patentability of novel shapes of compounds (polymorphs), new properties, or new applications of a known technique unless the known procedure resulted in a new product.[192] In Argentina, the standards for patentability for pharmaceutical and chemical innovations also prohibit the subject matter of polymorphs, hydrates, and solvates since it is deemed an intrinsic quality of the material and hence not an invention but only a finding.

Furthermore, new forms, uses, and formulas are not patentable in Argentina. The product description in line with the pre-existing formulation is not patentable. The Patents Act of Argentina contains terms such as new form, new usage, and new formulation and are adequately defined by the patent office. The subject matter is

[192] CENTER FOR STRATEGIC STUDIES AND DEBATES, BRAZIL'S PATENT REFORM INNOVATION TOWARDS NATIONAL COMPETITIVENESS(2013), http://infojustice.org/wpcontent/uploads/2013/09/ Brazilian_Patent_Reform.pdf.

mentioned in Japan's patent statute as the new use of a drug can be patented if the use is entirely innovative over the original, and its use must be clearly distinguishable.[193] The European Patent Office (EPO) issued guidelines pertaining to the patentability of polymorphs.[194] As per the guidelines, Polymorphs must exhibit amazing technical effects when contrasted to what is currently known for them to be recognized as innovative.[195]

The advantages of laws comparable to Section 3(d) in other nations can be outlined as follows, restriction on evergreening owing to patients' therapeutic efficacy clauses for drugs, reasonable pricing is available, raised the grant criteria for quality drug patents by supporting novel drug research and prohibiting incremental or secondary patenting of established drugs, and this sort of provision in patent legislation, along with others such as patent opposition, can serve as a protection and be utilised by public advocacy organisations to effectively challenge patents for modest modifications in life-saving drugs used to cure terrible diseases such as HIV and cancer.

2.10. CONCLUSION

India has a broad and robust legislative, administrative, and judicial structure compliant with the TRIPS Agreement. Section 3(d) could be interpreted as a criterion for patent eligibility for pharmaceutical inventions. The efficacy enhancement can be examined on non-obviousness grounds by a person skilled in the art, where new forms that demonstrate significantly more potency than what exists are suitable for the patent. India leverages the international framework's flexibility to address developmental features and concerns.

Section 3(d) has undoubtedly had a substantial influence on assessing the patentability of pharmaceutical derivatives in India. Section 3(d) prohibits modest incremental inventions and ever-greening, which was common before 2005. If incremental inventions are permitted, there will undoubtedly be fair and equitable possibilities of patent ever-greening. As a result of the monopolistic scenario in the future Indian market, medicine costs may stay high, putting the prices beyond the affordability of the

[193] Osamu Yamamoto, *Navigating medical use in Japan*. LSIPR (2017). https://www.lifesciencesipreview.com/contributed-article/navigating-medical-use-in-japan.
[194] European Patent Office, Patenting Polymorphic Forms at the European Patent Office (2014).
[195] *Id.*

majority of the Indian population. As a result, a robust patent protection framework is essential to support innovation in the pharmaceutical business, as ever greening does not stimulate innovation. The healthcare industry is entirely dependent on the patent system. According to the United States, India does not encourage incremental innovation. Pharmaceutical companies constantly plan to maintain market dominance, patenting tiny adjustments because of which only a few blockbuster pharmaceuticals are developed. Section 3(d) of the Indian Patents Act checks on ever-greening, ensuring a balance between public health and innovation. As a result, a desirable strategy would be to employ resources efficiently to study new blockbuster treatments in areas of concern to developing countries. New effective pharmaceuticals will undoubtedly promote and extend the market, resulting in a cost-efficient transaction with simple public access.

CHAPTER III
SECTION 3(d) AND THE INDIAN PATENT LAW REGIME

3.1. INTRODUCTION

Section 3(d) became part of the Indian patent law regime by virtue of the Patents (Amendment) Act,2005. Since its enactment, the provision has been a subject matter of debate. This chapter of the research paper dwells on the brief history of the patent laws in India. It specifically deals with the legislative history and the interpretation of Section 3(d). The chapter starts by discussing some of the essential characteristics of intellectual property that the Indian courts recognised through various judgments. After that, the history of the Indian patent regime is re-traced, focusing on the addition of Section 3(d) to the Patents Act,1970. Thereafter a much more detailed interpretation of Section 3(d) is followed.

3.2. ATTRIBUTES OF INTELLECTUAL PROPERTY AND INDIAN COURTS

The World Intellectual Property Organization(WIPO) defines intellectual property as the "creation of the mind."[196] This includes designs, images, names and symbols used in commerce, inventions, and literary and artistic works.[197] The intellectual property is protected by virtue of law, and this protection provided by the law enables the creator or owner of the intellectual property to earn recognition or to harvest financial benefits from their creation.[198] Establishing an intellectual property system aims to balance the interests of the innovator and that of the broader public interest, thereby incentivising the growth and thriving of the patent regime.

In the Indian legal context, the term "intellectual property rights" has not been defined under any statute. Mainly intellectual property can be categorised into nine categories: copyright and related rights, geographical indications, industrial design, layout designs

[196] WIPO, About IP. https://www.wipo.int/about-ip/en/.
[197] *Id.*
[198] *Id.*

of integrated circuits, new plant varieties, patents, patenting of micro-organisms, trademarks including service marks, and trade secrets. Being a signatory to the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), India has enacted multiple legislations to protect and enforce intellectual property rights of the categories mentioned earlier.

In the Indian scenario, the courts have played a significant role in attributing certain specific characteristics to intellectual property through their judgments.

In 2011, the SC of India, in its decision in *Institute of Chartered Accountants of India v. Shaunak H. Satya*,[199] referred to the definition of intellectual property to decide whether the subject matter in dispute constitutes to be the intellectual property of the party. The Black's Law Dictionary defines intellectual property as,

"*a category of intangible rights protecting commercially valuable products of human intellect comprising primarily trade mark, copyright and patent right, as also trade secret rights, publicity rights, moral rights and rights against unfair competition."*[200]

The SC of India, in its judgment in *K.T Plantation v. State of Karnataka*,[201] has held that the term "property" under Article 300A of the Constitution of India is not confined to merely land and also includes intangibles like intellectual property and embraces every possible interest recognised by law. In this decision, the Court has upheld the constitutional validity of intellectual property by equating it with tangible property.[202]

In 2017, while considering the case of McDonald's India Pvt. Ltd. v. Commissioner of Trade and Taxes, New Delhi, the High Court of Delhi went on to differentiate between the rights relating to intellectual property and real property. The Court made the distinction that,

"The peculiarity of intangibles or incorporeal property, of the kind this court has to deal with, i.e., intellectual property, is that unlike real property, its boundaries are unset. These rights are only real and effective to the extent they enable the owner or transferee to "keep out" from use those who are not permitted to do so. In other words, the nature of the intellectual property and the remedies provided for their enforcement

[199] AIR 2011 SC 3336.
[200] Black's Law Dictionary, 7th Edition.
[201] AIR 2011 SC 3430.
[202] K.T. Plantation V. State of Karnataka, AIR 2011 SC 3430.

hinge upon the right to exclude others from using it. The distinctiveness of a mark, earned through dint of continuous use and brand building, results in the trade mark which is classically known as "a badge of origin" that assures the user of the products the constancy of the quality associated with it. Only ensuring that others who do not own it are prevented from using or appropriating it ensures its enforcement."[203]

In 2016, the High Court of Kerala, in its judgment in *State of Kerala v. The Malayala Manorama Company Limited,*[204] made the distinction between ownership and intellectual property rights more explicit. According to the Court,

> *"The ownership is traditionally understood as a legal relationship between a person and a thing over tangible and corporeal property. Blackstone describes it as a "sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in this universe" (see Commentaries on the laws of England of Sir William Blackstone Vol. II of the Rights of things). Intellectual property rights, on the other hand represent monopoly of intellectual creation of the owner of such rights. It is more understood as conceptional rights on intangible and incorporeal properties. Ownership rights cannot be synonymously understood as intellectual property rights though such rights may overlap other rights in certain circumstances. The distinction however narrow or thin as the case may be, the legal distinction is copious and lucid."*[205]

The High Court of Gujarat in 2018, in its decision in *Gurukrupa Mech Tech v. State of Gujarat,*[206] discussed the concept of intellectual property and the rights attached to it. Here the Court held that intellectual property is incorporeal property resulting from the original thought.[207] One of the objectives of intellectual property law is excluding

[203] McDonalds India Pvt. Ltd. and Ors. v. Commissioner of Trade and Taxes, New Delhi.241 (2017) DLT 769.
[204] 2017(2) KLT36.
[205] State of Kerala v. Malayala Manorama Company Limited, 2017(2) KLT 36.
[206] (2018) 4 GLR 3324.
[207] Gurukrupa Mech Tech v. State of Gujarat (2018) 4 GLR 3324.

others from using the intellectual property without the owner's permission; it is regarded as a negative right.

From the judgments as mentioned above, some of the attributes of intellectual property by the Indian courts through their judgments are summarised as follows. Intellectual property is incorporeal and intangible in nature. Intellectual property rights are negative rights because the primary objective of granting the right is to exclude others from using the creator's property without permission—an intellectual property results from the creation of the mind. Article 300A of the Constitution of India recognises the constitutionality of intellectual property as property.[208] Unlike in the case of real property, the boundaries of intellectual property are unset. Finally, intellectual property rights provide for the exclusive monopoly of the creator or owner of the intellectual property.

3.3. HISTORY OF INDIAN PATENT LAW

The patent is one among the intellectual property rights granted to the owner of the intellectual property. The expression "patent" is derived from the Latin term *"patere"*, whose literal meaning is 'to lay open", the implied meaning being to make available for public inspection. The main motive behind the enactment of the Patent Act 1970 was to encourage the development in the field of technology by incentivising inventions. At present, the Patent Act 1970 governs the Indian patent law regime. The evolution of the Indian patent law regime can be traced back to the period of the British era in India. The onset of patent laws in the country is a contribution of the British colonial government. It was in 1856 that the very first law relating to patents was enacted in India. It was the Act VI of 1856 that was enacted to protect inventions.[209] This legislation was modelled based on the British Patent Law, 1852.[210] The enactment of the Act VI of 1856 lacked the consent of the British Crown and was therefore repealed by the Act IX of 1857.[211] Thereafter in 1859, the Act XV of 1859 was enacted, which provided for the exclusive privileges of inventors. Another significant change

[208] INDIA CONST., art. 300A.
[209] Act for granting exclusive privileges to Inventors , Act VI of 1856.
[210] Patent Law Amendment Act,1852.
[211] Act IX of 1857.

was that the new Act increased the priority period from six months to twelve months, and importers were excluded from investors' definitions.[212]

In 1872, the Act of 1859 was combined to provide protection relating to designs. The act was renamed "The Patterns and Designs Protection Act" under Act XIII of 1872, which was further amended in 1883.[213] This act remained in force for 30 years and was again amended in 1888.[214] The amendment brought in the provision on novelty that would ensure that the exhibition of inventions will not bar them from claiming the right to novelty.[215] The amendment in 1888 incorporated the changes made in the U.K. law to the Indian law.[216] This was to ensure that the Indian law conformed with the U.K. law.

The Indian Patent and Design Act, 1911, repealed all the previous acts.[217] At the time of independence, the country's patent law regime was governed by the Indian Patent and Designs Act, 1911. After that, a need arose for the inclusion of some provisions regarding the powers of the Controller of Patents to correct the register of patents, grant of secret patents, use of an invention by the government, increasing the term granted for patents from fourteen to sixteen years and patents of addition. Later, in 1945, an amendment was made that provides for nine months for filing provisional specifications and the complete specification to be submitted.[218]

Soon after the independence, a need for a new comprehensive legislation arose due to certain lacuna in the existing legislation and to update the laws to fit the country's changing economic and political scenario. In order to review the existing patent laws in India, a committee was appointed. The present Patents Act, 1970[219] came into force in 1972, further amending and combining the prevailing law relating to Patents in India. For the first time, the administration of patents was brought under the power of The Controller of the Patents as per this Act.[220]

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212 Act for granting exclusive privileges to inventors (Act XV of 1859).
213 The Patterns and Designs Protection Act,1872.
214 The Inventions and Designs Act, 1888 (Act V of 1888).
215 *Id.*
216 *Id.*
217 The Indian Patent and Designs Act,1911.
218 The Indian Patents and Designs (Amendment) Act, 1945 (Act No. IX of 1945).
219 The Patents Act,1970.
220 § 73,The Patents Act,1970.

3.4. THE TEK CHAND COMMITTEE

The Patents Enquiry Committee, also known as the Tek Chand Committee, was constituted by the Ministry of Industry and Supply under the Government of India by way of a resolution dated October 1 1948.[221] Dr Bakshi Tek Chand headed the Committee. He was a member of the Constituent Assembly of India and a retired High Court judge.[222] The Committee consisted of a total of seven members, including the chairman. The Swan Committee very much inspired the working of the Committee.[223] In 1944, to provide recommendations on improvising the Patent Laws in England, a committee headed by Kenneth swan was constituted by the Board of Trade 1944.[224] The recommendations of the Swan Committee lead to the revision of the patent laws and the enactment of the Patents Act,1949.[225]

The objective behind the appointment of the Tek Chand Committee was to review the prevailing patent laws in the country. This includes strengthening the provisions that obviate the misuse of patent rights, examining the need and viability of establishing a National Patent Trust, making the public more aware of the patent system, to review whether patents relating to medicine and food should be subjected to special restrictions, and also to suggest any other recommendations that the Committee finds falling in line with the national interests and also aids the use of inventions in commercial development and development of other new inventions.[226]

On examining the patent law prevailing in the land, the numerous drawbacks and loopholes came to the notice of the Committee. Therefore, the Committee came up with various recommendations. The Committee submitted its report in 1950. The recommendations include widening the scope of the definition of the term "invention" in the context of the Indian patent law regime.[227] The Committee recommended the replacement of the various provisions dealing with abuse of patent rights in the Patents and Designs Act, which resulted in the amendment in 1950.

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[221] REPORTS OF THE PATENT ENQUIRY COMMITTEE, 1948-1950.
[222] *Id.*
[223] COMMITTEE ON PATENT LAW AND PROCEDURE 1944 (UK).
[224] *Id.*
[225] The Patents Act, 1949.
[226] REPORT OF THE PATENTS ENQUIRY COMMITTEE,1948-1950.
[227] *Id*. at ¶ 139.

With regard to medical or food products prepared using chemical processes, the Committee recommends that it should not be patentable in India unless these products result from invented processes.[228] The primary motive of the Committee was to examine and review the compulsory licensing system in the context of medicine and food and to safeguard the public interest in this matter. In its final report, the Committee failed to arrive at a conclusive decision regarding the patents related to medicine and food.

