REGIONAL MECHANISM UNDER DOHA PARAGRAPH 6 SYSTEM—THE LARGELY UNTESTED ALTERNATIVE ROUTE FOR ACCESS TO PATENTED MEDICINES

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ABSTRACT

Contrary to the notion that the Doha Paragraph 6 system has failed in practice, this paper makes a strong case on why the largely undiscussed regional framework under the system has become relevant in light of the current trends in the pharmaceutical landscape. While the obvious failure of the Doha Paragraph 6 system is self-evident, having only been used by Rwanda and Canada in 2008, this paper argues that the regional mechanism option provided in the system offers a more sustainable pathway for low-income countries with limited market size and low purchasing power. While this paper substantiates the prospects of the regional coalition in South East Asia and Africa, it also questions Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS") Amendment's heavy reliance on developed countries to facilitate technology transfer and render technical and financial support under Articles 67 and 66.2. The paper analyses the shortcomings of the East African Community Regional Pharmaceutical Manufacturing Plan of Action

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(EACRPMPoA), which is the only ongoing regional alliance that explores the Doha Paragraph 6 system, to call for a more pragmatic option for exploring immediate alternative answers outside the promised obligations of developed countries under TRIPS Agreement. This paper concludes by forecasting the inevitability of a regional coalition but also recommends that regional solutions should be proffered to regional problems in the drive to deliver access to patented pharmaceuticals to the most vulnerable populations.

KEYWORDS: *access to essential medicines, regional mechanism, TRIPS amendment, pharmaceutical patent, Doha Paragraph 6 system*

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I. INTRODUCTION

The debates surrounding the far-reaching implication of patents on access to medicines have been going on for decades.[1] While the grant of patent right is needed to drive innovation in the society, it could also limit access to public goods by conferring monopoly rights to right holders.[2] Despite the significant scientific breakthroughs being recorded in the fields of medicine and pharmaceuticals, there remains a considerable disparity in the health status of developed and less-developed countries.[3] Millions of people still die daily, particularly in low-income countries, from diseases that could have been treated or prevented by effective medicines.[4] Older drugs are no longer effective due to human body resistance, while the high prices caused by patent monopolies continue to block access to newer and more effective medications.[5] Although there are several other factors responsible for the challenge of access to medicines, the Agreement on the Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS Agreement") has been purported to have exacerbated it.[6] Towards the end of the 20th century, the world trading system witnessed a significant evolution in the system's international standards on the protection of intellectual assets.[7] Significantly, the TRIPS Agreement provides that patent rights shall be granted to all forms of technology, including pharmaceuticals.[8] Although the TRIPS Agreement provides certain policy which allows the government in special circumstances to issue compulsory licenses to a third party without the patent holder's consent, compulsory licensing has arguably been proven to be ineffective in driving the kind of market competition needed to make drugs affordable.[9] Aside from the fact that most poor countries lack the capacity to locally manufacture, which reduces the potency of compulsory

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[1] *See generally* Eric W. Bond & Kamal Saggi, *Patent Protection in Developing Countries and Global Welfare : WTO Obligations Versus Flexibilities*, 122 J. INT'L. ECON. 103281 (2020).

[2] *See generally* Wenwei Guan, *IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment*, 29 LEIDEN J. INT'L. L. 411 (2016).

[3] *See* OLASUPO OWOEYE, INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN AFRICA 1 (2019).

[4] *See generally* Tim Eden et al., *Are Essential Medicines Available, Reliable and Affordable in Low-Middle Income Countries?*, 19 J. CANCER POL'Y 100180 (2019).

[5] *See generally* Esteban Burrone et al., *Patent Pooling to Increase Access to Essential Medicines*, 97(8) BULL. WORLD HEALTH ORG. 575 (2019).

[6] *See generally* Jae Sundaram, *Analysis of TRIPS Agreement and the Justification of International IP Rights Protection in the WTO's Multilateral Trading System, with Particular Reference to Pharmaceutical Patents*, 24(2) INFO. COMM. TECH. L. 121 (2015).

[7] CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS 1 (Bryan Mercurio & Daria Kim eds., 2017).

[8] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[9] Olasupo Owoeye, *Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa*, 92 BULL. WORLD HEALTH ORG. 214, 215 (2014).

