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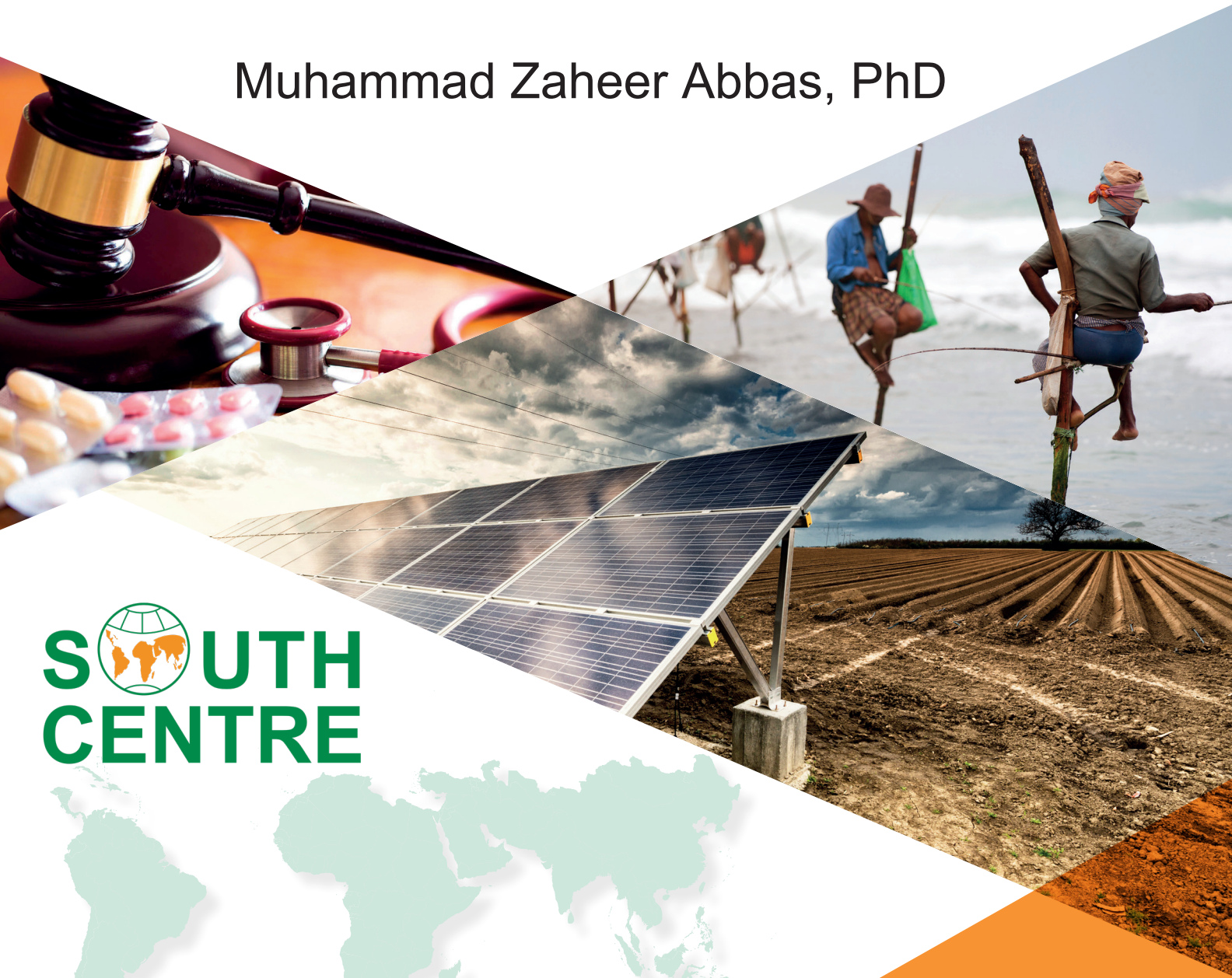

SOUTH CENTRE

# RESEARCH PAPER

# 158

# TWENTY YEARS AFTER DOHA: AN ANALYSIS OF THE USE OF THE TRIPS AGREEMENT'S PUBLIC HEALTH FLEXIBILITIES IN INDIA*

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**SOUTH CENTRE**

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## ABSTRACT

The World Trade Organization (WTO) linked intellectual property protection with trade. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), however, included a number of public health flexibilities in order to provide latitude to the Member States to tailor their national patent laws to fit their individual needs. In 2001, the Doha Declaration further clarified and reaffirmed the existing TRIPS flexibilities. This paper argues that India has taken the lead role in enacting the TRIPS Agreement's substantive and procedural patent flexibilities by introducing unique legislative measures to deal with the problem of access to medicines. This article evaluates India's use of section 3(d) as a subject matter exclusivity provision. It examines constitutional validity and TRIPS compliance of section 3(d). It also evaluates India's use of the flexibility to define the term "inventive step". Moreover, this article evaluates India's use of compulsory licensing, the most notable exception to patent rights provided under the TRIPS Agreement. This empirical study is important in the context of the COVID-19 pandemic, which has once again highlighted the same public health issues that the Doha Declaration sought to address twenty years ago.

*La Organización Mundial del Comercio (OMC) vinculó la protección de la propiedad intelectual con el comercio. Sin embargo, el Acuerdo de la OMC sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (Acuerdo sobre los ADPIC) incluyó una serie de flexibilidades en materia de salud pública con el fin de ofrecer a los Estados miembros la posibilidad de adaptar sus leyes nacionales de patentes a sus necesidades individuales. En 2001, la Declaración de Doha aclaró y reafirmó las flexibilidades existentes en el ADPIC. Este artículo sostiene que la India ha asumido el liderazgo en la promulgación de las flexibilidades sustantivas y de procedimiento en materia de patentes del Acuerdo sobre los ADPIC al introducir medidas legislativas únicas para abordar el problema del acceso a los medicamentos. Este artículo evalúa el uso que hace la India de la sección 3(d) como disposición de exclusión de materia patentable" . Examina la validez constitucional y el cumplimiento del ADPIC de la sección 3(d). También evalúa el uso que hace la India de la flexibilidad para definir el término "actividad inventiva". Además, este artículo evalúa el uso que hace la India de las licencias obligatorias, la excepción más notable a los derechos de patente prevista en el Acuerdo sobre los ADPIC. Este estudio empírico es importante en el contexto de la pandemia de COVID-19, que ha vuelto a poner de manifiesto los mismos problemas de salud pública que la Declaración de Doha pretendía abordar hace veinte años.*

*L'Organisation mondiale du commerce (OMC) a lié la protection de la propriété intellectuelle au commerce. L'Accord de l'OMC sur les aspects des droits de propriété intellectuelle qui touchent au commerce (Accord sur les ADPIC) prévoyait toutefois un certain nombre de flexibilités en matière de santé publique afin de donner aux États membres la possibilité d'adapter leurs lois nationales sur les brevets à leurs besoins particuliers. En 2001, la déclaration de Doha a clarifié et réaffirmé les flexibilités existantes de l'ADPIC. Ce document soutient que l'Inde a joué un rôle de premier plan dans la mise en œuvre des flexibilités substantielles et procédurales de l'Accord sur les ADPIC en matière de brevets en introduisant des mesures législatives uniques pour faire face au problème de l'accès aux médicaments.*

*Ce document évalue l'utilisation par l'Inde de la section 3(d) comme dispositif d'exclusion de matière brevetable. Il examine la validité constitutionnelle et la conformité aux ADPIC de la section 3(d). Il évalue également l'utilisation par l'Inde de la flexibilité pour définir le terme "activité inventive". En outre, le document évalue l'utilisation par l'Inde des licences obligatoires, l'exception la plus notable aux droits de brevet prévus par l'Accord sur les ADPIC. Cette étude empirique est importante dans le contexte de la pandémie de COVID-19, qui a une fois de plus mis en évidence les mêmes problèmes de santé publique que ceux que la Déclaration de Doha cherchait à résoudre il y a vingt ans.*

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# I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provided mandatory patent protection to inventions in all fields of technology.[1] Public health safeguards were included in the original draft of the TRIPS Agreement to address practical implications for poorer countries in accessing affordable medicines.[2] The Doha Declaration on the TRIPS Agreement and Public Health, adopted by consensus, affirmed that the "TRIPS Agreement does not and should not prevent members from taking measures to protect public health … the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health".[3] Despite not making any changes to the TRIPS Agreement, the Doha Declaration was hailed as a positive development, keeping in view the power asymmetries between the advanced world and the developing world.[4] The Doha Declaration was a rare negotiation win for Third World countries and a landmark development in terms of stabilising the relationship between the TRIPS Agreement and public health.

