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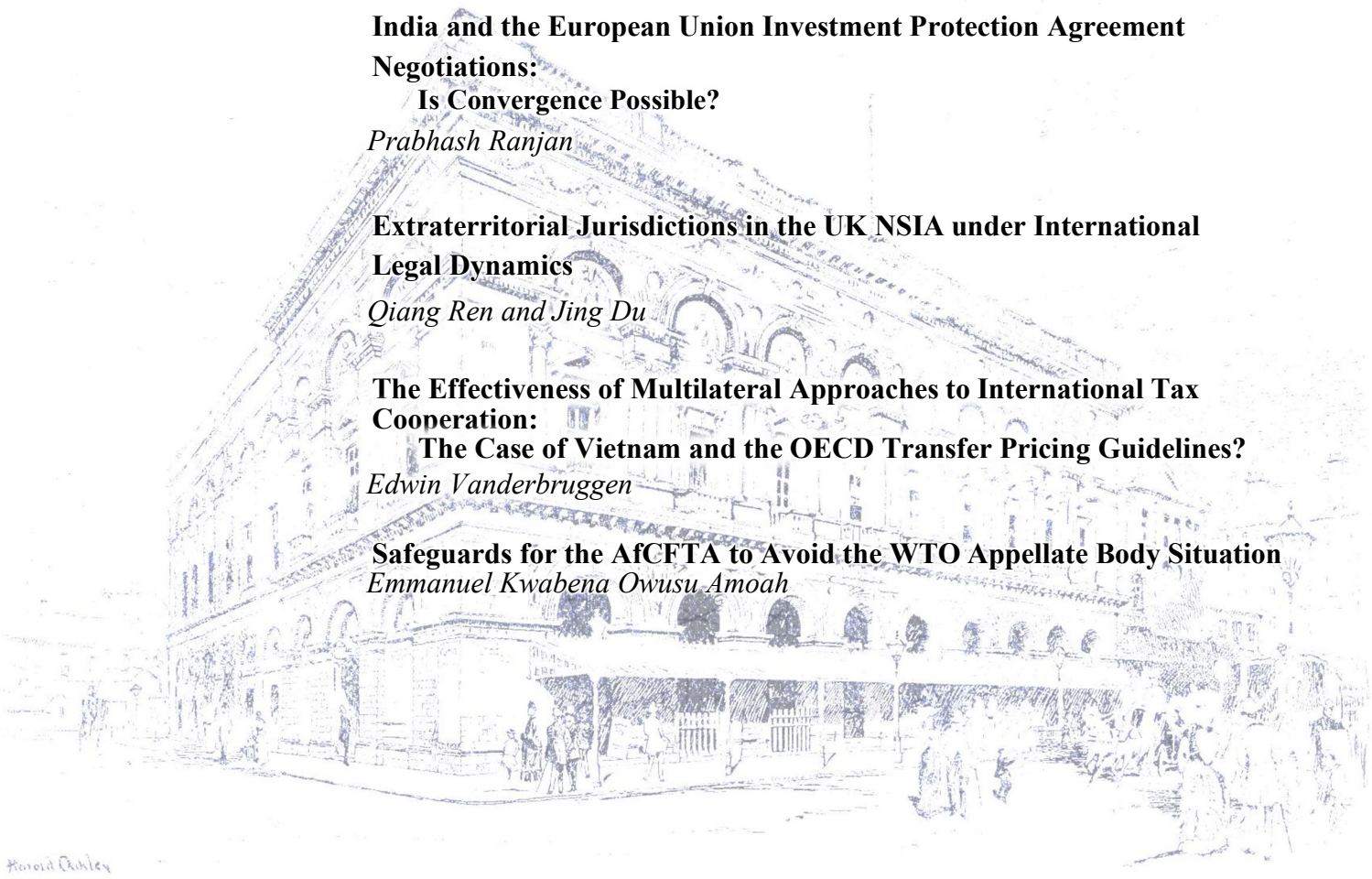

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– – Asif H Qureshi, Editorial, MJIEL, 2004, Volume 1, Issue 1

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The Curtailment of the TRIPS Agreement as an Option to Facilitate Access to Medicines

Laila Barqawi* and Mohammed El Said†

ABSTRACT: *The debate about the role of patent protection as a barrier to access to medicines has taken the frontlines in recent years.[1] Concurrently, calls for the possibility of terminating the TRIPS Agreement have gained momentum and are becoming an appealing prospect by many proponents in high- and middle-income countries. Such propositions are formulated in consideration of the constraints and the monopoly of rights and innovations that originator drug companies -mainly residing in high level income states- have illustrated so clearly during the Covid-19 Pandemic. The circumstances, therefore, that existed when negotiating TRIPS have shifted clearly from the circumstance and spirit of what TRIPS was initially set out to achieve.[2]*

The ongoing reviews of TRIPS which include the Doha Declaration,[3] amendments of Article 31 and more recently the Waiver on TRIPS provide strong evidence that the system is not functioning as originally envisaged. However, does this warrant the termination or rather the curtailment of TRIPS as a more realistic and practical solution? Curtailment, for the purpose of this paper, operates on two levels, at a national level whereby more patchwork legislation is needed to counteract the monopolistic impact of exclusive rights, and at an international level, where amendments to the TRIPS Agreement would trigger automatic mechanisms to limit the role of the patent system in certain circumstances under some specific conditions.

This paper advances the debate on these two levels, by proposing the urgent need to address the current global discrepancies and challenges surrounding medicines' affordability and availability. It contends that by addressing the current issues within the Agreement, the TRIPS Agreement and patent regimes could be preserved in the long run.