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licensing, they lack viable markets that could attract and justify the investment of foreign pharmaceutical companies.[10]

In the wake of the 21st century, the TRIPS Agreement had become the most controversial multilateral agreement of the World Trade Organization (hereinafter "WTO"). [11] The failure of the Agreement to meet the developmental needs of developing countries made it come under severe crises on the agreement's legitimacy. Controversies surrounding the agreement formed the front burner of discussions at the Fourth WTO Ministerial Conference held in Doha, Qatar from 9 to 14 November 2001.[12]

The resultant effect of the Doha round was the culmination of the Doha Declaration on the TRIPS Agreement and Public Health.[13] The Declaration recognizes the gravity of the public health problems afflicting less-developed countries. It stresses the fact that TRIPS Agreement should not stand as an impediment to exploring measures for tackling public health challenges.[14]

However, the 6th paragraph of the Declaration directed the TRIPS Council to find a solution to the difficulty faced by countries with little or no manufacturing capacity in effectively using compulsory licensing. After about two years of negotiations, the General Council concluded to waive the provisions of Article 31 Paragraph (f) and (h) of the TRIPS Agreement by carving out a special compulsory licensing regime popularly tagged "the Doha Paragraph 6 system".[15] By December 2005, the WTO members infused the 2003 waiver decision permanently into the TRIPS Agreement subject to the acceptance of two-thirds of WTO members. Upon attaining the two-thirds threshold on 23 January 2017, the amendment became a permanent part of the TRIPS Agreement, thereby becoming the first amendment made to a multilateral agreement in the WTO. [16] The amendment came with renewed hopes of relief to countries with little or no pharmaceutical production capacity, who are now allowed to import generic medicines at affordable prices under compulsory licensing.[17] Since the system became

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[10] Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10(4) J. INT'L. ECON. L. 921, 929 (2007).

[11] *See generally* Susan K. Sell, *Trips and the Access to Medicines Campaign*, 20(3) WIS. INT'L L. J. 481 (2001).

[12] *See generally* Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15(1) EUR. J. INT'L. L. 123 (2004).

[13] World Trade Organization [hereinafter WTO], Declaration on the TRIPS Agreement and Public Health, ¶¶ 4, 5(b)-(c), 7, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

[14] *Id.*

[15] Muhammad Z. Abbas & Shamreeza Riaz, *WTO "Paragraph 6" System for Affordable Access to Medicines: Relief or Regulatory Ritualism?*, 21 J. WORLD INTELL. PROP. 1, 5 (2018).

[16] T. A. Adekola, *Public Health-Oriented Intellectual Property and Trade Policies in Africa and the Regional Mechanism Under Trade-Related Aspects of Intellectual Property Rights Amendment*, 173 PUB. HEALTH 1, 3 (2019).

[17] *WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines*, WTO (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

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operational, it has only been used by Rwanda to import antiretroviral (ARV) drugs from Canada in 2007.[18] The inability of less-developed countries to effectively use the flexibilities has been ascribed to the very technical nature of the system. The existing literature on the Doha Paragraph 6 system leaves no hope for the system after almost two decades since its implementation.[19]

However, while much has been said about the Doha Paragraph 6 system, little has been explored about the regional mechanism option it provides for in Article 31*bis* 3 of the TRIPS Agreement as amended. To allow for better use of the flexibilities by low-income countries, the TRIPS Amendment crafts out a policy space for a regional mechanism.[20] Under the regional mechanism, WTO members who are party to a regional trade agreement, of which half are Least Developed Countries, are allowed to jointly import or locally produce pharmaceutical products under compulsory license. This provision permits pharmaceutical products imported by or produced in one member of the eligible group under compulsory license to be re-exported to other Members of the group without additional export licensing or adherence to the stipulated procedure for medicines procurement under the Doha Paragraph 6 solution. Asides the use of compulsory licensing in the regional context, the regional mechanism also has provisions aimed at facilitating the building of local pharmaceutical manufacturing capacity, regional patents and pooled procurement strategies.[21]

While this regional arrangement portends a positive direction for less-developed countries, it remains largely untapped as an alternative route. This paper lends credence to why the regional mechanism has assumed greater significance in the procurement of patented pharmaceuticals. The paper discusses the nature and prospects of the regional mechanism using hypothetical models in South East Asia and Africa. With the ongoing effort to explore the regional mechanism under TRIPS reform by the East African community, this paper explains why regional integration for pharmaceutical access remains inevitable. The paper recommends that solutions to low-income countries' technological and financial deficiencies should be sought outside the scope of developed countries' obligation under TRIPS agreement.

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[18] Adam R. Houston & Reed F. Beall, *Could the Paragraph 6 Compulsory License System Be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime*, 12(2) MCGILL J. L. & HEALTH 227, 231 (2019).

[19] Abbas & Riaz, *supra* note 15, at 14.

[20] *See* TRIPS Agreement art. 31 *bis* 3.

[21] *See* Annex to the TRIPS Agreement paragraph 5.