Two decades have passed since Doha. The Doha Declaration is not self-executing and requires changes in the national laws for its implementation.[5] Not all WTO Member States made optimal use of the policy space confirmed by Doha. It is important to consider how the WTO public health flexibilities have been practically used by the Member States. It is, however, beyond the scope of this study to consider the legislative approaches of all WTO Member States. This study only focuses on the use of these flexibilities by India, arguably a leader of the developing world in enacting the WTO public health flexibilities.

A vast majority of the Indian population cannot afford brand-name patented drugs. The annual income of an average Indian is too low to afford certain life-saving patented drugs because the annual cost of medicine is more than thirty times higher than the annual income of an average citizen.[6] According to the World Bank report "Poverty and Shared Prosperity", India accounts for the largest number of people living below the international poverty line, with 224 million people living under $1.90 a day.[7] Keeping in view India's budget constraints and enormous costs of achieving the goal of access to health technologies, India had excluded

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[1] The Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, *TRIPS Agreement*, Articles 27(1) and 33.

[2] Muhammad Zaheer Abbas, and Shamreeza Riaz, "Flexibilities under Trips: Implementation gaps between theory and practice" *NJCL* (2013).

[3] Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/W/2, Para 4. See more Muhammad Zaheer Abbas, and Shamreeza Riaz, "WTO "Paragraph 6" system for affordable access to medicines: Relief or regulatory ritualism?" *The Journal of World Intellectual Property* vol. 21, No. 1-2 (2018) 35-36.

[4] Muhammad Zaheer Abbas, "The issue of undeserving patent monopolies in innovation-based businesses and implications thereof for underprivileged consumers" *The Business and Management Review* vol. 9, No. 1 (2017) 443.

[5] South Bulletin, "The Doha Declaration on TRIPS: The State of Implementation", 6, doi:http://www.southcentre.org/index.php?option=com_content&view=article&id=1657%3Asb58&catid=144%3Asouth-bulletin-individual-articles&Itemid=287&lang=en.

[6] Jodie Liu, "Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act", *Harvard International Law Journal*, vol. 56(2015).

[7] World Bank Group, "Poverty and Shared Prosperity 2016-Taking on Inequality" (2016) <http://library1.nida.ac.th/termpaper6/sd/2554/19755.pdf>. 40.

pharmaceutical drugs from patent protection prior to signing the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The Indian Patents Act 1970 was tailored to promote the growth of local generic drug industry. It not only excluded product patents on medicines and food under section 5(a) but also reduced the term of patent protection even for process patents on medicines and food under section 53(1)(a) which stipulated that "in respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter".[8] Keeping in view the research and development (R&D) cost of innovation in the pharmaceutical industry, the minimal protection afforded, under the process patent for a very limited duration, did not offer sufficient incentive to pharmaceutical companies to seek such protection.[9] As a direct result of the amended legislation, the number of drug patent applications dropped significantly creating an opportunity for the local generic drug manufacturing sector to grow rapidly in the next two decades.[10]

Even if the drugs were protected under process patents in India, generic manufacturers could legally make copies of the patented drugs through the use of "reverse engineering" by using an alternate process to manufacture the same end product.[11] As a direct result of generic competition, prices of drugs in India dropped 5 to 30 times compared to countries where pharmaceuticals enjoyed product patent protection.[12] The growth of the local pharmaceutical industry, under conducive patent law regime, also complied with India's industrial or economic development objective. This legislative policy allowed the generic drug industry in India to flourish. Companies like Cipla, Dr. Reddy's, Ranbaxy, Sun Pharmaceuticals, and Aurobindo emerged as India's leading generic producers. India was able to attain its goal of self-sufficiency in the production of basic drugs over a relatively short period of time.[13] Since then, India has established a world-class generic drug manufacturing sector.[14] In addition to India's favourable patent regime, various other factors also contributed to the dramatic growth of the generic drug industry in India. For instance, India has "raw materials, technical capacity, manufacturing conditions, and a large market".[15]

The quality of generic drug manufacturing practices in India is quite high.[16] India has the largest number of FDA approved drug manufacturing plants outside the US.[17] India is one of the biggest exporters of reliable generic drugs and annually exports more than US$ 10 billion

[8] The Patents Act 1970, section 53(1)(a).
[9] Jodie Liu (n 6).
[10] Ibid.
[11] Yousuf A. Vawda, "After the Novartis Judgment - 'Evergreening' will never be the Same Again!" *Law Democracy and Development* 18 (2014) 307.
[12] Jae Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?", *Information and Communications Technology Law* 23 (2014) 6.
[13] Amy Kapczynski, "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, vol. 97 No. 6 (2009)1578.
[14] Janice M. Mueller, "Taking TRIPS to India – Novartis, Patent Law, and Access to Medicines", *The New England Journal of Medicine*, vol. 356, No. 6 (2007) 542.
[15] Peter K. Yu, "Access to Medicines, BRICS Alliances, and Collective Action", *American Journal of Law and Medicine*, vol. 34, No.2-3, (2008) 360-361.
[16] Ibid., 360.
[17] Padmashree Gehl Sampath, *India's Pharmaceutical Sector in 2008: Emerging Strategies and Global and Local Implications for Access to Medicines* (United Kingdom Department for International Development: 2008) 21.

worth of generics around the world, especially in the developing countries and LDCs.[18] More than 80 per cent of the generic drug needs of Sub-Saharan Africa are met by Indian exports.[19] India played a crucial role in terms of supplying significantly cheaper HIV/AIDS drugs to the affected countries. At one stage, Cipla alone produced 40 per cent of the ARVs used worldwide.[20] The Indian drug companies took the advantage of the lack of product patents in India and combined three different ARVs in one single pill, making HIV treatment simple and affordable.[21] As noted by Kajal Bhardwaj:

> [T]he real turning point for access to [HIV/AIDS] treatment in the developing world came in 2001 when an Indian generic company, CIPLA, made an unimaginable offer to provide first line triple combination AIDS medicines at $350 per person per year. Today competition from and between Indian generic producers has resulted in price reductions for first line AIDS medicines from as much as $15,000 in 2000 to less than $120 per person per year for the current preferred first line triple combination.[22]

Charitable foundations, like the Clinton Foundation, as well as the Global Fund and Médecins Sans Frontières (MSF), purchase cheap generic medicines from India for distribution in developing and least-developed countries.[23] MSF often uses the moniker "Pharmacy of the Developing World" or "Pharmacy to the Poor" for India keeping in view India's role in MSF's access campaign.[24] As a matter of fact, India, as an exporter of generic medicines to Japan and Europe[25] and with the US as its largest export market, is a pharmacy of both the developing and developed nations.[26]

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[18] Jodie Liu, "Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act" *Harvard International Law Journal* vol. 56 no 6 (2015)208. See more Yousuf A. Vawda, "After the Novartis Judgment - 'Evergreening' will never be the Same Again!", *Law Democracy and Development*, vol. 18 (2014) 306.

[19] Colleen V. Chien, "HIV/AIDS Drugs for Sub-Saharan: How Do Brand and Generic Supply Compare?" *Public Library of Science ONE*, vol. 2, No. 3 (March 2007) 278.

[20] Jean-Paul Gaudillière and Volker Hess (eds.), *Ways of Regulating Drugs in the 19th and 20th Centuries,* (Springer, 2012) 304.

[21] Hans Löfgren (ed.), *The Politics of the Pharmaceutical Industry and Access to Medicines: World Pharmacy and India* (Routledge, 2017) 36.

[22] Ibid., 135.

[23] Thomas Eimer and Susanne Lütz, "Developmental States, Civil Society, and Public Health: Patent Regulation for HIV/AIDS Pharmaceuticals in India and Brazil", *Regulation and Governance* vo. 4 (2010)139.