* Dr. Laila Barqawi, Al-Zaytoonah University of Jordan. E-mail: l.barqawi@zuj.edu.jo.
† Prof. Mohammed El Said, School of Law and Policing, UCLAN. E-mail: Mel-said@uclan.ac.uk.

[1] 'Opinion: Save America's Patent System' *New York Times* (16 April 2022), www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html (accessed 16 November 2023).

[2] Bryan Mercurio and Pratyush Nath Upreti, 'From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments', *World Trade Review*, 2022, 21(5), https://doi.org/10.1017/S147474562200012X (accessed 16 November 2023).

[3] See WTO, '*The Doha Implementation Decision Explained'*, www.wto.org/english/tratop_e/dda_e/implem_explained_e.htm (accessed 16 November 2023).

1. INTRODUCTION

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was established as part of the WTO's Uruguay Round of Trade Negotiations with the aim of establishing international minimum standards of protection for intellectual property rights.[4] TRIPS was significant because it imposed minimum standards of protection and extended patent protection to pharmaceutical products in a comprehensive manner.[5]

Whilst TRIPS was created with the assumption that patent protection would encourage innovation of medical products, access to these pharmaceutical products was restricted through increasing the cost of medicines as well as delaying entry of affordable generic medicines into the markets.[6] The effects of these restrictions were further realized more recently during the COVID-19 Pandemic, where TRIPS flexibilities such as compulsory licensing became even more difficult to utilize. As a result, access to medicines, vaccines and therapeutic treatments during this dire time became even more challenging.[7]

The need, therefore, to establish a more open approach towards access to medicines has never proven more necessary than today.[8] Equipped with the experience of how countries have reacted to the utilization of the TRIPS Agreement's flexibilities during the Pandemic as well as the TRIPS Waiver it is becoming an urgency to address middle- and low-income countries needs and priorities.

This paper is divided into three sections. The first section explains the issues that have arisen as result of TRIPS implementation, whilst the second section analyses the possibility of withdrawing/terminating, or curtailing TRIPS provisions which restrict access to medicines. Finally, this paper discusses the resulting technical considerations arising from the termination or curtailment of the patent provisions included within the TRIPS Agreement.

2. TRIPS AND ITS ISSUES

The TRIPS Agreement, as mentioned above, was the first international treaty which extended patent protection to pharmaceutical products and processes. However, since its inception TRIPS has faced

[4] *Agreement on Trade Related Aspects of Intellectual Property Rights* (adopted 15 April 1994, entered into force 1 January 1995); WTO, 'Intellectual Property: Protection and Enforcement' *WTO* (2019), www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (accessed 16 November 2023).

[5] Prior to the establishment of the TRIPS Agreement, there was a lack of uniform global standards for intellectual property protection where countries had more discretion in designing their national intellectual property laws. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 16 November 2023).

[6] Mohammed El Said, *Public Health-related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region* (World Health Organization Regional Office for the Eastern Mediterranean, ICTSD, 2010).

[7] Ghada Refaat El Said, 'How Did the COVID-19 Pandemic Affect Higher Education Learning Experience? An Empirical Investigation of Learners' Academic Performance at a University in a Developing Country', *Advances in Human-Computer Interaction*, 2021, https://doi.org/10.1155/2021/6649524 (accessed 16 November 2023); see also Laila Barqawi, 'Promoting Jordan's Use of Compulsory Licensing During the Pandemic', *South Centre Research Paper*, 15 September 2023, No. 184, www.southcentre.int/research-paper-184-15-september-2023/ (accessed 6 December 2024).

[8] Mohammed El Said, '*The Impact of "TRIPS-Plus" Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges*', in Carlos M. Correa & Reto M. Hilty (eds.), *Access to Medicines and Vaccines* (Springer, Cham, 2022), https://doi.org/10.1007/978-3-030-83114-1_11 (accessed 16 November 2023).

many criticisms, which grew over time, particularly following the Seattle Conference in 1999.[9] This event, criticized the WTO regime as a whole, and voiced developing countries' concerns that the TRIPS Agreement meant higher drug prices and restricted access to medicines in addition to various other issues with the global trading regime.[10]

The growing attacks against the TRIPS Agreement emanates from the foundations of the Agreement in assuming that intellectual property protection is solely essential for driving innovation.[11] Specific deficiencies, within the Agreement itself, such as those related to the shortcomings of compulsory licensing[12] mechanism and application to facilitate access to essential medicines and drugs also contributed to this sentiment. The rise of TRIPS-Plus rules, which have resulted in higher levels of monopoly rights and reduced levels of policy space and national discretion have also exacerbated these issues.[13] Criticisms and mounting pressure in effect led to the following important developments in the recent history of the TRIPS Agreement.

2.1. The Declaration on TRIPS and Public Health

The Declaration on the TRIPS Agreement and Public Health (hereinafter the Doha Declaration) was championed by India, the Africa Group as well as Brazil which took to the issue of essential medicines shortly after the TRIPS Agreement was first formed.[14] This resulted in the Doha Declaration which remains in force and is considered a cornerstone for clarifying essential articles in TRIPS such as those related to compulsory licensing.[15]

The Doha Declaration, however, was not the 'game changer' many hoped it would be. Although it emphasized the developing countries' right to use the TRIPS flexibilities in accordance with the objectives of the TRIPS Agreement, it came with nothing new in this regard as those were already embedded under the TRIPS Agreement anyway. Thus, it did not reach far enough in its goals and in addressing substantial TRIPS matters. It also failed to address the issue of local manufacturing

