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Balancing Acts: The Impact of Bilateral Investment Treaties on TRIPS Flexibility

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Abstract

Bilateral Investment Treaties are powerful tools to protect foreign investment from the arbitrary actions of the host states. However, the broad and unqualified clauses in Bilateral Investment Treaties have expanded their scope to challenge the states' regulations. Therefore, through the investor-state arbitration mechanism in Bilateral Investment Treaties, a legitimate regulation can be invalidated if it adversely affects the value of investment or expected future profit. Furthermore, in the absence of general or specific exceptions, limiting the broad scope of Bilateral Investment Treaties threatens the well-established Trade-Related Aspects of Intellectual Property Rights, flexibilities incorporated to safeguard developing countries' development concerns. In the evolving jurisprudence, Trade-Related Aspects of Intellectual Property Rights may constitute an act of indirect expropriation. Therefore, the stringent Intellectual Property protection in most modern Bilateral Investment Treaties may undermine Trade-Related Aspects of Intellectual Property Rights flexibility. In such a situation, a delicate balance needs to be struck between the rights of the states and investors to reduce Bilateral Investment Treaties' far-reaching implications on Trade-Related Aspects of Intellectual Property Rights flexibility to safeguard public health imperatives. This article analyzes the legal issues surrounding Intellectual Property protection under Bilateral Investment Treaties and its potential effects on the flexibility of Trade-Related Aspects of Intellectual Property

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Rights, suggesting mechanisms to ensure BITs do not undermine essential public health policies.

Keywords: Bilateral Investment Treaties, Expropriation, Intellectual Property, Investment, Investor-State Arbitration, TRIPS

I. Introduction

Bilateral Investment Treaties (BITs) are important tools for protecting private investment from discriminatory treatment by host states[2] through enforceable rights.[3] The fear that the host state's social, political, and economic uncertainty may backlash private investment necessitated the construction of a regime that protects the entity's valuable assets and profits.[4] However, the most contentious and controversial aspect of modern BITs is the investor-state arbitration dispute settlement mechanism,[5] through which an investor can directly challenge the state's regulatory measures, adversely affecting the value of the investment.[6] The peculiarity of investor-state arbitration is that it allows foreign investors to bypass the host state's domestic courts and bring claims directly to an international arbitral tribunal,[7] even if the host state's regulatory measures were pursued to safeguard legitimate public health[8] or other public policy issues.[9]

In the competition to attract foreign investment, developing countries accept onerous and strict restrictions on their power to exercise sovereign functions without being fully aware

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2 ShayerahIlias Akhtar & Martin A. Weiss, *U.S. International Investment Agreements: Issues for Congress* (Congressional Research Service 7-5700, 2013), https://fas.org/sgp/crs/row/R43052.pdf.

3 Kevin P. Gallagher & Elen Shrestha, *Investment Treaty Arbitration and Developing Countries: A Re-Appraisal* (Tufts University, Global Development and Environment Institute Working Paper No. 179093, 2011), http://ageconsearch.umn.edu/record/179093/files/11 ... ationReappraisal.pdf.

4 Wasseem Mina, *Political Risk Guarantees and Capital Flows: The Role of Bilateral Investment Treaties*, 9 ECONOMICS: THE OPEN-ACCESS, OPEN-ASSESSMENT E-JOURNAL (2015).

5 *The arbitration game*, THE ECONOMIST (October 11, 2014) https://www.economist.com/finance-and-economics/2014/10/11/the-arbitration-game.

6 Claire Provost & Matt Kennard, *The obscure legal system that lets corporations sue countries*, THE GUARDIAN (June 10, 2015) https://www.theguardian.com/business/2015/jun/10/obscure-legal-system-lets-corportations-sue-states-ttip-icsid.

7 *Michele Potestà*, *State-to-state dispute settlement pursuant to bilateral investment treaties: Is there potential?*, in INTERNATIONAL COURTS AND THE DEVELOPMENT OF INTERNATIONAL LAW: ESSAYS IN HONOUR OF TULLIO TREVES (Nerina Boschiero et al. eds., 2013).

8 *Trading IP through FTAs & BITs: Implications for access to medicines*, ACCESS (October, 2014) http://www.lawyerscollective.org/wp-content/uploads/2014/12/Access-News-Letter-IV-1-Trading-IP.pdf.

9 *The arbitration game, supra* note 4.

of their implications.[10] The uncritical adoption of the BITs is due to the perception that they are instruments that can bring a wide array of economic benefits, from technology transfers to the creation of employment for the host states.[11] However, there is no conclusive evidence that BITs alone attract Foreign Direct Investments (FDIs) to the host countries.[12] Instead, empirical studies have shown that the state's macroeconomic conditions and other governance factors are responsible for attracting FDIs.[13]

For instance, Brazil signed several BITs between 1994 and 2020 and 13 Cooperation and Facilitation Investment Agreements (which substantively deviate from traditional BITs) with investment provisions between 2015 and 2020 but has been broadly reluctant to ratify them.[14] Nevertheless, it received generous FDI[15] due to its liberal FDI regime and reasonably transparent and predictable governance.[16] Thus, International Investment Agreements (IIAs) or BITs do not significantly affect FDI inflows.[17] On the other hand, BITs result in a fall in FDI inflows in BRICS Brazil, Russia, India, China, South Africa) group.[18] Nevertheless, under the impression that BITs will increase economic activities, many developing countries are shoring up Intellectual Property (IP) protection under BITs, which could have a negative impact on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities that are designed to help them provide affordable innovation to their citizens.[19]

Ironically, when the TRIPS agreement was being negotiated, developing countries feared that a strong IP regime would restrict their ability to provide affordable essential life-saving

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[10] Eric Neumayer & Laura Spess, *Do bilateral investment treaties increase foreign direct to developing countries,* 33
WORLD DEVELOPMENT (2005) http://eprints.lse.ac.uk/627/1/World_Dev_(BITs).pdf.

[11] Deborah L. Swenson, *Why Do Developing Countries Sign Bits,* 2 U. C. DAVIS J. INT'L L. & POL'Y 1 (2005).

[12] *Neumayer, supra* note 9.

[13] Prabhash Ranjan, *Medical Patents and Expropriation in International Investment Law – with Special Reference to India,* 5 MANCHESTER J. INT'L ECON. L. (2008).

[14] Christian Bellak & Markus Leibrecht, *The (Political) Economics of Bilateral Investment Treaties—The Unique Trajectory of Brazil* 12(6) Economies (2024), 130.

[15] *See FDI in Figures – Latin America,* (OECD, 2019) https://www.oecd.org/investment/FDI-in-Figures-April-2019-Latin-America-English.pdf.

[16] Daniela Campello & Leany Lemos, *The non-ratification of bilateral investment treaties in Brazil: a story of conflict in a land of cooperation,* 22 REVIEW OF INTERNATIONAL POLITICAL ECONOMY (2015).

[17] Paulo Cavallo, *Brazil, BITs and FDI: A Synthetic Control Approach* 20(1) The Journal of World Investment & Trade, (2019), 68-97; Rodolphe Desbordes, *A Granular Approach to the Effects of Bilateral Investment Treaties and Regional Trade Investment Agreements on Foreign Direct Investment* (2016) https://aric.adb.org/pdf/events/aced2016/paper_rodolphedesbordes.pdf.

[18] Surabhi Gupta, et al, *Interlinkages between bilateral investment treaties and FDI flows to emerging economies: evidence from BRICS,* 21(4) Journal of Advances in Management Research (2024) 667-687.