[24] MSF is an international medical humanitarian organization that runs its medical programs in more than 60 countries. See Doctors without borders website http://www.doctorswithoutborders.org/article/obama-modi-meeting-new-york-msf-urges-india-protect-affordable-medicines-millions.

[25] Belinda Townsend, Deborah Gleeson and Ruth Lopert, "Japan's Emerging Role in the Global Pharmaceutical Intellectual Property Regime: A Tale of Two Trade Agreements", *The Journal of World Intellectual Property*, vol. 21 No. 1-2 (2018) 93.

[26] Cristoph Antons and R.M. Hilty (eds.), *Intellectual Property and Free Trade Agreements in the Asia-Pacific Region* (MPI Studies on Intellectual Property and Competition Law, 2015) 297. It has been noted that 'in the years 2007 and 2008, Indian companies accounted for one out of every four ANDA [Abbreviated New Drug Application] approvals in the United States'. See Susan Fyan, "Pharmaceutical Patent Protection and Section 3(d): A Comparative Look at India and the US", *Virginia Journal of Law and Technology*, vol. 15 (2010) 210. In 2014, around 40 per cent of the US total generic drug imports came from India. See Belinda Townsend, Deborah Gleeson and Ruth Lopert, "Japan's Emerging Role in the Global Pharmaceutical Intellectual Property Regime: A Tale of Two Trade Agreements", *The Journal of World Intellectual Property*, vol. 21, No. 1-2 (2018) 93.

India's generic drug industry thrived in the absence of product patent protection, but after joining the WTO in 1995, India had to amend its patent laws because implementing the TRIPS Agreement is a mandatory requirement for the WTO membership.[27] As a developing country, India was provided with a grace period up to 1 January 2005, for TRIPS compliance.[28] Since 2005, India has provided a detailed legislative framework for a number of public health safeguards to fully avail itself of the procedural and substantive flexibilities provided under the TRIPS Agreement. India's well-thought-out patent model is in line with India's two policy objectives: (a) affordable availability of essential medicines to underprivileged patients in India; and (b) promotion of a robust generic drug industry in India.

This empirical study undertakes an analysis of India's well-thought-out patent model with a key focus on TRIPS compliance of India's tailor-made legislative provisions. The approach of this article is to analyse, through the lens of access to medicines and vaccines, India's legislative response to the challenges posed by the TRIPS Agreement. This analysis, in respect of India's legislative and policy choices, draws upon a wide range of sources including legislation, treaties, court decisions, national and international reports, peer-reviewed journal articles, book chapters, blogs, quotations from stakeholders, and media reports.

This article has a five-part structure including the introduction and the conclusion. After the introduction, Part II evaluates India's use of section 3(d) as a subject matter exclusivity provision. It examines the constitutional validity and TRIPS compliance of section 3(d). Part III evaluates India's use of the flexibility to define the term "inventive step". Part IV examines India's extensive and detailed compulsory licensing regime. Part V concludes the discussion and provides recommendations.

[27] The Agreement Establishing the World Trade Organization, Art. II.2. It stipulates: "The agreements and associated legal instruments included in Annexes 1, 2 and 3 (hereinafter referred to as 'Multilateral Trade Agreements') are integral parts of this Agreement, binding on all Members".
[28] Ibid., Art. 65(2).

## II. SUBJECT MATTER EXCLUSIONS

The requirements for patentability i.e., novelty, inventive step and industrial applicability have been laid out in Art. 27(1) of the TRIPS Agreement which stipulates that "[s]ubject to the provisions of paragraph 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".[29]

The key terms prescribing criteria for patentability are not defined in the TRIPS Agreement, leaving sufficient latitude for the Member States to define scope and meaning of these terms according to their individual situations.[30] The purpose of "novelty" criterion is to make sure that inventions already in the prior art are prevented from patentability. By not providing guidance on "novelty", the TRIPS Agreement allows Member States flexibility in applying novelty criteria in their domestic laws.[31] Similarly, the TRIPS Agreement does not provide guidance on "inventive step". The official footnote 5, however, clarifies that the term "inventive step" is synonymous with the term "non-obvious". The WTO Member States are, therefore, afforded considerable flexibilities under TRIPS to decide an appropriate level of novelty and inventive step/non-obviousness criterion for the grant of patents within their national jurisdictions.

India took the lead role in enacting this TRIPS flexibility by introducing unique legislative measures to deal with the problem of evergreening of pharmaceutical patents.[32] The Indian Patents Act is unique in defining patentability criteria because of its novelty and inventive step standards which raise the bar or threshold for obtaining a patent in India. Under section 3(d) of the Patents Act, India does not allow patent protection for derivatives of known substances unless they meet the condition of "enhanced efficacy". The amended section 3(d) reads as:

> [T]he mere discovery of a **new** form of a **known** substance which does not result in the enhancement of the **known efficacy** of that substance or 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** (Emphasis added).[33]

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[29] TRIPS Agreement, Art. 27(1).
[30] Yousuf A. Vawda, "After the Novartis Judgment - 'Evergreening Will Never be the Same Again!", *Law Democracy and Development* vol. 18 (2014) 307. See more, Muhammad Zaheer Abbas, "Conflicting interests, competing perspectives and policy incoherence: COVID-19 highlights the significance of the United Nations high-level panel report on access to medicines", *Australian Intellectual Property Journal*, vol. 31, No. 1 (2020) 30.
[31] Muhammad Zaheer Abbas, "Strategic use of patent opposition safeguard to improve equitable access to innovative health technologies: A case study of CAR T-cell therapy Kymriah", *Global Public Health* (2020) 6.
[32] Jae Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?", *Information and Communications Technology Law*, vol. 23, No. 1 (2014) 2.
[33] The Patents Act 1970, section 3(d).

Section 3(d) is part of Chapter II of the Indian Patents Act titled “Inventions, not Patentable” which contains general exceptions to patentability in India. Section 3(d) is, however, different from other general exceptions provided in this chapter because it stipulates not only an exception to patentability but also covers all the three prerequisite conditions of patentability i.e., novelty (the term “new” that denotes novelty has been used in this provision), inventive step (the term “known” that denotes obviousness has been used in this provision), and industrial application (the terms like “efficacy” and “use” have been used in this provision that cover the condition of industrial application).

Other general exceptions provided in Chapter II of the Act are applied before determining the three positive prerequisite conditions of patentability. Section 3(d), because of its unique nature, is capable of application both before and after determining the conditions of patentability.

Section 3(d) provides an absolute exception to patentability for a new property or new use of a known substance. This provision is very important in restricting the evergreening of pharmaceutical patents as it does not recognize the novelty of use. This provision reflects India’s clear stance on strict novelty requirement for patent eligibility. Novelty per se is required for patent protection in India because there is no provision in the Patents Act to allow the novelty of use. Discovery of a new use of a known process may, however, qualify for patent eligibility subject to a condition that it results in a new product or employs at least one new reactant. This condition basically requires a technical contribution from the patentee to satisfy the requirements of inventive step and novelty.

This analysis of section 3(d) shows that it is a unique provision that raises the threshold for obtaining a patent in India by stipulating strict standards of novelty and inventive step. This provision ensures strict patentability criteria in India and plays a central role in hindering the practice of evergreening of pharmaceutical patents. For instance, Pfizer’s new use of already known sildenafil citrate as Viagra to address impotence, despite enjoying patent protection in several other jurisdictions, could not qualify for patent protection in India only because of section 3(d) which does not allow patent protection for new uses of a known drug.[34]

Section 3(d) distinguishes between incremental innovation, where there are additional therapeutic benefits and evergreening where there are no additional therapeutic benefits. The provision has remained controversial mainly because of the fact that “demarcating the line between incremental innovations that confer real clinical improvements, therapeutic advantages or manufacturing improvements, and those that offer no therapeutic benefits is not an easy task”.[35] Pharmaceutical companies consider section 3(d) as a stumbling block in acquiring patent protection in India but it is crucial to have safeguards “to avoid patents being used as barriers to legitimate competition”.[36] Section 3(d) provides a safeguard against the practice of evergreening because it creates a general presumption of non-patentability for modifications of known chemical compositions and shifts the burden of rebutting this presumption to patent applicants in each particular case.[37]

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[34] Generic version of Viagra is manufactured by several Indian generic manufacturers under following different trade names: Zenegra (Alkem Laboratories); Penegra (Zydus Cadila); Edegra (Sun Pharmaceutical); Silagra (Cipla); and Kamagra (Ajanta Pharma). See https://en.wikipedia.org/wiki/Sildenafil.