3.5. THE AYYANGAR COMMITTEE REPORT: THE GAME CHANGER

The Government of India appointed the committee headed by Justice N. Rajagopala Ayyangar in 1957 to revise the patent laws prevailing in the country.[229] The Ayyanger Committee submitted its report in September 1959.[230] The Ayyanagar Committee Report was very detailed, pointing out the pitfalls in the Indian patent laws and suggesting laws that will benefit the country's best interest. The Ayyanagar Committee Report is regarded as the bedrock based upon which the Patents Act, 1970, was drafted and enacted. The Ayyanagar Committee report has also acceded to the recommendation of the Tek Chand Committee that patents and designs must be dealt with under discrete legislations. On analysing the existing patent laws in the country, the Committee was of the opinion that even though Indian inventors have only harnessed a negligible part of the benefits under the patent system, in the era of industrialisation patent system is the best system for providing incentives to the inventors and to ensure the protection of the patents.[231] The Ayyanagar Committee Report have expressly dealt with the highly controversial issue of the patentability of drugs and has also referred to the practices adopted in other countries. Other topics detailed in the Ayyangar Committee report are compulsory licensing provisions and the degree of patent protection to be provided.[232] Regarding the laws relating to patenting of food and drug, the Ayyangar Committee Report recommended adding particular provisions.

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[228] REPORT OF THE PATENTS ENQUIRY COMMITTEE, CHAPTER VIII (1948-1950).
[229] JUSTICE N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW (1959).
[230] *Id.*
[231] *Id.*
[232] JUSTICE N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW (1959).

Drugs being chemical compounds, the patentability of chemical processes and chemical compounds have always been a topic of discussion in the Indian patent law regime, unless and until product patents were also granted for chemical compounds by way of the 2005 Amendment.[233] The 2005 Amendment will be discussed in detail later in this chapter. Regarding the opinion of the Ayyangar Committee, it recommended that only process patents should be granted for the chemical process.[234] Regarding the prohibition of product patents for chemical compounds in the Indian scenario, the Ayyangar Committee Report derived its decision mainly from the following various factors. Firstly, in the context of European countries, at that point of time, most of the countries had processes patent for chemical processes and not product patents for chemical compounds.[235] The history of granting patents for chemical processes and not the chemical compound can be traced back to the German Patent Law of 1877.[236] Since 1877, for the next thirty years, the world has witnessed the flourishing of the German chemical industry. The unprecedented burgeoning of the German chemical industry has been imputed to broadly limiting to only granting of processes patents and prohibiting product patents. Granting of process patents will result in new innovative methods in the manufacture of chemical compounds. The main argument against granting product patents is that, since the product is patented, any other efficient method for manufacturing the chemical compound will be ruled out. On witnessing Germany's experience with granting process patents, many other countries have also adopted this model.[237] The category of chemical compounds is vast, and drugs and foods only form a small category. On analysing the patent laws in various countries, it can be found that certain countries have different specific patent laws for drugs and food apart from the laws for chemical compounds. In the European context, the majority of the countries have specific restrictions regarding the patentability of pharmaceutical and food products. The Ayyangar Committee have observed in its report that no European country has permitted the grant of product patent in the case of pharmaceutical and food products. Also, claims for processes patents were not allowed in Italy for medical

[233] The Patents (Amendment) Act,2005, No. 15, Act of Parliament, 2005 (India).
[234] JUSTICE N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW (1959).
[235] *Id.*
[236] The Patent Act (*Patentgesetz*), 1877 (Germany).
[237] JUSTICE N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW, 24 (1959).

products and in Denmark for food articles. The restrictions on the patenting of pharmaceutical and food products vary across each European country. From 1844 to 1960, product patents for pharmaceutical products were not granted in France.[238] In the case of Switzerland, an amendment was made in 1954, according to which only processes which were used for the manufacturing of pharmaceutical products and food products were patentable, and patents were not granted for the products that resulted from these processes.[239] Secondly, for a developing country like India, permitting product patents for pharmaceutical products and food articles would be detrimental to the economic and research interests of the country. This is based on the fact derived from the experiences of other countries that granting patents for the processes of manufacturing products and not granting patents for the products resulting from these processes will incentivise further research and expedite novel inventions. Also, the national interest of India was to ensure the availability and affordability of pharmaceutical drugs at lower prices to its larger population.[240] The recommendation of the Ayyangar Committee regarding the Indian pharmaceutical industry is that the German system of granting only process patents should be adopted and implemented in the Indian context.[241] This will aid in the advancement of research in this field and the development of the chemical and pharmaceutical industry in the country. The Ayyangar Committee Report is still considered to be a crucial part of the development of the Indian patent law regime.

3.6. THE PATENTS ACT,1970

The Ayyangar Committee report is regarded as the bedrock upon which the country's modern patent system has been built. Based upon the recommendations of the Ayyangar Committee Report, the Patents Bill, 1965 was drafted and was introduced in the Lok Sabha on September 21, 1965. However, the Patents Bill, 1965, lapsed. The enactment of the Patents Act, 1970 was, to a great extent, based upon the report submitted on November 1, 1966, by the Joint Committee of Parliament. S.V.Krishnamoorthy Rao headed the Joint Committee of Parliament for revamping and consolidating the patent

[238] Maurice Cassier, *Patents and public health in France. Pharmaceutical patent law in-the-making at the patent office between the two world wars*, 24(2)History and Technology,135-151 (2008).
[239] Federal Act of 25 June 1954 on Patents for Inventions, SR 232. § 2 (Switzerland).
[240] Luigi Palombi. *The Role of Patent Law in Regulating Access to Medicines*. 6(2) SCRIPTed (2009).
[241] JUSTICE N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW, 35 (1959).

laws. The enactment of the Patents Act,1970 lead to the repealing of the Patents and Designs Act,1911 to the extent relating to laws being of interest to patents. The Patents and Designs Act,1911 was still applicable to designs until the Designs Act,2000 came into force.

Prior to 1970, it was observed that the patent laws had failed to fulfil the national interests. The majority of the patents were owned by foreigners. Precisely, in the pharmaceutical sector, more than seventy per cent of the domestic market was controlled by foreign pharmaceutical companies, and the drug prices in India were outrageous.[242] Despite that, the income generated from patents was much low.[243] This led to the rise of numerous concerns over the public health regulations in the country. It was in response to the public health concerns that Section 5, Patents Act, 1970, was drafted in order to prohibit the obtaining of product patents by pharmaceutical companies for their drugs. As per the Patents Act,1970, only process patents were granted for drugs. This led to the booming o the pharmaceutical industry in the sector. India even went on to become the largest producer of generic drugs in the world. This is due to the fact that since only process patents were granted over the method used in the manufacturing of the drugs, another company, by way of reverse engineering the drug, could come up with a completely different technique for the manufacturing of the same drug other than the patented process. This led to an increase in the competition in the pharmaceutical market. This surge in competition in the pharmaceutical industry ultimately leads to the availability of drugs at affordable prices. Under the Patent and Designs Act, the patent protection was granted for fourteen years. As per the new legislation, the duration for which patent protection shall be made available has been reduced to seven years. This is a brief time period taking into consideration the time required for the research, development and clinical trials that finally result in the production of a drug. Due to the shorter time period for the patent protection of processes, many pharmaceuticals were drawn back from availing of patent protection.[244] All these factors opened up the market for the growth of domestic pharmaceutical companies, and gradually the domestic market was captured by the Indian pharmaceutical companies, which were earlier held by foreign companies. The

[242] *Supra* note 142.
[243] *Id.*
[244] *Supra* note 142.

Tek Chand Report,1950 and the Ayyangar Committee Report,1959, have deliberately emphasised the importance of preventing foreign firms' monopolisation of the Indian pharmaceutical market.[245]

3.7. 2005 AMENDMENT: A WATERSHED IN THE HISTORY OF INDIAN PATENT LAW REGIME

India became a party to the World Trade Organisation in 1995. Being a member of the WTO, there is a mandatory obligation upon the member countries to tailor their national laws to be in compliance with the TRIPS. The TRIPS is recognised as an international document laying down the minimum standard of protection that must be ensured in case of protection of intellectual property. Being a developing country, India was given a transition period of ten years, within which the national law should be made to be in compliance with TRIPS. In order to achieve this goal, amendments to the Patents Act of 1970 were passed in 1999, 2002 and 2005. In 2005, the Patents Act,1970 was amended by way of the Patents (Amendment) Act, 2005. By virtue of the amendment in 2005, product patent was extended to all or any fields of technology, including food, drugs, chemicals, and micro-organisms. Section 5 of the Patents Act,1970, which prohibited the granting of product patents for pharmaceutical drugs, was omitted from the legislation by way of this amendment, thereby opening up the gates for product patents for drugs in India. This amendment repealed provisions relating to Exclusive Marketing Rights (EMR), whereas a provision for enabling the grant of compulsory license and pre-grant and post-grant opposition has been introduced. The Patents Act,1970 was amended in 2005 to bring it into compliance with the TRIPS provisions within the deadline of ten years. Even though product patents were reintroduced, the amendment also contained certain “flexibilities”, which were in consensus with the TRIPS. One among those TRIPS flexibilities which are of relevance in the context of the pharmaceutical industry is compulsory licensing and Section 3(d). Section 3(d) was widely known as the anti-evergreening provision.

[245] *Supra* note 23.

3.8. SECTION 3(d) & IT'S LEGISLATIVE HISTORY

The current version of Section 3(d) underwent the amendment in 2005. By way of the amendment to the Patents Act, 1970 in 2005, Section 3(d) was inserted into the Patents Act 1970 as an anti-evergreening provision. Before a bill becomes a legislation, there are various pre-legislative steps involved. In the ordinary course of action, the ministry or department of the government that deals with the particular matter draft the Bill. Before the Bill is sent to the Group of Ministers ("GoM"), the document will be made available to all Government ministries for their opinions and recommendations. The GoM will debate and discuss over the Bill. Once the GoM approves of the Bill, it will be sent to the Cabinet for the final approval. After the approval of the Bill by the Cabinet, it will be subsequently placed before the Parliament for its members to cast their votes and decide upon the Bill.

However, in the case of the Patent (Amendment) Act,2005, an additional level of consultations and debates were done with the Left Front because of specific political reasons. Even though the Left Front were supporters of the government, they were very much against the proposed provisions in the amendment bill. Therefore, it was crucial for the then Union Government to conciliate them.

The initial set of amendments that were proposed and discussed before the GoM in 2004 was drafted by the Department of Industrial Policy and Promotion (DIPP). In the meeting, the members have emphasised that India has to comply with the requirement of the timely implementation of laws in compliance with the TRIPS provisions, mainly because India has fully utilised the allowed transition period of ten years. After much deliberation and discussion, the recommendation made by the GoM regarding the proposed Section 3(d) was the addition of the term *"mere"* before the words *"new use"*. This specific recommendation was backed by the reasoning that it would curb the granting of patents to the mere new use of the known substance, thereby prohibiting the evergreening of patents. The minutes of the GoM meeting also provides that the members have mentioned that the prevailing legislation on patents also does not allow for the evergreening of patents. In addition to that, it will also aid in bestowing consistency in the drafting. After the approval of the proposed Bill by the GoM, further discussions with the Left Front were carried out. During these discussions, the Left Front raised certain objections. Regarding Section 3(d), no further proposals or

recommendations were proposed by the Left Front as to the proposed provision approved by the GoM. The Left Front was much more concerned with confining the scope of patentability of inventions in the pharmaceutical sector. In order to regulate this scope, they were concerned with defining the term "pharmaceutical substance' and inserting the proposed definition in the Bill. This was in order to fulfil the objective of the Left Front that the patenting of pharmaceutical derivatives should be prohibited entirely. In response to the recommendations made by the Left Front, the DIPP in its response has made it clear that the incorporation of the definition of "pharmaceutical substance" as suggested by the Left Front would be in violation of the TRIPS. The definition as proposed by the Left Front is as follows, *"pharmaceutical substances mean new chemical entity or new medical entity involving one or more inventive steps"*.[246] This particular definition, as proposed by the Left Front, was utterly dismissed by the DIPP. As per the reasoning provided by DIPP, the definition itself explicitly excludes a significant category of inventions from being getting patented and therefore goes in contravention of Article 27 of the TRIPS.[247]

Eventually, on March 18, 2005, the first draft of the Bill was placed before the Parliament. Regarding Section 3(d), the first draft contained the older version of the provision.[248] In order to transform to its current version, further changes were made to Section 3(d). Exactly one day before the introduction of the Bill in the Parliament, on March 17, 2005, a note written by the Director of DIPP was sent to the Legislative Department to draft certain final changes in the amendment Bill.[249] The present version of Section 3(d) has also resulted from these last-minute changes. The note makes it clear that the phrasing of Section 3(d) was according to the proposition proposed by Justice V.R Krishna Iyer. The last-minute change to the Bill also included the deletion of the term "mere" before the words "new use", which was earlier introduced by way of ordinance. As a response, the Legislative Department has informed the DIPP that in order make any changes in an already existing Bill in the Parliament, and the proposed

[246] Suggestion for Patents (Third) Amendment Bill to amend the Indian Patents Act, 1970.https://www.spicyip.com/docs/CPI1.pdf (last visited Jul.25, 2022).
[247] *Id.*
[248] Bill No. 32 of 2005. SPICY IP. https://www.spicyip.com/docs/firstversion.pdf, (last visited Jul. 20, 2022).
[249] Amendments in the Patent Bill, 2005. SPICY IP. https://www.spicyip.com/docs/Section3(d).pdf (last visited Jul.20, 2022).

amendments need to be approved by the Cabinet in the first instance.[250] in case that is not possible, before adding it to the amendment, approval has to be requested from the Prime Minister, and thereafter ex-post facto consent can be sought from the Cabinet later on. Based on the opinion of the Legislative Department, on March 19, 2005, a letter was sent from the DIPP to the Cabinet Secretary outlining the amendments to be added to the Bill before it was taken up for consideration. The document also provided for the reasoning for amending Section 3(d) as proposed by Justice V.R.Krishna Iyer. Two days later, on March 21, 2005, a reply was received from the Cabinet Secretary, which informed that the proposed amendments to be included in the Bill were approved by the prime minister. On the introduction of the Bill in the Parliament, not all members agreed upon the proposed Section 3(d). many argued that criteria of patentability under Section 3(d) should be limited to a "new chemical entity". In due course, even an amendment has been moved by a member of the Parliament with the objective to limit the patentability criteria as provided in Section 3(d) to "new chemical entities". In order to study about this recommendation and to examine its compatibility with TRIPS, it was referred to an expert committee which was headed by Dr Mashelkar. Meanwhile, the Bill was passed by both the Lok Sabha and the Rajya Sabha. Later on, the recommendation to limit the patentability criteria as provided under Section 3(d) to only "new chemical entities" were rejected by the Technical Expert Group on the reasoning that it was violative of the TRIPS provisions.

The significant criticisms faced in the drafting of Section 3(d), to be specific, are as follows. The authorship of Section 3(d) has been attributed to Justice V.R. Krishna Iyer. It is interesting to note that in 2000, Justice V.R Krishna Iyer heavily criticised the granting of pharmaceutical patents.[251] According to him, granting pharmaceutical patents violates Article 14, Article 19 and Article 21 of the Constitution. His arguments were based on the right to health guaranteed by the Constitution of India. In his article, it is evident that he is opposed to the idea of patenting of pharmaceuticals and expressly granting of product patents to pharmaceuticals. He criticises the government that, by signing the TRIPS, the government have prioritised the obligations under TRIPS over the principles enshrined in the Constitution. According to him, patent monopoly goes

[250] The Patent (Amendment) Bill,2005.Legislative Department. Ministry of Law and Justice. March 17,2005. SPICY IP. https://www.spicyip.com/docs/Section3(d).pdf.
[251] V.R. Krishna Iyer. *Human health and patent law*. FRONTLINE. https://frontline.thehindu.com/other/article30255155.ece. (last visited Jul. 30, 2022).

against the socialistic and welfare state principles enshrined in the Constitution. He goes even to the extent of terming these practices as "anti-Indian". Again, even though the changes to be made in the law were debated for almost six months, some very crucial changes which will have far-reaching effects were added to the Bill at the very last moment. There were no proper discussions and deliberations on the last-minute additions that were made.