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II. THE CHALLENGES OF A SINGLE STATE ACTION AND THE IMPERATIVE OF THE REGIONAL MECHANISM UNDER TRIPS AMENDMENT

A singular effort by individual countries to issue compulsory licenses is mostly faced with economic, legal and technical constraints.[22] While the issuance of compulsory licenses on patented drugs may be more comfortable in countries like India and Thailand, the same cannot be said of most low-income countries. Countries like Gabon, Namibia, Lesotho, and the Gambia with a population of fewer than three million people cannot boast of the economic size and purchasing power that could justify the use of compulsory licensing. The territorial nature of patent rights makes a single state action for the use of compulsory licensing very cumbersome and uneconomical.[23]

Compulsory licensing by its nature is a single market license which in itself cannot drive a sustainable drug price reduction through market competition.[24] Given the lack of synchronization among economically disadvantaged countries, procurement of patented drugs remained susceptible to sturdy legal and economic pressures from patent right holders.[25] With the unattractive nature of emerging countries' markets, pharmaceutical companies tend to invest and establish their business presences in countries where they are guaranteed profit. Hence, most low-income countries are left to depend on the importation of generics and charitable donations from patent pools.[26] This lends credence to the reason why a significant percentage of the medicines consumed in Africa are imported.[27] The regional mechanism under Doha Paragraph 6 system, therefore, provides the necessary window for making it commercially viable for foreign pharmaceutical companies to undertake the regulatory, industrial and commercial steps required to distribute medicine with the regional arrangement.

To further provide more normative arguments for establishing a regional coalition, it is crucial to further evaluate the viability of a regional collective effort relative to individual national government's efforts in using the flexibilities in the TRIPS Amendment.

Most low-income countries have the challenge of insufficient local

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[22] Abbott & Reichman, *supra* note 10, at 972.
[23] Owoeye, *supra* note 9, at 217.
[24] Olasupo Owoeye, *International Patents Law and Public Health: Revisiting the TRIPS Compulsory Licensing Regime and the Doha Paragraph 6 System*, 37(12) EUR. INTELL. PROP. REV. 782, 790 (2015).
[25] Peter K. Yu, *Access to Medicines, BRICS Alliances and Collective Action*, 34 AM. J. L. MED. 345, 370-71 (2008).
[26] Burrone et al., *supra* note 5, at 576.
[27] Owoeye, *supra* note 9.

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pharmaceutical manufacturing capacity.[28] This key constraint is exacerbated by the infrastructural deficits and inadequate research funding in those countries.[29] The few local pharmaceutical manufacturing companies in the East African Community, for instance, depend solely on the importation of active pharmaceutical ingredients for production.[30] The pharmaceutical industry being a technologically driven sector requires a high level of investment in research and development, which is deficient in low-income countries. Hence, the regional mechanism offers a better opportunity for economically weak countries to harness their economies of scale in building a regional-wide pharmaceutical industry. The fact that most low-income countries have small economies and limited resources presupposes that they cannot be self-sufficient. As such, there is the need to close ranks and come together for common benefit.

Another reason why the regional mechanism is preferred to individual national effort can be argued from the viewpoint of the challenges faced by low-income countries in regulating and approving medicines for consumption.[31] Most low-income countries have insufficient technical expertise and infrastructural facilities for the regulation of domestic medication. They rely mostly on foreign authorities to validate and set the necessary safety standards before medicines are certified safe for local consumption. This challenge deprives most generic manufacturers the benefit of using the bolar exception under the TRIPS agreement.[32] Alternatively, a pooled regional medicine regulatory framework will save a lot of resources and time for individual national governments.

The constraints on national efforts justify the need for less-developed countries to embrace the regional collaborative option to complement their existing national efforts. Public health is indeed a shared concern for all low-income countries, which requires concerted action. A regional collective effort will help in market expansion and economies of scale and give weak countries a voice in the international intellectual property (hereinafter "IP") debate. A south-south coalition founded on shared purpose and cooperation remains a more logical and beneficial approach in providing the needed leverage in balancing the asymmetries between the global north and the global south.

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[28] Adriana Mendoza-Ruiz et al., *Pharmaceutical Policy in Colombia*, *in* PHARMACEUTICAL POLICY IN COUNTRIES WITH DEVELOPING HEALTHCARE SYSTEMS 193, 213 (Zaheer-Ud-Din Babar ed. 2017).

[29] *Id.*

[30] EAST AFRICAN COMMUNITY, EAST AFRICAN COMMUNITY REGIONAL PHARMACEUTICAL MANUFACTURING PLAN OF ACTION (2012-2016) 17 (2016), https://www.unido.org/sites/default/files/2016-01/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action_0.pdf.

