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TRIPS FLEXIBILITIES AND ACCESS TO MEDICINES: AN ANALYSIS OF INDIA'S PATENT ACT

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Abstract

The Trade Related Aspects Relating to Intellectual Property Rights (TRIPS) Agreement, 1994 provides for minimum standards for protection of Intellectual Property Rights (IPR) to be followed by member countries. Before the adoption of the TRIPS Agreement in 1994, countries had the freedom to decide what they could patent and even to decide whether they should have a patenting system in their country at all. However, the TRIPS Agreement changed this situation as it required World Trade Organization (WTO) member countries to establish patent system in their national regimes, taking away the freedom to exclude certain fields from patenting. The obligation to have minimum standards of patent protection for pharmaceuticals has been a subject of debate since the inception of the TRIPS. Time and again it has been alleged that TRIPS Agreement interferes with human rights standards guaranteeing access to medicines. In this context, the role of TRIPS flexibilities in addressing the issue becomes very important. This paper firstly provides analysis of interference between patent protection for pharmaceuticals and right of access to medicines. It then elucidates the concept of TRIPS flexibilities and its relevance in addressing the patent versus access to medicines issue. The paper then focuses on incorporation of access to medicines related TRIPS flexibilities in the Indian Patent Act, 1970.

Keywords: Pharmaceuticals, Flexibilities, Licensing, Accessibility, Innovtaion.

1. Pharmaceutical Patents, Access to Medicines and TRIPS Flexibilities

1.1. Introduction

Since the beginning of the Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations, access to medicines has been one of the most contentious issues in the debate surrounding IPRs.[1] With regards to patents for pharmaceuticals, the

[*] Assistant Professor of Law, National Law University, Odisha.

[1] Owais H. Shaikh, *Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities under International Law* 1 (Springer, Berlin & Heidelberg, 2016).

main tussle is between innovation and access.[2] Before the TRIPS Agreement was enforced, countries had the freedom of excluding certain fields from patenting in their national laws.[3] Many countries previously excluded pharmaceutical products from patent protection, but under TRIPS, this exclusion was no longer permitted for member nations.[4] The TRIPS Agreement, by granting patent protection for both products and processes, effectively provides the patent holder with a monopoly over the production and sale of the patented product for the patent's duration.[5] This monopoly also allows the patent holder to control the pricing of the product.

There is a human right of access to medicines and deserves protection. The exact scope of the right of access to medicines varies according to the reference. For example, within the International Covenant on Economic, Social and Cultural Rights (ICESCR), States are mandated to guarantee access to essential medicines.[6] However, when referring to right to life under International Covenant on Civil and Political Rights (ICCPR), this obligation is restricted to the accessibility of life-saving medicines.[7] In a potentially emerging customary right, the observed state practices primarily focus on ensuring access to medicines in the specific context of pandemics like HIV/AIDS, tuberculosis, malaria, and others.[8]

The debate over pharmaceutical patents centres on balancing innovation and accessibility, especially following the TRIPS Agreement, which required countries to grant patents for pharmaceuticals.[9] This led to monopolies that often drive-up prices,

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2 World Trade Organization, World Health Organization and World Intellectual Property Organization, "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", *available at*: https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf (last visited on October 29, 2024).

3 Susan K. Sell, "TRIPS and the Access to Medicines Campaign", 20(3) *Wisconsin International Law Journal* 481 (2002).

4 Third World Network, "Patents and Medicines: The WTO Must Act Now: Joint NGO Statement on the Special Discussion in the WTO TRIPS Council on Patents and Access to Affordable Medicines", *Third World Network, available* at: https://www.twn.my/title/joint4.htm (last visited on October 29, 2024).

5 *Ibid*.

6 ICESCR, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* UN Doc. E/C.12/2000/4 (August 11, 2000), para 12(b).

7 The International Covenant on Civil and Political Rights, 1966, art. 6.

8 J. A. Sellin, *Access to medicines: The interface between patents and human rights. Does one size fit all?* 133 (Intersentia, Cambridge, 2014).

9 Bjorn Ley, "Patent Rights and Access to Medicines: Are Patents really the only Barrier for Good Health Care in Developing Countries?", in Mpasi Sinjela (ed.), *Human Rights and Intellectual Property Rights: Tensions and Convergences* 102 (Martinus Nijhoff Publishers, Leiden, 2007).

making medicines less affordable, particularly in developing countries. The resulting monopoly power enables pharmaceutical companies to set high prices, limiting access to essential medications for economically disadvantaged populations.[10] Developing nations, with limited healthcare resources, struggle to provide free or affordable medications to their people.[11] TRIPS restricts the production of generic, lower-cost drugs for 20 years, leading to high prices until patent expiry. Furthermore, practices like "evergreening," where companies make minor modifications to extend patents, hinder access to affordable generics.[12]

The United Nations has recognized a potential conflict between human rights specifically, the right to health and the intellectual property rights (IPRs) protected under TRIPS.[13] There are three conceptual approaches to this conflict exist: the subjugation approach, which gives primacy to human rights over IPRs; the integrated approach, which assimilates patent rights within human rights; and the co-existence approach, which views human rights and IPRs as reconcilable with careful balancing.[14]

One manner in which such a balance proposed by the co-existence approach can be reached is when the member countries themselves have the option of determining the standard of patent protection which they consider to be conducive for promoting access to medicines. This option is provided through "TRIPS-flexibilities." The TRIPS Agreement provides members the opportunity to avoid conflict and arrive at such balance through TRIPS flexibilities.

The ICESCR requires countries to take action towards the progressive realization of the rights acknowledged in the Covenant.[15] Consequently, states must ensure that affordable medicines are accessible. The TRIPS Agreement supports values

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[10] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* 76 (Oxford University Press, Oxford, 2008).

[11] *Ibid.*

[12] Mohammed K. El-Said, "TRIPS-Plus, Public Health and Performance-Based Rewards Schemes: Options and Supplements for Policy Formation in Developing and Least Developed Countries", 31(3) *American University International Law Review* 392 (2016).

[13] UN Sub-Commission on Human Rights, *Resolution 2000/7 Intellectual Property Rights and Human Rights* UN Doc. E/CN.4/SUB.2/RES/2000/7; 2000 (August 17, 2000), para 2.

[14] Emmanuel Kolawole Oke, "The Right to Health in Pharmaceutical Patent Disputes", *South Centre*, 9 February 2022, *available at*: https://www.southcentre.int/wp-content/uploads/2022/02/RP-145-The-Right-to-Health-in-Pharmaceutical-Patent-Disputes_EN.pdf (last visited on October 30, 2024).

[15] The International Covenant on Economic, Social and Cultural Rights, 1966, Preamble.

critical for human rights fulfilment, aiming to balance intellectual property rights protection with human rights standards. It includes flexibilities that give member states some autonomy in implementing the Agreement, enabling them to adopt measures that improve access to medicines. Therefore, to meet their international human rights obligations, states should utilize these TRIPS flexibilities.