3.9. SECTION 3(d): AN ANALYSIS

Section 3 of the Patents Act,1970 provides for what all do not constitute as inventions. The provision explicitly denies patenting of drugs for any incremental innovation unless a significant therapeutic edge can be established in comparison to the existing molecules.[252] Critics have identified the object of exercise behind the enactment of the provision to be identified as to thwart evergreening.[253] The Patent (Amendment) Act, 2005 is the sole law that adds Section 3(d) to the law. Prior to the inclusion of this clause, every kind of technology, including applications relating to pharmaceuticals, chemicals, food, and micro-organisms, was eligible for patenting, with the exception of those that merely improved upon already-known substances. In terms of determining whether or not a material deviates from any recognised substance, there were scarcely any stringent standards governing such criteria. A close reading of the total provision reveals one thing: this section prohibits the use of any new substance or innovation that has been applied for a patent and is only an improvement or development of any given patent that is currently in the market or has been appropriately utilised by the awarded patent applicant. It is essential to realise that by including specific chemicals like salts, ethers, esters, and others, we may deduce that the primary focus of this provision is on pharmaceutical drugs and patent applications for pharmaceuticals. Clause (d) of Section 3 is as follows:

> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance*

[252] Aayush Sharma. India: *Understanding The Section 3(D) Of The Patents Act, 1970 Is Essential To Appreciate The Patent Law*. MONDAQ, https://www.mondaq.com/india/patent/486342/understanding-the-section-3d-of-the-patents-act-1970-is-essential-to-appreciate-the-patent-law (last visited Aug. 1,2022).

[253] Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491,495 (2007).

or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."[254]

According to the provision, in the case of an already known substance, the discovery of the new form of the known substance per se will not be eligible to get patented unless it is proved that the new form exhibits enhanced efficacy. Therefore, there must be a difference in the properties of the properties of the different forms of the known substance, specifically in terms of efficacy. The core assumption behind section 3(d) is that derivatives that are structurally comparable to known pharmaceutical substances are likely to be functionally equivalent as well and if this is not the case and the new form of an existing substance functions better than the old form, it is up to the patent application to establish this and support the patent claim.[255] The examiner compares the qualities of the known drug and the new version of the known substance, as well as any improvements in effectiveness. The comparison is made between the current form and a new form, not between the base compound and a new form, in the event that the new form is further transformed into another new form.[256] Because it is impossible to establish a standard numerical value for effectiveness for all items, including pharmaceutical products, the efficacy need not be measured in terms of a numerical value to assess if the product is effective.

[254] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[255] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).
[256] Aayush Sharma. *India: Understanding The Section 3(D) Of The Patents Act, 1970 Is Essential To Appreciate The Patent Law*. MONDAQ, https://www.mondaq.com/india/patent/486342/understanding-the-section-3d-of-the-patents-act-1970-is-essential-to-appreciate-the-patent-law (last visited Aug. 1,2022).

3.9.1. INCREMENTAL INNOVATION v. EVERGREENING

In order to understand the purpose behind the enactment of Section 3(d), it is imperative to understand the history as well as the objective which was aimed to be achieved. The instances and the history which led to the enactment of the provision have already been discussed in detail. It is identified that the objective behind the enactment of Section 3(d) is to inhibit "evergreening" in the Indian patent law regime.[257] Along with the enactment of the provision, the disparity between incremental innovation and evergreening was widely debated. In black and white letters, not much difference can be made between the two. In particular, in the pharmaceutical sector, incremental innovation is reckoned to be the initial step toward the discovery of a blockbuster drug[258] .[259] In distinguishing between incremental innovation and evergreening, there exist a thin line of difference, according to which the patentability of the former is debated by the academics while the latter is not regarded to be deserving patent protection.[260] The development of safer, more effective, and more valuable drugs that are better suited to specific patient profiles or needs results from incremental pharmaceutical innovations, which also involve the discovery of new forms and uses for chemical compounds or substances that are already known.[261] As a result, patient compliance and general wellness are likely to rise.[262] Robin Feldman[263] describes 'evergreening' as the process of artificially prolonging the life of a patent or other exclusivity by securing extra protection to extend the monopoly term.[264] Simple strategies can include gaining fresh patent protection for existing pharmaceuticals by filing for additional patents, often on methods of producing or manufacturing the drugs or on other elements. More advanced evergreening tactics include the creation of new formulations, dosage regimes, or combinations that can be utilised to acquire new

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[257] K.D Raju. *Interpretation Of Section 3(D) In The Indian Patents Act 2005:A Case Study Of Novartis.* INJLIPLAW, 7(2008).

[258] James Chen. INVESTOPEDIA. https://www.investopedia.com/terms/b/blockbuster-drug.asp. (A drug which generates more than billion dollars for its company in a year) (last visited Jul. 30,2022).

[259] Albert I. Wertheimer and Thomas M. Santella. *Pharmacoevolution: the advantages of incremental innovation*. IPN WORKING PAPERS ON INTELLECTUAL PROPERTY, INNOVATION AND HEALTH. https://dyahperwitasari.files.wordpress.com/2009/11/pharmacoevolution.pdf.

[260] *Supra* note 142.

[261] U.S-INDIA BUSINESS COUNCIL, THE VALUE OF INCREMENTAL PHARMACEUTICAL INNOVATION(2009), http://www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReport Final.pdf.

[262] *Id.*

[263] Arthur J. Goldberg Distinguished Professor of Law and Director of the Institute for Innovation Law at the University of California Hastings.

[264] *Supra* note 29.

patents.[265] In the context of debates on the pros and cons of Section 3(d), it can be summarised that those who were in favour of Section 3(d) argued along the lines of prohibiting the evergreening of patents.[266] At the same time, those against the enactment of Section 3(d) argued that extending of patent protection for incremental innovation in the pharmaceutical sector will be beneficial for the growth of the pharmaceutical sector.[267] At the end of the day, the decision was reached favouring the supporters of Section 3(d).[268]

3.9.2. DISCOVERY

Only the "mere discovery of new forms" is prohibited in Section 3(d).[269] One may argue that "discovering" an already existing new form is not the same as generating a new form. A court may be unlikely to support such a proposal since it appears to be a very technical reading of the clause that does not entirely accord with the Parliamentary purpose of restricting "ever-greening."[270] However, because a court might construe the language literally, section 3(d) should be changed to eliminate references to "discovery."

3.9.3. KNOWN SUBSTANCE

Any patent held by an individual or entity with a valid patent tenure that has been correctly registered and approved by the Controller is considered a known substance.[271] The only criteria required by the Patent Controller for new inventions is that the patent applicant show "efficacy" or, in common parlance, "efficiency" in their product to signify and prove that their invention is more advanced and not a simple improvement over the composition of a known or already-patent substance. This is because it is a

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[265] *Supra* note 29.

[266] Suresh Kurup.Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005.March 22,2005. http://loksabhaph.nic.in/Debates/result14.aspx?dbsl=1866.

[267] Kharabela Swain. Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005.March 22,2005. http://loksabhaph.nic.in/Debates/result14.aspx?dbsl=1866.

[268] Combined discussion on the Statutory Resolution regarding disapproval of Patents (Amendment) Ordinance, 2004 (No.7 of 2004) and the Patents (Amendment) Bill, 2005.March 22,2005. http://loksabhaph.nic.in/Debates/result14.aspx?dbsl=1866.

[269] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).

[270] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).

[271] Vasishtan P & Samhitha Reddy. *Rethinking The Need For Defining 'Efficacy' In The Indian Patent Regime*. 1(1) E-JAIRIPA, 103 (2020).

decided rule that any new products that attempt to secure a patent cannot be a trivial development or a mere discovery of a new form of a known substance.

3.9.4. NEW FORM OF A KNOWN SUBSTANCE

3.9.4.a. INDIA

The first clause of Section 3(d), which forbids patents *for "the mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance,"* precludes patents for derivatives of known substances unless such derivatives exhibit "enhanced efficacy."[272] The explanation that follows the rule defines which substances would be regarded as derivatives of recognised drugs and requires that efficacy "differ significantly."[273] To prolong their protection of known active compounds, pharmaceutical corporations frequently submit independent patent applications on variants of recognised chemicals.[274] Some therapeutically active chemicals, for example, are found in polymorphic forms (a crystallisation in multiple forms), which may have diverse therapeutic qualities.[275] Pharmaceutical businesses frequently file composition patents to protect the finished product, which contains active chemicals and suitable additions. They also seek patents on the active metabolite, which is the chemical that occurs in the patient's body after the medicine is consumed and has the intended therapeutic effect.[276]

3.9.4.b. OTHER JURISDICTIONS

The need for efficacy is contentious since it has no express counterpart in any other patent regime in the world.[277] The efficacy of pharmacological substances is typically handled through drug safety regulation, and it has no bearing on the patentability of substances.[278] Section 3(d) appears to have been directly lifted from a European legislative directive dealing with drug safety regulation.[279] Furthermore, Section 3(d)

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[272] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[273] *Id.*
[274] *Supra* note 23.
[275] Carlos M. Correa. *Public Health and Patent Legislation in Developing Countries*. 3 JTIP, (2001).
[276] *Id.*
[277] Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15, 18 (2005).
[278] *Supra* note 23.
[279] Article 10(2)(b) of Council Directive 2004/27/EC defines a "generic medicinal product" as: a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the

raises concerns about the type of evidence necessary to show efficacy and how much an improvement results in considerably improved efficacy.[280]

While Section 3(d) has no direct analogue in other patent statutes, other nations, including the United States, have a plethora of indirect techniques to deal with patents on minor alterations to recognised active substances.[281] For example, under the doctrine of inherent anticipation, U.S. courts have invalidated patents on compounds of known substances.[282] In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*,[283] the Federal Circuit invalidated a patent on an antihistamine drug metabolite because the metabolite was necessarily and inexorably generated following administration of previously patented antihistamine under standard settings.[284]

Furthermore, under the complicated doctrine of double patenting,[285] which tries to prevent a patentee from having more than one patent with claims to the same invention or noticeable changes or variations of the same invention, U.S. courts prohibit the patenting of derivatives.[286] The ban against double patenting in the United States has a legislative foundation, which forbids a patentee from having more than one patent with identical claims,[287] as well as a judicially constructed equitable doctrine, which states that a patentee may not have a later-issued patent with claims directed to an obvious modification of the subject matter of claims in an earlier-issued patent.[288]

The patent abuse doctrine, which prohibits pharmaceutical corporations from prolonging patent rights by getting several patents covering substantially the same

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reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixture of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines. Council Directive 2004/27, art. 10(2)(b), 2004 O.J. (L 136) 39 (EC).

[280] Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491,495.

[281] *Supra* note 23.

[282] Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373 (Fed. Cir. 2003).

[283] 339 F.3d 1373 (Fed. Cir. 2003).

[284] Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373 (Fed. Cir. 2003).

[285] Emily A. Evans & Jill A. Jacobson, *Double Patenting Recapitulated*, 87 J. PAT. & TRADEMARK OFF. Soc'y 625 (2005).

[286] *Supra* note 23.

[287] 35 U.S.Const. § 101.

[288] Emily A. Evans & Jill A. Jacobson, Double Patenting Recapitulated, 87 J. PAT. & TRADEMARK OFF. Soc'y 625 (2005).

innovation, is another strategy used in the United States.[289] Finally, when dismissing some pharmaceutical patents in the United States, courts rely on the 35 U.S.C. 103 non-obviousness doctrine.[290] The Federal Circuit invalidated Pfizer's patent on a hypertension drug on non-obviousness grounds in *Pfizer. v. Apotex*[291] because the active component of the drug was essentially a salt version of a known molecule.[292]

3.9.5. EFFICACY

The Madras High Court decided that the phrase "efficacy" in section 3(d) implied "therapeutic" efficacy based on a medical dictionary meaning. The types of derivatives that qualify for protection are likely to be severely limited under such a criterion. For example, salt formulations that improve stability and allow the medicine to last longer on the market or be carried to diverse regions of rural India without refrigeration will not be patentable.[293] As seen above, a plain/literal interpretation of section 3(d) may not agree with this limiting meaning because the provision is not confined to pharmacology. The term "efficacy," like other notions in patent law, is a powerful policy lever[294] that India might interpret narrowly or widely. The effects of both choices are discussed below.

Section 3(d) might be construed narrowly to entail just "therapeutic efficacy," as the Madras High Court recommends.[295] As a result, all other types of benefits, such as greater heat stability and novel drug delivery modalities, are ineligible.[296] A "bright line"[297] regulation like this has the benefit of being administratively simple to execute by a patent office that is understaffed and new to assessing pharmaceutical product patent applications. However, as discussed in the section below, such a criterion will

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[289] Dan L. Burk and Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RSRV. L. REV. 691 (2004).

[290] 35 U.S.Const. § 103(a) provides that, "A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made."

[291] 480 F.3d 1348 (Fed. Cir. 2007).

[292] Pfizer v. Apotex, 480 F.3d 1348 (Fed. Cir. 2007).

[293] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d),* 5 SCRIPTed 232 (2008).

[294] D L Burk & M A Lemley, "*Policy Levers in Patent Law*" (2003) 89 VA. L. REV. 1575, at 1630.

[295] Novartis AG v. Union of India, (2007) 4 MLJ 1153.

[296] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d),* 5 SCRIPTed 232 (2008).

[297] Miranda v. Arizona. 384 U.S. 436 (1966).

preclude the possibility of patents for a substantial number of incremental advances made by Indian pharmaceutical firms.

The term "efficacy" should not be limited to tightly defined therapeutic efficacy. Instead, it should incorporate all of the new form's favourable qualities, such as thermal stability, increased bioavailability, humidity resistance, and new drug delivery systems. Some of the most well-known discoveries from Indian pharmaceutical firms have been successful in non-therapeutic ways, which may be a fundamental cause for broadening the spectrum of efficacy. One of the most frequently mentioned instances is Ranbaxy's CIPRO tablet, a revolutionary drug delivery method.[298] The discovery, known as Cipro-OD, allows patients to take the medication only once a day (OD).[299] Ranbaxy's drug will be classified as a "combination" under the Explanation to Section 3(d) of India's Patent Act.[300] As a result, unless it displays considerably improved "efficacy" above and beyond Bayer's CIPRO, it is not patentable.