[19] Jennifer L. Tobin & Susan Rose-Ackerman, *When BITs have some bite: The political-economic environment for bilateral investment treaties,* THE REVIEW OF INTERNATIONAL ORGANIZATIONS (2011).

medicines to cater to public health needs.[20] However, they do not seem apprehensive about the same concern while signing and ratifying BITs. Historically, the US started incorporating IP into BITs to further its economic interest. It also forced developing countries like South Korea and Brazil to negotiate the stringent IP standards in their BITs.[21] As a result, most BITs now explicitly recognize IP as a form of investment and accord stringent protection to foreign investment.[22] This transition has expanded the protection available to IP beyond the existing TRIPS standard, which may have a negative impact on TRIPS flexibilities available to developing countries.[23]

TRIPS is a multilateral agreement that sets minimum standards for IP protection. However, it also includes flexibilities that allow developing countries to derogate from its strict implementation.[24] On the other hand, BITs are a mechanism to protect foreign investment. However, they are curtailing the TRIPS flexibilities by allowing foreign investors to directly sue host countries for breaching their commitment.[25] Therefore, BITs not only restrict the state's regulatory power but also conflict with the objectives and norms stipulated in the TRIPS agreement.[26] Despite the potential conflict between BITs and TRIPS, not much adequate research has been done to find ways to harmonize them.[27] Often, the existing research focuses

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[20] Carlos M. Correa, *The Trips Agreement and Developing Countries*, in THE WORLD TRADE ORGANIZATION: LEGAL, ECONOMIC AND POLITICAL ANALYSIS, 1 (Patrick F. J. Macrory et al., eds., 2005).

[21] Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331 (2004).

[22] Deepak Raju & Ayesha Ali Khan, *Hurdles in Way of Compulsory Licensing by Developing Nations: Multilateral Murder or Bilateral Suicide?: An Empirical Analysis of Bilateral Investment Treaties of India, Bangladesh and Pakistan*, 2 NUJS L. Rev. 213 (2009).

[23] Carlos M. Correa, *Bilateral investment agreements: Agents of new global standards for the protection of intellectual property rights?*, GRAIN (August 3, 2004) https://www.grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights.

[24] Antonietta Di Blasé, *Intellectual property protection in investment agreements and public concerns*, in GENERAL INTERESTS OF HOST STATES IN INTERNATIONAL INVESTMENT LAW (Pia Acconci et al., eds., 2014).

[25] *Ranjan, supra* note 12, at 104.

[26] Reiko Aoki et. al, *Patent policy and public health in developing countries: lessons from Japan,*84 BULLETIN OF THE WORLD HEALTH ORGANIZATION (2006) https://www.who.int/bulletin/volumes/84/5/417.pdf.

[27] Crina Baltag, Riddhi Joshi & Kabir Duggal, *Recent Trends in Investment Arbitration on the Right to Regulate, Environment, Health and Corporate Social Responsibility: Too Much or Too Little?*, 38 (2) *ICSID Review - Foreign Investment Law Journal* (2023), 381–421; Jean Paul Roekaert, *Investment Treaty Arbitration and the Trips Patent Waiver: Indirect Expropriation Analysis of Covid-19 Vaccine Patents Expropriation Analysis of Covid-19 Vaccine Patents,* 46 HASTINGS INT'L & COMP. L. Rev. 59 (2023); Carlos M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement* in ACCESS TO MEDICINES AND VACCINES (Carlos M Correa & Reto M. Hilty, eds, Springer 2022);Christine Haight Farley, *Trips-Plus Trade and Investment Agreements: Why More May Be Less for Economic Development,* 35 U. Pa. J. Int'l L. 1062 (2014); Bertram Boie, *The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is there a TRIPS-plus Dimension?*, Working Paper No 2010/19, NCCR TRADE,

on investor-state arbitration under BITs and its impact on economic growth, while less attention has been paid to its potential implications for public health.

This article examines the BITs and their consequences on the TRIPS agreement. It also explores how the two regulatory frameworks can be balanced. Section II examines the various unqualified IP definitions in BITs and their repercussions on the TRIPS flexibilities. Section III focuses on the adverse effects of BITs on compulsory licensing and parallel import. Section IV analyses the recent developments in the Philips Morris and Eli Lilly cases to contextualize BITs and their relationship with the TRIPS agreement.

II. Broad Assets-Based Definition of IP

The term 'investment' is relatively new. The economic liberalization, particularly factors such as 'duration' and 'movement,' compelled states to use the more dynamic phrase 'investment' instead of 'foreign property.' In the context of BITs, rapid developments in technology and pharmaceuticals led to the crystallization of IP as a valuable asset, requiring maximum and effective protection in the form of investment.[28] However, its imprudent application resulted in the adoption of a broad and unqualified definition of BITs.[29] Generally, the definition of 'investment' in BITs determines the scope of investors' rights and obligations.[30] However, no standard definition exists as to what constitutes an investment as the object and purpose of investment differ from one BIT to the other.[31] Modern BITs ordinarily refer to the phrase 'every kind of assets' followed by the general statement[32] and then a non-exhaustive list of categories.[33] For example, the US-Model BITs (2012)[34] states that

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https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a
4ae491c6abb3/the_protection_of_iprs_through_bits.pdf;

[28] *Intellectual Property Provisions in International Investment Arrangements*, UNTCAD (IIA Monitor No. 1, 2007) https://unctad.org/en/pages/PublicationArchive.aspx?publicationid=2445.

[29] INTERNATIONAL INVESTMENT LAW: UNDERSTANDING CONCEPTS AND TRACKING INNOVATIONS 47 (2008).

[30] *Id.*

[31] *Id.* at 46.

[32] *Id.*at 49.

[33] Rudolf Dolzer & Christoph Schreuer, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW (2013). *See* Rachel Lavery, *Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment Treaties and Free Trade Agreements*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).

[34] *U.S. Model Bilateral Investment Treaty*, (2012) https://ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf.

‘investment means every asset that an investor owns or controls, directly or indirectly, that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. Forms that an investment may take include: (a) an enterprise; (b) shares, stock, and other forms of equity participation in an enterprise; (c) bonds, debentures, other debt instruments, and loans;(d) futures, options, and other derivatives; (e) turnkey, construction, management, production, concession, revenue-sharing, and other similar contracts; (f) intellectual property rights; (g) licenses, authorizations, permits, and similar rights conferred pursuant to domestic law and (h) other tangible or intangible, movable or immovable property, and related property rights, such as leases, mortgages, liens, and pledges.’

A cursory look at the US Model BIT’s asset-based definition reveals that the language adopted is quite broad and without any exception. The same broad assets-based definition is followed by many other countries, except for Canada, which combines a broad definition with a specific exception on the line of the North American Free Trade Agreement (NAFTA).[35]

The definition of “Investment” is a cornerstone of the investment treaty protection.[36] Therefore, a claimant enterprise must be qualified as an investment to succeed in substantive and procedural guarantees under bilateral agreements.[37] Thus, the definition of investment is a jurisdictional prerequisite for bringing a dispute before a treaty-based tribunal such as the International Centre for Settlement of Investment Disputes (ICSID).[38] Consequently, the definition of investment prescribes the limits of protection granted under the ICSID Convention and bilateral investment treaties. However, the ICSID Convention does not define what constitutes investment but only refers to it.[39]

Does the absence of a specific definition of investment in the ICSID mean Article 25 of the Convention does not limit what transactions are considered investments, or that certain

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[35] *INTERNATIONAL INVESTMENT LAW: UNDERSTANDING CONCEPTS AND TRACKING INNOVATIONS, supra* note 26, at 50.

[36] Mavluda Sattorova, *Defining Investment Under the ICSID Convention and BITs: Of Ordinary Meaning, Telos, and Beyond*, 2 Asian Journal of International Law (2012), 261

[37] *Id.*

[38] *Id.*

[39] Article 25(1) of the ICSID Convention provides that ‘the jurisdiction of the Centre shall extend to any legal dispute arising directly out of an investment, between a Contracting State (or any constituent subdivision or agency of a Contracting State designated to the Centre by that State) and a national of another Contracting State, which the parties to the dispute consent in writing to submit to the Centre.’

transactions do not qualify as investments because they lack characteristic features?[40] In Salini v. Morocco,[41] the ICSID tribunal held that to be considered an investment under Article 25(1), it must satisfy four criteria: (1) a contribution; (2) a certain duration; (3) a risk; and (4) a contribution to the economic development of the host State. Generally, ICSID tribunals apply the Salini test to determine what constitutes an investment under Article 25(1) of the ICSID Convention. However, some tribunals have adopted divergent approaches to what constitutes investment, as the Salini test converts descriptive characteristics of investments into rigid and legally binding requirements to establish jurisdiction.[42] Despite this, most BITs continue to incorporate an expansive asset-based definition of investments for dispute settlement.[43]