[35] Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health (World Health Organization, 2006) 134.

[36] Ibid.

[37] Janice M. Mueller, “Taking TRIPS to India — Novartis, Patent Law, and Access to Medicines”, *The New England Journal of Medicine*, vol. 356, No. 6 (2007) 543.

Ever since its inclusion in the Indian Patents Act, section 3(d) has been a subject of controversy between brand-name drug manufacturers and generic drug manufacturers as well as public health groups. Drug manufacturing companies seeking secondary patent protection over minor improvements in existing drugs consider section 3(d) as a stumbling block because of its additional requirement of enhanced efficacy. The multinational pharmaceutical companies also enjoy political support of their powerful governments in opposing section 3(d). India is on the "Priority Watch List" of the United States Trade Representative (USTR) which includes countries with IP regimes of serious concern for the USTR.[38] In order to exert pressure on India to amend this provision, the USTR repeatedly cited section 3(d) as one of the reasons for putting and keeping India on this list.[39] For instance, the 2013 Special 301 Report states:

> India's prohibition on patents for certain chemical forms absent a showing of 'enhanced efficacy' may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations would include drugs with fewer side effects, decreased toxicity, or improved delivery systems. Moreover, … India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude the issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application.[40]

Similarly, Special 301 Report 2013 states: "The unpredictable application of Section 3(d) of the Patents Act led to additional rejections of patent applications for innovative pharmaceutical products".[41]

PhRMA considers section 3(d) an impermissible hurdle to patentability.[42] PhRMA repeatedly raised the concern that the patent environment in India is unpredictable because of procedural and substantive barriers that disproportionally affect foreign patent applicants.[43] PhRMA argues that the fourth substantive criterion of "enhanced efficacy" required under section 3(d), in addition to the TRIPS requirements of novelty, inventive step, and industrial application, is an impermissible hurdle.[44] PhRMA further argues that indiscriminate and routine use of section 3(d) poses an unnecessary burden on the innovators because the onus of proving enhanced efficacy is on the applicant.[45] PhRMA claims that additional substantive requirements for patentability are inconsistent with India's international obligations.[46] PhRMA further claims that section 3(d) is in conflict with the non-discrimination principles provided by TRIPS Art. 27 and WTO rules as it represents an additional hurdle for patents on inventions specifically relating to chemical compounds.[47] PhRMA contends that section 3(d) is

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[38] United States Trade Representative, Special 301 Reports (2010-2016), http://www.keionline.org/ustr/special301.
[39] Ibid.
[40] United States Trade Representative, Special 301 Report (2013), http://www.keionline.org/ustr/special301.
[41] Ibid.
[42] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2018), 84.
[43] Ibid., 85.
[44] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2014), 26. See more Cynthia M. Ho, "Should All Drugs Be Patentable?: A Comparative Perspective", *Vand. J. Ent. & Tech. L.* vol. 17 (2015) 295 <http://library1.nida.ac.th/termpaper6/sd/2554/19755.pdf>.340).
[45] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2018), 85.
[46] Ibid.
[47] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2014), 26.

objectionable from a policy perspective as it undermines incentives for biopharmaceutical innovations, for instance, innovations relating to the improved safety of a product, that do not relate to efficacy.[48]

In response to PhRMA criticism, it is argued that this provision does not represent an unauthorised fourth substantive criterion or fourth requirement because this provision has no universal application and applicability of this provision is "limited to one small question in one subject matter".[49] Evergreening of patents is a controversial issue not just in India but also in the US, where PhRMA is based. In the US, section 716.02 and section 2144.09 of the Manual of Patent Examination Procedure specifically memorialize "unexpected results" as a test to demonstrate non-obviousness of structurally similar compounds.[50] The requirement of "unexpected results" or "surprising effect" as a test to determine the patentability of the new forms of known substances has been reiterated by the Court of Appeals for the Federal Circuit.[51]

The TRIPS Agreement allows lawful pluralism among WTO Member States about standards of patentability as they are allowed, under Art. 7 and 8, to tailor their patent laws and their implementation to serve their domestic needs.[52] The TRIPS Agreement, in its Preamble, recognizes an "underlying public policy objective of national systems for the protection of intellectual property, including developmental and technological objectives".[53] According to Art. 7, the objective of the TRIPS Agreement to protect and enforce IP rights "should contribute … to a balance of rights and obligations" of Member States in a manner conducive to social and economic welfare.[54] The sovereign right of Member States to adopt public interest or public health measures, within the flexibility provided under TRIPS, has been recognized under Art. 8 of the TRIPS Agreement.[55] Art. 1(1) of the TRIPS Agreement further clarifies the right of Member States to pluralistically adopt minimum standards of IP protection.[56] India is therefore within its legitimate rights to deny patent protection to new forms or uses of existing and known molecules that do not show enhanced therapeutic effectiveness.[57] Legal compliance of section 3(d) has been evaluated in detail in the subsequent section.

### A. Constitutional Validity of Section 3(d)

Section 3(d) was highlighted as a controversial provision at global level after the Assistant Controller of Patents, as a result of pre-grant opposition, rejected Glivec patent application on

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[48] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2018), 85.
[49] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law* vol. 7 (2014-2015).
[50] Manual of Patent Examination Procedure, sections 716 and 2144 (8th edition, rev. 2012).
[51] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law* vol. 7 (2014-2015) 7.
[52] Ibid., 3.
[53] Annex IC to the General Agreement on Tariffs and Trade- Uruguay Round, World Trade Organization, 15 April 1994, 33 I.L.M 1981 (1994).
[54] TRIPS Agreement, Art. 7.
[55] Ibid., Art. 8.
[56] Ibid., Art. 1(1).
[57] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law* vol. 7 (2014-2015) 3.

8 March 2006 by invoking section 3(d) of the Patents Act.[58] Novartis, the patent applicant for Glivec moved the High Court of Judicature at Madras with two writ petitions.[59] In the first petition, Novartis challenged the decision of the Assistant Controller Chennai Patent Office rejecting Glivec patent application. In the second petition, Novartis requested the Court to declare section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act 2005 as unconstitutional and TRIPS non-compliant.[60] It was the first formal challenge to the legality of section 3(d).

In its petition filed in the High Court of Judicature at Madras, Novartis alleged the following:

(a) Section 3(d) was discriminatory against the drug industry (because explanation to s 3(d) specifically mentioned salts, esters, ethers, polymorphs, metabolites, and isomers). Section 3(d) was unconstitutional on the ground that it goes against the Right to Equality provided under Art. 14 of the Constitution of India[61] which reads as: 'The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India'.[62]
(b) Section 3(d) was arbitrary and vague because the condition of 'enhancement of known efficacy' for patent eligibility was a very 'ingenious concept' that defied logic. The phrase 'differ significantly in properties with regard to efficacy' lacked clear meaning. In the absence of guidelines to understand 'enhanced efficacy', the Controller was allowed under section 3(d) to apply her uncontrolled discretion. The Controller's 'arbitrary exercise of power' offended Art. 14 of the Constitution.[63]
(c) Section 3(d) was not in compliance with India's obligations as a signatory to the TRIPS because it was in violation of Art. 27(1) of the TRIPS Agreement.[64]

The Government of India contended that a common understanding of the terms existed both in the Indian Patent Office and in the industry and it was possible for experts in the field to scientifically establish sufficient improvement in efficacy.[65] The Controller of Patents was competent to judge patentability on grounds of efficacy because of her training and technical expertise.[66] The Indian Government further contended that if a patent application is wrongly rejected by the Controller "such a decision could always be corrected by the Appellate Authority and then by higher forums".[67]

On 6 August 2007, the Court held that section 3(d) was not in violation of Art. 14 of the Indian Constitution.[68] The Court ruled that section 3(d) did not discriminate against the drug industry. The differentiation made under this provision was justified keeping in view the specificity of salt forms in the drug industry. The difference in salt forms was not significant for other technology sectors like electronics or mechanicals because no issues arise in these sectors from different salt forms.[69]

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[58] Novartis v Cipla Ltd. (2005) 4.
[59] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[60] Ibid.
[61] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.)
[62] The Constitution of India, Art. 14.
[63] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.)
[64] Ibid.
[65] Ibid.
[66] Zoee Lynn Turrill, "Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard", *Georgetown Journal of International Law* vol. 44 (2012-2013) 1566.
[67] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[68] Ibid.
[69] Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge, 2010) 394.