To some degree, this expansive definition of efficacy is paralleled in the patent systems of the United States and the European Union, where structural similarities between a pharmaceutical substance sought to be patented and an earlier known drug generate a prima facie obviousness presumption. This presumption, however, can be overturned if the patent applicant shows that the applied-for substance produces "unexpected or unanticipated outcomes."[301] Unexpected outcomes are not restricted to "therapeutic" benefits alone.[302] However, it is vital to recognise that section 3(d) and the relevant U.S. laws on the patentability of chemical/pharmaceutical compounds differ significantly.[303]

As per Section 3(d), the provision does not need the proof of any purpose or explanation for identifying the lead chemical or modifying it in the manner recommended. Instead, it focuses on two rather "objective" questions. Firstly, whether the claimed compound is a derivative of a known drug? Secondly, if so, does it outperform the present

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[298] Gehl Sampath, Padmashree. *Economic Aspects of Access to Medicines After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*. CIPIH(2005).
[299] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).
[300] *Id.*
[301] *In re* Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990).
[302] Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491,495 (2007).
[303] A. Mc Tague, *Secondary Pharmaceutical Patents Post-KSR : Do They Have A Future ?* , 6(3) Pharmaceutical Law & Industry Report, (2008).

substance in terms of efficacy? If the answer to the second question is "yes", the requirement under Section 3(d) is fulfilled, and the patent may be awarded, subject to additional patentability standards being met. If the response is "no," the patent application is automatically denied. It is crucial to remember that even after passing the section 3(d) barrier, an invention is examined for conformity with other patentability requirements such as novelty, non-obviousness or inventive step,[304] and utility.

Even if the claimed derivative has a superior and surprising "efficacy" above its predecessor substance, it may nevertheless be deemed "obvious" under US law since the prior art may provide a person versed in the art with adequate motive to reach such derivative.[305] In this context, while such a derivative may pass the section 3(d) hurdle in India, it will still be challenged on the grounds that it lacks an inventive step. Furthermore, when it comes to determining an "inventive step," the Indian patent office or a court may reach the same conclusion as the US Court of Appeals in *Pfizer v. Apotex*,[306] notably, that because a skilled person in the art had only a limited range of substances to work with, finding the particular salt would have amounted to "routine optimisation."[307]

3.9.6. NEW USES OF KNOWN SUBSTANCES

3.9.6.a. INDIA

The second clause of Section 3(d), which states that "any new property or new use for a known substance or the simple application of a known process, equipment, or apparatus unless such known process results in a new product or uses at least one new reactant,"[308] governs the granting of "new use" patents.[309] Patents are regularly granted for the novel therapeutic use of existing products.[310] New use patents are crucial to

[304] The Patents Act, 1970, §2(1)(ja), No. 39, Act of Parliament, 1970 (India).
[305] Pfizer v. Apotex. 480 F.3d 1348 (2007).
[306] 480 F.3d 1348 (2007).
[307] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).
[308] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[309] Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491,495 (2007).
[310] *Supra* note 23.

pharmaceutical firms' patent strategy, as they rely on them to extend the commercial life of product patents.[311]

3.9.6.b. OTHER JURISDICTIONS

The patentability of new uses of the known substances is contentious, and other nations usually treat it inconsistently.[312] A process patent can protect a novel use of an existing product in the United States.[313] The patent is limited to a specific technique of use and does not include product protection.[314] Process patents are loathed by patent holders since they are difficult to enforce and cannot be used to prevent rivals from selling the same product for other purposes.[315]

Europe takes a broader view on new use patents.[316] In Europe, a novel use might be either a product claim or a process claim, depending on whether the product has previously been used in the pharmaceutical industry.[317] A product patent can protect a new therapeutic application of a known product with no previous pharmaceutical usage, known as a "first indication" or "first medical use."[318] This unique type of product patent claim is known as a "purpose-limited-product" claim because it restricts the scope of the patent protection to the product's specific purpose or use.[319] A process patent, on the other hand, protects a new use for a product that already has an existing pharmaceutical usage, known as a "second indication" or "second medical use."[320] The claim structure is known as a "Swiss claim" because it is only confined to the innovative application of a known component or mixture.[321]

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311 Edson B. Rodrigues Jr. & Brian Murphy, *Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines*, 16 ALB. L.J. SCI. & TECH. 423, 430 (2006).
312 Jean Lanjouw, *A New Global Patent Regime for Diseases: U.S. and InternationalLegal Issues*, 16 HARV. J.L. & TECH. 85, 95 (2002).
313 Rohm & Haas Co. v. Roberts Chemicals, 245 F.2d 693(1957).
314 Rebecca S. Eisenberg, *The Problem of New Uses*, 5(2) YALE J. HEALTH POL'Y L. & ETHICS, (2005).
315 *Id.*
316 *Supra* note 23.
317 Carlos M. Correa. *Public Health and Patent Legislation in Developing Countries*. 3 JTIP, (2001).
318 *Id.*
319 Srividhya Ragavan, *A "Patent" Restriction on Research & Development: Infringers or Innovators?* U. ILL. J.L. TECH. & POL'y 73 (2004).
320 *Id.*
321 *Id.*

3.9.7. DERIVATIVES

Section 3(d) stipulates that new forms of known substances, such as polymorphs, salts, ethers, esters, and all "other derivatives," are the same "substance" unless their qualities change considerably in terms of efficacy.[322] Based on a reading of section 3(d) and an understanding of its objective to avoid evergreening, one may argue that the drafters were aiming for structurally comparable forms rather than technically defined derivatives. The underlying premise appeared to be that identical structures (new forms) were expected to work in substantially similar ways, and if that is not the case, it was the patent applicant's responsibility to explain this.[323] This interpretation is also consistent with intellectual property standards in more developed I.P. jurisdictions such as the United States[324] and the European Union, where there is an assumption of prima facie obviousness if the patent application claims a similar compound to a previously known substance.[325]

3.10. CONCLUSION

The chapter has discussed the history of the Indian patent law regime and the legislative history of Section 3(d). Understanding the history and objective behind the enactment of a provision plays a crucial role in the better understanding and the interpretation of the provision. Section 3(d) can be regarded as one among the most debated provisions under the Patents Act,1970. Here, the test is that of "enhanced efficacy", and justice V.R. Krishna Iyer is the mastermind behind the provision.[326] Nevertheless, how do we measure efficacy? Because the term "efficacy" has not been defined anywhere in the patent law. This opens up the room for the judiciary to interpret the term as per the objectives behind the legislation.

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[322] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[323] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).
[324] Takeda v. Alphapharm, 480 F.3d 1348 (Fed. Cir. 2007).
[325] Shamnad Basheer & T. Prashant Reddy, *The Efficacy of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232 (2008).
[326] Spadika Jayaraj. *Justice VR Krishna Iyer's IPR Legacy: S.3(d) of the Indian Patent Act*. SPICYIP. .https://spicyip.com/2014/12/justice-vr-krishna-iyers-ipr-legacy-s-3d-of-the-indian-patent-act.html (last visited Jul.28, 2022).

CHAPTER IV
SECTION 3(d) & THE INDIAN COURTS

4.1. INTRODUCTION

The test of efficacy is regarded as the heart and soul of Section 3(d), the Patents Act,1970.[327] The brilliance behind the drafting of a provision becomes evident only when a dispute relating to the provision arises. A provision which stands the test of time can be regarded as an efficiently drafted provision. Similarly, after the amendment of Section 3(d) in 2005,[328] the provision was challenged before the courts. To date, the 2013 judgment of the SC in *Novartis AG v. Union of India*[329] remains the sole case in which the issue of Section 3(d) was discussed and deliberated at the apex level. In addition, a few high court judgments also discuss Section 3(d). This chapter of the research work focuses on discussing the various issues pertaining to the existence and applicability of Section 3(d) that were raised and decided by the SC, high courts and the Intellectual Property Appellate Board. The chapter focuses on outlining the cases which dealt with Section 3(d). Thereafter focuses on examining the interpretation of the test of efficacy by Indian Courts.

4.2. INDIAN APPROACH TOWARDS THE TERM "EVERGREENING" OF PATENTS

As the stated goal of Section 3(d) is the prevention of evergreening, a deconstruction of alternative theories of evergreening and an examination of whether evergreening happens in India are critical to understanding Section 3(d). Evergreening is not the practice of re-patenting the same subject matter during the term of a prior patent. The Indian Patent Office forbids such patents by demanding "inventive step"[330] and "novelty" in all new patents. In simple words, it would be evident if a second drug had identical features and claims, and the patent office would not grant a patent on it.[331]

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[327] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[328] The Patents (Amendment) Act, 2005. No. 15, Act of Parliament, 2005.
[329] AIR 2013 SC 1311.
[330] The Patents Act, 1970, §2(1)(ja), No. 39, Act of Parliament, 1970 (India).
[331] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d),* 21 J. INTELL. PROP. L. 223 (2014).

There would be no debate. The question is whether specific additional enhancements are sufficient to warrant a new patent.[332] Indian patent law also prohibits patenting a drug reformulation that would allow the term of the original patent to be extended.[333] When a patent expires, a generic version may be manufactured. The procedure of Patent expiry is a legal affair.[334] There is no way for a pharmaceutical corporation to ignore or override it; therefore, a generic entity may begin making it.[335]

In pharmaceutical patenting, after patenting the raw active molecule at an early stage of drug research, a drug developer can acquire a secondary patent on a later iteration of the drug, including the commercial formulation of the drug.[336] As aforementioned, a secondary patent will not prohibit generic drug firms from utilising an earlier version of the drug, including the active molecule if that was patented, when the patent on that iteration expires.[337] Thus, if the newer version of the drug is not a genuine improvement over the version that was initially patented, it is in the interest of generic companies to manufacture and sell the older version because patients should be agnostic about the difference between the cheap expired and expensive on-patent versions.[338] The only way secondary patents might evergreen or postpone the entry of significant generics into the market is when the modified version is superior to the original, as indicated by substantial patient demand.[339]

4.3. SECTION 3(d): THE CONUNDRUM AND THE CONTROVERSY

The whole Section 3(d) is a reflection of what the researcher noticed after conducting an extensive study on the struggle to define 'efficacy' between the Pharma Companies and the High Court's or the Government's refusal to do so. As the researcher observed the design, implementation, and process of how Section 3(d) is handled both by the Controller of Patents in determining new applications as well as the way in which the High Courts have handled such cases that have come before them on appeal, they

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[332] *Id.*
[333] *Id.*
[334] *Id.*
[335] *Id.*
[336] *Id.*
[337] Dorothy Du, Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d), 21 J. INTELL. PROP. L. 223 (2014).
[338] *Id.*
[339] *Id.*

comprehend and deduced that despite many disparagements and criticisms arising against the validity of Section 3(d) by various multinational Pharma Companies or other Governments, Novartis raised the same issue as a challenge in the Madras High Court case.[340] Not only do the existing pharma businesses in India oppose Section 3(d), but the United States of America's government has categorised India as a "Priority Watch List Country" in its Special 301 report[341] dated 30th April 2014.[342] The Indian Ministry of Commerce and Industry defended the Indian Patent Regime, stating that the nature of Section 3(d), which prohibits evergreening of patents, has been a source of concern for US Pharma Companies, implying that the US Government issued such a Special Report to promote US-based pharma companies in other countries subtly.[343]

Nevertheless, the bigger question that is to be pondered is the logic behind the defending of Section 3(d) by the Indian courts and the Government of India without providing any definition to the term "efficacy".[344] In order to understand, we must first understand the additional issues that arise as a result of the term "efficacy" not being defined.

The primary and solitary element for any new patent application to surpass Section 3(d) and be accepted as a patent by the Controller of Patents in India is efficiency.[345] Specific tactics are used by pharmaceutical companies to prolong their patent applications. The fundamental logic is that they will be able to earn more money and get rights to their items. Because the time period for holding a patent in India is just 20 years,[346] the longer such rights remain with them, the more money they would gain as a result of the exclusivity of such items. If a corporation generates a lot of money off of such a patent, it is logical to assume that the company would seek to increase its earnings and so attempt to prolong the patent's term in some way.[347]

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340 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
341 SPECIAL 301 REPORT, *Supra* note 34.
342 US Opposition to Section 3(D) of the Indian Patent Act. Press Information Bureau, Government of India. July 30,2014. https://pib.gov.in/newsite/printrelease.aspx?relid=107612.
343 *Id.*
344 Vasishtan P & Samhitha Reddy. *Rethinking The Need For Defining 'Efficacy' In The Indian Patent Regime*. 1(1) E-JAIRIPA, 103 (2020).
345 The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
346 The Patents Act, 1970, § 53, No. 39, Act of Parliament, 1970 (India).
347 Vasishtan P & Samhitha Reddy. *Rethinking The Need For Defining 'Efficacy' In The Indian Patent Regime*. 1(1) E-JAIRIPA, 103 (2020).

This is when large corporations may embrace the practice of discovering another new innovation or enhancement to an existing substance and attempting to patent the same, allowing them to maintain the same benefits as the prior patent while having a fresh application on hand. To do this, the corporations would create new ideas based on previously awarded patents and demonstrate substantial improvements over the old ones in order to contrast and differentiate the new application as a brand-new invention.

In the Novartis case, the Madras High Court determined that 'therapeutic efficacy' is required for the Controller of Patents to issue a patent.[348] The new invention's final criterion would be its therapeutic efficacy.[349] This is in contrast to prior patented technologies where the effect of the medicine's use is demonstrated in the medicine's ability to heal.

As a result, it is exceedingly difficult for firms to demonstrate the same ultimate output for a new treatment or drug despite having almost identical elemental compositions with an existing patent application. This effectively nullifies their ability to get the Patent. Thus, the Indian Patent Regime has disallowed the idea of patent evergreening by the indirect use of the word "therapeutic efficacy."[350]

4.4. TRIPS AND SECTION 3(d): DISSECTING THE RAPPORT

The compliance of Section 3(d) with the TRIPS Agreement was challenged before the High Court of Madras.[351] In considering the issue, the validity of the jurisdiction of the Indian courts in examining a violation of the TRIPS was also explored. The court reiterated that the essential nature of an international treaty is a contract. Hence, in these circumstances, when a dispute resulting from an International Treaty is brought before a court, the court would not be committing any error in considering the case on contract grounds. On analysing the Dispute Settlement System (DSS) as provided under the TRIPS Agreement, the Court has held that, in the presence of a comprehensive settlement mechanism that is agreed upon by the member states, it lacks the proper jurisdiction to evaluate as to whether Section 3(d) is in violation of Article 27 of the

[348] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[349] *Id.*
[350] *Id.*
[351] *Id.*

TRIPS[352] Agreement.[353] Citing its lack of jurisdiction, the Court has withdrawn from deciding the issue of compatibility of Section 3(d) with the TRIPS Agreement.[354]

The High Court of Madras adopted an interesting "contractual" approach to argue its lack of jurisdiction, arguing that an international treaty like TRIPS amounted to a contract between states.[355] As a result, it had to be read in line with standard contractual standards. The Madras High Court made an error by relying on an overly basic contractual framework to determine whether a domestic court may interpret an international treaty.[356] Instead, it should have approached this question through the lens of constitutional law. According to SC rulings, the Indian Constitution, in keeping with a dualist heritage, forbids the "direct effect" theory[357] of international treaties from being applicable in India.[358]

Article 23 forbids a complaining member State from deciding on a WTO breach unilaterally.[359] In other words, the Swiss government (in the case of Novartis) cannot conclude unilaterally that Section 3(d) infringes TRIPS.[360] However, nothing in the DSU or other WTO agreements precludes an Indian court from making such a finding. In other words, India or any other defendant member State is free to give its international commitments "direct effect" and provide complaining member States or their citizens with the option of bringing WTO matters before its domestic courts. Nothing in the World Trade Organization Agreement forbids this.[361] Because the WTO and the TRIPS agreement allowed for an exclusive dispute settlement mechanism, the Madras High Court was incorrect in ruling that it lacked jurisdiction to hear Novartis

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352 TRIPS. art.27.
353 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
354 *Id.*
355 *Id.*
356 *Id.*
357 Doctrine of direct effect: A private person in a State (or union) may base a claim in, and be granted relief from, the domestic courts of that State against another private person or the State on the basis of the State's obligations under an international treaty. Such claims can be made without a transformation of the obligation by national or regional rule makers. They may equally be made against implementing legislation on the grounds that such legislation is not compatible with international law. T. Cottier & K.N. Schefer, *The Relationship between World Trade Organization Law*, 1 J. INT'L ECON. L. 83-122 (1998).
358 Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
359 Dispute Settlement Understanding, art. 23.
360 Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
361 Dispute Settlement Understanding, art. 23.