1.2. TRIPS Flexibilities

1.2.1. Meaning

TRIPS Flexibilities can be defined as "*the policy space which the TRIPS Agreement provides to all Member States to implement the Agreement's provisions in different manners, to legislate in areas which are not subject to the minimum standards under the Agreement, and to develop legal interpretations of such provisions to determine the scope and content of the applicable obligations.*"[16]

The terminology for referring to the policy space existing for the implementation of the TRIPS Agreement has evolved with time.[17] Earlier, expressions such as "room to manoeuvre", "margins of freedom", "margin of discretion" and "safeguards" were used. Presently, the diversity of legislative options provided under the Agreement is referred to as "TRIPS flexibilities."[18]

During the TRIPS negotiations, several developing countries were not in favour of having an international framework of IPRs as they considered it to be detrimental to their needs. Their concerns are reflected in the manner the Agreement has been drafted incorporating sufficient degree of interpretative flexibility. The autonomy which the developing countries had been asking for can be said to be provided to them through TRIPS flexibilities. These flexibilities provide a wide room of manoeuvre to Member States to interpret and implement the provisions of the TRIPS Agreement. Consequently, countries can exercise sufficient freedom regarding interpretation and implementation of TRIPS requirements pertaining to pharmaceutical patents, catering to their socio-

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16 Carlos M. Correa, "Interpreting the Flexibilities Under the TRIPS Agreement" in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines: Implementing Flexibilities Under the Intellectual Property Law* 2 (Springer, Cham, 2022).

17 German Velasquez, *Some Critical Issues Related to Access to Medicines and Intellectual Property* 7 (South Centre, Geneva, 2014).

18 *Id.* at 8.

economic needs, provided they fulfil the minimum obligations. This includes promoting balance between patent protection for pharmaceuticals and public health objectives of right of access to medicines.

1.2.2. Basis of TRIPS Flexibilities

The TRIPS Agreement created a significant multilateral framework requiring Members to adopt minimum standards for protecting and enforcing IPR. However, it stops short of mandating a uniform or standardized IP system.[19]

In the course of negotiations resulting in WTO-TRIPS Agreement, the fact that not all member countries are at the same level of development was recognised.[20] Many developing countries were actually not in favour of having an international standard of IPR protection as they thought that it would hamper their socio-economic interests. The consideration that all Member States cannot have a uniform standard of IPR protection significantly contributed in the broad and accommodative language of the Agreement.[21]

The TRIPS Agreement stresses the need for promoting adequate and effective protection of IPRs, but it is part of a series of broader economic objectives. The protection of IPRs is not an absolute and exclusive obligation.[22] The Preamble recognizes the need of striking a balance involves safeguarding IPRs as individual rights, aligning with public policy goals, and addressing the distinctive requirements of the least-developed nations by allowing for maximum flexibility.[23]

Under Article 1.1 of TRIPS, the possibility of different interpretations of the Agreement is recognized. The provision imposes the minimum obligation on Member States to give effect to the provisions of the TRIPS Agreement. It recognizes the option

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19 Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* 8 (South Centre and WHO, Geneva, 2006).

20 Donald P. Harris, "TRIPS Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States", 25 *Northwestern Journal of International Law & Business* 99 (2004).

21 Antony Taubman, "Thematic Review: Negotiating Trade-Related Aspects of Intellectual Property Rights" in Jayashree Watal and Antony Taubman (eds.), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* 16 (WTO, Geneva, 2015).

22 German Velasquez and Pascale Boulet, *The WHO "Red Book" on Access to Medicines and Intellectual Property- 20 Years Later* 18 (South Centre, Geneva, 2015).

23 The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994, Preamble.

of providing higher, broader or more extensive IPR protection.[24] It also recognizes the freedom of Member States to choose suitable interpretation of the Agreement. The initial concerns of the developing countries regarding dissemination and transfer of technologies and knowledge finds place in Article 7 of TRIPS. It provides for "*balancing between protection and enforcement of IPRs and social and economic welfare*."[25] In addition to this, Article 8 of the TRIPS specifically provides Members with the possibility of taking action for protection and promotion of certain public policy objectives, namely, "*protection of public health and nutrition, and to promote public interest in sectors of vital importance to their socio- economic and technological development*."[26]

The room for different interpretation in the Agreement arises from many aspects of the language used in the Agreement. For instance, absence of definition; use of general terms such as "reasonably", "unreasonably", "unjustifiable" or "unjustifiably". The actual policy space under the Agreement depends on the interpretation of the provisions.[27] From a social and public health policy perspective, the provisions provide the opportunity to establish national regulations, acknowledging the imperative to guarantee the best possible access to drugs.[28]

1.2.3. Utilizing the TRIPS Flexibilities

The interpretation of the TRIPS Agreement plays a crucial role in utilizing its flexibilities. According to the Dispute Settlement Understanding (DSU), the TRIPS Agreement, like other WTO agreements under the GATT framework, must not be interpreted in isolation.[29] It is to be interpreted in line with customary rules of public international law.[30] The Vienna Convention on the Law of Treaties (VCLT), 1969 is

[24] *Id.*, art. 1.
[25] *Supra* note 23, art.7.
[26] *Supra* note 23, art. 8.
[27] *Supra* note 16.
[28] *Supra* note 22 at 21.
[29] World Trade Organization, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, WTO Uruguay Round Agreement (April,1994).
[30] Philippe Cullet, "Patents and Medicines: The Relationship between TRIPS and the Human Right to Health", 79(1) *International Affairs* 139 (2003).

central to such interpretation.[31] Article 31(1)[32] and Article 32[33] of the VCLT are recognized as customary international law.[34] The GATT is not to be read in isolation from public international law.[35] These provisions emphasize three key elements for treaty interpretation: the ordinary meaning of the text, its context, and the treaty's object and purpose.[36] In cases of ambiguity, reference can be made to the treaty's preparatory work and the circumstances of its conclusion, alongside subsequent state practices.[37]

The Preamble of the TRIPS Agreement, along with Articles 1, 7 and 8 outlines its context, object, and purpose, serving as essential tools for interpreting provisions with broad legal concepts or exceptions.[38] These elements offer member states significant flexibility to address public healthcare needs while shaping intellectual property laws and policies. The Agreement's negotiation history reflects a compromise between the demands of developed and developing countries, which must also be considered during interpretation to ensure equitable outcomes.[39]

1.3. Recognizing TRIPS Flexibilities for Public Healthcare

1.3.1. The Doha Declaration

The Doha Declaration on the TRIPS Agreement and Public Health was adopted by consensus on 14th November, 2001 by the Fourth Ministerial Conference in Doha, Qatar. The HIV-AIDS crisis reflected the conflict between the haves and have nots.[40] In the backdrop of the HIV-AIDS pandemic, the adoption of the Doha Declaration resulted from the influence of the developing country coalition along with the alliance of NGOs.[41] Considering the challenges created by high prices of anti-retroviral medicines and their