As regards the Controller's use of uncontrolled discretion, the Court highlighted a "broad distinction between discretion which has to be exercised with regard to a fundamental right guaranteed by the Constitution and some other right which is given by [a] statute" and noted that patent rights, being statutory rights, belonged to the second category.[70] The Court ruled that a statute conferring such discretionary powers may be challenged successfully if the litigant is able to show that there is a "possibility of a real and substantial discrimination and [that] such exercise [of discretion] interferes with [a] fundamental right guaranteed by the Constitution".[71] Further, the Court stated: "We cannot presume that the authorities will administer the law "with an evil eye and an unequal hand" in order to invalidate the law.[72] Furthermore, the Court found that "legislative incompetence" and "violation of a fundamental constitutional right" were the only two grounds to challenge the validity of a law passed by the Parliament.[73] Novartis could not establish either of these two grounds to the satisfaction of the Court.

The Court responded to the concerns of the petitioner regarding the absence of guidelines or clear legal standards to understand "enhanced efficacy" by defining the term efficacy, using Dorland's Medical Dictionary, as "the ability of a drug to produce the desired therapeutic effect… therapeutic is healing of disease- having a good effect on the body".[74] The analysis of the Court suggested that the term "efficacy" in the section 3(d) must be construed as "therapeutic efficacy".[75]

The High Court took into consideration the intent of the legislature behind section 3(d). The Court concluded that the Parliament intended not to provide a fixed definition of what constitutes "enhanced efficacy" or "efficacy" itself because facts of each case are different and a fixed formula cannot be applied in all situations.[76] The Court found that a high degree of discretion for the Controller to deal with situations on a case-by-case basis was intended by the legislative body.[77] The Court appears to have concluded that the mere absence of guidelines or definitions in legislation does not make it arbitrary and it was appropriate to delegate the power of technical decision making to the Patent Office.[78] The Court concluded that section 3(d) accurately reflected the constitutionally sound and appropriate intent of the legislature to provide easy access to life-saving drugs by preventing the evergreening of patents.[79] As a welfare and a developing country, India was obligated under its Constitution to provide good health care to its citizens. Keeping in view the demographics of India, with its predominant population living below the poverty line, providing easy access to life-saving drugs by allowing generic competition was a justifiable approach of the Union of India.[80]

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[70] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[71] Ibid.
[72] Ibid.
[73] Ibid.
[74] Ibid.
[75] Susan Fyan, "Pharmaceutical Patent Protection and Section 3(d): A Comparative Look at India and the U.S", *Virginia Journal of Law and Technology* vol. 15 (2010)198 and 210.
[76] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[77] Ibid.
[78] Shamnad Basheer and Prashant Reddy T., "The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)" *SCRIPTED* vol. 5, No. 2 (2008) 241-242.
[79] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[80] Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge, 2010) 394.

## B. TRIPS Compliance of Section 3(d)

Novartis challenged the compatibility of section 3(d) with the TRIPS Agreement mainly on the basis of Art. 27 and 1(1) of the TRIPS Agreement. Under Art. 27(1), WTO Member States are obligated to provide patent protection "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".[81] Novartis alleged in its petition that the "enhanced efficacy" requirement under section 3(d) of the Patents Act was in violation of the TRIPS Agreement because it was designed to deprive innovators of patent protection guaranteed under Art. 27 of the TRIPS Agreement.[82]

In response to Novartis' petition, the Indian Government contended that the TRIPS Agreement offered wide latitude to the Member States to craft their national laws in compliance with the TRIPS Agreement.[83] The Indian Government further argued that as a welfare State, India had a constitutional commitment to provide good health care to its citizens and it had "every right to bring in any local law in discharging … obligations under TRIPS to suit to the needs and welfare of its citizens".[84] Furthermore, the Government of India contended that the Court lacked jurisdiction to adjudicate the issue of compatibility of national laws with international treaty obligations, especially when the purpose of the national law is to ensure the welfare of the Indian citizens.[85]

In response to assertion of the Indian Government, that the Court lacked jurisdiction to decide the matter, Novartis argued that even in the absence of jurisdiction to strike down the controversial domestic law, the Court was not barred from making a declaratory judgment to declare the controversial provision non-compliant with India's obligations under international treaty.[86] To support its assertion, Novartis cited a case from the United Kingdom, *Equal Opportunities Commission and Another v. Secretary of State for Employment*.[87] In this case, the House of Lords declared that a local British law was not in compliance with Britain's obligations under European Community Law.

The Madras High Court distinguished the facts of the English case cited by Novartis. The Court found that the European Community Law had been "domesticated as domestic law in England" under the European Communities Act and could be enforced directly by British courts.[88] In contrast, the TRIPS Agreement, in the instant case, was not "domesticated" in India.[89] The Court agreed with the Counsel for the Government that domestic courts lack jurisdiction to test the validity of domestic law when its compliance with international treaty obligations is challenged.[90] The Court cited a case from the United Kingdom to support its decision.[91] Further, the Court found that the nature of an international treaty was like a contract with government entities as parties to the contract.[92] In the instant case, the body of the international treaty (TRIPS) contained a comprehensive centralized dispute settlement

[81] TRIPS Agreement, Art. 27(1).
[82] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[83] Ibid.
[84] Ibid.
[85] Ibid.
[86] Ibid.
[87] Equal Opportunities Commission and Another v. Secretary of State for Employment (1995) 1 A.C. 6-7.
[88] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[89] Ibid.
[90] Ibid.
[91] Ellerman Lines, Ltd. v. Murray (1931) A.C. 126.
[92] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).

mechanism[93] and the Court should respect the choice of parties to the treaty.[94] The Dispute Settlement Body of the WTO was the most appropriate forum for resolving disputes related to enforcement of the TRIPS Agreement.[95]

As regards the argument of Novartis about the grant of declaratory relief, the Court reasoned that though it had broad discretionary powers, under art. 32 of the Constitution of India, to grant declaratory relief, it should not be granted if no useful purpose is served to the petitioner. The Court dismissed the petition under art. 226 of the Constitution of India and refused declaratory relief to Novartis because even if the controversial provision was declared as TRIPS non-compliant, the petitioner could not compel the Indian Parliament to repeal or amend the provision.[96]

The Madras High Court held that WTO Dispute Settlement Body (hereinafter the DSB) was the appropriate forum to raise the issue of TRIPS compliance of section 3(d). Let's assume that TRIPS compliance of section 3(d) is challenged before the WTO Dispute Settlement Body. Will section 3(d) pass the test of TRIPS Compliance?