[9] Martin Khor, 'The Revolt of Developing Nations', *Third World Resurgence*, No. 112/113, Dec 99/Jan 00, https://twn.my/title/deb1-cn.htm (accessed 16 November 2023).
[10] WHO, 'WHO to Address Trade and Pharmaceuticals' *WHO* (22 May 1999); Frederick M. Abbott, 'TRIPS in Seattle: The Not-so-Surprising Failure and the Future of the TRIPS Agenda', *Berkeley Journal of International Law*, 2000, 18(1): 165, https://ssrn.com/abstract=1918351 (accessed 6 December 2024); see also Susan K. Sell , *Private Power, Public Law*, (Cambridge: Cambridge University Press, 2003), https://doi.org/10.1017/CBO9780511491665 (accessed 16 November 2023).
[11] Nils Thumm, 'Regulation of Patents and the Impact on Innovation', in Ruth Taplin (ed.), *Handbook of Innovation and Regulation* (2023), at 346; see also Thi Phuong Thao Nguyen, Feng Huang, and Xiaolan Tian, 'Intellectual Property Protection Need as a Driver for Open Innovation: Empirical Evidence from Vietnam', *Technovation*, 2023, 123: 102714, https://doi.org/10.1016/j.technovation.2022.102714 (accessed 16 November 2023).
[12] Lucy Davies, 'Compulsory Licensing: An Effective Tool for Securing Access to Covid-19 Vaccines for Developing States?', *Legal Studies*, 2023, 43(1): 86-103; Chia-Liang Liu, 'Beyond Compulsory Licensing: Pfizer Shares Its COVID-19 Medicines with the Patent Pool', *New York University Journal of Legislation & Public Policy*, 2023, 25(1): 1-30, www.nyujlpp.org/compulsory-licensing-2023/ (accessed 16 November 2023).
[13] See Mohammed El Said, 'From TRIPS-minus to TRIPS to TRIPS-plus: Implications of IPRs for the Arab World', *The Journal of World Intellectual Property*, 2005, 8(1): 53-65; see also Valbona Muzaka, 'The Pharmaceutical Patent System and Access to Medicines', in Carlos M. Correa & Reto M. Hilty (eds.), *Handbook on the Political Economy of Health Systems* (Edward Elgar Publishing, 2023), pp. 380-95.
[14] *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* (adopted 14 November 2001), WT/MIN(01)/DEC/W/2, www.wto.org/english/thewto_e/minist_e/min01_e/mind (accessed 6 December 2024).
[15] *Ibid.*, paragraph 5.b states that: 'each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licenses are granted'.

capacities arising from Article 31 with relation to developing countries and as such was perceived as lacking in many respects.[16]

2.2. The Dilemma of Article 31 *bis*

With the continuous calls to revisit Article 31, the TRIPS Agreement was amended in 2005.[17] The negotiations which resulted in the birth of Article 31bis in effect allow 'pharmaceutical products made under compulsory licenses to be exported to countries lacking production capacity'[18] and incorporates an appendix which deals, inter alia, with assessing lack of manufacturing capability in the importing country.[19]

However, Article 31bis was not far-reaching in achieving the desired outcome as evidenced by the lack of its application and utilization. Article 31bis has been rarely applied or invoked by member countries since its adoption. The limited use of Article 31bis suggests that its provisions have not been far-reaching as initially intended in addressing the challenges of access to essential medicines in developing countries.[20]

Further, the poor utilization of Article 31 bis raises further issues as to the effectiveness of the amendments proposed in resolving the challenge of access to medicine especially when there is no support by high income countries for importation in accordance with Article 31bis. For instance, if African and Latin American countries would request from India to produce drugs under compulsory licensing for exportation purposes, Indian manufacturers might be unable to supply the same products to high-income countries.[21] This could lead to reduced production efficiencies in Indian facilities that cater to a global market.[22] Consequently, fulfilling these compulsory license requests might decrease their cost-efficiency, potentially leading to higher prices for medicines worldwide.[23]

2.3. The TRIPS Waiver

The COVID-19 Pandemic was a watershed moment in recent time due to the impact it had globally. It highlighted the critical importance of ensuring widespread access to vaccines and therapeutics.[24] This in turn brought to the forefront the proposal for a Waiver of certain provisions of the TRIPS Agreement with relation to intellectual property rights for COVID-19-related medical products. This Waiver was

[16] Kevin Outterson, 'Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases', *American Journal of Law & Medicine*, 2008, 34(2): 279-81.
[17] *Amendment of the TRIPS Agreement*, WTO General Council Decision WT/L/641 (8 December 2005), www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 16 November 2023).
[18] *Ibid.* WTO, 'Members OK Amendment to Make Health Flexibility Permanent' *WTO* (6 December 2005).
[19] *Ibid.*
[20] Some even view this as a failure see Nicholas G. Vincent, 'Trip-ing Up: The Failure of TRIPS Article 31bis', *Gonzaga Journal of International Law*, 2020, 24(1): 1-30; Muhammad Z. Abbas, 'Inefficiency of the TRIPS Agreement's Article 31bis Mechanism: The Bolivia-Biolyse Case' *Creative Commons Global Summit* (2021), www.creativecommons.org/summit2021/presentation (accessed 16 November 2023); see also 'Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement' (7 April 2020), www.keionline.org/32707 (accessed 16 November 2023).
[21] Frederick M. Abbott and Jerome H. Reichman, 'Facilitating Access to Cross-border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic', *Journal of International Economic Law*, 2020, 23(3): 535-61.
[22] *Ibid.*
[23] *Ibid.*
[24] Olivier J. Wouters, Kenneth C. Shadlen, Michael Salcher-Konrad, Andrew J. Pollard, Heidi J. Larson, Yot Teerawattananon, and Mark Jit, 'Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment', *The Lancet*, 2021, 397(10278): 1023-34.

seen as a necessary measure to facilitate the rapid production and distribution of vaccines and treatments globally in a timely manner, especially in low- and middle-income countries where access was limited.