In the modern economy, IP is an important source of capital for entities and businesses. Therefore, the investment definition in BITs is much broader than that generally found in the domestic laws of host states.[44] The broad 'investment' definition in BITs acknowledges that IP is a valuable and critical asset for the economic growth of the states and investors.[45] As IP is an invaluable asset, BITs not only contain phrases such as 'intellectual property rights' but also consist of copyrights and patents.[46] For example, the BIT between Australia and Egypt (2001) states that 'Investment means every kind of asset, owned or controlled by investors of one Party and admitted by the other Party subject to its law and investment policies applicable from time to time and includes: (iv) intellectual property rights, including rights with respect to copyright, patents, trademarks, trade names, industrial designs, trade secrets, know-how and goodwill.' Such broad phraseology has enabled foreign investors to bring disputes against host states for the actions or omissions, either directly or indirectly, adversely affecting their investment.[47]

[40] Michael Waibel, *Subject Matter Jurisdiction: The Notion of Investment* 19 (2021) *ICSID Reports*, 25–82.
[41] Salini Costruttori SpA and Italstrade SpA v. Kingdom of Morocco, ICSID Case No. ARB/00/4, Decision on Jurisdiction (16 July 2001).
[42] Anhad Miglani, *Revisiting 'Investment' under Article 25 of the ICSID Convention,* Kluwer Arbitration Blog (June 2022) https://arbitrationblog.kluwerarbitration.com/2022/06/20/revisiting-investment-under-article-25-of-the-icsid-convention/#comments
[43] Wenhua Shan & Lu Wang, *The Concept of "Investment": Treaty Definitions and Arbitration Interpretations* in HANDBOOK OF INTERNATIONAL INVESTMENT LAW AND POLICY (Julien Chaisse et al., eds., 2021).
[44] Mahnaz Malik, *Recent Developments in the Definition of Investment in International Investment Agreements,* 2nd Annual Forum for Developing Country Investment Negotiators, held in Marrakech, Morocco, 2–4 November, International Institute for Sustainable Development (2008) https://www.iisd.org/pdf/2008/dci_recent_dev.pdf.
[45] WIPO, *Intellectual Property as a Business Asset,* https://www.wipo.int/sme/en/ip_business/ip_asset/business_assets.htm.
[46] *Lavery, supra* note 32.
[47] Gavin Pereira, *India's Obligations under Bilateral Investment Treaties (Part A): "Bilateral Inhibiting Treaty?" — Investigating the Challenges that Bilateral Investment Treaties pose to the Compulsory Licensing of Pervasive Technology Patent Pools*, Centre for Internet & Society (Aug. 2013) http://cis-

Moreover, the general reference to 'intellectual property rights' internalized that IP is a protected investment under BITs.[48]

Some BITs, such as Canada-Argentina BIT (1991), refer to the 'rights' over IP. It states that investment includes 'intellectual property rights, including rights with respect to copyrights, patents, trademarks as well as trade names, industrial designs, goodwill, trade secrets, and know-how.' The incorporation of 'rights' over different IP types in the BITs definition has enlarged and expanded its enforcement, which could become problematic for developing countries as governments would have less flexibility to regulate IP in the public interest.[49] Therefore, this broad and unqualified investment definition, covering enforcement to application beyond the TRIPS agreement, may make poor and developing countries vulnerable to expropriation claims.[50] The problem with the broad assets-based definition of 'investment' in BITs is that it covers every kind and phase of IP, from its enforcement to application that goes beyond the TRIPS agreement, which, in effect, attenuates its flexibilities.[51] For instance, the farmers' and breeders' rights have not been contemplated under the TRIPS.[52] However, some BITs protect these kinds of IP but, due to the potential expropriation claims, could limit the ability of developing countries to implement policies that support farmers and breeders.[53]

The broad and wide definition of 'investment' in BITs enables foreign investors to challenge almost any measure that dilutes the economic value as expropriation.[54] In addition, these broad assets-based definitions open up endless possibilities for foreign investors to use the general guarantees afforded to investors in the form of National Treatment (NT) and Most-Favored Nation (MFN) to challenge states.[55] In this context, it is desirable to find ways and devise

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india.org/a2k/blogs/bilateral-inhibiting-treaty-investigatingchallenges-that-bilateral-investment-treaties-pose-to-compulsory-licensing-of-pervasive-technology-patent-pools.

[48] Henning Grosse Ruse-Khan, *Protecting intellectual property rights under BITs, FTAs and TRIPS: Conflicting regimes or mutual coherence?*, in EVOLUTION IN INVESTMENT TREATY LAW AND ARBITRATION, 485 (Chester Brown & Kate Miles eds., 2011).

[49] *Correa*, *supra* note 20, at 8.

[50] *Correa*, *supra* note 19.

[51] *Id.*

[52] *The Agreement on Trade-Related Aspects of Intellectual Property Rights*, https://commerce.gov.in/writereaddata/trade/wtopdfs/TRIPS_matter_amended.pdf.

[53] *Correa*, *supra* note 19, at 338.

[54] *Raju*, *supra* note 21, at 224.

[55] *UNTCAD*, *supra* note 27, at 4.

approaches to shield the states' legitimate 'regulatory power' by narrowing the scope of IP in the definition of investment.[56]

One way to protect the state's regulatory power over IP is to limit its protection to the national laws of the contracting states, as done in the BIT between Benin and Ghana (2001). It provides that 'investments mean every kind of asset and in particular, though not exclusively, includes '(iv) intellectual property rights, goodwill, technical processes and know-how and all similar rights recognized by the national laws of both Contracting Parties…' Another approach is to protect specific IP types registered with national authorities, reducing the scope of protection conferred to it as done in the BIT between Benin and Ghana (2001).[57]

However, a better proposition is to completely immunize IP definition from MFN, NT, or indirect expropriation claims.[58] The most suitable example is provided in the BIT between the United States and Uruguay (2004), which articulates that 'Articles 3 and 4 do not apply to any measure covered by an exception to or derogation from, the obligations under Article 3 or 4 of the TRIPS Agreement, as specifically provided in those Articles and in Article 5 of the TRIPS Agreement.' These approaches can effectively restrict the ability of foreign investors to sue states for failing to protect their IP investment. However, they should be implemented at the time of negotiation of BITs. Once BITs come into force, their amendment is an arduous process that requires the consent of both states.[59]

Many BITs incorporate the phrase 'intangible property' in their definition of investment,[60] which comprises both granted rights and pending applications.[61] Some IPs, such as copyright and trade secrets, do not require any formal process for their registration. They get protection

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[56] *Id.*
[57] *Id.*
[58] Simon Lester, *Tobacco Etc. Carveout in the New Australia-Hong Kong Investment Agreement,* INTERNATIONAL ECONOMIC LAW AND POLICY BLOG (March 29, 2019) https://worldtradelaw.typepad.com/ielpblog/2019/03/tobacco-in-the-new-australia-hong-kong-investment-agreement.html.
[59] *See* Article 39, Vienna Convention on the Law of Treaties.
[60] The BIT between Mexico and Austria (1998) states that: (2) investment by an investor of a Contracting Party means every kind of asset in the territory of one Contracting Party, owned or controlled, directly or indirectly, by an investor of the other Contracting Party, including:(h) any other tangible or intangible, movable or immovable property, or any related property rights, such as leases, mortgages, liens, pledges or usufructs. *See Lavery*, *supra* note 32.
[61] *Correa*, *supra* note 19, at 340.

as soon as they come into existence.[62] However, other IPs, such as patents, trademarks, and designs, undergo a rigorous scrutiny process for registration and must be registered to be enforceable. However, the inclusion of pending IP rights in the definition of investment implies that even if an IP has not yet been registered, it can still be protected under a BIT.[63] Thus, any action that prevents a business from obtaining exclusivity over pending IP registration could be considered an infringement of BITs.[64] Similarly, if a patent is revoked or invalidated without conformity with national law or done through a change to the law, it could also be challenged as expropriation under a BIT.[65] The Eli Lilly[66] case is an example of that. Therefore, under BITs, unregistered intangible properties have economic value, thus are investments unless the definition of investment categorically excludes pending IP applications.