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31 WTO Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (May 20, 1996).
32 The Vienna Convention on the Law of Treaties, 1969, art. 31.
33 *Id*., art. 32.
34 *Supra* note 31.
35 *Ibid*.
36 Anthony Aust, *Modern Treaty Law and Practice* 234 (Cambridge University Press, New York, 2nd edn., 2007).
37 *Supra* note 32, art. 32.
38 Henning Grosse Ruse-Khan, "Proportionality and Balancing Within the Objectives for Intellectual Property Protection" in Paul L.C. Torremans (ed.), *Intellectual Property Law and Human Rights* (Wolters Kluwer, Alphen aan den Rijn, 2020).
39 *Supra* note 16 at 13.
40 Winston P. Nagan, "International Intellectual Property, Access to Health Care, and Human Rights: South Africa v. United States", 14 *Florida Journal of International Law* 157 (2002).
41 *Supra* note 12 at 259.

extensive patenting, it was realised that TRIPS Agreement can possibly be interpreted flexibly to promote procurement of low- priced drugs.[42] The developing countries sought greater recognition of their position that the TRIPS Agreement provides countries flexibility and discretion in addressing public health needs. Consequently, their efforts resulted in the adoption of the Doha Declaration.[43]

The severity of public health issues impacting numerous developing and least-developed nations made the Members realise the flexibility within the TRIPS Agreement.[44] It was stressed that the TRIPS Agreement is part of the broader national and international action for addressing public health problems.[45] It was explicitly acknowledged that IP protection, which is important for development of new medicines, can affect medicine prices and therefore, hamper access.[46]

It was recognised that countries may fully utilize TRIPS provisions, which provide flexibility for this objective.[47] Paragraph 4 of the Doha Declaration is quoted as follows: "*We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.*"

The Declaration clarified how the TRIPS Agreement should be interpreted and implemented.[48] It encouraged the WTO member countries to implement the TRIPS

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42 Ellen FM't Hoen *et. al.*, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016," 96(3) *Bulletin of WHO* 185 (2018).

43 *Supra* note 19 at 11.

44 World Trade Organization, *Declaration on the TRIPS agreement and Public Health*, WT/MIN(01)/DEC/2, para 1 (November 20, 2001).

45 *Id.*, para 2.

46 *Supra* note 44, para 3.

47 S.K. Verma, "The Doha Declaration and Access to Medicines by Countries without Manufacturing Capacity" in Carlos M. Correa (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules - Intellectual Property in the WTO* (1) 640 (Edward Elgar, Cheltenham/Northampton 2010).

48 *Supra* note 19 at 11.

Agreement in a manner supportive of their rights to protect public health.[49] Member countries can utilize several options regarding public health while framing their national laws and policies on IPRs such as applying the customary rules of interpretation of public international law, reading the provisions of the Agreement in light of object and purpose of TRIPS, particularly Article 7 and Article 8; freedom of Member countries to determine the grounds of compulsory licence; determining what constitutes a national emergency or situations of extreme urgency, particularly in the context of public health crises; freedom of Members to establish their own regime for exhaustion etc.[50]

Many times, the status of the Doha Declaration has been doubted and it has been stated to be merely a "political declaration."[51] However, it has been clarified that the Doha Declaration, adopted by consensus, is to be considered a 'subsequent agreement' under Vienna Convention on Law of Treaties, 1969.[52] Subsequent Agreement is an integral part of the rule of treaty interpretation. Therefore, while interpreting a treaty, it must be considered together with the context. The Doha Declaration on TRIPS and Public Health is an interpretative tool for determining and clarifying the meanings of the TRIPS provisions.[53] It is a significant milestone in addressing the concerns of developing countries regarding access to medicines.[54]

1.3.2. Role of other international bodies in implementing TRIPS flexibilities

Since the adoption of Doha Declaration, TRIPS flexibilities have been referred by several international bodies, particularly (but not only) in relation to access to medicines. They have been referred in several resolutions of the United Nations agencies and bodies, including the World Health Organization (WHO),[55] the Human Rights

[49] *Supra* note 19.
[50] *Supra* note 44, para 5.
[51] *Supra* note 16 at 24.
[52] WTO Appellate Body Report, *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS435/AB/R WT/DS441/AB/R (June 8, 2020).
[53] Eric M. Solovy, "The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health", 42 *Northwestern Journal of International Law & Business* 253 (2022).
[54] Frederick M. Abbott, "The Doha Declaration on The TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO", 5 *Journal of International Economic Law* 469 (2002).
[55] World Health Organization, *Public Health: Innovation and Intellectual Property Rights* (Report of the Commission on Intellectual Property Rights, Innovation and Public Health, 2006).

Council (HRC),[56] and the United Nations Assembly, as well as in reports of the United Nations Special Rapporteur on the Right to Health.[57] It has also been referred by World Health Assembly (WHA)[58] and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and Resolution.[59]

Importantly, the Resolution adopted by the United Nations General Assembly on 25th September, 2015 titled as "*Transforming Our World: The 2030 Agenda for Sustainable Development*" provides a plan of action for several areas of critical importance for humanity and the planet. Among other concerns, the Sustainable Development Goals also focus on "*ensuring healthy lives and promote well- being for all at all ages*" (Goal 3).[60]

Particularly, Goal 3.b aims to support "*the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health, and in particular, provide access to medicines for all*."

Additionally, the Committee on Development of Intellectual Property (CDIP) under the aegis of WIPO has established the Database on Flexibilities in the Intellectual Property System.[61] It contains data drawn from WIPO documents on Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at

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[56] UN Human Rights Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover* UN Doc. A/HRC/11/12 para 41.

[57] Carlos M. Correa, "Interpreting the Flexibilities Under the TRIPS Agreement" in Carlos M. Correa and Reto M. Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under the Intellectual Property Law* 5 (Springer, Cham, 2022).

[58] World Health Assembly, *Intellectual Property Rights, Innovation and Public Health* 56th WHA, Agenda item 14.9, (2003) para 1.2.

[59] World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* 61st WHA, Agenda item 11.6, (2008).

[60] United Nations General Assembly, *Resolution adopted by the General Assembly on 25 September 2015- Transforming our World: the 2030 Agenda for Sustainable Development* A/RES/70/1, 2015 Goal 3.

[61] WIPO Database on Flexibilities in the Intellectual Property System, *available at:* https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html (last visited on October 30, 2024).

the national and regional levels. The database allows searches for implementation of flexibilities in national IP laws in selected jurisdictions.

1.4. TRIPS Flexibilities Related with Pharmaceutical Patents

The minimum standards for patent protection to be followed by member countries are provided in Section 5 of Part II of the TRIPS Agreement. It contains provisions regarding subject matter of patents, criteria for patentability, rights of patent holder, exceptions to rights, term of protection and revocation of patents.