The TRIPS Waiver sought to relieve member states from the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19 lasting until widespread vaccination is emplaced.[25] This essentially allows countries to temporarily bypass certain intellectual property restrictions to ensure widespread access to vaccines and treatments during the health crisis.

The TRIPS Agreement's Wavier[26] is reminiscent of the Doha Declaration in many respects. Firstly, both were championed by India and South Africa which have been at the forefront of efforts to balance intellectual property rights with public health needs. Secondly, the core objective of both the TRIPS Waiver and the Doha Declaration is to improve access to essential medicines. The Doha Declaration affirmed the rights of WTO members to use the available flexibilities under the TRIPS Agreement, such as compulsory licensing, to protect public health and promote access to medicines for all.[27] Similarly, the TRIPS Waiver seeks to temporarily suspend certain intellectual property rights to expedite the production and distribution of COVID-19 vaccines and treatments.[28] Finally, the TRIPS wavier is reminiscent of the Doha Declaration because both had outcomes which were viewed by many as missed opportunities and criticized for not going far enough in achieving greater access to medicines.[29]

2.4. The TRIPS Flexibilities

The 'TRIPS Agreement's flexibilities' is a term coined in the events leading up to the Doha Declaration. This term has been widely spread to include the wide interpretation of intellectual property commitments in a manner which would cater for the special needs of low- and middle-income countries in accordance with the objectives clearly set out in the TRIPS Agreement's Preamble and Article 66.1.[30]

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[25] Carlos M. Correa, Nirmalya Syam and Daniel Uribe, 'Research Paper September 2021 Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements', *South Centre Research Paper*, No. 35, September 2021; WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19 (Revised Decision Text)' (25 May 2021), IP/C/W/669/Rev.1, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True (accessed 16 November 2023).

[26] Part II relates to Standards Concerning the Availability, Scope and Use of Intellectual Property Rights. Section 1 relates to copyright and related rights, section 4 relates to industrial designs, section 5 relates to patents, and section 7 relates to protection of undisclosed information. *TRIPS Agreement*; WTO, *ibid.*

[27] See *Doha Declaration*.

[28] See the TRIPS Waiver at the WTO, www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm (accessed 14 October 2024).

[29] Ranjan Prabhash and Priti Gour, 'The TRIPS Waiver Decision at the World Trade Organization: Too Little Too Late!', *Asian Journal of International Law*, 2023, 13(1): 10-21, https://doi.org/10.1017/S2044251322000571 (accessed 16 November 2023); Human Rights Watch, 'Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver' *hrw.org* (3 June 2021), www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver (accessed 16 November 2023); see also Médecins Sans Frontières (MSF), 'WTO COVID-19 TRIPS Waiver Proposal' (3 December 2020), https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf (accessed 16 November 2023).

[30] Article 66.1 of TRIPS states: 'In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5'; WIPO, 'Meaning of Flexibilities in the TRIPS Agreement', www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html (accessed 16 November 2023); see also CDIP/5/4 Rev. - Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels.

Further, and in conjunction to the TRIPS' Waiver discussions, advanced by low- and middle-income countries, higher income countries argued that the TRIPS Agreement's flexibilities should be the tool to redress any imbalance related to the accessibility of vaccines. They also contended that the notion of a Waiver was not necessary considering the exitance of the compulsory licensing mechanism under TRIPS.[31]

However, there have been many issues relating to the use of compulsory licensing as a flexibility. Such issues relate to the difficulty in applying it as well as the lengthy process involved in the manufacturing, exportation, and importation of medicines as per Article 31bis has highlighted.[32]

It is evident that there are issues with the application of many of the TRIPS Agreement's provisions today despite the that fact that more than two decades have passed since the TRIPS Agreement's inception as shown through the previous attempts led by India, South Africa, and other like-minded group of countries.[33] Further, despite all the solutions presented above, low- and middle-income countries are still being disadvantaged. In fact, access to medicines is no longer a challenge confined to those countries, but rather represents a global challenge facing all including high income countries as well.

3. TERMINATION VS. CURTAILMENT

3.1. Withdrawing and Terminating of the TRIPS Agreement

The notion of termination is fueled by a perceived failure of the TRIPS Agreement to achieve its objectives and to adequately address the needs sought after by low- and middle-income countries, as evidenced by past revisions of Article 31 and, notably, the Waiver on TRIPS during the Covid-19 Pandemic. This notion was more recently advanced by Anne Orford,[34] who stressed that the circumstances and the landscape which prevailed during the drafting of the TRIPS Agreement have drastically changed and that, essentially, the TRIPS Agreement is not delivering its aims and objectives of encouraging innovation.[35] To the contrary, others proclaim that patent protection is in fact discouraging innovation in the medical sector and is leading to the evergreening of monopolies. As such, the change to the material circumstances which TRIPS Agreement was born into demands a change to meet the current circumstances.