In essence, broad and unqualified IP definitions in BITs can give unfettered power to foreign investors to restrict the host state's ability to regulate IP.[67] It is irrelevant whether the state exercises that power to give effect to any legitimate public policy or whether such authorization is permissible under TRIPS.[68] Thus, the broad and unqualified IP definitions in BITs can negatively impact the TRIPS flexibilities, which are critical for protecting public health.[69]

III. Subtle or Profound Erosion of TRIPS Flexibilities?

The primary objective of the IP is to promote and disseminate technological innovation for socio-economic benefits[70] while incentivizing people for their efforts.[71] To achieve these goals, the TRIPS agreement introduced global minimum standards for protecting and enforcing nearly

[62] WIPO, *Understanding Copyright and Related Rights*, http://www.wipo.int/edocs/pubdocs/en/intproperty/909/wipo_pub_909.pdf. *See* WIPO, *How are Trade Secrets Protected?,* http://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm.
[63] *Correa*, *supra* note 19, at 340.
[64] *Id.*
[65] Marie Louise Seelig, *Can Patent Revocation or Invalidation Constitute a Form of Expropriation?,* 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).
[66] *Eli Lilly and Company v Government of Canada,* ICSID Case No. UNCT/14/2.
[67] *Id.* at 335.
[68] Lorenzo Cotula, *Do investment treaties unduly constrain regulatory space?*, QUESTIONS OF INTERNATIONAL LAW (November 24, 2014) http://www.qil-qdi.org/investment-treaties-unduly-constrain-regulatory-space/.
[69] *Ranjan, supra* note 12, at 73.
[70] Sisule Musungu, *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines,* Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH Studies, 2005) https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.
[71] Karin Timmermans & Togi Hutadjulu, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals Jakarta, 2-4 May 2000*, World Health Organization (2000) http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf.

all forms of IP, including patents.[72] During the TRIPS negotiations, developing countries raised concerns that the agreement would significantly impact public health. Consequently, to address these concerns, a compromise was reached in the form of various flexibility or exemptions from the TRIPS agreement. These flexibilities reflect a conciliatory approach of the member states to reconcile two conflicting positions, i.e., to maximizing IP protection (developed countries) and protecting public interests, especially public health (developing countries).[73] One such flexibility vital for public health is a compulsory license, provided under Article 31 of the TRIPS agreement.[74]

Nevertheless, Article 31 of TRIPS does not provide any specific grounds for issuing a compulsory license. Instead, it merely recognizes the inherent rights of the member states to grant a compulsory license without the consent of the right holder and lays down procedural safeguards.[75] In other words, Article 31 does not confer any right to the member states to grant compulsory licenses. It only provides that states may authorize the issuance of a compulsory license in specific situations.[76] In light of this, it is important to analyze whether foreign investors can bring investment-related disputes under BITs against host states if flexibilities, especially compulsory license, and parallel import, result in an economic loss to the investment.[77]

i. Compulsory License

The pharmaceutical industry relies heavily on patent protection,[78] which gives companies the exclusive rights to sell their products for a certain period as huge resources were invested in research and development, and patents are seen to incentivize such investment.[79] However, this exclusivity to pharmaceutical products and processes has raised fears among developing countries that it can lead to high medicine prices for medicines, making it difficult for people

[72] Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement,* 46 HOUS. L. REV., 979 (2009) https://houstonlawreview.org/article/4269-the-objectives-and-principles-of-the-trips-agreement.
[73] *Raju, supra* note 21, at 214.
[74] *See* Article 31: Other Use Without Authorization of the Right Holder.
[75] *Raju, supra* note 21, at 214.
[76] *Raju, supra* note 21, at 219.
[77] *Correa, supra* note 20, 1.
[78] *Timmermans, supra* note 70, 8.
[79] Bruce Lehman, *The Pharmaceutical Industry and the Patent System,* https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf.

to access essential medicines.[80] For example, product-process protection prevents a generic manufacturer from developing affordable medicines. In the absence of competition in the market, higher medicine prices would make essential drugs unaffordable to millions of people worldwide.[81] Therefore, in terms of accessibility and affordability, patented pharmaceutical products significantly affect public health.[82]

The TRIPS agreement contains flexibilities for member states to derogate from its strict implementation after fulfilling certain conditions.[83] Later on, to allay the fears of the developing countries over the TRIPS implications on public health, the WTO, in the Doha Declaration on Public Health,[84] reaffirmed various flexibilities institutionalized in the TRIPS agreement.[85] The Doha Declaration states that the TRIPS agreement can and should be interpreted in such a manner that the member state's right to protect public health and access to medicine can be maintained.[86] To reflect on the public health concerns, one of the flexibilities provided in the TRIPS agreement is 'Compulsory Licensing.'[87] However, this phrase has not been used in the TRIPS agreement but is employed in the Doha Declaration.[88]

As noted earlier, compulsory licensing allows states to authorize third parties to use IP without the permission of the rights holders.[89] However, a compulsory license is only an exception to the exclusive rights. The IP rights remain with the holder even in the event a compulsory license is issued to the third party.[90] It is widely accepted that certain measures may be tantamount to expropriation, even if the investment's ownership remains with the investors.[91] If investors believe the remuneration paid does not mitigate the economic loss suffered, they can directly bring disputes against the host state under a BIT.[92] In this context, BITs may severely

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80 Carlos Correa, *Integrating Public Health Concerns Into Patent Legislation In Developing Countries,* WTO (2000) http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf.
81 *Aoki, supra* note 25.
82 *Correa, supra* note 69.
83 *Blasé, supra* note 23,194.
84 *See* Declaration on the TRIPS agreement and public health, WTO (2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
85 *Timmermans, supra* note 70, 10.
86 *Ranjan, supra* note 12, at 78.
87 *See* Article 31: Other Use Without Authorization of the Right Holder.
88 *See* Declaration on the TRIPS agreement and public health, WTO (2001), https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
89 Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation,* 25 AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW 364 (2010).
90 *Correa, supra* note 19, 347.
91 *Ranjan, supra* note 12, at 102.
92 *Id.* at 85.

compromise compulsory license flexibility guaranteed under the TRIPS agreement.[93] Therefore, huge tension exists between the right of states to protect public health and the right of investors to be protected from expropriation.

In Middle East Cement Shipping v Egypt,[94] a tribunal held that the import prohibition of cement into Egyptian territory constitutes indirect expropriation. Interpreting the expression 'the effect of which is tantamount to expropriation' in the concerned BIT, the tribunal held that any deprivation of the use and benefit of an investment would amount to 'creeping' or 'indirect' expropriation, irrespective of nominal ownership over investment. Similarly, in the Starrett Housing Corporation v Islamic Republic of Iran,[95] a tribunal held that if a state's interference with property rights rendered them useless, then such interference is deemed to have expropriated the property, even if title to the property formally remains with the owner. Therefore, full or total deprivation of the use, enjoyment or sale of the properties may qualify as indirect expropriation. However, it gets complicated when the deprivation or interference is less than total.[96] In such a scenario, it is unclear whether partial deprivation of property for a temporary period is tantamount to expropriation. The approach adopted by some tribunals suggests that even lesser destruction of property can also constitute deprivation and, hence, expropriation.

In Metalclad v Mexico,[97] a tribunal found that the Mexican government's refusal to grant a permit for a hazardous waste landfill constituted expropriation under the NAFTA provisions. The tribunal held that expropriation not only includes the taking of property, such as outright seizure or formal or obligatory transfer of title in favor of the host state, but also comprises any covert or incidental interference with the use of property that deprives the owner in whole or in significant part, of the use or reasonably-to-be-expected economic benefit of property. Therefore, the grant of a compulsory license to the third party by the host state can instigate an investor to bring a compensation claim.[98] Accordingly, the issuance of a compulsory license

[93] *Id.*
[94] Middle East Cement Shipping v. Egypt ICSID Case No. ARB/99/6.
[95] Starrett Housing Corporation v. Islamic Republic of Islam (1983) 4 Iran–US Claims Trib Rep 122, 154.
[96] Santiago Montt, STATE LIABILITY IN INVESTMENT TREATY ARBITRATION: GLOBAL CONSTITUTIONAL AND ADMINISTRATIVE LAW IN THE BIT GENERATION (2012).
[97] Metalclad v. Mexico ICSID Case No. ARB(AF)/97/1.
[98] *Correa*, *supra* note 19, 348.

can amount to indirect expropriation if it erodes the economic benefits of the investment,[99] even though the ownership or exclusive rights remain with the investor.