In this part of the chapter, flexibilities related to patents in the TRIPS Agreement are discussed. The aim is to explore the policy space which can be utilized for promoting access to medicines.

i. Countries have been given a transition period to align with TRIPS obligations, recognizing their diverse developmental stages.[62] Developing nations had relaxation until 2005 to comply with TRIPS, while Least Developed Countries (LDCs) have received multiple extensions, currently extended until 2033 for pharmaceutical patents, allowing them to delay full implementation.[63]

ii. Patent standards under TRIPS include product and process patents across all technology fields, including pharmaceuticals.[64] Although no specific definitions are provided for invention, novelty, inventiveness and industrial applicability, Members can interpret these terms based on national needs.[65] Article 27 also permits exclusion from patentability on grounds of public order, morality, health, or environmental protection, giving member states significant leeway.[66]

iii. TRIPS requires a minimum patent term of 20 years from filing but does not mandate compensation for regulatory delays in market approval.[67]

iv. Article 30 allows exceptions to patent rights, such as for teaching, research, or regulatory approval (Bolar exception), facilitating faster entry of generic drugs

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62 *Supra* note 22 at 31.
63 *Supra* note 23, art. 66.1.
64 *Id.*, art. 27.
65 *Id.*, art. 27.1.
66 *Id.*, art. 27.2.
67 *Id.*, art. 33.

post-patent expiration.[68] Government use exceptions also allow non-commercial public use without patent holder consent in cases of public interest.[69]

v. Compulsory licensing, under Article 31 is a key tool for balancing public health needs with patent rights, allowing governments to authorize use of a patent without owner consent under certain conditions, especially in emergencies or for non-commercial purposes. Member States determine the grounds for compulsory licenses, which can support access to affordable medicines.[70]

vi. Parallel importation enables countries to import patented products from markets where they are sold at lower prices, based on the concept of "exhaustion" of rights after the first sale. Members can set an exhaustion regime suited to their needs (national, regional or international), enabling cheaper imports.[71]

vii. Revocation of patents is permissible under TRIPS, although the grounds are unspecified, allowing flexibility for public health reasons.[72]

viii. Procedural flexibilities like pre and post-grant oppositions help improve patent quality and prevent "evergreening" where minor modifications extend patent life unnecessarily.[73]

ix. The Agreement allows suspending obligations in emergencies,[74] and Member States can employ competition law to address abuse of IPRs.[75]

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68 WTO Panel Report, *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R (April 7, 2000).

69 Carlos M. Correa, "Guide for the granting of compulsory licenses and government use of pharmaceutical patents", *South Centre*, April 2020, *available at*: https://www.southcentre.int/research-paper-107-april-2020/ (last visited on October 30, 2024).

70 Carlos M. Correa, "Intellectual Property Rights and the Use Of Compulsory Licenses: Options for Developing Countries", *South Centre*, October 1999, *available at:* https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf (last visited on October 30, 2024).

71 *Supra* note 23, art. 6.

72 *Id.*, art. 32.

73 Sandeep K. Rathod, "Patent Oppositions in India" in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines: Implementing Flexibilities Under the Intellectual Property Law* 151 (Springer, Cham, 2022).

74 *Supra* note 23, art. 73(b).

75 *Supra* note 16 at 8.

x. Other measures, such as limiting injunctions in public health contexts, further empower nations to balance patent protections with the need for accessible healthcare solutions.[76]

By utilizing the above flexibilities, countries can exercise sufficient freedom regarding interpretation and implementation of TRIPS requirements pertaining to pharmaceutical patents, catering to their socio-economic needs, provided they fulfil the minimum obligations. However, these flexibilities are required to be operationalized at the domestic levels in national patent legislations. Unless flexibilities are incorporated in the domestic laws, the gains made at the international level through the TRIPS Agreement would not transform into real benefits for people.

2. Pharmaceutical Patents and Access to Medicines in India

2.1. Right to Access to Medicines in India

India ratified the two key covenants of the Universal Declaration of Human Rights (UDHR), 1948 - ICESCR and ICCPR, thus as part of its obligations under these covenants, the Government of India, through the Ministry of Health and Family Welfare, implements various programs[77] and schemes[78] to provide medicines to its citizens.

The Constitution of India incorporates civil and political rights as fundamental rights[79] and socio-economic rights within the Directive Principles of State Policy (DPSPs).[80] The DPSPs provides explicit directions to the State relating to health: "*to secure health and strength of workers, men, women and children*;[81] *to make provisions for public assistance in sickness and disablement*;[82] *and to raise the level of nutrition and standard of living of people and public health"*.[83]

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76 *Supra* note 16.

77 Shalini Arora and Rekha Chaturvedi, "Impact of TRIPS on Providing Easy Access to Affordable Medicines in India", 22 *Journal of Intellectual Property Rights* 263 (2017).

78 Jagdish Wamanrao Khobragade, "Interface Between Human Rights and Intellectual Property Rights with Special Reference to Patent Regime and Right to Health in India", 25 *Journal of Intellectual Property Rights* 208 (2020).

79 The Constitution of India, part III.

80 *Id*., part IV.

81 *Id*., art. 39 (e).

82 *Id*., art. 41.

83 *Id*., art. 47.

However, the DPSPs are non-justiciable and cannot be enforced in courts.[84] Over time, Indian courts have adopted a broader interpretation of socio-economic rights by linking them to justiciable civil and political rights, especially under the fundamental right to life enshrined in Article 21 of the Constitution.[85] This expanded interpretation has allowed the judiciary to address matters related to health, originally listed as DPSPs.[86]

The judiciary has recognized the right to health as an integral part of the right to life, emphasizing that it is essential for living a meaningful and dignified life.[87] This includes ensuring hygienic conditions and a better standard of living.[88] Courts have specifically held that the failure of government hospitals to provide timely medical treatment constitutes a violation of the right to life.[89] Furthermore, the state cannot justify its inability to deliver adequate medical services on grounds of financial constraints.[90] Importantly, it has been recognized that India being a signatory to UDHR and ICESCR, it has a core and non-derogable obligation to provide access to medicines.[91] Efforts of the Indian judiciary for promoting access to medicines was seen during the Covid-19 pandemic wherein the courts gave directions to Government to take suitable measures for ensuring access to Covid medicines and vaccines.[92] Thus, it can be said that right to access to medicines is recognized in India.

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84 *Supra* note 79, art. 37.

85 Yepuri Sai Chaitanya, "Article 21: The Ever-Evolving Article of the Indian Constitution", *3 International Journal of Law Management and Humanities* 2143 (2020).

86 Niloy Bagchi, "Right to Healthcare in India: A Study of Constitutional Guidelines", 7 *Indian Journal of Law and Justice* 160 (2016).

87 *Consumer Education & Research Centre* v. *Union of India and others* 1995 SCC (3) 42.

88 *Ibid*.

89 *Paschim Banga Khet Samity* v. *State of West Bengal* (1996) 4 SCC 37.

90 *State of Punjab and others* v. *Ram Lubhaya Bagga* (1998) 4 SCC 117.

91 *Mohd. Ahmed (Minor)* v. *Union of India* W.P.(C) 7279/2013 (Decision of the High Court of Delhi at New Delhi, April 17, 2014).

92 *In Re: Distribution of Essential Supplies and Services During Pandemic* 2021 SCC OnLine SC 355; *Rakesh Malhotra* v. *Government of National Capital Territory of India* 2021 SCC OnLine Del 1811; *Dharmendra Kumar Aggarwal* v. *Govt. Of NCT of Delhi*, 2021 SCC OnLine 1995.