TRIPS complaint.[362] Instead, it should have concluded that its inability to strike down Section 3(d) as violating TRIPS was due to Indian law's prohibition on direct enforcement of international treaties. Direct effects are often relevant in nations with a monist heritage rather than a dualist tradition.[363] Articles 51(c) and 253 of the Indian Constitution expressly prohibit a treaty from having a "direct effect" in India.[364] Article 51(c) requires the State to follow international legal norms.[365] However, because this Article is just a Directive Principle of State Policy (DPSP), it is unjustifiable.[366] Similarly, Article 253 simply grants Parliament the authority to enact any legislation for the entire or any part of India's territory in order to carry out any treaty, agreement, or convention with any other nation.[367] It does not treat treaties on the same footing as domestic law. As a result, the Indian Constitution does not require treaties to be given "direct effect" and locally implemented. In other words, lacking an express mandate in the Indian Constitution, a statutory provision such as Section 3(d) cannot be declared illegal because it violates an international treaty.[368]

The Indian legal system is dualist in character, and the idea of "direct effects" is not recognised.[369] A treaty provision that has not yet been incorporated into domestic law is only enforceable if it does not contradict with domestic law. However, if they contradict, domestic law would certainly take precedence. As a result, even though Section 3(d) of the Patents Act of 2005 breaches TRIPS, the courts cannot knock it down. The absence of a "direct effect" theory is critical in understanding why domestic courts cannot directly enforce international agreements that contradict with prevailing domestic standards.[370] To be fair, the Madras High Court did make a reference to such a notion in *Salomon v. Commissioner of Customs*[371] .[372] Although the court was correct

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[362] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[363] Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
[364] INDIA CONST. art. 51(c), 253.
[365] INDIA CONST. art. 51(c).
[366] INDIA CONST. art. 37.
[367] INDIA CONST. art. 253.
[368] The Constitutional framework makes it clear that a legislation may only be challenged on two grounds: that it breaches basic rights or another provision of the Constitution, or that the Parliament lacks legislative competence to enact it. See State of A.P. v. McDowell & Co., AIR 1996 SC 1627.
[369] Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
[370] 3(d) demonstrates a clear intention of the legislature to avoid a phenomenon known colloquially as "ever-greening." If this is what the legislature meant, it must be upheld, even if it is determined to be in violation of TRIPS.
[371] Salomon v. CCE, [1966] 3 All ER 871.
[372] Novartis AG v. Union of India, (2007) 4 MLJ 1153.

in relying on the *Salomon case*, it did not follow through on its analysis.[373] It also failed to accept the presence of multiple Indian precedents indicating the absence of a "direct effects" concept in India.[374] As previously stated, it altered its analysis framework to one of contract law. It also depended on an archaic 1884 American case to bolster its contractual framework of evaluation.[375] Patentability standards have been developed in the context of particular domains of technology, taking into consideration the unique challenges provided by such innovations. Section 3(d) may be seen as a revision of patentability requirements to address "evergreening," a specific concern in pharmaceutical discoveries.[376] More specifically, the enhanced efficacy criteria may be viewed as a refinement of non-obviousness principles, in that most present pharmacological substances are considered obvious unless they exhibit greater efficacy.[377] Alternatively, it might be viewed as a refined utility test, in which only novel forms that exhibit significantly different benefits than what existed previously in the form of "significantly enhanced efficacy" are patentable.[378]

In summary, because TRIPS do not establish patentability standards, a deeming provision like Section 3(d) that caters to a specific technological area is utterly compatible with TRIPS. However, care must be taken to ensure that this clause is not read in such a way that no pharmaceutical derivative or incremental innovation is ever patentable; otherwise, the provision may violate TRIPS.

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[373] Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).

[374] The Madras High Court appears to have neglected the principle of *stare decisis*, or binding precedent, which works in relation to Indian Supreme Court decisions but not in relation to House of Lords decisions or American Supreme Court decisions by deriving its conclusions purely on the basis of American and English judgements. This common law principle is codified to some extent in Article 141 of the Indian Constitution, which deems all Supreme Court of India decisions to be the law of the nation.

[375] Edye v. Robertson, 112 US 580 (1884) at 588, 599 (United States Supreme Court). "A treaty is basically a compact between sovereign states, and the execution of its articles is dependent on the honour and interest of the governments that are parties to it," the court stated. However, the court ignored the latter half of the same phrase, which said that a treaty might also have the character of municipal law. In such cases, the treaty's terms are enforceable in a national court by private persons.

[376] Shamnad Basheer, *Lifting The Scope Of Pharmaceutical Patents And Micro- Organisms: A Trips Compatibility Review*. INTELLECTUAL PROPERTY INSTITUTE, 47 (2005).

[377] *Id.*

[378] FA KHADER: WITH A SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA, THE LAW OF PATENTS (Lexis Nexis 2007).

4.5. SECTION 3(d) AND THE CONSTITUTION OF INDIA: VETTING THE CONSTITUTIONALITY OF THE PATENT LAW PROVISION

By virtue of a writ petition filed before the High Court of Madras, the constitutional validity of Section 3(d) was challenged before the court on the grounds of violation of Article 14[379] of the Constitution.[380] The above-mentioned provision was argued to be "illogical," "arbitrary", and "vague."[381] The contentions are based on the fact that, although Section 3(d) provides for the enhanced efficacy test, there do not exist any rules or regulations regarding the calculation and quantification of efficacy.[382] It is argued that in the absence of such regulations for the calculation of efficacy, the provision provides for unlimited discretionary power to the Patent Controller to make the decision.[383] Also, the term "enhancement efficacy" is also left undefined by the legislator.[384] The ambiguous nature of the terms leaves the decision-making according to the whims and fancies of the Patent Controller. In India, a legislation can be challenged as breaching the constitution mainly on two grounds. Firstly, that it infringes on the petitioner's fundamental rights, and secondly, that the parliament lacks legislative competence to adopt the statutory provision in issue.[385]

In *Novartis v. UOI*,[386] the validity of Section 3(d) was challenged on the basis of both the above-mentioned grounds. First, it claimed that Section 3(d) infringed the fundamental right to equality guaranteed by Article 14 of the Indian Constitution.[387] It contended, especially, that the use of phrases like "improvement of known efficacy" and "substantially vary in attributes with regard to efficacy" without supporting rules explaining their meaning constituted section 3(d) unclear and arbitrary.[388] Furthermore, such arbitrariness, aided in large part by the delegation of unfettered power to a statutory authority, strikes at the heart of the notion of equality contained in Article 14

379 INDIAN CONST. art.14.
380 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
381 *Id.*
382 *Id.*
383 Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
384 *Id.*
385 State of A.P. v. McDowell & Co., AIR 1996 SC 1627.
386 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
387 *Id.*
388 *Id.*

of the Indian Constitution[389] .[390] Novartis' second argument, which was similar to the first one outlined above in many ways, argued that the structure of section 3(d) gave the patent office free power to establish its own policy and evaluate what constituted a significant improvement in efficacy.[391] Novartis claimed that this was a violation of the Constitution since it amounted to delegating a fundamental legislative responsibility. The court, however, rejected each of the preceding arguments.[392] First, the bar for any statutory provision to be deemed "arbitrary" and hence in violation of Article 14 is extremely high, and Indian courts have been hesitant to strike down legislation on this basis.[393] The Madras High Court likewise followed this pattern of judicial caution, emphasising that just because legislation is a skeleton and without definitions or rules does not always imply that it is arbitrary.[394] To measure the boundaries of a section, one must consider variables such as the wording of the legislation, the degree of discretion provided, the ability of appeal to remedy any incorrect judgement, and the goal of the statute. Furthermore, determining when a new form exhibits a "substantial" increase in efficacy as compared to the old material is not amenable to a consistent formula but must be based on the facts of each individual situation. As a result, it is exceedingly difficult to characterise section 3(d), which was enacted to restrict a phenomenon known as "evergreening," as "arbitrary" or unclear.

In various judgments, the SC has declared that, while Parliament may delegate some responsibilities to administrative entities, it should not assign an essential legislative role.[395] In other words, the legislature may establish broad policy and transfer rule-making authority to the statutory authority to carry it out. Delegated legislation is prevalent in areas of specialised knowledge when the legislature lacks the information and experience to design specific laws.[396] Using the preceding argument, the Madras High Court correctly suggested that section 3(d) is an example of delegation of a non-

[389] INDIA CONST. art. 14.
[390] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[391] *Id.*
[392] *Id.*
[393] Shamnad Basheer & T. Prashant Reddy. *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d).* 5 SCRIPTed. 232, (2008).
[394] *Id.*
[395] The court emphasises that "in the absence of express delegation powers granted by the Constitution, the Parliament has no power to delegate its essential legislative functions to others, whether State legislatures or executive authorities, except, of course, functions that are truly ministerial in their true nature." In Re Delhi Laws Act, AIR 1951 SC 332,¶ 252.
[396] Jyoti Pershad v. Administrator for Union Territory of Delhi, 1961 SC 1602.

essential legislative duty.[397] Moreover, just because it is "skeletal" or does not define concepts like "improvement of known efficacy" does not imply the patent office has "uncanalised discretion."[398] Though it cannot be criticised for its conclusions, several of the court's arguments show a lack of understanding of the technology in question, the nature of pharmaceutical innovation, and the limits of Section 3(d). These faults are most likely the result of the hastily constructed section 3(d).

4.6. INTERPRETING EFFICACY: UNLOCKING THE PANDORA'S BOX

Section 3(d) emphasises the significance of efficacy.[399] However, the Patents Act 1970 does not expound on it. It is also not stated quantitatively how much effectiveness may be considered significant. There is a discrepancy between the standard of efficacy required in the main section 'improvement in known efficacy' and its related explanation 'differ considerably in attributes' with regard to efficacy in Section 3(d).[400]

The judgment of the High Court of Madras in *Novartis AG v. UOI*[401] was the initial instance where the court interpreted the term "enhanced efficacy" in the context of Section 3(d).[402] The court's decision that the word "enhancement of known efficacy" is not ambiguous was based, in part, on the assumption that "efficacy" meant medicinal efficacy.[403] While interpreting the term "efficacy", the Court has placed its reliance on the medical definition of the term.[404] The court emphasised that "efficacy is independent of drug potency," and further clarification was provided that, in order to regard the finding of a novel form of a known substance to be an innovation, it is required that the Patent applicant must establish that the substance thus discovered has a superior therapeutic effect."[405] Later, based on the definitions of the words "efficacy" and "therapeutic" derived above, the patent application is required to demonstrate how successful the new discovery would be in curing an illness / having a positive effect on

[397] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[398] ARVIND P DATAR, DATAR ON CONSTITUTION OF INDIA (Lexis Nexis 2001).
[399] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[400] Aditya Kant. *An Attempt at Quantification of 'Efficacy' Factors under Section 3(d) of the Indian Patents Act.* 18 JIPR , (2013).
[401] (2007) 4 MLJ 1153.
[402] Novartis AG v. Union of India, (2007) 4 MLJ 1153.
[403] *Id.*
[404] DORLAND'S MEDICAL DICTIONARY.
[405] Novartis AG v. Union of India, (2007) 4 MLJ 1153.

the body. The types of derivatives that qualify for patent protection are likely to be limited under such a criterion. For example, in the context of *Novartis v. Union of India*, as it is interpreted by the High Court of Madras,[406] it is unclear whether increased "bioavailability" can be considered "therapeutic" efficacy.

According to the Oxford English Dictionary, 'efficacy' is a drug's ability to generate the desired therapeutic effects.[407] The Madras High Court defined the "efficacy of pharmaceutical product" as the effectiveness of a newly discovered medicine in treating ailment and producing a desired impact on the patient body.[408] The applicant for a patent for a novel drug must demonstrate the distinction between his patent application and an already granted patent on the basis of therapeutic efficacy.[409]

According to the reading of the EU directive, the term 'efficacy' would be defined in the context of drug regulation.[410] It may be difficult for patent applicants to appease patent examiners because the majority of applications are filed by the pharmaceutical sector during the early stages of drug research. Only after completing sufficient clinical trials will the applicant be able to obtain the necessary information on the therapeutic efficacy of the medicine.[411]

In 2008 the High Court of Delhi[412] has also referred to the decision rendered by the High Court of Madras in *Novartis AG v. Union of India.*[413] The amendment made to Section 3(d) in 2005[414] is noteworthy as it established the notion of the requirement for the discovery of a new form of a known drug or a derivative, which is judged to be a substance that differs considerably in attributes with reference to the known efficacy.[415] The Court clarified that Section 3(d) could not merely be construed as a clarification

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406 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
407 THE OXFORD LEARNER'S DICTIONARY OF ACADEMIC ENGLISH.
408 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
409 *Id.*
410 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, (2004) OJ (L 136) 34.
411 Shamnad Basheer, *'The "Glivec" Patent Saga: A 3-D Perspective on Indian Patent Policy and Trips Compliance'* (2007) ATRIP, www.atrip.org/upload/files/essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc(last visited Jul.29,2022).
412 F. Hoffman v. Cipla, MIPR 2008 (2) 35.
413 Novartis AG v. Union of India, (2007) 4 MLJ 1153.
414 THE PATENTS (AMENDMENT) ACT, 2005. No. 15 OF 2005.
415 F. Hoffman v. Cipla., MIPR 2008 (2) 35.¶ 55.

for the prevailing law.[416] Based on the interpretation of statutes, a legislation is to be interpreted as a whole. The Parliament purposefully set the non-obviousness criteria as a requirement for patentability; it also barred some things, i.e., derivatives of known compounds, unless they differ considerably in attributes in the known efficacy.[417] As a result, it must be determined that the test of the non-obviousness of an invention and the finding of the presence of a considerable enhancement in the known efficacy of a substance are prerequisites for patentability.[418] In other words, even if the non-obviousness of an invention in the pharmaceutical or chemical industries is shown, the applicant must additionally demonstrate that if the invention claimed is a derivative of a known substance, it does not fall under the excluded category, as defined in the Explanation to Section 3(d),[419] since it includes the discovery of a significant enhancement in the known efficacy of the such known substance.[420] The Single Judge argued that pharmaceutical patents do not require an exceptional concept of inventive step under the Patent Act of 1970, footing on the UK case law.[421] [422] In that instance, the Court rejected the strict Teaching-Suggestion-Motivation (TSM) test,[423] claiming that it generates a semi-presumption of validity when no such presumption exists in Indian law. The Court was not swayed by the opposing position supported in US[424] and EU case law.[425] It was decided that even while Cipla could demonstrate that the invention was based on examples of the recognised prior art, it was unable to prove 'by positive proof' that the invention was not significantly outside of the scope of the depiction and had no use.[426] In order to prove the validity of the selection, the Single

[416] F. Hoffman v. Cipla., MIPR 2008 (2) 35. ¶ 58.
[417] *Id.*
[418] *Id.*
[419] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[420] F. Hoffman v. Cipla., MIPR 2008 (2) 35. ¶ 58.
[421] Dr Reddy's Laboratories (UK) Ltd. v. Eli Lilly & Co. Ltd. 2010 RPC 9.
[422] F. Hoffman v. Cipla., MIPR 2008 (2) 35.
[423] US standard for patentability that has received a lot of criticism. While novelty necessitates demonstrating the entire claimed invention in a single reference (i.e., a piece of prior art), obviousness can be demonstrated by integrating references to demonstrate that they together constitute the invention. The Federal Circuit-established TSM test demands proof of a justification for combining numerous references that teach the invention's claimed components. The Federal Circuit typically holds that the availability of evidence must be established by demonstrating that the references came from virtually the same subject or that the references contained some hint that would encourage (motivate) a reader to consider merging them. TECHNOLOGY AND IP LAW GLOSSARY. http://www.ipglossary.com/glossary/teaching-suggestion-motivation-tsm-test/#.YtwXR3ZBzIV.
[424] KSR International Co v. Teleflex, (2007) 550 US 1.
[425] F. Hoffman v. Cipla, MIPR 2008 (2) 35.
[426] *Id.*

Judge excluded the submitted references to the prior art and cited the drug's commercial success.[427] It was decided that Cipla could not satisfy its obligation to prove revocation.