In contrast, some tribunals held that expropriation could occur only in the event of substantial deprivation of investors' rights.[100] For example, in LG&E Energy Corp v Argentine Republic,[101] the tribunal held that the deprivation must be substantial to qualify for compensation, even if the expropriation reduces profit. Similarly, in Telenor Mobile Communications A.S. v The Republic of Hungary,[102] the tribunal held that 'the interference with the investor's rights must be such as substantially deprive the investor of the economic value, use, or enjoyment of its investment.' In such a situation, what constitutes substantial deprivation? Some tribunals have adopted a legal approach, focusing on the rights that have been interfered with.[103] Others have adopted an economic approach, focusing on the economic impact of the interference.[104]

Although the tribunals may use a legal or economic approach to examine deprivation, it is not clear what would be the threshold for substantial deprivation. Is it 50%, 70%, or more? How do we draw lines between mere interference and substantial deprivation?[105] Therefore, it is inconclusive as to what shrinking constitutes substantial deprivation.[106] However, the combination of legal and economic approaches was applied in the Plama Consortium Limited v Republic of Bulgaria case.[107] The tribunal held that the decisive elements in the evaluation of expropriation conduct should be the assessment of (i) substantially complete deprivation of the economic use and enjoyment of the rights to the investment or of identifiable, distinct parts thereof, i.e. approaching total impairment; (ii) the irreversibility and permanence of the contested measures, i.e. not ephemeral or temporary); and (iii) the extent of the loss of economic value experienced by the investor.

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[99] *Correa, supra* note 19, 348.
[100] Dolzer*, supra* note 32, 104.
[101] LG & E Energy Corp v. Argentine Republic ICSID Case No.ARB/02/1.
[102] Telenor Mobile Communications A.S. v. The Republic of Hungary ICSlD Case No.ARB/04/15.
[103] *See* Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania ICSID Case No. ARB/05/22; Pope & Talbot Inc. v The Government of Canada (2000)*;* CMS Gas Transmission Co. v Republic of Argentina ICSID Case No. ARB/01/8.
[104] Telenor Mobile Communications AS v. Republic of Hungary ICSID Case No. ARB/04/15; Técnicas Medioambientales Tecmed, S.A. v The United Mexican States ICSID Case No. ARB (AF)/00/2.
[105] *Montt, supra* note 95, 261-264.
[106] *Montt, supra* note 95, 261-264.
[107] Plama Consortium Limited v. Republic of Bulgaria ICSID Case No. ARB/03/24.

From the above discussion, tribunals can analyze whether issuing a compulsory license has lasting effects and substantially deprives investment when determining expropriation. However, merely having an adverse economic impact on the investment cannot be qualified as expropriation.[108] In the case of Sporrong and Lönnroth v Sweden,[109] the European Court of Human Rights (ECtHR) held that restricting the party from selling the property and undertaking renovation did not amount to expropriation. The ECtHR pointed out that although the right has lost some of its substance, the applicant continues to use and possess the property. Therefore, the effects of the measures did not deprive the applicant of the possession.

Evidently, the above approaches adopted by tribunals suggest that mere economic loss due to the issuance of a compulsory license may not amount to expropriation because it only targets the 'use' of the IP and does not deprive foreign investors of their ownership.[110] However, if the compulsory license severely impacts on the investor's ability to enjoy or use the IP-based investment, it may qualify as expropriation.[111] The cumulative effect term, scope, duration, and remuneration of the compulsory license determines whether an expropriation has taken place.[112] There is no straight-jacket formula to determine whether the issuance of a compulsory license is an expropriation. It must be decided on a case-to-case basis,[113] taking into account the specific facts of the case.[114]

On the other hand, one may argue that the issuance of a compulsory license, if done in accordance with the TRIPS framework, is an exercise of sovereign regulatory powers.[115] It cannot be challenged as a discriminatory measure, even if it substantially or significantly deprives the economic value of the investment. However, this approach is problematic. In the absence of any explicit exception to a compulsory license, it would be difficult to convince an arbitral tribunal to give effect to public interests or argue that states are exercising their sovereign power. The treaty language must support the 'sovereign authority' argument. Otherwise, it will fall short of normative value before a tribunal. Even if compatible with TRIPS obligations, the issuance of a compulsory license may still be tantamount to

[108] *Correa*, *supra* note 20, 348.
[109] Sporrong and Lönnroth v. Sweden IHRL 36 (ECHR 1982).
[110] *Gibson, supra* note 88, 365.
[111] *Gibson, supra* note 88, 384.
[112] *Gibson, supra* note 88, 384.
[113] *Correa*, *supra* note 20, 11.
[114] *Gibson, supra* note 88, 392.
[115] *Correa*, *supra* note 19, 349.

expropriation, as BITs and the World Trade Organization (WTO) are two different, distinct, and independent frameworks within international law. Additionally, under the guise of receiving FDI, states have ceded their sovereignty by undertaking BIT obligations. Therefore, states cannot claim unfettered regulatory power over foreign investors under the BIT framework.[116]

Nonetheless, the obligation on the host state to pay adequate remuneration in Article 31 of TRIPS, foreign investors may find it difficult to prove that the issuance of a compulsory license can amount to 'creeping' or 'indirect' expropriation unless it substantially reduces the economic value of their investment. Thus, the TRIPS remuneration mechanism in relation to compulsory licenses largely excludes the possibility of substantial deprivation.[117] Nonetheless, the possibility of it being challenged in the investor-state arbitration always looms large. In any case, whether a compulsory license is an indirect expropriation or not can only be determined on a case-to-case basis.[118] If a tribunal finds that the issuance of a compulsory license substantially deprives the investors of economic value or profit from the investment, in such a situation, the tribunal may favor foreign investors, and the host state may end up paying significant compensation.[119]

Most of India's BIT contains the phrase 'measures having effect equivalent to expropriation.' For example, clause 5(1) of the BIT between India and Germany (1995) states that

'Investments of investors of either Contracting Party shall not be expropriated, nationalised or subjected to measures having effect equivalent to nationalisation or expropriation in the territory of the other Contracting Party except in public interest, authorised by the laws of that Party, on a non-discriminatory basis and against compensation which shall be equivalent to the value of the expropriated or nationalized investment immediately before the date on which such expropriation or nationalization became publicly known. Such compensation shall be effectively realizable without undue delay and shall be freely convertible and transferable.

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[116] Carlos Correa, *Intellectual Property Rights as an Investment: Options for Developing Countries*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).
[117] *Ruse-Khan, supra* note 47, 10.
[118] Rosa Castro Bernieri, *Compulsory Licensing and Public Health: TRIPS-Plus Standards in Investment Agreements*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).
[119] Julian Davis Mortenson, *Intellectual Property as Transnational Investment: Some Preliminary Observations*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).

Interest shall be paid in a fair and equitable manner for the period between the date of expropriation or nationalization and the date of actual payment of compensation.'

India's BIT with Germany has used the phrase 'the effects of the measure' as a basis for expropriation, not the intention. Therefore, the above clause in the BIT between India and Germany suggest legitimate objectives behind issuing a compulsory license. However, the arbitral tribunals, irrespective of the intent behind the measure, may favor foreign investors if the economic loss is substantial. This is corroborated by the opinion in the Siemens v. Argentina case,[120] in which the tribunal held that the BIT refers to measures that have the effect of expropriation, not the intent of the state to expropriate. Although it is up to the foreign investors to resort to the extreme action of challenging the compulsory license issuance as expropriation, the broad phrase in the BIT between India and Germany has opened such possibilities.

In the context of compulsory license, the increasing significance of the IP, combined with the unqualified definition and in the absence of a general or specific exception, opens possibilities for expropriation.[121] If such a situation occurs, on merits, the tribunal may decide a case in favor of foreign investors, which can cause a long-term chilling effect on public health. Therefore, the threat of 'expropriation' looms over the issuance of a compulsory license.[122] In light of this, states should review their existing BITs to protect themselves from expropriation claims by foreign investors.

By providing express and specific exceptions to the compulsory license issuance, the India-Singapore Comprehensive Economic Cooperation Agreement, to some extent, resolves this perplexing issue.[123] It states that 'This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.'