2.2. Patent Regime in India

2.2.1. Goals and Objectives of the Indian Patent Regime

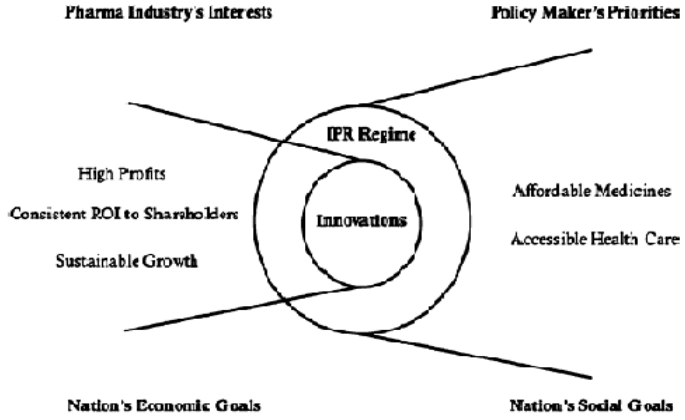

Figure 1: Dilemma of the Indian policy makers' goals and priorities

Source: Uday S. Racherla, Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry[93]

The figure summarizes the two sides of spectrum of the goals and priorities of the Indian policy makers. The pharmaceutical companies in India rely on successful innovation for making high profits, delivering consistent rate of interest to shareholders, competitive advantage and achieving sustainable growth.[94] This is however, only one side of the spectrum. On the other side, an important objective of the government and policy makers in India is ensuring that pharmaceutical innovations result in affordable medicines being available to people. This dilemma of the Indian policy makers is summarized in Figure 1. Thus, countries like India aspire to balance social goals against economic goals – the social goals being ensuring affordable medicines and accessible healthcare and, economic goals being the ones which are aligned with the interests of pharmaceutical companies.[95] This aim has been shaping the policies of the Indian patent regime.[96]

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93 Uday S. Racherla, "Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry" in Kung-Chung Liu and Uday S. Racherla (eds.), *Innovation, Economic Development, and Intellectual Property in India and China Comparing Six Economic Sectors* 275 (Springer, Singapore, 2019).

94 *Ibid.*

95 *Ibid.*

96 *Ibid.*

2.2.2. Historical Background of Indian Patent Regime

The patent regime of India has developed and evolved with time. Initially, the patent laws were introduced in Indian by the British in the late 19th century.[97] During 1948-50, Bakshi Tek Chand Committee was appointed for reviewing the Patents Laws in India.[98] The Committee suggested including compulsory licensing and commercial working of patented inventions in India, except for importations. It also suggested that food and medicines should be available at cheap prices to people.[99]

In 1957, a committee was constituted under Rajagopala Ayyangar,[100] for building upon the recommendations of Bakshi Tek Chand Committee Report. The Ayyangar Committee Report observed that *"strong patent protection had failed to stimulate new inventions and did not necessarily encourage development of new inventions for industrial purposes that could benefit the country."*[101] Focusing on the need of ensuring access to affordable medicines, it was recommended by the Ayyangar Report that the Indian patent law should not provide patent protection to products pertaining to food and pharmaceuticals for ensuring their availability at a reasonable price. The main argument of the Committee was: *"laws should be designed keeping in mind the economic conditions, state of scientific and technological advance and future needs of a country so as to minimize the abuse that can result from a patent monopoly system."*[102]

After independence, it was only in 1970 that India enacted its first Patent legislation.[103] Based upon the recommendations of the Ayyangar Report, the Patent Act, 1970 permitted patent protection only for pharmaceutical processes.

2.2.3. India becomes a member of TRIPS Agreement

The patent regime pertaining to pharmaceuticals in India gradually began to transform with its accession to the WTO in 1995. India was one of the developing

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97 Janice M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation", 68 *University of Pittsburgh Law Review* 504 (2007).

98 Government of India, "Report of the Patents Enquiry Committee" (Ministry of Industry and Supply, 1948-50).

99 *Ibid.*

100 Government of India, "Report on the Revision of the Patents Law by Shri Justice N. Rajagopala Ayyangar" (Ministry for Commerce and Industry, 1959).

101 *Ibid.*

102 *Ibid.*

103 *Supra* note 98.

countries which had strongly opposed the adoption of minimum standards of IPR protection at the international level. However, facing the unfeasible option to remain completely outside the WTO system, India signed the TRIPS Agreement in 1995. The patent law in India has been significantly influenced by India's opposition to inclusion of intellectual property within the GATT and WTO framework.[104]

India's patent law reflects the tensions between its efforts of promoting domestic research based pharmaceutical industries and preserving the capacity of supplying low-cost pharmaceuticals to domestic and foreign markets.[105] Notably, India managed to cull out crucial flexibilities regarding patent law, having the result of limiting the effects of the changes mandated by TRIPS.[106] A critical examination of the Patents Act, 1970 is undertaken in the next section to assess how far India has incorporated TRIPS flexibilities which are useful for promoting access to medicines.

2.2.4. National Intellectual Property Rights (IPR) Policy, 2016

The National IPR Policy, 2016, seeks to establish a dynamic and balanced IPR system in India that enhances healthcare access.[107] It prioritizes creating effective IPR laws that balance the rights of holders with public interest. India reaffirms its commitment to the Doha Declaration on TRIPS and Public Health.[108] It pledges to use available legislative space and TRIPS flexibilities.[109] Additionally, India will constructively participate in international treaty negotiations. The policy's primary goal is to improve access to affordable medicines and healthcare solutions.[110]

2.3. Flexibilities in India's Patent Act, 1970 - An Analysis

2.3.1. Transition Periods

i) Delaying Patent Protection for Pharmaceutical Products

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[104] *Supra* note 93 at 276.
[105] Jerome H. Reichman and Rochelle C. Dreyfuss, "Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty", 57 *Duke Law Journal* 96 (2007).
[106] Cynthia M. Ho, "A New World Order for Addressing Patent Rights and Public Health", 82 *Chicago Kent Law Review* 1469 (2007).
[107] Government of India, "National Intellectual Property Rights Policy" 1 (Ministry of Commerce and Industry, Department of Industrial Policy & Promotion, 2016).
[108] *Id.* at 2.
[109] *Id.* at 9.
[110] *Id.* at 15.

India utilized the transition period provided by the TRIPS Agreement for preparing its domestic pharmaceutical industry. India was a founding member of the WTO when the TRIPS Agreement came into force on 1st January, 1995. Developing countries had to implement the TRIPS obligations after five years. However, India utilized the additional five years period for extending patent protection to pharmaceutical products. Only from January 1, 2005, India began to provide for both product and process patent protection for pharmaceuticals.[111]

India had taken an important policy decision for implementing TRIPS obligations relating to public health by delaying the provision of patent protection for pharmaceutical products till 2005.[112] This was in consideration of social issues within the country as high medicine prices could deny access to India citizens.[113] Absence of product patent for pharmaceuticals played an important role in the expansion of Indian pharmaceutical industry and helped achieve self- sufficiency.[114] Indian companies were easily able to introduce new drugs in the market. Moreover, this increased competition in the pharmaceutical market and made Indian companies to develop cost effective processes for manufacturing medicines.[115] The domestic manufacturers in India were reverse engineering drugs, regarding which research and development had already been done in other countries. This had been an important strategic option.[116]

However, even in India manufacturers could still patent methods or processes for making drugs.[117] This resulted in an impressive development of the generic pharmaceutical industry in India,[118] resulting in reduced medicine prices. India was also exporting low priced generic medicines to other countries.[119] This led India to get the

[111] Juan He, "Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?" in Kung-Chung Liu and Uday S. Racherla (eds.), *Innovation, Economic Development, and Intellectual Property in India and China Comparing Six Economic Sectors* 266 (Springer, Singapore, 2019).