On an appeal from the judgment of the single judge of the High Court of Delhi, the matter came up before the division bench to decide upon the patentability of Polymorph B.[428] The allegation by Cipla that the patent was invalid due to obviousness since 'Erlotinib' was a derivative of a known compound, and so the criterion under section 3(d) of the Patents Act was unmet as the 'improved efficiency' condition was also not fulfilled out was outright refused by the single judge bench, and they found that the plaintiff's assertion that it was not apparent for a person versed in the same art to have replaced methyl for ethynyl.[429] Finally, the division bench determined that there was no infringement because the patent in question was a drug containing Polymorphs A and B, but the drug Tarceva had just Polymorph B.[430] The vital aspect to notice here is that Roche sought for a patent on Polymorph B, but it was refused by the Indian Patent Office because it did not meet the conditions of Section 3(d) and the patentability test.[431] Furthermore, the court weighed the legislature's objective in creating Section 3(d) and anti-evergreening statutes and prioritised public interest over all else.[432] The court recognised that a life-saving drug was at stake. Therefore the drug made accessible by Cipla was three times less expensive than the drug provided by Roche.[433] On analysing section 3(d), the Court pointed out that the explanation incorporated into the provision was explicitly targeted at pharmaceutical products.[434] It discourages evergreening and bans such derivatives or other forms of an already patented product from being given a patent unless the derivatives or other forms "differ considerably in efficacy attributes."[435] The plaintiffs refute the claim that Erlotinib Hydrochloride is a derivative of the recognised chemical EP'226.[436] However, it appears that the closest prior art teaches the substance for which the plaintiffs have received a patent. As a result, the

[427] F. Hoffman v. Cipla, MIPR 2008 (2) 35.
[428] F. Hoffman v. Cipla, MIPR 2009 (2) 1.
[429] F. Hoffman v. Cipla, MIPR 2008 (2) 35.
[430] F. Hoffman v. Cipla, MIPR 2009 (2) 1.
[431] *Id.*
[432] *Id.*
[433] F. Hoffman v. Cipla, MIPR 2009 (2) 1.
[434] *Id.*
[435] F. Hoffman v. Cipla, MIPR 2009 (2) 1. ¶ 60.
[436] *Id.*

patent could not have been awarded unless the increased efficacy required by Section 3(d) was proven.[437]

Upon deciding the constitutionality and TRIPS compatibility of Section 3(d), the High Court of Madras has transferred the matter to the IPAB to decide upon the patentability of the Imatinib Mesylate. The IPAB has also concurred with the definition of efficacy as defined by the High Court of Madras.[438] According to Section 3(d) of the Act, only novel forms or derivatives that exhibit a considerable improvement in qualities in terms of efficacy are patentable.[439] The IPAB has pointed out that the term "significantly" is likewise not defined in this section.[440] According to IPAB, the term “significantly” cannot be quantified by any general formula in order to prove considerable augmentation of known efficacy.[441] It may differ from case to case depending on the circumstances. The IPAB has further gone ahead and pointed out that Section 3(d) is applicable to all chemicals and is not merely restricted to pharmaceuticals.[442] Therefore in such cases in which Section 3(d) of the Act also applies, demonstrating significant enhancement of efficacy cannot be done in the same way but can be done by demonstrating significantly "improved power of producing an effect" as defined by the Chambers Dictionary.[443] Regarding the issue as to whether the concepts of bio-availability and therapeutic efficacy are identical, the IPAB has clarified that they are not the same. According to IPAB, the Appellant's purported invention, which includes claims for the product, beta crystalline form of imatinib mesylate, a pharmaceutical composition including the same, and technique for making the beta crystalline form of imatinib mesylate, is original and innovative.[444] The innovative process is also governed by "inventive selection." It is also evident that bioavailability is not synonymous with therapeutic efficacy. Therapeutic efficacy differs from a drug's beneficial attribute. Imatinib mesylate and its beta form are therapeutically equivalent compounds, as are imatinib and its beta form in terms of efficacy. It has also been discovered that imatinib mesylate is a well-known chemical. The conclusion that the Appellant could not show any actual enhancement of known efficacy for its subject

[437] F. Hoffman v. Cipla, MIPR 2009 (2) 1. ¶ 60.
[438] Novartis AG v. Union of India, MIPR 2009 (2) 345.page 103.
[439] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[440] Novartis AG v. Union of India, MIPR 2009 (2) 345.
[441] *Id.*
[442] *Id.*
[443] *Id.*
[444] *Id.*

compound with respect to either imatinib or imatinib mesylate as the known substance by demonstrating enhanced bio-availability of 30%, which is also obvious due to increased solubility of the salt in water.[445] As a result, the IPAB has reached the conclusion that Appellant failed to meet the efficacy requirement for its beta crystalline version of imatinib mesylate under Section 3(d) of the Act.[446]

In its 2013 judgment,[447] the SC of India extensively discussed and deliberated upon as to the definition of efficacy. In addressing as to what amounts to "efficacy", the Court reiterated that the capacity to generate a desired or expected effect is referred to as efficacy.[448] As a result, the efficacy test in the context of Section 3(d) would be based upon the desired or intended result of the product under consideration.[449] In other words, the efficacy test would be determined by the function, utility, or purpose of the object under evaluation. As a result, in the event of a pharmaceutical that promises to cure an illness, the only efficacy test that may be used is "therapeutic efficacy." The question then becomes, what would be the therapeutic efficacy parameter, and what are the advantages and benefits that may be considered for evaluating therapeutic efficacy enhancement? Regarding the origins of Section 3(d) and precisely the circumstances under which Section 3(d) was altered to make it even more restrictive than previously, the Court opined that a medicine's "therapeutic efficacy" must be considered severely and narrowly. The apex Court reached the conclusion that the improved efficacy test in the case of chemical substances, particularly medicine, should be narrowly and strictly interpreted and is based not only on external reasons but also on actual internal data. It should be noted that the 2005 Amendment[450] to Section 3(d) included the criteria of "improvement of the established efficacy." Furthermore, the rationale needs the derivative to differ significantly in efficacy attributes.[451] As a result, it is clear that not all beneficial or advantageous features are significant, but only those that directly connect to efficacy, which in the case of medicine is its therapeutic efficacy. In dealing with the explanation of the provision, the Court emphasised that each of the several forms indicated in the explanation has some features that are unique to that form.[452]

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445 Novartis AG v. Union of India, MIPR 2009 (2) 345.
446 *Id.*
447 Novartis AG v. Union of India, AIR 2013 SC 1311.
448 THE NEW OXFORD DICTIONARY OF ENGLISH.
449 Novartis AG v. Union of India, AIR 2013 SC 1311.¶ 180.
450 The Patents (Amendment) Act, 2005. No. 15 OF 2005.
451 The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
452 Novartis AG v. Union of India, AIR 2013 SC 1311. ¶ 181.

These forms are specifically excluded from the concept of "invention" unless they differ considerably in terms of efficacy. As a result, the "enhancement of efficacy" of a known chemical would not be qualified by a simple change in form with qualities inherent to that form. The Court summarised that the explanation is intended to indicate what should not be deemed therapeutic efficacy.[453]

In 2015, an issue that came up before the Delhi High Court to decide was as to whether the variations of a substance are also covered under the patent for the substance.[454] Because Section 3(d) deals with incremental modifications, it was necessary in this case to interpret the purpose and scope of Section 3(d). A more exhaustive analysis was done by the Division Bench, taking into account Sections 2(1)(j),[455] 2(1)(ja),[456] 2(1)(l),[457] 2(1)(ta)[458] and Section 3(d).[459] It was held that, as argued by learned Senior counsel for Cipla, Section 3 of the Act establishes a criterion for patent eligibility and does not constitute a deviation from Section 2(1)(j).[460] While Section 3 illustrates what is not an invention,[461] Section 2(1)(j) offers a theoretical definition of an invention.[462] In other words, if a topic is beyond the scope of Section 3, a qualitative analysis must be used to determine if it satisfies the requirements of Section 2(1)(j), whereas if a matter is inside the scope of Section 3, an analysis under Section 2(1)(j) need not be done because it will be rejected at the threshold. As a result, the procedures in analysing a new chemical entity for which a patent application is made will be as a new chemical entity (NCE) that is structurally different but functionally identical to an existing chemical entity and is thus merely a substance under Section 3(d).[463] When a substance has an additional layer of improved efficacy, it is considered a "new product" and is subject to Section 2(1)(j) evaluation to see whether an inventive step was taken in its creation.[464] A novel product would be considered a pharmaceutical substance if it involved one or

[453] Novartis AG v. Union of India, AIR 2013 SC 1311.
[454] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., MIPR 2016 (1) 1.
[455] The Patents Act, 1970, § 2(1)(j), No. 39, Act of Parliament, 1970 (India).
[456] The Patents Act, 1970, § 2(1)(ja), No. 39, Act of Parliament, 1970 (India).
[457] The Patents Act, 1970, § 2(1)(l), No. 39, Act of Parliament, 1970 (India).
[458] The Patents Act, 1970, § 2(1)(ta), No. 39, Act of Parliament, 1970 (India).
[459] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., MIPR2016(1)1. ¶ 61.
[460] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., MIPR 2016 (1) 1.
[461] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[462] The Patents Act, 1970, § 2(1)(j), No. 39, Act of Parliament, 1970 (India).
[463] F. Hoffmann-La Roche Ltd. v. Cipla Ltd, MIPR 2016 (1)1. ¶ 62.
[464] The Patents Act, 1970, § 2(1)(j), No. 39, Act of Parliament, 1970 (India).

more inventive steps. As a result, the court rejected the claim that Section 3(d) sets a criterion for patentability. [465]

It should be noted that the SC did not rule whether Section 3(d) was a patent eligibility or patentability criteria in *Novartis v. Union of India*[466] because that question did not affect its decision on validity in that case. It did, however, indicate that for pharmaceuticals, Section 3(d) would function as a threshold for 'invention,' i.e., a patent eligibility condition, rather than as a patentability test.[467] There arises a curious case as to what would have been the situation if Section 3(d) were to be referred to as a patent eligibility standard rather than a patentability standard. There is a case to be made that this strengthens Section 3(d) by making it a predicate question for the tripartite patentability test. Additionally, it ensures that difficult questions involving anticipation and obviousness are kept separate from the Section 3(d) screening test so that it can function as a clean and distinct examination.

In terms of the conceptual difference between the two, Section 3(d) aims to prevent evergreening and the exploitation of these monopoly rights, while the novel, non-obvious and industrial application test for patentability addresses the suitability of a product to monopoly rights. The nature of the inquiry involved in Section 3(d) as a patent eligibility and patentability standard, therefore, seems to be the same, despite the fact that the goals of these two standards can be characterised in slightly different ways.[468] On examining Section 3(d), the Court determines that it contains a deeming fiction that substances such as salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substances are to be treated as the same substance as the known substance.[469] The Court then elucidates that the deeming fiction in Section 3(d) means that when a patent application for a substance is denied because it is a derivative of a known substance, a such substance is automatically assumed to be covered and disclosed by the prior art on the grounds of which the application was rejected.[470]

[465] F. Hoffmann-La Roche Ltd. v. Cipla Ltd. MIPR 2016 (1) 1.
[466] AIR 2013 SC 1311.
[467] Novartis AG v. Union of India, AIR 2013 SC 1311.
[468] F. Hoffmann-La Roche Ltd. v. Cipla Ltd. MIPR 2016 (1) 1.
[469] Novartis AG v. Union of India, AIR 2013 SC 1311.¶ 180.
[470] F. Hoffmann-La Roche Ltd. v. Cipla Ltd. MIPR 2016 (1) 1, ¶ 73.

In the 2019 judgment of the Delhi High Court in *AstraZeneca AB v. P.Kumar,*[471] one of the issues pleaded by the defendant is that in this case, the plaintiffs have attempted the evergreening of a life-saving drug and hence it is barred by Section 3(d).[472] The defendants have placed their arguments based on structural similarity. In dealing with the issue of coverage and disclosure of a genus patent, the Court has relied upon the 2013 decision[473] of the SC of India.[474] The issue may be summarised by noting that the limit established by the claim for coverage may be significantly broader than the disclosure/enablement/teaching in a patent.[475] This issue has already been decided and settled by the apex Court.[476] The attempted conflict between coverage or claim on the one hand and disclosure, enablement, or teaching in a patent on the other appears to strike at the heart of the patent law's justification.[477] A monopoly is conferred to a private individual under the patent scheme in return for the invention being made public so that at the termination of the patent period, the invention may belong to the general public, who may profit from it.[478] To claim that a patent's coverage may extend much beyond the disclosure would appear to contradict the fundamental rule underpinning patent issuance.[479] On deciding the issue raised under Section 3(d), the Court has come to a conclusion that the patents in the suit cannot be said to be completely new.[480] The suit patents are required to satisfy the enhanced efficacy test, as specified in section 3(d) read with its explanation.[481] In the plaint, there is no mention of any enhanced efficacy of the suit patents by the plaintiff. This requires the plaintiff to showcase the satisfaction of Section 3(d) requirements.[482] In order to establish therapeutic efficacy, the defendants have submitted an affidavit from an expert. The affidavit provides that the compound shows increased metabolic stability and a lower predicated dose. On considering the affidavit by the expert, the Court opined that the affidavit lacks the explanation for how the purported advantage, namely reduced dosage and improved metabolic stability, would equate to increased therapeutic efficacy above the already

[471] 262 (2019) DLT 118.
[472] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118.
[473] Novartis AG v. Union of India, AIR 2013 SC 1311.
[474] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118.
[475] Novartis AG v. Union of India, AIR 2013 SC 1311. ¶ 118.
[476] Novartis AG v. Union of India, AIR 2013 SC 1311. ¶ 119.
[477] *Id.*
[478] *Id.*
[479] *Id.*
[480] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118.
[481] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118. ¶ 69.
[482] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118. ¶ 70.

available chemical.[483] The court reiterated the decision in *Novartis AG v. Union of India*[484] and held that only qualities that are directly related to therapeutic efficacy are relevant.[485] The plaintiff has failed to demonstrate the improvement of the known efficacy of the suit patents over the goods and hence fails the test of section 3(d) of the Act.[486]

In 2020, it was held by IPAB, Chennai, that the currently claimed invention is a combination of known compounds rather than a novel form of a known substance.[487] Therefore Section 3(d) is not applicable as it prohibits the patentability of a novel form of a known substance and does not apply.[488] In order to reach its decision that Section 3(d) is not applicable to a combination of known substances, the Court has interpreted the provision based on previous case laws.[489] Based on these interpretations, the Court differentiated as to inapplicability in this particular case.