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[120] Siemens v. Argentina ICSID CASE No.ARB/02/8.

[121] *Gibson, supra* note 88, 360.

[122] Bayer Corporation v. Union of India Special Leave to Appeal (C) NO(S). 30145/2014: The Supreme Court of India upholds the grant of compulsory license to NATCO for the anti-cancer drug – sorafenibtosylate which neither fulfills reasonable requirement nor sufficiently work in India.

[123] Similarly, the India–Colombian BIT (2009), the India–Japan FTA (2011), the India–Malaysia FTA (2011) and the India–ASEAN Agreement (2014), exempt the issuance of compulsory licenses from the scope of expropriation.

Significantly, this exception to the issuance of compulsory licenses in BIT diminishes the possibility of expropriation claims. Beyond compulsory licenses, it also covers creation, and revocation measures compatible with the TRIPS agreement.[124] This exception is an excellent example of maintaining a regulatory space to issue or exercise flexibility stipulated in the TRIPS agreement without worrying that states' actions may amount to expropriation.[125] Having said that such an exception only applies if it is explicitly included in all state's BITs. Otherwise, a foreign investor could invoke a broadly worded MFN clause to borrow a more beneficial provision from another BIT that does not provide an adequate exception to a compulsory license or other flexibilities.[126] In effect, the MFN clause can neutralize the exception to expropriation in the first BIT.[127] Therefore, states should ensure that an explicit exception should be present in all BITs. Otherwise, they are susceptible to investment-related claims for breaching BIT as their mandate goes beyond the IP standard outlined in the WTO. The above-discussed vulnerability of possible breach of the BIT standard in the case of issuance of a compulsory license has brought the competing legal regimes of international investment law and intellectual property law into stark focus.[128]

Although many tribunals have focused on the effects or substantial deprivation tests to determine expropriation, some have also developed two more tests - the police powers test and the proportionality test to determine expropriation. On the police power test, tribunals held that a State has an inherent right to safeguard the public interest if policies or measures have been enacted in a manner that is bona fide, non-discriminatory, proportionate, and in accordance with due process.[129] In WNC Factoring Limited v Czech Republic, the claimant alleged that freezing the company's accounts (later causing insolvency) indirectly expropriated its investment in a state-owned company.[130] However, the tribunal held that the Central Bank's

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[124] *Ranjan*, *supra* note 12, at 97.
[125] *Ranjan*, *supra* note 12, at 97.
[126] Foreign investors are often using the MFN clause to borrow beneficial provisions from other BITs. *See White Industries Australia Limited v. The Republic of India* (2010)
[127] *Correa*, *supra* note 20, 11.
[128] *Gibson, supra* note 88.
[129] Methanex Corporation v. United States of America, NAFTA-UNCITRAL, Award (3 August 2005): The tribunal held that: As a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process and, which affects, inter alios, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.
[130] WNC Factoring Ltd (WNC) v. The Czech Republic (PCA Case No. 2014-34), Award, 22 February 2017.

decision was a legitimate exercise of police powers to curb money laundering.[131] It concluded that the host State had exercised its powers in good faith, for a public purpose, and in a proportionate and non-discriminatory manner.[132]

On proportionality, some tribunals maintained that the police powers doctrine applies only to measures that have a proportionate impact on investors. In PL Holdings v Poland, the tribunal held that measures adopted by the banking regulator amounted to indirect expropriation.[133] It concluded that by prohibiting the investor from exercising shareholder-voting rights and disposing of their investment without restriction, the banking regulator has restricted the right of ownership of the investor.[134] Thus, the measures constitute an expropriation.[135] The tribunal noted that broadly, the principle of proportionality is similar across jurisdictions.[136] Therefore, any measure must be (a) suitable by nature for achieving a legitimate public purpose, (b) necessary for achieving that purpose in that no less burdensome measure would suffice and (c) not be excessive in that its advantages are outweighed by its disadvantages.[137] After applying these criteria, the tribunal held that the host State's measures were not suitable, necessary, or proportionate and, therefore, had a similar effect to an expropriation.[138]

Cumulatively, applying the police power and proportionality tests, even issuing a compulsory license, which results in a substantial deprivation of investment, may not be considered an expropriation. Therefore, tribunals must strive to use police power and proportionality tests instead of effect or substantial deprivation tests to shield the host state from issuing a compulsory license.

ii. Parallel Import

Parallel import is a principle based on the 'doctrine of exhaustion,' which states that once the authorized sale of the IP occurs, the owner or holder loses their exclusive rights.[139] It implies that when an authorized sale occurs, the IP holder cannot control its exploitation, use, resale,

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[131] *Id.*
[132] *Id.*
[133] PL Holdings S.a.r.l. v. Poland (SCC Case No. 2014/163), Partial Award, 28 June 2017.
[134] *Id.*
[135] *Id.*
[136] *PL Holdings, supra* note 132.
[137] *PL Holdings, supra* note 132.
[138] *PL Holdings, supra* note 132.
[139] Shamnad Basheer & Mrinalini Kochupillai, '*Exhausting' Patent Rights in India: Parallel Imports and TRIPS Compliance*, 13 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS (2008).

and re-distribution.[140] In other words, as soon as the rights holder licenses IP in the market, the right holder can no longer control its exploitation, use, resale, and re-distribution due to exhaustion of rights over it.[141] However, it must be lawfully acquired and permitted for sale. Otherwise, it will be considered an IP infringement.[142]

The natural corollary of exhaustion of IP rights is parallel import,[143] which allows the import of IP products from one market to another without the authorization of the rights holder.[144] In other words, parallel import refers to a form of trade where authorized IP products are produced, sold, and exported[145] subject to the laws preventing parallel import.[146] For instance, India follows international exhaustion, which means that if an authorized sale takes place in any part of the world, rights over that product are exhausted, and it can be legally imported without authorization.[147] However, other countries, such as the United States and China, do not recognize international exhaustion.[148] The European Union recognizes regional exhaustion in virtually all products but not international exhaustion.[149]

Article 6 of the TRIPS agreement recognizes that states are free to authorize parallel imports. It states that 'for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.' Apart from that, the TRIPS agreement gives deference to the member states to establish the exhaustion of rights.[150] It means that the states

[140] *Id.*at 486.
[141] *Correa*, *supra* note 20, 13.
[142] *Correa*, *supra* note 20, 13.
[143] *Basheer*, *supra* note 138, at 487.
[144] Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries,* World Intellectual Property Organization (2001) https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.
[145] Christopher Heath, *Parallel Imports and International Trade*, International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) Annual Meeting, World Intellectual Property Organization (1999) https://www.wipo.int/meetings/en/details.jsp?meeting_id=3794.
[146]*Maskus*, *supra* note 143, at 2.
[147] *Basheer*, *supra* note 138, at 488.
[148] *Basheer*, *supra* note 138, at 488.
[149] *Maskus*, *supra* note 143, at 2.
[150] Part B of the TRIPS Article 6 states that Interpretation and Application of Article 6With respect to the exhaustion of intellectual property rights, paragraph 5(d) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, reads as follows "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Article 3 and 4".

can choose to allow or forbid parallel imports.[151] To protect and safeguard research-intensive industries such as pharmaceuticals, developed countries advocate for strong IP protection and do not generally support international exhaustion or parallel imports. In contrast, developing countries, importers of IP, generally support international exhaustion and parallel importation because they help lower consumer prices and increase market competition.[152]

The above incompatible perspectives on parallel import have created disharmony in the global trading order. Therefore, foreign investors may challenge parallel imports on the grounds of loss of revenue and market share due to exhaustion of rights. In such a case, whether erosion in the economic value of IP due to parallel import can be challenged as expropriation.[153] To a great extent, this depends on what constitutes an investment. As discussed in reference to a compulsory license, if parallel import substantially diminishes foreign investors' investment's economic value or profits, the possibility of an expropriation claim cannot be ruled out. In such circumstances, whether the parallel import complies with the TRIPS Agreement is irrelevant.