[112] *Supra* note 23, art. 65.

[113] Gopakumar K. M., "Product Patents and Access to Medicines in India: A Critical Review of the implementation of TRIPS Patent Regime", 3 *The Law and development Review* 329 (2010).

[114] *Ibid*.

[115] *Supra* note 111 at 330.

[116] *Supra* note 106.

[117] Ryan Abbott, "Balancing Access and Innovation in India's Shifting IP Regime, Remarks", 35 *Whittier Law Review* 343 (2014).

[118] *Supra* note 113.

[119] *Ibid*.

reputation of "pharmacy of the developing world".[120] The transition decade was the fastest growing period for the Indian pharmaceutical industry. The average profit margin of pharmaceutical industry in India increased and generic drug entry in the Indian market grew rapidly.[121] By the Patent (Amendment) Act, 2005 pharmaceutical products were included in the scope of patentability.

ii) Mailbox applications

The mailbox procedure for patent applications for pharmaceutical products was formally implemented through an amendment passed in 1999. It was given retroactive application from 1st January, 1995. Mailbox applications were required to be deposited in a "black box" and they were not to be taken out for examination until March 2005. Some applicants who filed mailbox applications during the transition period also sought Exclusive Marketing Rights (EMRS) for their inventions.[122] EMR conferred the exclusive right to sell or distribute the invention in India for a period of five years.[123] (India's mailbox rule was challenged by US in front of WTO panel. The WTO Panel and the Appellate Body found such filing system to be inconsistent with Article 70.8 of TRIPS and EMR to be inconsistent with Article 70.9 of TRIPS).[124]

In order to comply with TRIPS transition requirements, the mailbox applications system was ended for India on December 31, 2004. The provisions dealing with mailbox applications/EMRs became obsolete in 2005 and they were repealed by the Patents (Amendment) Act, 2005.

2.3.2. Scope of patentability

Keeping in mind nation's social and economic goals, India took important steps in its patent law to check the patenting of known substances, also called, ever-greening of patents. In 2006, Mashelkar Committee Report on Pharmaceutical and Micro-organism Patents recommended that "*every effort must be made to prevent the practice of 'ever*

[120] Ellen't Hoen *et. al.*, "Driving a decade of change: HIV/ AIDS, patents and access to medicines for all", 14 *Journal of the International Society* 15 (2011).
[121] *Supra* note 111 at 259.
[122] *Hetero Drugs Ltd*. v. *Wockhardt Ltd.*, 2007 (34) PTC 173 (SC).
[123] *Supra* note 113 at 330.
[124] WTO Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 1998 (April 15, 1999).

greening' ……..by making claims based sometimes on 'trivial' changes to the original patented product".[125] This has been done by limiting the scope of patentability.

The Indian Patent Act follows both methods for limiting the scope of patentability.[126] Firstly, since the expression *invention* has not been defined in the TRIPS Agreement, there is flexibility in interpreting patentable subject matter. The definition of inventive step in the Indian law is comparatively stricter than several other countries because it requires an invention to include technical advance, economic significance or both, besides the fact that the invention is not obvious to a person skilled in the art.[127]

The threshold of inventive step is important in ensuring that genuinely innovative inventions are granted patent. India has utilized the flexibility of defining inventive step. India has incorporated a high threshold for inventive step by defining it in Section 2(ja) as: "*a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to person skilled in the art*". Non-obviousness is a standard requirement for inventive step but the additional requirements of technical advance and economic significance are unique to India, raising the standard of patentability in India. The important terms, technical advance and economic significance, however, do not find definition in the Indian Patent laws or guidelines of patent office.[128] The non-obviousness requirement in India is stricter in comparison to the United States.[129]

Secondly, Section 3 of the Patent Act, 1970 excludes several categories of inventions from patent protection. The most significant exclusion is under Section 3(d). It restricts patenting of known substances and derivates without any enhanced efficacy. The introduction of this provision shows India's concern regarding evergreening of

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[125] Shamnad Basheer, "The Mashelkar Committee Report on Pharma Patenting Resurfaces" *SpicyIP*, 18 April 2009, *available at*: https://spicyip.com/2009/04/mashelkar-committee-report-on-pharma.html (last visited on October 31, 2024).

[126] Sonali Kokane, "What Cannot Be Patented in the Jurisdiction of India?", 25 *Journal of Intellectual Property Rights* 196 (2020).

[127] The Patents Act 1970 (Act 39 of 1970), s. 2(1)(j).

[128] Muhammad Zaheer Abbas, "Twenty Years After Doha: An Analysis of the Use of the Trips Agreement's Public Health Flexibilities in India", *South Centre*, 15 June 2022, *available at:* https://www.southcentre.int/wp-content/uploads/2022/06/RP158_Twenty-Years-After-Doha.-An-Analysis-of-the-Use-of-the-TRIPS-Agreements-Public-Health-Flexibilities-in-India_EN.pdf (last visited on October 31, 2024).

[129] *Ibid*.

patents being an obstacle to patients' access to medicines.[130] Utilization of Section 3(d) as a means of promoting access to medicines can be seen in the landmark case decided by the Supreme Court of India, Novartis AG v. Union of India.[131] By clarifying that under Section 3(d) "efficacy" means "therapeutic efficacy", an important step was taken to curb evergreening of patents. This decision takes into account the impact prolonged patent monopoly can have on access to medicines. The IPAB[132] and the Madaras High Court[133] had also decided on similar lines.

Generally, as processes to prepare formulations or compositions are well known, inventions pertaining to them may lack inventive step.[134] Section 3(e) of the Patents Act, 1970 seeks to reduce the number of such compositions or formulations by excluding from patentability: *"a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such a substance."* Also, under Section 3(i): *"any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease to increase their economic value or that of their products"* is not considered an invention.

A 2017 report identifies and analysed the 1723 pharmaceutical patent applications that were rejected by the Indian Patent Office (IPO) between January 2009 and January 2017.[135] Chief amongst the grounds for rejection was the basic criterion of patentability (Section 2(1)(j) and 2(1)(ja)) which requires an invention to be novel, involve an inventive step, and to have industrial applicability to be patentable. 77% of applications were rejected because they failed to satisfy this basic criterion. These applications were predominantly rejected due to lack of an inventive step. Over one-third of orders for rejection in this category make a particular reference to a new definition of

[130] Jodie Liu, "Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act", 56 *Harvard International Law Journal* 219 (2015).
[131] (2013) 6 SCC 1.
[132] *Novartis A.G.* v. *Union of India*, 2009 SCC OnLine IPAB 79.
[133] *Novartis A.G.* v. *Novartis India*, Ltd. 2007 SCC OnLine Mad 658.
[134] Arti Malik, "Pharmaceutical Industry, The Health System and Intellectual Property Policy in India", in Carlos M. Correa (ed.), *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* 73 (South Centre, Penang, 2013).
[135] *Supra* note 130.

inventive step (Section 2(1)(ja)), which introduced a heightened standard of patentability in India.[136]

Statutory exceptions to patentability also featured prominently in the reasons for rejection, with around 65% of rejections citing Section 3 as a ground for rejection. Various sub-sections under Section 3 were often cited in combination, with exceptions to patenting new forms of known substances (Section 3(d)), mere combinations of known drugs (Section 3(e)), and methods of treatment (Section 3(i)) being the most commonly cited grounds in this category.[137]

The flexibility utilized by India in framing the grounds of exclusion from patentability have served as an important means to limit the patent monopoly over pharmaceuticals.