Realistically, Novartis does not have *locus standi* to approach the DSB because only the WTO Member States can bring disputes to this forum. Art. 1(1) of the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereinafter the DSU) stipulates: "The rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations".[97] So far, no Member State challenged the validity of the controversial section 3(d) in the DSB of the WTO.[98] It looks unlikely that Switzerland, the home country of Novartis, will bring the case to the DSB. In the wake of the Madras High Court's judgment in the Novartis case, Doris Leuthard, the Federal Councillor for the Department of Economic Affairs of the Swiss Confederation categorically announced that "the Swiss Government never gets involved in any judicial pronouncements of other countries. We accept any case which is settled in India. It is normal litigation in which one party happens to be a company while the other is a country".[99]

If any Member State challenges the validity of section 3(d) of the Indian Patents Act at the DSB of the WTO, what can be the possible outcome? Will section 3(d) be able to pass the test of TRIPS compliance? Art. 3(2) of the DSU is relevant here according to which the dispute settlement system of the WTO "serves to preserve the rights and obligations of Members under the covered agreements, and to *clarify the existing provisions* of those agreements in accordance with *customary rules of interpretation* of public international law" (Emphasis added).[100]

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[93] TRIPS Agreement, Art. 64(1).
[94] Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.).
[95] Ibid.
[96] Ibid.
[97] Understanding on Rules and Procedures Governing the Settlement of Disputes, Art. 1(1).
[98] C. Scott Hemphill and Bhaven N. Sampat, "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals" *Journal of Health Economics*, vol.31, No. 2 (2012) 331. The Indian Commerce Minister, Kamal Nath, asserted that the Indian Patent Law was TRIPS compliant because ever since adoption of the amended law no member state had challenged its validity in the WTO. See http://www.business-standard.com/article/economy-policy/swiss-govt-not-to-take-novartis-case-to-wto-107080700041_1.html.
[99] "Swiss Govt. not to take Novartis Case to WTO", http://www.business-standard.com/article/economy-policy/swiss-govt-not-to-take-novartis-case-to-wto-107080700041_1.html.
[100] Understanding on Rules and Procedures Governing the Settlement of Disputes, Art. 3(2).

In order to determine what "rights and obligations of Members" have been breached, the DSB needs to "clarify the existing provisions". In the instant case, Art. 27(1) of the TRIPS Agreement is a related existing provision which stipulates that:

> [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (Footnote 5 reads as follows: For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively).[101]

The Vienna Convention on the Law of Treaties 1969 (hereinafter the VCLT) is relevant here because "customary rules of interpretation of public international law" have been codified in this treaty. Art. 31(1) of the VCLT stipulates: "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".[102] Art. 27(1) of the TRIPS Agreement, the relevant existing provision, in this case, can be clarified by the DSB of the WTO by interpreting it in the light of (i) ordinary meaning; (ii) context of the text; and (iii) object and purpose of this provision.

**1. Ordinary Meaning**

Key terms in art. 27.1 like "invention", "new", and "inventive step" are not defined in the TRIPS Agreement. Footnote 5 provided that "the term inventive step **may be** deemed by a Member to be synonymous with the term 'non-obvious' (Emphasis added)" as required under the US patent law. The language used in footnote 5 does not create a mandatory requirement for Member States to equate with the US criterion of "non-obviousness".[103] It is argued that this ambiguity is intentional in order to provide freedom or flexibility to the Member States to determine patent eligibility criteria. The term "inventive step", for instance, lacks a standard or uniform definition because the Member States defined this term differently to determine what should be patent-eligible keeping in view the individual situation of each country.[104] The ordinary meaning of the terms in art. 27(1) does not pose a serious challenge for TRIPS compliance of section 3(d) of the Indian Patents Act because it is itself vague and leaves room for a diversity of definitions of key terms.

**2. The Context of the Text**

The DSB of the WTO is directed, under art. 31(1) of the VCLT, to interpret the text of the provision in the light of its context or surrounding terms and headings. The surrounding terms and headings are of no considerable help in ascertaining the meaning of the term "inventive step". The surrounding term "new", however, goes in favour of section 3(d) because of the special focus of this provision on the "new" requirement.[105]

**3. Object and Purpose**

The DSB is directed, under art. 31(1) of the VCLT, to evaluate the terms in the light of the object and purpose of the TRIPS Agreement. The TRIPS Agreement, in its preamble,

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[101] TRIPS Agreement, Art. 27(1).
[102] Vienna Convention on the Law of Treaties 1969, Art. 31(1).
[103] Janice M. Mueller, "Taking TRIPS to India – Novartis, Patent Law, and Access to Medicines", *The New England Journal of Medicine*, vol. 356, No. 6 (2007) 543.
[104] Zoee Lynn Turrill, "Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard", *Georgetown Journal of International Law,* vol. 44 (2012-2013) 1581.
[105] Ibid., 1582.

recognizes "the underlying public policy objectives of national systems for the protection of IP, including developmental and technological objectives".[106] Article 7 of the TRIPS Agreement states the objectives of the treaty in the following words:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and **in a manner conducive to social and economic welfare**, and to a balance of rights and obligations (Emphasis added).[107]

In the case of India, the following two public policy objectives are considered of utmost importance: (a) constitutional commitment to provide good health care to citizens;[108] and (b) protection of robust generic industry in India.[109] These policy objectives are in line with the **social and economic welfare** objective of the TRIPS Agreement as enunciated in art. 7. India's use of TRIPS flexibility to make sure availability of generic drugs in order to meet its constitutional obligation of public health and to protect its huge generic drug industry can, therefore, be justified under art. 7 of the TRIPS Agreement. Interpretation of the art. 27(1) in the light of object and purpose of the TRIPS Agreement allows India to achieve its public policy objectives by requiring "enhanced efficacy" standard for patent eligibility under section 3(d) of the Indian Patents Act.[110]

If the validity of section 3(d) of the Indian Patents Act is challenged at the DSB of the WTO by any Member State, it looks unlikely that the provision will be held TRIPS non-compliant because TRIPS allows considerable discretion and flexibility to the Member States to design their patent laws according to their individual situations.[111] It was noted in the UNDP Guidelines for the examination of patent applications relating to pharmaceuticals that:

> An important flexibility allowed to WTO members is to determine what is meant by 'invention', a concept that is not defined in the TRIPS Agreement. In fact, there is significant diversity in national laws and practices around the notion of invention… WTO members may adopt different concepts of novelty (universal, local or a mix); inventive step or non-obviousness; and industrial applicability or utility. Noting prevents WTO members from applying rigorous patentability criteria to avoid low-quality patents.[112]

Art. 1(1) of the TRIPS Agreement reads: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and

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[106] TRIPS Agreement, Preamble.
[107] Ibid., Art. 7. See Johanna Sheehe, "Indian Patent Law: Walking the Line", Northwestern Journal of International Law and Business, vol. 29, No. 2 (2009) 592.
[108] Government of India is obligated to provide public health care under Art. 21 and 47 of the Constitution of India.
[109] India's generic industry is one of the largest industries in the country with an annual export of around US$ 10 billion. See Yousuf A. Vawda, "After the Novartis Judgment – 'Evergreening' will Never be the Same Again!", *Law, Democracy and Development*, vol. 18 (2014) 306.
[110] Zoee Lynn Turrill, "Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India's Section 3(d) Efficacy Standard", *Georgetown Journal of International Law vol. 44,* (2012-2013) 1584.
[111] Carlos M. Correa (ed.), *A Guide to Pharmaceutical Patents* (South Centre: 2012). This book shows the diversity of solutions or policy measures adopted by WTO Member States at the national level in exercise of their discretion under the TRIPS Agreement.
[112] Carlos M. Correa, *Guidelines for The Examination of Pharmaceutical Patents: Developing A Public Health Perspective* (United Nations Development Programme, 2007) 18.

practice".[113] Article 27(1), by leaving the key terms undefined, affords substantial leeway to the Member States in implementing the three patentability requirements.[114] In relation to this provision, the Max Planck Declaration on Patent Protection stated that:

> Article 27(1) of the TRIPS Agreement requires states to provide protection for any inventions that are not a *priori* excluded from patentability, provided that they are 'new, involve an inventive step and are capable of industrial application'. States enjoy considerable discretion in implementing these requirements.[115]

The Max Planck Declaration on Patent Protection further stated that "[i]n the absence of codified or customary international consensus, states have latitude in which to define these terms. These are not required to provide protection for subject matter that they classify as discoveries rather than inventions".[116] The TRIPS Agreement's objectives and principles, set forth in art. 7 and 8 respectively, and the subsequent Doha Declaration also lend support to India's interpretation. India, therefore, made appropriate use of the discretion or flexibility granted to the Member States under the TRIPS Agreement.