To shield from expropriation claims arising from parallel imports, the states should carve out parallel import provisions from BITs on the lines of Japan-Vietnam BIT. Concerning IP protection, the Japan-Vietnam BIT explicitly states that its provisions should not be construed to derogate from the rights and obligations under multilateral agreements.[154] Alternatively, providing regulatory space for preventing parallel importation as contained in the US FTAs with Australia, Morocco, and Singapore could be explored. Otherwise, any substantial loss in the value of IP attributable to parallel import could be construed as expropriation.[155]

During TRIPS negotiations, developing countries protested against the rigid procedural formalities and obligations in the implementation of TRIPS flexibilities.[156] For example, they made reservations about the fulfillment of stringent procedural safeguards for the issuance of a compulsory license, which can unduly restrict their ability to give effect to public health

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[151] Lahra Liberti, *Intellectual Property Rights in International Investment Agreements: An Overview*, OECD Working Papers on International Investment 11 (2010).
[152] Christopher J. Clugston, *International Exhaustion, Parallel Imports, and the Conflict between the Patent and Copyright Laws of the United States*, 4 BEIJING LAW REVIEW (2013).
[153] *Correa*, *supra* note 20, 13.
[154] *Liberti, supra* note 150, at 8.
[155] *Liberti, supra* note 150, at 10.
[156] Thomas Cottier, *Working together towards TRIPS*, in THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS (Jayashree Watal & Antony Taubman eds., 2015).

goals.[157] However, taking into account the sheer number of BITs signed and ratified,[158] the developing countries that supported the broad TRIPS agreement willingly conceded sovereign regulatory powers to the BITs.[159] This concession of regulatory power to BITs endangered public health objectives. Thus, BIT commitments have diluted flexibilities under the TRIPS, and it would be difficult to implement TRIPS flexibilities without facing legal challenges from foreign investors.[160]

Nonetheless, the recent arbitration experience with BITs has prompted countries such as Bolivia, Brazil, Ecuador, India, South Africa, Pakistan, Venezuela, and Indonesia to review, terminate, or allow them to lapse without renewal.[161] Parallelly, other OECD countries-initiated re-drafting model BITs in a manner that included more safeguards for their regulatory autonomy. This suggests that countries are beginning to understand potential negative impact of BITs on the economy and other public policies.[162] Overall, the recent experience with unqualified BITs has shown that countries need to be careful about signing and ratifying BITs because the threat of arbitration is not artificial but real.[163]

IV. Philips Morris and Eli Lilly Cases: Is Regulatory Chill Dwindling?

IP is a driving engine of the modern economy that enables a knowledge-sharing system.[164] To 'enforce IP efficiently' and to mitigate 'differential treatment', foreign investors often protect their IP investment through BIT, which provides a legal framework that is independent of the national system of the host state.[165] However, the presence of IP as an investment in BITs has

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[157] Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AMERICAN UNIVERSITY INTERNATIONAL LAW REVIEW (2000).
[158] Jeswald W. Salacuse, *BIT by BIT: The Growth of Bilateral Investment Treaties and Their Impact on Foreign Investment in Developing Countries*, in GLOBALIZATION AND INTERNATIONAL INVESTMENT (Fiona Beveridge ed., 2005).
[159] *Raju*, *supra* note 21, at 214.
[160] *Ford, supra* note 156.
[161] Philip Nel, *The Rise and Fall of BITs*, https://www.otago.ac.nz/politics/otago061036.pdf.
[162] Prabhash Ranjan, *India and Bilateral Investment Treaties: A Changing Landscape,* 29 ICSID REVIEW: FOREIGN INVESTMENT LAW JOURNAL (2014).
[163] *Id.*
[164] Tobias Boyd, *Innovation and economic growth: the bottom line*, 6 WIPO MAGAZINE (2015), https://www.wipo.int/wipo_magazine/en/2015/06/article_0004.html.
[165] James M. Hosking & Markus Perkams, *The Protection of Intellectual Property Rights Through International Investment Agreements: Only a Romance or True Love?*2 TRANSNATIONAL DISPUTE MANAGEMENT 17 (2009).

generated a ‘regulatory chill’ for public health because they can erode the flexibilities built into the TRIPS agreement.

As discussed earlier, BIT frameworks can prevent countries from taking necessary steps to protect public health. For instance, the legal battle over graphic warnings on cigarette packets in Philip Morris v Uruguay[166] raised concerns for public health. In this case, Philip Morris invoked the BIT between Uruguay and Switzerland to challenge the ‘Framework Convention on Tobacco Control (FCTC)[167] complied plain packaging measure on the ground that such requirements diminish its trademark, thus in breach of the BIT obligation. The tribunal ruled in favor of Uruguay and stated that ‘the trademark holder does not enjoy an absolute right of use, free of regulation, but only an exclusive right to exclude third parties from the market so that only the trademark holder can use the trademark in commerce, subject to the state’s regulatory power.’[168] On the positive side, by giving policy deference, the arbitral tribunal has recognized the host states’ regulatory authority in relation to public health.[169] However, Philip Morris’s strategy was to delay, preempt, and weaken anti-smoking regulations,[170] the only binding multilateral convention on an aspect of public health.[171]

In the case of Eli Lilly and Company v The Government of Canada,[172] Eli Lilly – a pharmaceutical company, filed a claim against Canada under NAFTA, claiming compensation for the invalidation of patents by the Canadian court, showing that BITs can be used to challenge multilateral agreements. In this case, Eli Lilly argued that the invalidation of patents amounted to an expropriation of its investment by Canada in violation of NAFTA guarantees.[173] Owing to the lack of adequate evidence, although Eli Lilly lost the case, it has

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166 Philip Morris v. Oriental Republic of Uruguay ICSID Case No.ARB/10/7.

167 World Health Organisation Framework Convention on Tobacco Control (adopted 21 May 2003 and entered into force 27 February 2005)

168 *Philip Morris, supra* note 165, at 76.

169 Caroline E. Foster, *Respecting regulatory measures: Arbitral method and reasoning in the Philip Morris v Uruguay tobacco plain packaging case*, 26 RECIEL (2017).

170 Sergio Puig, *The Internationalization of Tobacco Tactics,* 28 DUKE JOURNAL OF COMPARATIVE & INTERNATIONAL LAW (2018).

171 Cecilia Olivet and Alberto Villareal, *Who really won the legal battle between Philip Morris and Uruguay?,* The Guardian (July 28, 2016) https://www.theguardian.com/global-development/2016/jul/28/who-really-won-legal-battle-philip-morris-uruguay-cigarette-adverts.

172 *Eli Lilly, supra* note 65.

173 Veronica Clamens, *Eli Lilly and Company v. The Government of Canada*, *Case No. UNCT/14/2*, Symposium on State-Owned Enterprises in China, 16 WORLD TRADE REVIEW (2017).

opened the possibility of foreign investors challenging IP under BITs, even if those are consistent with TRIPS, NAFTA, or other multilateral treaties or agreements.[174]

The impact of the Eli Lilly case would be that the BITs could be used to significantly impact the ability of developing countries to use TRIPS flexibilities.[175] The chilling effect generated by the case could be extended beyond the use of well-established TRIPS flexibilities to undermine legitimate regulatory law or policy that promotes access to medicines or public health.[176] In other words, the Eli Lilly case demonstrates that foreign investors can use BITs to claim compensation for regulatory changes, including its court's interpretation that affects the economic value of IP.[177] Although the Eli Lilly case was brought under NAFTA rather than a BIT, it has made states, especially developing countries, vulnerable to the potential claims of expropriation if they use, exploit, or implement TRIPS flexibilities or regulate IP law or policy in a manner that diminishes the value of IP investment. The foreign investors only have to produce cogent and credible evidence before the arbitral tribunal to win the case.

The Philip Morris and Eli Lilly cases have raised concerns in developing countries about the far-reaching impact of BITs on public policies. However, states should avoid the knee-jerk reaction against BITs, which would be detrimental to their reputation as favorable investment destinations. Though it might be debatable whether BITs bring FDI,[178] they give confidence to foreign investors that the host state is committed to protecting their investments and is a favorable place to conduct business. A better approach to restrict foreign investors from challenging the IP regulatory measure is to carve out critical policy areas from the purview of BITs[179] or introduce TRIPS or other treaty-based specific exceptions as found in the BIT between the US and Uruguay (2004).[180] Such exceptions not only safeguard public health-

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[174] Cynthia M. Ho, *TRIPS Flexibilities Under Threat From Investment Disputes: A Closer Look At Canada's "Win" Against Eli Lilly*, IP Watch (April 27, 2017) https://www.ip-watch.org/2017/04/27/trips-flexibilities-threat-investment-disputes-closer-look-canadas-win-eli-lilly/.