2.3.3. Exceptions to patent rights

The Patent Act, 1970 provides patent term of twenty years from the date of filing of application.[138] The patent owners are conferred with an exclusive set of rights to exclude competitors from the market.[139] The Indian Patent Act lays down several exceptions to the rights conferred upon a patent holder. These exceptions can be used to ensure or promote access to medicines.

(i) Early working exception/Bolar exception

The Indian Patent Act provides for Bolar exception in Section 107 A(a). It provides that: "*any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country*

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136 *Ibid.*
137 *Ibid.*
138 *Supra* note 127, s. 53.
139 *Id.*, s. 48.
'Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee -
(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.'

other than India, that regulates the manufacture, construction, use, sale or import of any product." This is in accordance with the general exception provided by TRIPS Agreement under Article 30.[140] Importantly, Section 107A(a) can also be utilized for exporting the medicines for the stated purposes.[141]

The design and implementation of the Bolar exception is of particular relevance in countries that have domestic production capacity for generics and biosimilars. The Bolar exception in Indian legislation is of special interest as India is a global leader in the global supply of affordable generic and biosimilar products. The Bolar exception contributes to a favourable environment for the generic and biosimilar industry in India to develop and expand.[142]

The exception applies to any regulated sector, and extends to acts done for submission of information not only in India but in any other country. The scope of acts covered can include the manufacture of the patented protected product, export of pharmaceuticals or finished formulation by a generic company, conduct of clinical trials, or import of the pharmaceuticals or formulation by a third party to support relevant regulatory approvals in India or other countries.[143]

(ii) Research and Experiment Use Exception

The research and experimental use exception under the Patent Act provides that "*any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.*"[144]

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[140] *Supra* note 23, art. 30.

[141] *Bayer Corporation* v. *Union of India*, 2019 SCC OnLine Del 8209.

[142] Viviana Munoz Tellez, "Bolar Exception" in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines, Implementing Flexibilities under Intellectual Property Law* 135 (Springer, Cham, 2022).

[143] *Ibid*.

[144] *Supra* note 127, s. 47(3).

(iii) Government use provision

Under certain circumstances, the government is authorized for using the patented invention. For such use by the government, adequate remuneration is given to the patentee. The government is required to notify the patent holder regarding such use as soon as possible, except in case of emergency. Moreover, government can also import patented medicines for its own use, or for distribution.[145]

2.3.4. Parallel Importation

India's Patent Act enforces the principle of international exhaustion of patent rights and provides for parallel importation. It provides that: "*importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights*."[146] In this regard, India has utilized TRIPS flexibility to the fullest extent.[147]

2.3.5. Compulsory Licensing

India has extensive compulsory licensing provisions.[148] It is considered as the most comprehensive non-voluntary licensing system in the world.[149] India has crafted its compulsory licensing provision in accordance with the TRIPS Agreement and the Doha Declaration. The Patents (Amendment) Act, 2005 played a significant role in incorporation of extensive and detailed compulsory licensing provisions.[150]

Under Section 84 of the Indian Patent Act, 1970, compulsory licensing may be invoked after three years from the grant of patent[151] upon satisfaction of the following conditions: "*the reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available to the public at a reasonable price and the patented invention is not worked in the territory of India*."[152]

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145 *Id.*, s. 100.
146 *Id.*, s. 44.
147 *Supra* note 113 at 326.
148 *Supra* note 125 at 213.
149 Kamini Shanmugaiah, "The Impact of TRIPS Agreement on Access to Medicines in Developing Countries: Legal Challenges Faced by the Pharmaceutical Industry Particularly in India", 3 *UUM Journal of Legal Studies* 26 (2012).
150 *Supra* note 128.
151 *Supra* note 127, s. 84.
152 *Id.*, s. 84.

Furthermore, the Indian government may grant a compulsory license in circumstances involving *"national health emergencies; circumstances of extreme urgency or public non- commercial use"*.[153] The Patent Act, 1970 also provides for the mechanism to *"manufacture and export patented medicines to other countries without local manufacturing capacity."*[154]

In the landmark case of *Bayer Corporation* v. *Union of India*,[155] compulsory licensing was granted on the ground of high price of the medicines, making it difficult for people in India to economically afford it. India's Controller General of Patents, Designs, and Trademarks granted the country's first and only compulsory licence to *Natco Pharma Ltd*., an Indian generic pharmaceutical company, allowing it to manufacture and sell Nexavar (Sorafenib Tosylate), a chemotherapy drug patented by Bayer. Although the drug prolongs life by approximately six months, it does not cure the disease. The compulsory licence was issued under Section 84 of the Indian Patents Act, based on three grounds: the drug did not meet the reasonable needs of the public; it was unaffordable for most patients; and it was not being adequately manufactured or worked in India as required by law. Bayer's Indian patent for Nexavar was granted on March 3, 2008, and the company received regulatory approval to import and market the drug in India. However, the Indian Patent Office (IPO) determined that Bayer failed to meet public demand. In 2008, Bayer did not import the drug at all, and only limited quantities were brought into the country in 2009 and 2010. As a result, only about 2% of eligible patients had access to the drug, falling short of the public's needs. Furthermore, Bayer priced Nexavar at Rs. 2,80,000/- per month (approximately US$5,600), a cost that was far beyond the reach of most Indian cancer patients. In contrast, Natco proposed selling the drug for no more than Rs. 8,800/- per month (around US$176) for the full 120-tablet monthly dosage. Natco also committed to providing free medication annually to 600 underprivileged patients.

Another key issue was that Bayer was not manufacturing Nexavar within India, relying solely on imports from overseas facilities. This failed to meet the legal requirement of working the patent domestically. Additionally, Bayer rejected Natco's

[153] *Id.*, s. 92.
[154] *Id.*, s. 92-A.
[155] 2014 SCC OnLine Bom 963.

request for a voluntary licence limited to the Indian market. As a result, the compulsory licence was granted with a condition that Natco pay a 7% royalty on sales to Bayer.

This is the only instance when compulsory license has been granted in India. Other applications were filed but could not be accepted as essential requirements for compulsory licensing were not fulfilled by the applicants such as insufficient efforts to secure voluntary license,[156] failure to prove unmet public need and non-working of the patent[157] etc.