In 2022, a judgment was delivered by the Delhi High Court relating to the patentability of a process for producing an already existing substance, the Tofogliflozin tablet.[490] The subject matter of the patent application explicitly discloses a technique for directly compressing a tablet containing Tofogliflozin from a powder combination.[491] It is contended that the invention provides a tablet containing Tofogliflozin with superior disintegration and dissolve qualities as compared to previous patent techniques and therefore is patentable.[492] Tofogliflozin is already a pharmacological formulation protected by already granted patents.[493] The current patent application is nothing more than an attempt to extend the life of the existing patent. The simple process of preparing a tablet form of Tofogliflozin by direct compression would not be patentable since it would not provide an enhancement in the drug's therapeutic effectiveness.[494] The Court believes that if a process/method patent is issued for Tofogliflozin tablets, it will be no

[483] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118. ¶ 73.
[484] Novartis AG v. Union of India, AIR 2013 SC 1311.
[485] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118. ¶ 73.
[486] AstraZeneca AB v. P.Kumar, 262 (2019) DLT 118.
[487] UCB Pharma v. Controller General of Patents, Designs & Trademarks. MANU/IC/0073/2020. ¶ 24.
[488] *Id.*
[489] *Id.*
[490] Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/2022. ¶ 4.
[491] *Id.*
[492] Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/2022.Para4.
[493] Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 14.
[494] *Id.*

different from the already awarded patent for Tofogliflozin.[495] Unless shown otherwise, the different techniques, procedures, and so on for the creation of Tofogliflozin tablets cannot result in a new patent for the same pharmaceutical preparation.[496] This would plainly be a violation of Section 3(d) of the Patent Act since the tablet form of Tofogliflozin to be claimed by method patent cannot be a patentable invention. In as much as the original patent also involves the production of Tofogliflozin tablets, no significant improvement of the known efficacy of Tofogliflozin has been described in the subject patent with comparative data.[497] Furthermore, the Appellant has tried to support the method patent on the grounds that comparable data has been brought forth in the examples provided in the patent specification.[498] The different forms of Tofogliflozin in monohydrate crystal form and tablet form were also recognised in prior art materials, according to this Court.[499] A review of the comparative data given forth in the examples in the patent specifications reveals that the Appellant aims to differentiate the subject patent from Tofogliflozin hydrate tablets made using the wet granulation method.[500] The Appellant's case is founded on two factors: the time required for the breakdown and the hardness of the pill.[501] Although the tablet hardness was the same, it was claimed that disintegration occurred faster than in the case of wet granulation tablets.[502]

Relying upon the *Novartis case*,[503] the Court held that the comparative evidence, in this case, does not qualify as a significant augmentation of therapeutic effectiveness.[504] There is no evidence to demonstrate what the effect of an early or shorter period of disintegration would be, what the amount of the aforementioned shorter duration of disintegration would be, and what the influence of the same would be on a patient's therapy.[505] The Court has derived its decision based upon the data provided in the patent specifications along with the *Novartis case*. Accordingly, This Court concluded that the current patent application is nothing more than an attempt to extend the term of

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495 Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 23.
496 *Id.*
497 *Id.*
498 Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 24.
499 *Id.*
500 *Id.*
501 Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 24.
502 *Id.*
503 Novartis AG v. Union of India, AIR 2013 SC 1311.
504 Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 25.
505 Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 25.

the prior Tofogliflozin patent, which would not be accepted without a significant improvement in therapeutic effectiveness.[506]

4.7. ENHANCED EFFICACY

The notion of enhanced efficacy is at the heart of the *Novartis case.*[507] The Indian SC opted between three distinct interpretations of increased effectiveness in Novartis AG.[508] Each interpretation has its own implications for evergreening, public health, and innovation, and each has compromised. In India and the EU, inventive step closely resembles non-obviousness in the US; and industrial application, utility in the US.[509] The first interpretation is that improved efficacy is totally covered by India's "inventive step" and "industrial application" criteria.[510] Accordingly, the increased effectiveness criterion in Section 3(d) is essentially a re-articulation of the inventive step or industrial application requirement in pharmaceutical product patents.[511] Under this understanding of enhanced efficacy, Section 3(d) is least likely to violate TRIPS Article 27.1. TRIPS Article 27.1 already requires an inventive step and industrial application in India.[512] An "invention," according to Section 2(1)(j) of the 1970 Act, is defined as a new product or procedure that incorporates an innovative step and is capable of industrial application.[513] As a result, Section 3(d) is virtually not an improved efficacy criterion and adds no new barriers to patentability.[514] Section 3(d) is India's response to the specific utility or significant utility requirement that is one of Section 101's requirements in the United States.[515] Section 3(d), similar to specific utility or significant utility in the United States, may simply require patent applicants to specify a sufficiently well-defined purpose for the new drug or establish a real-world benefit to the public at the time of filing.

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[506] Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents and Design, MANU/DE/1172/202, ¶ 27.
[507] Novartis AG v. Union of India, AIR 2013 SC 1311.
[508] *Id.*
[509] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d),* 21 J. INTELL. PROP. L. 223 (2014).
[510] *Id.*
[511] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d),* 21 J. INTELL. PROP. L. 223 (2014).
[512] TRIPS AGREEMENT, Article 27.1
[513] The Patents Act, 1970, § 2(1)(j), No. 39, Act of Parliament, 1970 (India).
[514] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d),* 21 J. INTELL. PROP. L. 223 (2014).
[515] 35 U.S. Consti. § 101.

The second interpretation is that enhanced efficacy refers to any enhancement in how a pharmaceutical works as a therapy. The Indian SC has interpreted Section 3(d) enhanced efficacy to entail medically significant efficacy that differs fundamentally from the inventive step and industrial application criteria.[516] This view differs from traditional notions of pharmaceutical patent protection in the United States.[517] The SC has adopted an interpretation of Section 3(d) that requires more than an innovative step and an industrial application. The fundamental advantage of requiring greater effectiveness is obvious: while it would have little effect on increasing access to generic medications, Section 3(d) would prevent patents on worthless and relatively harmless items from being granted.[518] Conversely, to the extent that the idea of evergreening as patenting and generating demand for a worthless version 2.0 of a drug on the market occurs in some situations, Section 3(d) might have some demonstrable effect on encouraging access to generic medicines by prohibiting the practice.

The final interpretation is that enhanced efficacy solely refers to therapeutic efficacy, as determined by the Madras High Court and the IPAB. If, as proponents of Section 3(d) say, the fundamental goal of Section 3(d) is to distinguish minor alterations from genuine innovation, the SC should have chosen a broad interpretation of enhanced efficacy that prohibits secondary patents on treatments that do not improve patient outcomes while allowing the patenting of important new medication iterations. A restrictive interpretation of enhanced efficacy would not encourage innovation in accordance with patent law philosophy, as generic manufacturers would be able to profit from improvements generated as a consequence of patent incentives available exclusively in other nations.[519] There are typically many methods for attempting to convert an active drug molecule into a pharmaceutically acceptable formulation, and the various methods might have quite diverse features.[520] As in the case of Glivec, the "secondary" product may be more stable, more powerful, less poisonous, simpler to

[516] Novartis AG v. Union of India, AIR 2013 SC 1311.
[517] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).
[518] *Id.*
[519] ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS 288-89 (2003). Argues that, according to the instrumental theory of patent law, "the patent system promotes individuals to innovate" and that "too few inventions would be made" in the absence of a patent system.
[520] J. Keith Guillory, *Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids*, in POLYMORPHISM IN PHARMACEUTICAL SOLIDS 64 (Harry G. Brittain ed., 1999).

administer, or produce fewer adverse effects, and it may even be the only economically viable form of the medicine.[521] Nonetheless, the SC upheld the Madras High Court's and the IPAB's interpretation of efficacy as simply therapeutic efficacy, rendering some of these actual enhancements over prior art medicines unpatentable under Section 3(d) of the Patent Act.[522] Section 3(d) requires modifications that increase therapeutic efficacy by having a unique therapeutic impact on the body, but modifications that improve pharmaceuticals in other ways do not.[523] Because this restricted interpretation of efficacy would render many real therapeutic improvements unpatentable, it cannot be justified on the concept of prohibiting pharmaceutical corporations from extending monopoly protection on their drugs without creating significant drug modifications.

A new theory would be necessary to justify the distinction made between "therapeutic" and other sorts of "efficacy." Instead of the kind and degree of invention in a patent application, the theory might simply be that India should limit pharmaceutical patenting anytime it benefits India to do so, balancing improved access to affordable medications with loss of incentives to innovate. The apparent advantage of prohibiting secondary patents under this social welfare-oriented theory is that it permits India's enormous population of impoverished patients to obtain generic drugs sooner.[524]

Both the Indian legislature and the courts in *Novartis AG* have made it plain that the central goal of section 3(d) is to encourage access to critical, life-saving generic drugs, which aligns more with the social welfare theory than the evergreening theory, given that medicines are unlikely to be both too important to the public to patent and not necessarily enough to patent.[525]

4.7.1. AN ANALYSIS OF ENHANCED EFFICACY BY IPAB

Based on three weak grounds, the IPAB concluded that the imatinib mesylate application failed Section 3(d). First, rather than evaluating the legislative purpose and history of the term efficacy, the IPAB relied heavily on the definition of efficacy

[521] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).
[522] Novartis AG v. Union of India, AIR 2013 SC 1311, 17-18, 98-100.
[523] Novartis AG v. Union of India, AIR 2013 SC 1311, 90-92.
[524] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).
[525] Novartis AG v. Union of India, AIR 2013 SC 1311.

provided in Dorland's Illustrated Medical Dictionary (Dorland's).[526] According to Dorland's, efficacy is *"the ability of a drug to produce the desired therapeutic effect, independent of potency."* [527] On this premise, the board determined that improved efficacy needs something called therapeutic efficacy, which they left unspecified.[528] The board incorporated the qualifier "therapeutic" into the Act in this manner. The plain wording of the Act nowhere suggests a restriction of the term "efficacy" from its conventional meaning.

Second, IPAB used its judgement that "bioavailability and therapeutic efficacy are not the same" to determine whether the improved bioavailability provided by the imatinib mesylates beta crystalline form meets the therapeutic efficacy requirement.[529] Its result, however, is based on an overly simplified view of the interaction between bioavailability and therapeutic effectiveness. It does not matter whether they are the "same thing."

Although higher bioavailability is not necessarily enough to result in enhanced therapeutic benefit, it can be a contributing factor. In other words, alterations in bioavailability might have clinical implications. Assuming a drug already has a therapeutic effect, increasing its bioavailability would improve that impact if all else is equal. Improved bioavailability can naturally contribute to enhanced therapeutic efficacy. In reality, several prospective therapeutic candidates have been dropped due to bioavailability complications.[530] In such circumstances, an increase in bioavailability that allows the molecule to be utilised pharmaceutically enhances therapeutic efficacy indisputably. As a result, IPAB's disregard of bioavailability as proof of improved therapeutic efficacy was overly simplistic.

Third, the IPAB's ruling appears to be motivated by a concern that an inventor may utilise an expansive definition of efficacy to patent multiple doses of the same essential medicine by arguing that utilising a more significant amount causes the treatment to have enhanced efficacy.[531] However, the circumstances of the current situation are far from this fictitious ploy.

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[526] Novartis AG v. Union of India, AIR 2013 SC 1311.
[527] *Id.*
[528] *Id.*
[529] *Id.*
[530] *Factors That Determine Therapeutic Drug Bioavailability*, 23(35) NIH GUIDE (1994).
[531] Novartis AG v. Union of India, MIPR 2009 (2) 345.

In this case, Novartis effectively claims that a lesser dose of the medicine would have the same therapeutic benefit.[532] The patent application does not assert that the beta crystalline form of imatinib mesylate is more effective than imatinib free base because it has a larger concentration of the active molecule; instead, the patent claims it as a salt not an amount or concentration.[533] Instead, the claimed salt is said to be more effective because the active molecule has been chemically converted by reaction with methane sulfonic acid and subsequent crystallisation to be more thermodynamically stable, less hygroscopic, and have better flow characteristics.[534]

Furthermore, the polymorph of imatinib described in the patent is the only form suitable in a patient-administrable form. If a medicine cannot be delivered, its chemical potency in vitro has no therapeutic impact. In this regard, neither imatinib-free base nor imatinib mesylate, in general, have any therapeutic impact; only the beta-crystalline form of imatinib mesylate has any therapeutic effect.

4.7.2. ENHANCED EFFICACY: WHAT THE SUPREME COURT HAS FORMULATED

Novartis lost on appeal for the simple reason that the SC of India upheld the IPAB's interpretation of efficacy as therapeutic efficacy, as defined by the IPAB.[535] If the SC had interpreted enhanced efficacy to require some type of improved efficacy while interpreting efficacy broadly, Novartis' application would have met Section 3(d)'s requirements. Finally, if the Court had opted to incorporate greater efficacy within the inventive step and industrial application criteria, Novartis' patent application would have survived Section 3(d). The different outcomes under these three interpretations highlight the issue that Section 3(d) poses to the future of pharmaceutical innovation and operations in India. An analysis of the judgments that were delivered post-2013 points to the fact that all of the decisions dealing with Section 3(d) were in consensus with the requirement of "therapeutic efficacy" as held by the SC.

[532] Dorothy Du, *Novartis AG v. Union of India: Evergreening, Trips, and Enhanced Efficacy under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).
[533] Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, 7.
[534] Novartis AG v. Union of India, A.I.R. 2013 S.C. 1311, 85, 88, 94.
[535] Novartis AG v. Union of India, MIPR 2009 (2) 345.

However, it does not address or clarify what sorts of ingredients can come under therapeutic efficacy. For example, it does not address whether decreased toxicity or increased bioavailability might be considered for therapeutic efficacy. As a result, the patent application may claim that these features result in increased therapeutic efficacy. Another wave of lawsuits might define the therapeutic criteria's essential aspects. Most critically, the Court has not addressed the conditions for demonstrating an improvement in therapeutic efficacy. Despite the fact that considerations such as whether higher bioavailability or fewer adverse effects can be viewed as an improvement in therapeutic efficacy were addressed, the Court did not provide an answer. The Court has not ruled that greater bioavailability can be viewed as an improvement of therapeutic efficacy in and of itself. It states that improved bioavailability should be stated independently, with research data to support the claim. These issues might be contested in the future. As a result, the Novartis decision represents a watershed moment but not the final word. The fundamental problem of Section 3 (d) is that it does not preclude the patenting of known drugs and enables the patenting of known substances on a case-by-case basis, provided the patent applicant can demonstrate that the claimed invention differs substantially in efficacy attributes. In other words, Section 3(d) does not prohibit the patenting of known substances in and of themselves but somewhat limits the patenting of known substances. This necessitates a case-by-case approach and the scrutiny of each patent application. While narrowing the ambit of efficacy standards, the SC does not rule out patent protection for known substances. The Court ruling simply limited the meaning of the term "efficacy." On the whole, patent assessment should be done on a case-by-case basis, at least for claims involving known substances with increased efficacy. Furthermore, Section 3(d) gives examiners and judges some leeway in interpreting the term efficacy.