[175] Cynthia M. Ho, *Investor-State Arbitration: A New Threat to Global Access to Affordable Medicine*, (2018) https://ssrn.com/abstract=3143243.

[176] *Id.*

[177] Daniel J. Gervais & Jared Doster, *Investment Treaties and Intellectual Property: Eli Lilly v. Canada and Phillip Morris v Uruguay*, Vanderbilt Law Research Paper No. 18-38 (2018) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3188745.

[178]*See* Niti Bhasin & Rinku Manocha, *Do Bilateral Investment Treaties Promote FDI Inflows? Evidence from India*, 41 VIKALPA: THE JOURNAL FOR DECISION MAKERS (2016); Rashmi Banga, *Impact of government policies and investment agreements on FDI inflows*, WORKING PAPER NO. 116, Indian Council For Research On International Economic Relations (2003) http://www.icrier.org/pdf/WP116.PDF.

[179] *Puig, supra* note 169.

[180] Article 6(5) states that: This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or

related flexibilities but also emphasize that IP is protected and governed by TRIPS standards, not by BITs.[181] However, if the state's measure is not consistent with TRIPS, foreign investors may still challenge it on the grounds of non-compliance.

One of the dangers of the BITs is that they can create a two-parallel system for protecting IP.[182] The emergence of BITs has added a layer of protection to IP. However, this additional protection comes at a cost, as it can make it more difficult for states to implement public policies that may affect the value of IP investments.[183] As a result, foreign investors can challenge IP measures under the WTO dispute settlement system and investor arbitration in BIT. This raises the possibility that investor-state arbitration tribunals could act as supranational courts of appeal[184] that can review IP measures for TRIPS compatibility, which exclusively comes within the domain of the WTO dispute settlement system.[185] It is still ambiguous which system will prevail, but it would be challenging to harmonize such conflicting positions.

In terms of remedies available for expropriation, the WTO dispute settlement system requires an erring state to bring its measure, regulation, or policy in compliance with the WTO standards.[186] In contrast, BITs seek compensation for erosion in investment value or profit.[187] The fallout of these two systems is that the states may face a double whammy. If it violates its TRIPS obligation, the member states can initiate dispute resolution proceedings at the WTO's dispute settlement body. If the same breach also results in substantial economic loss to a foreign investor, it can launch investor-state arbitration for higher compensation. Since BIT falls outside of the WTO rules, it does not require expropriation claims to be settled by its dispute

creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement.

181 *Ruse-Khan, supra* note 47, 25.

182 One is BITs and other is TRIPS agreement.

183 *Raju, supra* note 21, at 215.

184 Asaf Niemoj, *Investment Arbitrations: Do Tribunals Take the Role of a Supra-National Appellate Court above National Courts?* Kluwer Arbitration Blog (July 27, 2018) http://arbitrationblog.kluwerarbitration.com/2018/07/27/investment-arbitrations-tribunals-take-role-supra-national-appellate-court-national-courts/; *See* Michael D. Goldhaber, *The Rise of Arbitral Power Over Domestic Courts*, 1 STANFORD JOURNAL OF COMPLEX LITIGATION (2013) https://law.stanford.edu/wp-content/uploads/2018/05/goldhaber.pdf.

185 *Ruse-Khan, supra* note 47, 25.

186 Article 19.1 of the DSU provides in relevant part that: Where a panel or the Appellate Body concludes that a measure is inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement.

187 *Gibson, supra* note 88, 417.

settlement mechanism.[188] Thus, foreign investors have multiple channels to pursue their claims and seek remedies against host states. For instance, if a state issues a compulsory license that substantially reduces investment, the foreign investor could concurrently initiate investor-state arbitration under the BIT and petition its own government to file a trade violation complaint against the host country in the WTO dispute settlement system.[189]

Having said that, foreign investors may prefer investor-state arbitration in BIT against the WTO dispute settlement primarily for two reasons: Firstly, the WTO system is designed to promote compliance with its rules instead of awarding compensation.[190] Therefore, in the WTO system, the possibility of getting monetary compensation is less in comparison to investor-state arbitration, which a foreign investor may not prefer. Secondly, states may be hesitant to initiate a trade violation complaint against host states in the WTO, especially if they are important allies or trading partners. Such actions can damage diplomatic and political relations. In such a situation, investors cannot solely rely on the home states to file a case against the erring host state in the WTO.[191] Instead, they may prefer to initiate investor-state arbitration proceedings directly in BIT. Additionally, one of the key differences between the WTO dispute settlement system and investor-state arbitration is that foreign investors have more control over the claims in investor-state arbitration. [192] As in the WTO system, individual investors cannot bring claims directly, foreign investors do not have control over claims, and may not receive compensation if the WTO awards a favorable ruling to their home state.[193]

To safeguard TRIPS flexibilities, states should carefully undertake the cost and benefit analysis of BITs before ratifying them to ensure protection from expropriation claims.[194] However, it should be done cautiously, as the primary objective of BITs is to promote and protect foreign investment. Accordingly, host states should not be rigid, excessively favoring their interest over foreign investors' profit-seeking goals, as such a scheme could discourage foreign investment.[195] Therefore, the challenge lies in constructing a BIT framework that is not too

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[188] *Liberti, supra* note 150.
[189] *Gibson, supra* note 88, 402.
[190] *Cynthia*, *supra* note 173, at 22.
[191] *Gibson, supra* note 88, 407.
[192] *Gibson, supra* note 88, 408.
[193] *Hosking, supra* note 164.
[194] Alan M. Anderson & Bobak Razavi, *International Standards for Protection of Intellectual Property Rights Post-TRIPS: The Search for Consistency*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).
[195] Peter B. Rutledge, TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration, 13 N.C. J. L. & TECH. ONLINE 149 (2012).

broad, restricting states from taking measures to affect public health and, at the same time does not give foreign investors too much leeway to bring expropriation claims against them.[196]

V. Conclusion

The present forms of BITs used by most states not only restrict their public policy space but also endanger carefully negotiated TRIPS and other multilateral flexibilities vital for public health. The broad and unqualified definition of IP as an investment in BITs gives foreign investors a platform to challenge the use of TRIPS flexibilities. Any dilution in IP investment that significantly deprives the foreign investors of its economic value or profits, irrespective of whether it is non-discriminatory or applied to achieve public health objectives, would be considered as expropriation.

Often, BITs contain provisions that expand the scope and obligations of IP. Therefore, even a legitimate exercise of TRIPS flexibilities adversely affecting an investment can be construed as expropriation and challenged in investor-state arbitration. The states cannot take the defense of the exercise of sovereign power to avoid paying compensation. To escape, they should limit the broad and unqualified investment definition as they give foreign investors ample scope to bring an action against states, even when the measures applied by them are TRIPS compliant or intended to give effect to public health.

To avoid unintended consequences impacting TRIPS flexibilities, states should carefully negotiate and draft BIT obligations by incorporating specific and explicit exceptions. Moreover, states should carve out separate exception clauses similar to the WTO system to maintain policy space. For instance, states could consider the Canada - US Model BIT approach, which provided that non-discriminatory measures taken to protect public welfare should not be considered as indirect expropriation. This approach helps maintain states' regulatory authority to pursue public policy objectives.

States have a fundamental duty to maintain the well-being of their people, and protecting public health is an intrinsic part of their sovereignty.[197] Therefore, in the cases of indirect expropriation, tribunals should carefully assess the nature of the interference, its negative

[196] *Id.* at 152.
[197] Valentina Sara Vadi, *Mapping Uncharted Waters: Intellectual Property Disputes With Public Health Elements in Investor-State Arbitration*, 2 TRANSNATIONAL DISPUTE MANAGEMENT (2009).

impact on public health or public policy, and the limitations prescribed within TRIPS or other multilateral treaty obligations before annulling measures taken by states to ensure that both frameworks BIT and TRIPS remain the instruments of welfare.