Further, TRIPS has consistently fallen short in facilitating access to essential medicines, especially for countries with limited resources and manufacturing capabilities. The COVID-19 Pandemic demonstrated this at the global scale. In addition, the subsequent revisions of the TRIPS Agreement have been insufficient to address the specific challenges faced by low- and middle-income

[31] Communication From the European Union to the Council for TRIPS, 'Urgent Trade Policy Responses to the Covid-19 Crisis: Intellectual Property' (4 June 2021), WTO document IP/C/W/681.
[32] *Supra* note 26.
[33] Frederick M. Abbott and Jerome H. Reichman, 'Facilitating Access to Cross-border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic', *Journal of International Economic Law*, 2020, 23(3): 535-61.
[34] Anne Orford, 'Annual Kirby Lecture on International Law' (30 June 2022), https://youtu.be/jQGQe5_-j1M (accessed 6 December 2024); see also Anne Orford, 'The 2022 Annual Kirby Lecture in International Law: Why It's Time to Terminate the TRIPS Agreement', *The Australian Yearbook of International Law Online*, 2023, 41(1): 3-30, https://doi.org/10.1163/26660229-04101012 (accessed 16 November 2023).
[35] *Ibid.*

countries, leading to the growing interest in exploring more drastic and radical measures such as the argument for withdrawal and/or termination of the Agreement.

Furthermore, the perceived shortcomings of the TRIPS Agreement in facilitating access to medicines and the ensuing debate around the Waiver during the Covid-19 Pandemic, prompted a departure from the usual TRIPS obligations framework. This culminated in a growing interest in exploring the restriction, withdrawal from, or even termination of the TRIPS Agreement. This reflects a wider discourse on the need for the remaking of a more balanced, flexible and equitable approach to patent protection, particularly in the context of global health crises.

Evidently and in broader terms, terminating the obligations under the TRIPS Agreement may be guided through Part V of the Vienna Convention on invalidity, termination and suspension of the operation of treaties applies. Article 54 of the Vienna Convention states: 'The termination of a treaty or the withdrawal of a party may take place: (a) in conformity with the provisions of the treaty; or (b) at any time by consent of all the parties after consultation with the other contracting States'. This means that, from a theoretical standpoint, the TRIPS Agreement can be terminated as set out in the Vienna Convention, however, how can this be translated into reality given that the focus of the debate is on patent protection, which is just one branch of IP covered by the Agreement?

The Marrakesh Agreement establishing the World Tarde Organization under Article XV provides guidance on the process by which a member state submits a written notice of withdrawal to the Director General of the WTO. Once six months have elapsed from the said notice, the member state would have been deemed as withdrawn from the WTO as well as all multilateral trade agreements.[36] Thus, withdrawal is possible whereby a member state submits a six months' notice[37] and withdrawal of the WTO would be triggered as a result since TRIPS is under the umbrella of the WTO and is in effect part of a broader package.[38]

However, because the TRIPS Agreement is an integral part of the WTO's single undertaking framework, i.e. when a country becomes a member of the WTO, it agrees to abide by all the organization's agreements, including the TRIPS Agreement (covering all branches of IP rights). These agreements are not standalone treaties but are part of the larger WTO 'single undertaking package' framework. Therefore, a country cannot selectively withdraw from individual agreements like the TRIPS Agreement without withdrawing from the WTO as a whole. This is because the agreements are interlinked, and the withdrawal from one could affect the balance of rights and obligations across the

[36] WTO, 'Marrakesh Agreement Article XV Entitled "Withdrawal"', www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art15_oth.pdf (accessed 16 November 2023).
[37] WTO, 'Article XXVII Entitled "Withholding or Withdrawal of Concessions"', www.wto.org/english/res_e/publications_e/ai17_e/gatt1994_art27_gatt47.pdf (accessed 6 December 2024); WTO, 'Concerns and Responses (1)', www.wto.org/english/thewto_e/minist_e/min99_e/english/book_e/stak_e_6.htm (accessed 16 November 2023); see also WTO, 'Seattle: What's at Stake? Concerns and Responses', www.wto.org/english/thewto_e/minist_e/min99_e/english/book_e/stak_e_6.htm#:~:text=Final%20rulings%20on%20disputes%2C%20if,even%20threatened%20to%20do%20so (accessed 6 December 2024).
[38] Article XV states:

> 1. Any Member may withdraw from this Agreement. Such withdrawal shall apply both to this Agreement and the Multilateral Trade Agreements and shall take effect upon the expiration of six months from the date on which written notice of withdrawal is received by the Director-General of the WTO.
>
> 2. Withdrawal from a Plurilateral Trade Agreement shall be governed by the provisions of that Agreement.

entire system. Notably, we are yet to encounter the situation whereby a country has withdrawn from the WTO, although calls for such a measure have been growing in recent years.[39]

3.2. Curtailing the TRIPS Agreement

Reverting to a status where TRIPS does not exist means that countries will be able to reverse engineer medicinal products and have greater access to medicines through manufacturing generics without any restraints.[40] Nevertheless, this approach would resurrect the challenges and factors that necessitated the establishment of TRIPS, such as safeguarding inventions and R&D, fostering innovation, and curbing anti-competitive practices. More important, this may not be consistent with the approach of some high-income countries that has an interest in protecting their globally leading exporting pharmaceutical companies. Unilteralsim and bilateralism will also take precedence as opposed to multilateralism in this regard.

From the perspective of low- and middle-income countries, curtailing the TRIPS Agreement is another approach which can be taken into consideration while considering the current challenges, as it allows for a more tailored response that can address access to medicine concerns without dealing with possible legal and economic ramifications as a result of withdrawing from the WTO. This approach maintains the balance between intellectual property protection and the need to facilitate access to essential medications and technologies in times of regional and global health emergencies and crises.