4.8. CONCLUSION

The researcher has gathered from all of this that the Government or Courts of India have kept the term 'efficacy' undefined, not due to a lack of expertise or to avoid pressure from Big Pharma Companies. In a nation like India, where the majority of the population lives below the poverty line, the urgent necessity when an endemic illness spreads or to keep the health ratio of the people healthy is to make pharmaceuticals available to such people at a cost they can pay. The Government of India cannot directly

participate in bringing such drugs at affordable prices, which would require it to act in violation of the TRIPS Agreement; however, the Government can engage in drafting its policies while the Courts can issue suitable decisions in such a way, both of which would maximise the benefit for the ordinary people or the public at large. Keeping a country's people healthy is the first indication of growth, and given its economic position, India must conquer its difficulty rather than complicate it.

The Madras High Court was correct in upholding Section 3(d)'s constitutionality.[536] Its conclusions were similar to previous SC rulings, which said that the absence of guidelines or definitions in a provision does not imply that the part is arbitrary or unclear or that it grants "uncanalised" power to a legislative body.[537]

Defining 'effectiveness' would create many additional complexions at the small and large levels, resulting in the clashing of many concerns at once, eventually shrouding more complications.[538] However, the public, who are the eventual users of these patents, will be the ultimate victims of these misunderstandings. As a result, abstaining from clearly defining 'effectiveness' would result in fewer confusions and would also permit a case-by-case analysis by vesting all authority to determine what would constitute efficacy in the Patent Controller.[539] The Government and Courts of India have fought an ethical war to defend the public's broader interests in the best way feasible, as well as to meet their position of responsibility to serve the public in the best way possible.[540] While watching all this, the researcher thanks the government and the courts for resolving the situation in this manner, assuming all is judged correct in his observations.

[536] Novartis AG v. Union of India, (2007) 4 MLJ 1153, 8.
[537] Shamnad Basheer & Prashant Reddy. *Ducking TRIPS In India: A Saga Involving Novartis and The Legality of S.3(d)*, 20 (2), NLSIR (2008).
[538] Vasishtan P & Samhitha Reddy. *Rethinking The Need For Defining 'Efficacy' In The Indian Patent Regime*. 1(1) E-JAIRIPA, 103 (2020).
[539] *Id.*
[540] *Id.*

CHAPTER V
CONCLUSION AND SUGGESTIONS

5.1. INTRODUCTION

The evolution of the "test of enhanced efficacy" pertaining to patenting of pharmaceuticals in the Indian law regime has evolved through judicial pronouncements. This chapter will conclude the research work by summarising the key findings of the research in the context of the objectives and the research questions relating to the interpretation of Section 3(d)[541] by the courts in the Indian patent law and pharmaceutical context. Various international agreements and national laws were examined in this context. The term enhancement of efficacy is not defined under Indian patent law. The interpretation of the provision was based upon the judicial pronouncements rendered by the courts. Analysing the history of TRIPS helps understand the background behind allowing flexibilities for member countries to incorporate into their national legislations. As enshrined in Section 3(d), the test of enhanced efficacy is particular to the Indian patent law. It provides an additional requirement of proving enhanced efficacy in the case of pharmaceutical drugs if the new form is that of an already existing known substance. This provision is regarded to be enacted based upon the flexibilities provided under the TRIPS. The provision is very much in compliance with the requirements of the TRIPS. Section 3(d)[542] has extensively been reckoned as an anti-evergreening provision. A perusal of the Indian regulations and policies will palpably showcase India as a country that denounced the idea of evergreening of patents. Many countries have also added similar provisions to their patent laws upon realising the importance of Section 3(d) in strengthening the patent law regime of pharmaceuticals in India. The Indian pharmaceutical industry plays an indispensable role in the global market, and Section 3(d) has played a paramount role in the thriving of the pharmaceutical sector. The Ayyangar Committee

[541] The Patents Act, 1970, § 3(d), No. 39, Act of Parliament, 1970 (India).
[542] *Id.*

report[543] has portrayed a pivotal role in the chiselling of the patent law regime in India post-independence.

Only by way of an amendment in 2005[544] the present version of Section 3(d) become part of the Patents Act,1970. Justice Krishna Iyer is chalked up as the mastermind behind crafting the provision. To understand the true essence of Section 3(d), it is imperative to understand the various ingredients of the provision such as, discovery, known substance and efficacy. These terms are compared with their interpretation in other jurisdictions. There exists a thin line of difference between incremental innovation and evergreening.

Nevertheless, understanding these two terms are exigent in discerning the intention of Section 3(d). Since the legislature has undefined the enhancement of efficacy under patent laws, the point at issue came up before the courts to interpret these terms. The case of *Novartis AG v. Union of India*,[545] has captured attention from the global population while deciphering the unerring *raison d'être* of the legislature behind enacting Section 3(d). Even almost after a decade, the *Novartis case* still remains as the only judgment in which the apex Court has interpreted and explained the true objectives of Section 3(d).[546] Thereafter, various cases at the lower courts have dealt with the same issue.

5.2. FINDINGS

Although not explicitly stated in the legislation, the true purpose behind the enactment of Section 3(d) by way of the 2005 amendment[547] is to prevent the evergreening of patents.[548] It also enshrines the correct policy approach in dealing with pharmaceutical patents, as read in the Novartis decision: protection should be granted when genuine inventions are claimed, but refused when patent applicants simply seek to create barriers to generic competition by patenting a wide range of minor, often trivial improvements. The advantage of preventing patent evergreening is that it helps poor patients who rely on life-saving drugs. It also contributes to keeping the cost of vital

543 N. RAJAGOPALA AYYANGAR, REP. ON THE REVISION OF THE PATENTS LAW (1959).
544 The Patents (Amendment) Act,2005, No. 15, Act of Parliament, 2005 (India).
545 Novartis AG v. Union of India, AIR 2013 SC 1311.
546 *Id.*
547 The Patents (Amendment) Act,2005, No. 15, Act of Parliament, 2005 (India).
548 Lisa L. Mueller, *Section 3(d) of the Indian Patents Act- Part I*, 3 NATIONAL LAW REVIEW (2013).

drugs within the financial means of ordinary people in developing and underdeveloped nations.

Chapter I outlines the scope and research questions upon which the research work is based upon. It is made clear that the research work focuses on the interpretation of the term "efficacy" under Section 3(d) of the Patents Act, by the Indian judiciary through its various decisions. The need for interpretation of this provision is because it is undefined by the legislature and is unique to the Indian Patent law regime.

Chapter II is devoted to examine the history of TRIPS and the role played by the TRIPS in the enactment of Section 3(d). The Parliament has enacted Section 3(d) by virtue of the TRIPS's flexibility. The TRIPS includes some flexibility in how TRIPS responsibilities are implemented. These are the results of Article 1.1 of the agreement,[549] which states that WTO members can use creative ways of incorporating into their national laws and put it into practice certain TRIPS Agreement principles that have been referenced but not defined. Thus, Section 3(d) of the Patents Act of 1970 was born, which is nothing more than an exercise of liberty granted to all TRIPS member states. Also, Article 27.1, TRIPS requires WTO members to provide patent protection for all inventions in all domains of technology.[550] Apart from stating out the criterion of patent eligibility, the stated article also provides considerable freedom in that it does not define the parameters of novelty, inventiveness, and industrial applicability, providing WTO members discretion to decide how these should be construed and implemented. With the adoption of Section 3(d), India has taken advantage of the flexibility granted to WTO members in determining the eligible subject matter for national patent law.

Chapter III focuses on analysing Section 3(d) in the context of its legislative history under the Indian law regime. Section 3(d) tries to limit ever-greening by allowing only those pharmaceutical derivatives that have significantly improved "efficacy" to be patentable. Section 3(d) distinguishes between evergreening and incremental innovation. The plain reading of the provision as mentioned above clearly states what is not patentable. In other words, if the "prospective patent" material improves on the existing efficacy of the drug, it is patentable. The section merely attempts to weed out

[549] TRIPS, art. 1.1.
[550] TRIPS, art. 27.1.

frivolous inventions produced in an attempt to patent evergreening by incorporating tiny adjustments, unless such changes result in a considerable improvement in efficacy. It is worth noting that Section 3(d) was only created by the Legislature to deter pharmaceutical firms from evergreening patents.

Chapter IV peruses into how the Indian judiciary has interpreted the provision. The legislature has left the term "efficacy" undefined under the law. Hence the interpretation of the term was done by the courts through judgments. The IPAB interpreted the term "efficacy" to mean "therapeutic efficacy"[551] and was upheld by the SC.[552] It was also placed before the Court to decide whether increased bioavailability would qualify as therapeutic efficacy. Considering this issue, the Court clarified that mere increase in bioavailability does not mandatorily amount to enhanced efficacy.[553] The Court emphasised that the production of valid clinical trial data is required to clarify whether increase in bioavailability would amount to increase in therapeutic efficacy.[554] In this circumstance, Novartis provided no proof that the increase in bioavailability has resulted in an improved therapeutic effect of the substance on the human body. As a result, the patent application was barred by Section 3(d) of the Indian Patent Act, and the SC concurred with the decision of the IPAB.[555] Through its judgment in Novartis case, the SC has stressed on the fact that with respect to the patenting of pharmaceutical products, the approach endorsed by India is much stringent than that of EU and US.

In the Novartis case, the SC narrowly interpreted "efficacy" as "therapeutic efficacy".[556] An analysis of various judgments makes it clear that the calculation of enhanced efficacy would be determined based on the clinical reports submitted to the court. There is no straight jacket formula, and would depend on the clinical results in each case. Moreover, it has to remembered that, Section 3(d) is not merely restricted to pharmaceuticals and also applies to other chemicals. Therefore, the court has correctly interpreted the requirement of "enhanced efficacy" in case of pharmaceuticals. Therefore, the "enhanced efficacy" requirement for chemicals other than pharmaceuticals is still open for further interpretations. Therefore, it can be concluded

[551] Novartis AG v. Union of India, MIPR 2009 (2) 345.
[552] Novartis AG v. Union of India, AIR 2013 SC 1311.
[553] *Id.*
[554] *Id.*
[555] *Id.*
[556] Novartis AG v. Union of India, AIR 2013 SC 1311.

that Novartis case, can be regarded only as a limited precedent in analysing Section 3(d).

The SC has upheld the narrow interpretation of Section 3(d) by the IPAB, in such a way that "efficacy" means "therapeutic efficacy" in case of pharmaceuticals.[557] In post-Novartis decisions, all the analysed decisions in this research work have conferred with the Novartis judgment of the apex Court. The narrow interpretation of "efficacy" aids in fluffing the objective behind the enactment of the provision, which is to prevent patenting of frivolous improvements of already patented product or process. In a welfare state like India, the emphasis will be to incentivise and promote inventions that benefit the society rather than helping the patentee to monopolise the invention for a long term that goes against the public interest. An analysis of the judgments proves that the Indian courts favour the narrow interpretation of Section 3(d).

5.3. SUGGESTIONS

From the wording of Section 3(d), it provides that the provision applies to all chemical substances. Pharmaceuticals only form a small part of chemical substances. It is evident that the Indian courts have interpreted "efficacy" as "therapeutic efficacy". However, this interpretation is only applicable to pharmaceuticals. The interpretation in the case of chemical substances other than pharmaceuticals are still to be clarified. Since pharmaceuticals hold a special place in the Indian patent law regime, it is recommended that a provision to be reserved explicitly to deal with the conditions governing the patenting of pharmaceuticals.

Regarding patentability of a new form with a new use, there are some inconsistencies between the main section and the explanation. The Explanation broadens the definition of "enhancement of known efficacy" as used in the main section. A new use of a new form would not be patentable under the main section since it refers to "enhancement of known use." However, according to the explanation, it appears to qualify for a patent due to a "substantial variation in efficacy with regard to property." Suppose the objective of this clause is to raise the obviousness threshold and weed out frivolous and reasonably obvious patents. In that case, this appears to be an irrational consequence, as a new use for a new form is unquestionably more innovative than merely

[557] Novartis AG v. Union of India, AIR 2013 SC 1311.

demonstrating an increase in known efficacy. As a result, section 3(d) must be amended to expressly provide for the patentability of new uses of existing pharmaceutical substances in new forms.

From the point of view of incremental innovations, it is highly contested that Section 3(d) prohibits inventions that would otherwise fulfil patentability standards and are therefore legitimately innovative. A suggestion is to involve people with backgrounds in pharmacology, rather than merely pharma chemistry, in the patent review process to help examiners judge the efficacy of a specific incremental improvement. Proponents of this technique say that it will ensure that incremental innovations that result in major improvements in therapeutic efficacy are protected by patent.[558] While such a suggestion may alleviate some of the issues connected with having patent examiners assess therapeutic efficacy who may lack the requisite background or experience, it does not address the more fundamental way that a significant proportion of advantageous and beneficial pharmaceutical innovations are not entitled to patent protection due to the categorical hurdle created by Section 3(d).

Only the "mere discovery of new forms" is prohibited in Section 3(d). As Novartis did in its writ petition to the Madras High Court, one may argue that "discovering" an existing new form is not the same as inventing a new one.[559] A judge may be unlikely to support such a proposal since it appears to be a very technical reading of the section that does not entirely comply with Parliamentary purpose to prohibit "evergreening." Section 3(d) should be changed to eliminate references to "discovery" because a judge might construe the section literally.

It is critical to instruct both the patent office and the judiciary on the SC's interpretation of Section 3(d) and the steps that must be followed to interpret the therapeutic efficacy standards using a public health-oriented jurisprudence. Furthermore, the training should ensure that both the judiciary and the patent office reflect the legislative purpose when interpreting Section 3(d), i.e., determining the patentability of known substances. To that end, the government should revise its Memorandum of Understanding(MoU) with

[558] U.S-INDIA BUSINESS COUNCIL, THE VALUE OF INCREMENTAL PHARMACEUTICAL INNOVATION(2009), http://www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReport Final.pdf.
[559] Novartis AG v. Union of India, WP No. 24759 (2006), (Mad HC).

the developed-country patent office and eliminate capacity building elements. Furthermore, defined rules and standards should be established for judicial officers' interactions with their overseas counterparts, as well as their involvement in conferences and other events organised by academic institutions, non-governmental organisations (NGO), industrial lobbies, and law firms.

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APPENDIX

CERTIFICATE ON PLAGIARISM CHECK

1.	Name of candidate	Divya Elizabeth Sebastian
2.	Title of thesis/ dissertation	EFFICACY UNDER SECTION 3(d): AN ANALYSIS THROUGH THE LENS OF INDIAN JUDICIARY
3.	Name of the supervisor	Dr Liji Samuel
4.	Similar content (%) identified	4%
5.	Acceptable maximum limit (%)	10%
6.	Software used	Grammarly
7.	Date of verification	29.07.2022

Name and Signature of the Candidate : Divya Elizabeth Sebastian

Name & Signature of the Supervisor : Dr Liji Samuel