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[113] TRIPS Agreement, Art. 1(1).
[114] Amy Kapczynski, "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, vol. 97, No. 6 (2009)1596.
[115] Matthias Lamping et al., "Declaration on Patent Protection-Regulatory Sovereignty under TRIPS*", Max Planck Institute for Innovation and Competition Research Paper No. 14-19* (2014) 5.
[116] *Ibid*

## III. INVENTIVE STEP THRESHOLD

The inventive step threshold plays a crucial role in making sure that patent protection is granted to genuinely innovative inventions. The inventive step threshold is particularly important in the case of pharmaceutical patents because of the social costs of exclusive rights resulting from patent protection. To determine and establish the threshold for the inventive step or non-obviousness requirement is the undisputed sovereign right of the WTO Member States.[117] India utilized this flexibility to define the term "inventive step". India set 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 a person skilled in the art".[118] "Non-obviousness" is a standard requirement for inventive step but the additional requirements of "technical advance" and "economic significance" is unusual and unique to India and it raises the patentability standard in India.[119] These important terms, "technical advance" and "economic significance", are, however, not defined in the Indian patent laws or patent office guidelines.

The non-obviousness requirement in India is much more stringent as compared to the United States.[120] It is argued that as a result of unduly lowering the bar, especially for determining non-obviousness, with an aim to facilitate more patents, the US is currently facing the issues of strategic patenting.[121] Justice Breyer rightly noted in *Laboratory Corporation v. Metabolite* that it is important to avoid diminished incentives resulting from under protection, but it is equally important to avoid the dangers of overprotection or unjustified protection.[122] India is trying hard to avoid such issues that arise from unjustly rewarding very low levels of innovation, by including unique provisions, like section 2(ja), in its patent laws.

India raised the bar, under sections 3(d) and 2(ja), to narrow down the class of innovations in the pharmaceutical industry that may be patent-eligible in India. If India is refusing or invalidating patents of multinational companies by using lawful patentability standards and non-discriminatory processes as required by the TRIPS Agreement, it should not be considered as a sign of TRIPS non-compliance.[123] India's unique provisions, refusing to grant

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[117] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative" *The Indian Journal of Intellectual Property Law* vol. 7, (2014-2015) 3. See more Cynthia M. Ho, *Access to Medicine in The Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, 2011) 97.

[118] The Patents (Amendment) Act 2005, section 2(ja).

[119] Amy Kapczynski, "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, vol. 97, No. 6 (2009) 1593. See more Cynthia M. Ho, *Access to Medicine in The Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, 2011) 97.

[120] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law*, vol. 7 (2014-2015) 6.

[121] Ibid., 8.

[122] Laboratory Corporation of America Holdings v. Metabolite Laboratories. Inc., 548 US 124, 127, 126 S. Ct. 2921 (2006).

[123] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law* vol. 7 (2014-2015) 8.

exclusive rights for trivial or incremental changes, fall well within the ambit of the TRIPS Agreement.

India also used another TRIPS flexibility to complement its high threshold substantive standards. Patents issued in India do not enjoy the evidentiary presumption of validity. It has been stipulated in the Indian Patents Act that:

> The examination and investigations required under section 12 of this section shall **not be deemed in any way to warrant the validity of any patent**, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon (Emphasis added).[124]

The Supreme Court of India interpreted this provision to mean that "no patent which is granted in India enjoys presumptive validity owing to the mere factum of grant" and that "the validity of a patent must be established before the issue of infringement is considered by the Court".[125] In the Pegasys Case, the Intellectual Property Appellate Board (IPAB) noted that there was no presumption of validity of the granted patent in the Patents Act. The Board referred to section 13(4) of the Act and reasoned that: "Due to the purely non-adversarial nature of the grant of a patent where there is no pre-grant opposition, we cannot exclude the possibility of an unjustifiable invention getting a grant".[126]

India's approach is markedly different from other countries that consider granted patents to have a presumption of validity, requiring a heightened evidentiary standard to invalidate a patent once it is granted.[127] India has used this as yet another way to reinforce its heightened patentability criteria, even after the lapse of the opposition period. There is no issue of TRIPS compliance because TRIPS is completely silent about evidentiary presumptions related to the validity of issued patents.

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[124] The Patents Act 1970, section 13.4.

[125] Intex Techs. (India) Ltd. v Telefonaktiebolaget LM Ericsson, Case No. 76 of 2013. See J. Gregory Sidak, "FRAND in India: The Delhi High Court's Emerging Jurisprudence on Royalties for Standard-Essential Patents", *Journal of Intellectual Property Law & Practice*, vol. 10, No. 8 (2015) 613.

[126] Sankalp Rehabilitation Trust v F. Hoffmann La Roche AG & Others, IPAB, OA/8/2009/PT/CH & M.P.No.85 & 111/2012 In OA/8/2009/PT/CH, (2012) [9].

[127] Cynthia M. Ho., *Access to Medicine in The Global Economy: International Agreements on Patents and Related Rights,* (Oxford, Oxford University Press, 2011) (103).

## IV. COMPULSORY LICENSING

Compulsory licensing of drug patents is one of the legal mechanisms to introduce cheaper generic medicines by bypassing drug patents. Though the term "compulsory licensing" has not been used in the TRIPS Agreement, a set of conditions have been stipulated under art. 31 for grant of a non-voluntary license or "other use without authorization of the right holder".[128] Article 31 mentions some possible grounds for the grant of compulsory licensing but does not provide an exhaustive list of grounds. Paragraph 5(b) of the Doha Declaration confirmed that "[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted".[129] Paragraph 5(c) further clarifies that public health crisis related to HIV/AIDS, malaria, tuberculosis, and other epidemics can be a justifiable ground for the grant of compulsory licenses.[130]

India crafted the most sophisticated compulsory licensing provisions in conformity with the TRIPS Agreement and the Doha Declaration.[131] The Patents (Amendment) Act 2005 contained liberal[132] and world's most extensive and detailed compulsory licensing provisions.[133] India tailored its patent laws keeping in view its goal to "encourage the founding of local industries to break the chokehold of foreign chemical companies".[134] The 2005 Act contains a wider legislative framework for compulsory licensing with three very detailed provisions on compulsory licensing of patents.

First, section 84 of the Act provides for ordinary compulsory licensing provision. Second, section 92 of the Act provides for the special provision of compulsory licenses on notifications by Central Government in situations of "national emergency" or "extreme urgency" or "public non-commercial use". Third, section 92(A) of the Act incorporates the spirit of the WTO Council's Waiver Decision 2003[135] and provides for special fast-track compulsory licensing provisions to allow the Indian generic manufacturers to make legally valid copies of patented drugs for export to poorer countries with no drug manufacturing capacity of their own. India

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[128] TRIPS Agreement, art. 31.

[129] Doha Ministerial Declaration on TRIPS Agreement and Public Health, 20 November 2001, Para 5(b).

[130] Ibid., Para 5(c).

[131] Srividhya Ragavan et al., "Justifying India's Patent Position to the United States International Trade Commission and Office of United States Trade Representative", *The Indian Journal of Intellectual Property Law*, vol. 7 (2014-2015) 12.

[132] Dora Kripapuri, "Applying US Antitrust's "Rule of Reason" to TRIPS' Compulsory Licensing Provision", *New England Law Review* vol. 36, No. 3 (2002) 688.

[133] Janice M. Mueller, "Taking TRIPS to India – Novartis, Patent Law, and Access to Medicines", *The New England Journal of Medicine* vol. 356, No. 6 (2007) 541-543; Ellen 't Hoen and Tido von Schoen-Angerer, "A Patent Pool for Medicines: More Medicines", *The World Today*, vol. 65, No. 2 (2009) 30-31.

[134] Dora Kripapuri, "Applying US Antitrust's "Rule of Reason" to TRIPS' Compulsory Licensing Provision", *New England Law Review*, vol. 36, No. 3 (2002) 688.