Curtailing TRIPS refers to imposing limitations or restrictions on the scope or application of certain articles within the TRIPS Agreement in a more systemic manner and with lower levels of formalities. The TRIPS Waiver that was agreed during the Pandemic has brought to light the possibility of restricting access to TRIPS and facilitated implementing Articles XI3 and 4 of the Marrakesh Agreement to increase access to medicines during times of urgency/emergencies.[41]

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[39] For example, see DNA India, 'Farmers' Protest: Why Are Farmers Demanding India's Withdrawal from WTO?' *DNA India* (13 February 2024), www.dnaindia.com/india/report-farmers-protest-why-are-farmers-demanding-india-s-withdrawal-from-wto-fta-msp-law-world-trade-org-3077878 (accessed 16 November 2023); see also IISD, 'Russia Plans to Exit World Trade Organization and Other Global Bodies' *International Institute for Sustainable Development* (6 June 2022), www.iisd.org/articles/news/russia-plans-exit-world-trade-organization (accessed 16 November 2023).

[40] Sonja Babovic and Kishor M. Wasan, 'Impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India as a Supplier of Generic Antiretrovirals', *Journal of Pharmaceutical Sciences*, 2010, 100(3): 816-17.

[41] WTO, Articles IX 3 and 4 state the following:

> 3. In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph.
>
> (a) A request for a waiver concerning this Agreement shall be submitted to the Ministerial Conference for consideration pursuant to the practice of decision-making by consensus. The Ministerial Conference shall establish a time-period, which shall not exceed 90 days, to consider the request. If consensus is not reached during the time-period, any decision to grant a waiver shall be taken by three fourths of the Members.
>
> (b) A request for a waiver concerning the Multilateral Trade Agreements in Annexes 1A or 1B or 1C and their annexes shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or the Council for TRIPS, respectively, for consideration during a time-period which shall not exceed 90 days. At the end of the time-period, the relevant Council shall submit a report to the Ministerial Conference.
>
> 4. A decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate. Any waiver granted for a period of more than one year shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the

There are no other specific provisions in TRIPS which refer to waiving obligations in relation to access to medicines. However, Article 73 of the TRIPS Agreement provides a security exception by which member countries could suspend their obligations under the TRIPS Agreement.[42] Despite this, the need to utilize such provisions should take place once certain conditions are met and without opening the door for frivolous objections which may defeat the desired purpose.

4. CONSIDERATIONS

4.1. The Reality of Terminating TRIPS

The TRIPS Agreement is an integral part of the WTO, therefore whilst it is in theory possible to withdraw from TRIPS as an agreement, an assessment on how this will be translated into action includes bigger considerations on the member state in terms of its trading relationships globally.

In addition to this, there are technical considerations related to access to medicines which may take place in instance of withdrawing/termination of the TRIPS agreement which includes:

4.1.1. Impact on access to medicine

There must be a distinction between the impact which withdrawing/terminating of the TRIPS Agreement will have on middle- and high-income countries.

High Income Countries

High income countries have utilized the TRIPS Agreement to sway their interest by initially resisting low- and middle-income countries' use of the TRIPS flexibilities such as compulsory licensing. However, at times of need, high income countries did not hesitate to apply the flexibilities to their interest such as in the case of US use of compulsory licenses and government use.[43]

Low- and Middle-Income Countries

Low- and middle-income countries have benefited the least from signing of the TRIPS Agreement with the increasing loss of access to medicines.[44] Prior to TRIPS, low- and middle-income countries had

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> waiver terminates. In each review, the Ministerial Conference shall examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. The Ministerial Conference, on the basis of the annual review, may extend, modify or terminate the waiver.

WTO, 'Article IX: Decision Making of the WTO Agreement', www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleIII (accessed 16 November 2023).

[42] Carlos M. Correa, 'Expanding the Production of COVID-19 Vaccines to Reach Developing Countries Lift the Barriers to Fight the Pandemic in the Global South' *South Centre* (April 2021), www.southcentre.int/covid-19-openletter/ (accessed 16 November 2023); see also South Centre, 'COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security' *South Center*, www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf (accessed 16 November 2023); Frederick Abbott, 'The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic' *South Center* (August 2020), available at www.southcentre.int/wpcontent/uploads/2020/08/RP-116-reduced_1.pdf (accessed 16 November 2023).

[43] Yusuf A. Vawda, 'Compulsory Licenses and Government Use: Challenges and Opportunities', in Carlos M. Correa & Reto M. Hilty (eds.), *Access to Medicines and Vaccines* (Springer, Cham, 2022), https://doi.org/10.1007/978-3-030-83114-1_3 (accessed 16 November 2023).

[44] Robert Sherwood, 'The TRIPS Agreement: Implications for Developing Countries', *The Intellectual Property Law Review* 1997, 37(4): 491-528, https://heinonline.org/HOL/LandingPage?handle=hein.journals/idea37&div=26&id=&page= (accessed 16 November 2023); Peter K Yu, 'TRIPS and Its Discontents', *Marquette Intellectual Property Law Review*, 2006, 10(3): 369-403, https://heinonline.org/HOL/LandingPage?handle=hein.journals/marq10&div=19&id=&page= (accessed 16 November

more 'wiggle room' in designing their national patent regime and in accessing generic medicines. With the advent of the TRIPS Agreement, this wiggle room diminished.