2.3.6. Procedural Safeguards

An important mechanism under the Patents Act, 1970 is the provision of both pre-grant[158] and post-grant opposition.[159] This helps to filter out fortuitous patent claims.[160] India is amongst the few countries which provide both forms of opposition procedures.[161] The grounds of both types of oppositions are identical. While pre-grant opposition can be made by *"any person"*, post grant opposition can be done by *"any person interested"*. They are important tools for general public, generic producers and civil society for promoting access to medicines. The TRIPS Agreement does not have any specific provision regarding opposition. Hence, the compliance of such procedure with TRIPS is dependent upon whether it is a "reasonable" procedure under Article 62[162] of the TRIPS Agreement.[163] India has used the approach of not having a presumption of validity for invention which have been granted patent.[164] It is another manner to curb the unjustified patent monopoly.

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156 *Bristol Myers Squibs Company* v. *BDR Pharmaceuticals International Pvt. Ltd*. C.L.A. No. 1 of 2013.
157 *Astrazeneca AB* v. *Lee Pharma Ltd.* C.L.A. No. 1 of 2015.
158 *Supra* note 127, s. 25(1).
159 *Supra* note 127, s. 25(2).
160 Brenda Pamela Mey, "Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: A Dead-End Journey for Patients? Kenya and India Case Studies", 13(3) *The Journal of World Intellectual Property* 443 (2010).
161 V. K. Unni, "Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health", 25 *Pacific McGeorge Global Business & Development Law Journal* 339 (2012).
162 *Supra* note 23, art. 62.
'(1) Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.'
163 *Supra note* 10 at 380.
164 *Supra* note 128 at 23.

A significant number of the early oppositions filed between 2005 and 2015 primarily revolved around statutory provisions, particularly Section 3 (which delineates what does not qualify as inventions) and predominantly Section 3(d) of the Patents Act (which prohibits the granting of patents for new forms of known substances or mere use of known processes).[165] Over time, opponents have progressed beyond solely relying on Section 3(d) and have successfully constructed and won opposition cases based on more intricate arguments, such as lack of inventive step, obviousness to try, anticipatory disclosures etc. In parallel, just as opposition arguments have evolved beyond Section 3(d), so too have patent examiners, adapting their approach for scrutinizing pharmaceutical claims.[166]

Data shows that in the recent years there has been a spate in pre-grant oppositions while the post-grant oppositions have remained stagnant. The same is depicted in the following figure:

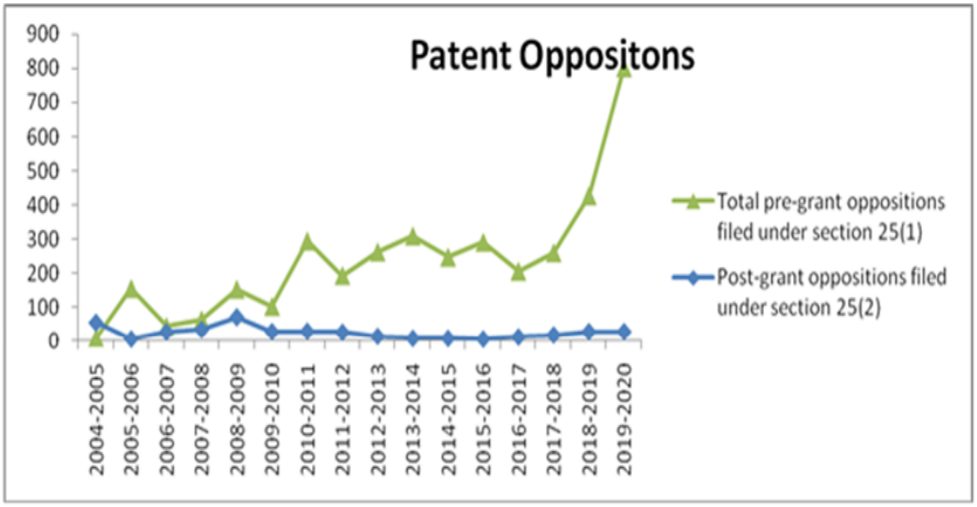

Figure 2: Patent Oppositions applications filed (2004-2020)[167]

Though opposition is an important mechanism, however, pendency of both pre-grant and post-grant oppositions in India poses a challenge to the viability of this

[165] *Supra* note 73 at 153.
[166] *Supra* note 73 at 154.
[167] N. Batra, "Lessons from India's Implementation of Doha Declaration on TRIPS and Public Health", *South Centre*, 6 October 2022, *available at:* https://www.southcentre.int/research-paper-166-6-october-2022/ (last visited on October 10, 2024).

option.[168] The annual opposition disposal rate has not kept pace with the trend of increased patent application filings.[169]

2.3.7. Revocation of patent

Another flexibility provided in the Indian Patents Act is the provision of revocation of patent.[170] In cases of public health emergencies, this flexibility can be useful. In *La Renon Health Care Pvt. Ltd*. v. *Kibow Biotech Inc. and Ors*.,[171] the patent was revoked on the ground of not being a patentable invention under the Act.[172]

2.3.8. Security Exception

The Central Government can take necessary actions in the time of emergency in international relations.[173] This can be construed to include public health related emergencies.

2.3.9. Acquisition of Patents

The Patent Act, 1970 provides for acquisition of a patent or an invention which is the subject matter of application of patent by the Central Government for public purposes.[174] The Supreme Court in the case in Re: Distribution of Essential Supplies and Services During Pandemic,[175] recommended the utilization of Section 102 of the Patents Act, 1970[176] for providing access to COVID-19 drugs and vaccines.

3. Conclusion

Since the time India became a member to the TRIPS, it has adopted a pro-access to medicines approach. It has been able to utilize the flexibilities the agreement provides to a large extent in its patent law. India considered its domestic situation and utilized the provision of transition periods in the agreement. Thereby, it made its patent law TRIPS complaint in a gradual and steady manner. Within the Indian Patent Act, 1970, several provisions are incorporated which can be utilized for promoting access to medicines.

[168] *Supra* note 73 at 172.
[169] *Id.* at 173.
[170] *Supra* note 127, s. 64.
[171] MANU/IC/0100/2013.
[172] *Supra* note 127, s. 64(d).
[173] *Id.*, s. 157 A.
[174] *Supra* note 127, s. 102.
[175] 2021 SCC OnLine SC 355.
[176] *Supra* note 127, s. 102.

Different types of flexibilities related to standards of patentability; patentable subject matter; procedural measures etc. find place in the Act. Also, specific mechanisms such as compulsory licensing, early use exceptions etc. are also provided. The Patents Act implements extensive measures for ensuring balance between granting patent protection to pharmaceuticals in accordance with TRIPS requirement and ensures such protection does not obstruct access to a sustainable supply of affordable medicines. TRIPS flexibilities have been sufficiently incorporated in the Patents Act, 1970.

4. Suggestions

Some suggestions for further implementation of flexibilities for promoting access to medicines are as follows:

- Training of Patent Offices regarding flexibilities so that access to medicine can be considered while assessing patent applications.
- Promote national dialogue amongst judging which would allow judges to discuss complex IP issues like TRIPS flexibilities in pharmaceutical patents.
- Expanding IP Divisions across High Courts, as seen with Madras in 2023, would further strengthen IP adjudication efficiency and expertise.
- Ensuring the presence of technical experts in benches pertaining to patent related matters.
- Ensuring presence of patent related technical law researchers aiding judges.