[135] Least Developed Countries (LDCs), lacking drug manufacturing capacity, were seriously handicapped to use the original compulsory licensing safeguard provided under art. 31 of the TRIPS because the drugs manufactured under compulsory license were barred from being exported. This issue was raised by developing and least developed countries at the WTO in the wake of an outbreak of epidemics and pandemics like HIV/AIDS in Africa. WTO General Council's Waiver Decision 2003 waived the "domestic market" condition imposed by art. 31(f) of the TRIPS Agreement to address the problems of the developing countries and LDCs lacking drug manufacturing capacity.

provided both traditional grounds, like the failure of the patent owner to work the patented invention locally,[136] and some unusual grounds, like non-availability of the patented invention "at a reasonably affordable price".[137] There is also a fourth channel for compulsory licensing, provided under section 96 of the Act, in situations when efficient working of an invention is hindered because dependent patents block each other.[138]

India has provided an elaborate framework for different channels of compulsory licensing. India's expanded legislative scheme however lacks clarity on certain key issues. For instance, the Act does not provide any helpful guidance on what constitutes "a reasonable royalty". There are other ambiguous terms—like "national emergency", "extreme urgency" and "public non-commercial use"—that are not defined in the Act. These ambiguities "may be recipes for misunderstandings and disagreements in law, which can eventually explode into protracted court wrangles".[139] India needs to revisit and address these issues to make its regime less complex and more effective, taking into account the spirit of the Doha Declaration.

It is important to note that India's detailed compulsory licensing regime has been practically used only once so far to override a pharmaceutical patent. The Controller issued the first Indian compulsory license to Natco[140] in March 2012 for manufacture and sale of Bayer Corporation's patented anticancer drug "Sorafenib Tosylate".[141] India had to face objections from the US.[142] India was placed on the Priority Watch List by the USTR.[143] The USTR Special 301 Report 2012 stated: "The US would closely monitor developments concerning compulsory licensing of patents in India, following the broad interpretation of the law in a recent decision by the Controller General of Patents".[144] In 2013, India's Special 301 Watch List status was elevated by the USTR and in 2014, the USTR announced an out-of-cycle review of India's status.[145]

The Union for Affordable Cancer Treatment (UACT) wrote a letter to USTR, to justify India's need to grant further compulsory licenses for drugs like dasatinib, which stated that:

> The BMS price for dasatinib in India is 6,627 rupees for a daily dose of 100 mg. This is roughly $108 per day, for a country with a per capita income of just $1,570 per

[136] The Patents Act 1970, section 84(1)(c).
[137] Ibid., section 84(1)(b).
[138] 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", *The Journal of World Intellectual Property,* vol. 13, No. 3 (2010) 422.
[139] Ibid., 423.
[140] Natco proposed to sell a month's therapy of Sorafenib Tosylate for INR8800. The cost of patented drug was INR280,428 per month. See Beatrice Stirner, and Harry Thangaraj, "Learning from practice: Compulsory licensing cases and access to medicines", *Pharmaceutical Patent Analyst*, vol. 2, No. 2 (2013) 206.
[141] Natco Pharma Ltd. v. Bayer corporation, CLA, no 1, 2011 (9 March 2012).
[142] The US had serious reservations about India's compulsory licensing regime even before the TRIPS Agreement came into force. In May 1991, India faced the Special 301 investigation after being included in the Priority Foreign country list for its overly broad compulsory licensing provisions. See Aswathy Asok, "Compulsory licensing for public health and USA's Special 301 pressure: An Indian experience", *Journal of Intellectual Property Rights* vol. 24 (2019) 127.
[143] Joe C Mathew, "US to Keep an Eye on India's Compulsory Drug Licensing Move" (2012), https://www.business-standard.com/article/economy-policy/us-to-keep-an-eye-on-india-s-compulsory-drug-licensing-move-112050602001_1.html.
[144] Ibid.
[145] Shamnad Basheer, "The Dasatinib Dance Continues: Compulsorily Licensing and Public Non-Commercial Use", *SpicyIP* (November 11, 2014) https://spicyip.com/2014/11/the-dasatinib-dance-continues-compulsorily-licensing-and-public-non-commercial-use.html.

> year, and where most patients pay for cancer drugs out of pocket. Companies seeking a compulsory license have offered to supply generic versions of dasatinib for $4 per day, and that price would likely fall if competition was permitted.[146]

Pharmaceutical industry condemned the decision. Ranjit Shahani, Chief Executive Officer, Novartis India and President, Organization of Pharmaceutical Producers of India, noted that "the move will work to the detriment of patients through the negative impact they [compulsory licenses] will have on future investment in innovative pharmaceuticals".[147] The decision was condemned by Mr. John Castellani, President and CEO of PhRMA. He noted that "it was not an appropriate tool even if granting compulsory licenses might be a legal option. The responsibility to promote the development of new drugs lies with all countries, not solely those in the developed world".[148] PhRMA argued that governments should grant compulsory licenses, in accordance with international rules, only as a last resort in exceptional circumstances.[149] Later, in its 2015 Special 301 submission, PhRMA once again expressed its dissatisfaction with India's grant of a compulsory license in 2012.[150]

In this context, in 2016, the US-India Business Council publicly stated that the Government of India has privately reassured that "the country would not invoke compulsory licensing for commercial purposes that could allow local drug makers to make cheaper products by overriding patents of big global players".[151] The Government press office, however, rejected such reports and asserted that India retains its sovereign right to make use of public health safeguards provided under the TRIPS Agreement.[152]

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[146] Ibid.

[147] Ranjit Devraj, "India Affirms Role as Developing World's Pharmacy" (2012), http://www.ipsnews.net/2012/03/india-affirms-role-as-developing-worldrsquos-pharmacy/.

[148] "PhRMA Speaks out Against Compulsory Licensing in India" (2012), http://gabionline.net/Policies-Legislation/PhRMA-speaks-out-against-compulsory-licensing-in-India.

[149] Pharmaceutical Research and Manufacturers of America (PhRMA), Special 301 Submission (2018), 22.

[150] Aswathy Asok, "Compulsory licensing for public health and USA's Special 301 pressure: An Indian experience", *Journal of Intellectual Property Rights* vol. 24 (2019) 127.

[151] "India 'privately' against patent-overriding drug permits: USIBC" , *The Economic Times*, March 8, 2016 https://economictimes.indiatimes.com/news/economy/policy/india-privately-against-patent-overriding-drug-permits-usibc/articleshow/51315139.cms.

[152] "Clarification on Media Reports regarding Compulsory licence", Press Information Bureau, Government of India Ministry of Commerce & Industry, 22 March 2016. https://pib.gov.in/newsite/PrintRelease.aspx?relid=138271&utm_source=twitterfeed&utm_medium=twitter.

## V. CONCLUSION AND RECOMMENDATIONS

India, as a leading manufacturer of generic medicines, has a key role in affordable access to essential medicines and vaccines not only within its territory but also in many regions of the world. India took the lead role in enacting TRIPS public health flexibilities by introducing unique legislative measures to deal with the problem of access to medicines. The Indian Patents Act is unique in defining patentability criteria because of its heightened substantive threshold standards. Under section 3(d) of the Patents Act, India does not allow patent protection for derivatives of known substances unless they meet the condition of "enhanced efficacy". India also set a high threshold standard for "inventive step". "Non-obviousness" is a standard requirement for an inventive step but the requirements of "technical advance" and "economic significance" are peculiar modalities of implementing the inventive step standard in India. India, therefore, made good use of the policy space and raised the bar to narrow down the class of patentable innovations.

India's distinguished patent model included liberal and world's most extensive and detailed compulsory licensing provisions. The Patents (Amendment) Act 2005 provided a wider legislative framework for compulsory licensing with three very detailed provisions on compulsory licensing of patents.[153] With only a single instance of actually granting a compulsory license so far, India's detailed and sophisticatedly crafted compulsory licensing provisions remained seriously underused. India was pressured by the USTR which ignores the interests of resource-poor countries in saving human lives and supports the patentee corporations to maximize their profits. To gain more autonomy for the actual use of public health flexibilities, India needs to make concerted efforts in South-South collaboration.

The Indian Government showed responsibility and adopted a well-thought-out patent model. India's exemplary use of the policy space provided under the WTO regime offers a template or model solution to the other WTO Member States in achieving an appropriate balance between international commitments under the TRIPS Agreement and domestic public health needs. Such a balanced approach is critical in addressing the problems faced by financially challenged patients, especially in low- and middle-income countries, in accessing affordable medicines. This is particularly important in the context of the current COVID-19 health crisis. The global community is facing the very same public health issues which the Doha Declaration sought to address two decades ago.

[153] The Patents Act 1970, sections 84, 92 and 92(A).

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