More recently, the use of TRIPS flexibilities has also been diminishing further as a result of the signing of Free Trade Agreements (FTAs). However, and within the current debate, what would be the fate of those FTAs in the case where a country that is both a member of an FTA and the WTO decides to withdraw from the WTO. These FTAs impose strong restrictions on access to medicines known as 'TRIPS-Plus standards'. It is said that the FTAs are signed because there are terms which the US could not include under the WTO's umbrella and therefore has implemented those through bilateral free trade agreements[45] while signing such FTAs in some instances has also been a pre-requisite to accession into the WTO.[46] One would wonder then if low and middle income countries now equipped with the knowledge of the harmful effects of FTAs, would sign similar agreements once TRIPS is curtailed. Notably, the US FTAs refer to the TRIPS Agreement either within the text of the Agreement[47] or within the FTA's side letters, which form an integral part of the FTAs[48] and in essence states that if TRIPS is amended then this gives the right to the US to amend the article concerning intellectual property and public health.[49] However, even if a country that is a party to an FTA withdraws from the WTO, that country will still be subject to TRIPS-Plus standards if it has such a commitment under the FTA.[50]

4.1.2. WTO's role in intellectual property

The WTO stands as the sole international entity governing the regulations of commerce and trade among countries. Central to its operations are the WTO's agreements. These agreements have been negotiated and endorsed by the majority of the world's trading nations and ratified within their legislative bodies. The primary aim is to facilitate trade in a way that is smooth, predictable, and unencumbered.[51]

The agreements that are included at the heart of the WTO are sixty agreements in total which include areas such as goods, services, intellectual property.[52]

2023); Ben Tenni, H. V. J. Moir, Ben Townsend, et al., 'What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review', *Global Health*, 2022, 18: 40, https://doi.org/10.1186/s12992-022-00826-4 (accessed 16 November 2023).

[45] Pedro Roffe & Christoph Spennemann, 'The Impact of FTAs on Public Health Policies and TRIPS Flexibilities', *International Journal of Intellectual Property Management*, 2006, 1(1/2): 75-79, https://doi.org/10.1504/IJIPM.2006.010780 (accessed 16 November 2023).

[46] See Mohammed El Said, *Public Health-Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region* (World Health Organization Regional Office for the Eastern Mediterranean, ICTSD, 2010).

[47] E.g., Articles 4, 20 and 21 of the Jordan-US FTA, Chapter 17 at Australia US-FTA, Chapter 17 of the Chile-US FTA, Chapter 16 of the Colombia US FTA.

[48] 'US-Bahrain Side Letter', https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file447_6296.pdf (accessed 16 November 2016); 'CAFTA-DR-US FTA (Dominican Republic-Central America FTA)', https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf (accessed 2 February 2024); 'Morocco-US FTA Side Letter', https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file258_3852.pdf (accessed 6 December 2024).

[49] *Ibid.*

[50] See Mohammed El-Said, 'From TRIPS-minus to TRIPS to TRIPS-plus: Implications of IPRs for the Arab World', *Journal of World Intellectual Property*, 2005, 8: 53.

[51] See WTO, 'The WTO', www.wto.org/english/thewto_e/thewto_e.htm#:~:text=What%20is%20the%20WTO%3F,-Who%20we%20are&text=The%20WTO%20has%20many%20roles,the%20needs%20of%20developing%20countries (accessed 6 December 2024).

[52] WTO, www.wto.org/english/thewto_e/whatis_e/tif_e/agrm1_e.htm (accessed 6 December 2024).

Acceding into the WTO means that each member had to be a signatory to TRIPS. Whereas, withdrawing from the WTO is unprecedented,[53] as no country has withdrawn from the WTO since its establishment in 1995. Withdrawal, in many instances, will require countries to resort to bilateral agreements to maintain trade relations and access to foreign markets. This would also have implications for the country's domestic industries as well as economy. This may lead to focusing on other outcomes, such as curtailing or suspending of the TRIPS Agreement's articles.

With the WTO's role also under scrutiny,[54] it is imperative that the WTO's role is re-defined in line with the termination of TRIPS. The WTO's role in dispute resolution should be preserved as terminating an agreement such as the TRIPS Agreement will result, in the absence of an alternate framework to litigate intellectual property rights disputes between countries.

Further, in the scenario where the WTO's role is redefined in connection with the termination of the TRIPS Agreement, the World Intellectual Property Organization's (WIPO) role could become even more critical. WIPO could potentially play a larger part in setting international intellectual property standards and providing a platform for dispute resolution, especially if an alternative framework to the TRIPS Agreement is not immediately established.[55] However, it is important to note that any changes to the global intellectual property framework would require significant international cooperation and negotiation.[56]

4.2. Curtailment

While this paper raised the issue related to the termination or withdrawal of the TRIPS Agreement, one important consideration to take note of is that not all low- and middle-income countries would find it in their interest to curtail the Agreement in its totality as they may want to retain some parts which they have no issues with (such as other intellectual property protection forms such as geographical indications, trademarks and industrial designs). This raises another difficulty related to the partial curtailment of the TRIPS Agreement (with a more focused targeting of the patents and trade secrets for instance).

Curtailing TRIPS in this paper essentially means amending TRIPS to allow for greater access to medicines without the need for a cumbersome procedure as that witnessed during the COVID-19 Pandemic's Waiver. This amendment may take place by granting a permanent waiver to allow greater access to medicines or the withdrawal of a sizable number of member states of the Agreement hence leading to its infectiveness. The authors contend that this is possible subject to the following considerations:

[53] This is despite the fact that the U.S. has threatened to withdraw from the WTO under the Trump administration. 'Trump Threatens to Pull US Out of World Trade Organization' *BBC* (31 August 2018), www.bbc.com/news/world-us-canada-45364150 (accessed 16 November 2023).
[54] Centre, South and Syam, Nirmalya, 'A Review of WTO Disputes on TRIPS: Implications for Use of Flexibilities for Public Health' *South Centre* (16 February 2022), https://ssrn.com/abstract=4082862 (accessed 16 November 2023).
[55] Rochelle Dreyfuss and Jerome Reichman, 'WIPO's Role in Procedural and Substantive Patent Law Harmonization', in Carlos M. Correa & Reto M. Hilty (eds.), *Research Handbook on the World Intellectual Property Organization* (Edward Elgar Publishing, 2020), pp. 108-30.
[56] See, for example, Gregory R. Schutt, '(Dis)Trust in the Process: US Foreign Policy as an Obstacle to an Efficient International Intellectual Property Regime', *Texas Intellectual Property Law Journal*, 2023, 32: 187-210.

4.2.1. Consensus

Any amendment under WTO's umbrella would require consensus among member states.[57] Resistance from high income countries and their pharmaceutical companies is inevitable, as evidenced through the TRIPS' waiver discussions.[58] However, signs of movement are emerging such as the US position in relation to the Waiver[59] and the EU's current reform concerning compulsory licensing.[60] These stances, by the US and EU, show that amending TRIPS may be a possibility if the right conditions are in place. Further, amending TRIPS, is possible and in fact has already taken place in 2018 demonstrating that it is a possible outcome especially with the continuous calls from important low and middle income countries such as India, Brazil and South Africa.

4.2.2. Compulsory licensing reform

Curtailing TRIPS will have to tackle all the failed attempts to address compulsory licensing and failed attempts to provide greater access to medicines. For instance, the EU has recently adopted a legislative framework aimed at enhancing access to affordable medicines, particularly in the context of public health emergencies.[61] However, some still suggest that those reforms do not reach far enough and that[62] the EU regulation only addresses emergency situations, when public health should have been prioritized in all situations.[63]

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[57] Article IX entitled 'Decision Making' of the WTO Agreement which states:

> 1. The WTO shall continue the practice of decision-making by consensus followed under GATT 1947(1). Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting. At meetings of the Ministerial Conference and the General Council, each Member of the WTO shall have one vote. Where the European Communities exercise their right to vote, they shall have a number of votes equal to the number of their member States(2) which are Members of the WTO. Decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast, unless otherwise provided in this Agreement or in the relevant Multilateral Trade Agreement(3);

and Article X of the WTO Agreement entitled 'Amendments'.

[58] WTO, 'Members Discuss Intellectual Property Response to the COVID-19 Pandemic' *WTO* (20 October 2020), www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm (accessed 16 November 2023); see also MSF, 'India and South Africa Proposal for WTO Waiver from Intellectual Property Protections for COVID-19-related Medical Technologies' (18 November 2020), https://msfaccess.org/sites/default/files/202011/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf (accessed 16 November 2023).

[59] See USTR Report 2021 which lacks criticism on countries utilizing compulsory licensing in comparison with USTR Report 2020, USTR, '2021 Special 301 Report: Review of Countries Utilizing Compulsory Licensing', https://ustr.gov/sites/default/files/2021%20Special%20301%20Report.pdf (accessed 16 November 2023); see also WTO, 'Compulsory Licensing Flexibility as Cited by Developing Countries', WTO document IP/C/W/672, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W672.pdf&Open=True (accessed 16 November 2023).

[60] The EU's current reform regarding compulsory licensing aims to bring in a mechanism to be used in a cross-border emergency or crisis within the EU which falls outside of the scope of national compulsory licensing schemes; for more see Silvia Gabriele, 'The European Commission's New Compulsory Licensing Proposal: A Step Forward?' *Health Law Policy* (2023), https://medicineslawandpolicy.org/2023/08/the-european-commissions-compulsory-licensing-proposals-are-sensible-but-do-not-go-far-enough/ (accessed 16 November 2023); see also Ellen't Hoen, 'The European Commission's Compulsory Licensing Proposals Are Sensible But Do Not Go Far Enough', *Medicines Law & Policy* (9 August 2023), https://medicineslawandpolicy.org/2023/08/the-european-commissions-compulsory-licensing-proposals-are-sensible-but-do-not-go-far-enough/ (accessed 16 November 2023).

[61] This has been achieved through launching a call which resulted in the adoption of the proposal 'Regulation of the European Parliament and of The Council On Compulsory Licensing For Crisis Management' and amending Regulation (EC) 816/2006; see also European Commission website for a chronology of the public consultation: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents_en (accessed 16 November 2023).

[62] *Supra* note 60.

[63] *Ibid.*

5. CONCLUSIONS

Whilst theoretically it is not impossible to withdraw or terminate the TRIPS Agreement, from a practical point of view this may not be easily achieved if the right conditions are not in place. This led some to suggest that 'it might be easier to begin the process of starving the TRIPS agreement of oxygen than terminating it'[64] while others are going as far as celebrating 'a new world – without patents'.[65] Various alternative strategies should be nurtured to achieve this objective.[66]

A more practical approach would be to consider curtailing TRIPS itself. This is possible, and has been achieved by the TRIPS waiver in activating Articles XI3 and 4 of the Marrakesh Agreement. A more concerted effort, therefore, should be made to facilitate access to medicines with the hope that another Pandemic won't be knocking at our doors soon.

[64] Siva Thambisetty, 'Termination of the TRIPS Agreement: Necessary and Impossible' *Opinio Juris* (11 January 2023), https://opiniojuris.org/2023/01/11/termination-of-the-trips-agreement-necessary-and-impossible/ (accessed 16 November 2023).
[65] See Calixto Salmao Filho, 'A New World – Without Patents' *South Centre* (12 July 2024), www.southcentre.int/southviews-268/ (accessed 16 November 2023).
[66] Mohammed K. El-Said, 'TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries' *American University International Law Review*, 2016, 31: 3, http://digitalcommons.wcl.american.edu/auilr/vol31/iss3/2 (accessed 16 November 2023), article 2.

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  WTO/GATT:
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