[31] *See generally* Dawn Willow, *The Regulation of Biologic Medicine: Innovators' Rights and Access to Healthcare*, 6(1) CHI.-KENT J. INTELL. PROP. 32 (2006).

[32] SISULE F. MUSUNGU ET AL., UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS 28 (2004).

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To address the constraints discussed above, the regional mechanism under the Paragraph 6 system provides an alternative route to the single state action. Article 31 *bis* 3 of the amended TRIPS Agreement allows developing or least-developed country (hereinafter "LDC") WTO members, who belong to regional trade agreements to jointly import or locally produce generic drugs under compulsory licensing for the collective use of the members of the regional coalition.[33]

A review of the provision of Article 31 *bis* 3 shows that its main target is to provide an alternative legal pathway for low-income countries who may have found it difficult to issue compulsory licensing due to their low buying power, small market sizes, financial constraints and local manufacturing deficiency.[34] The main crux of the regional model is the opportunity it affords members of the regional coalition to harness their economies of scale and purchasing power in the drive to deliver sustainable access to affordable medicines.

Article 31 *bis* 3 also points out that the primary goal of the regional framework is to facilitate local production of pharmaceutical products. It is important to note that having insufficient local pharmaceutical manufacturing capacity has always been the major constraint inhibiting the use of compulsory licensing.[35] As such, overcoming the challenge of inadequate local pharmaceutical manufacturing capacity through the regional coalition remains to be a step in the right direction.

Nevertheless, the system stipulates certain conditions that must be fulfilled before any regional trade community can invoke the mechanism. Firstly, members of the regional alliance must share similarities in public health problem(s). Secondly, at least half of the current membership of the Regional Trade Agreement (hereinafter "RTA") must be LDC. Thirdly, the

[33] TRIPS Agreement art. 31 *bis* 3 states:

> With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

[34] MUSUNGU ET AL., *supra* note 3210, at 28.

[35] *See generally* Giuliano Russo & Geoffrey Banda, *Re-Thinking Pharmaceutical Production in Africa; Insights from the Analysis of the Local Manufacturing Dynamics in Mozambique and Zimbabwe*, 50 STUD. COMP. INT'L. DEV. 258 (2015).

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RTA must comply with the relevant provisions of the WTO laws. Although the system does not explicitly state the eligible LDCs, it can be inferred that the system targets African and Asian countries due to the LDC profile of the two continents.

On the scope of the diseases for which medicines can be produced or imported, the mechanism adopts a broad approach. Although during the negotiation process, the United States (hereinafter "US") and the European Union lobbied to confine the scope of diseases solely to infectious diseases and situations of grave public health crises, developing countries firmly rejected this proposal.[36] They sought for a more comprehensive range for the covered illnesses. The system, therefore, clarifies that the scope of diseases should be limited to the public health problems highlighted in paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health which are, "HIV/AIDS, tuberculosis, malaria and other epidemics". The expression "other epidemics" leaves ample space for the accommodation of various other ailments. Furthermore, the system in expounding the meaning of the term "pharmaceutical products" defines it to mean "any patented product or product manufactured through a patented process", which includes active pharmaceutical ingredients (APIs) and diagnostic kits.[37]

III. THE CHANGING NARRATIVE OF DOHA PARAGRAPH 6 SYSTEM'S SIGNIFICANCE

This section identifies four reasons why the "Doha paragraph 6 solution" has become more significant in light of the current trends in the pharmaceutical landscape.

A. World Health Organization's Growing List of Patented Essential Medicines

The World Health Organization (hereinafter "WHO") rolls out the list of essential medicines every two years.[38] The list contains drugs which are to "satisfy the priority health care needs of the population".[39] The "essential" nature of the drugs suggests that they should be affordable and available in sufficient amount. However, certain on-patent medications for the treatment of cancer, hepatitis C, leukemia and tuberculosis are contained on the list.[40]

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[36] Abbott & Reichman, *supra* note 10, at 936.
[37] TRIPS Agreement Annex 1(a).
[38] *See generally* Muhammad Atif et al., *Essential Medicine List, Policies, and the World Health Organization, in* ENCYCLOPEDIA OF PHARMACY PRACTICE AND CLINICAL PHARMACY 239 (Zaheer-Ud-Din Babar ed., 2019).
[39] Victoria A. Marks et al., *On Essentiality and the World Health Organization's Model List of Essential Medicines*, 83(3-4) ANNALS GLOBAL HEALTH 637, 637 (2017).
[40] Atif et al., *supra* note 38.

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Furthermore, the 2019 edition of the WHO list of essential medicines makes the addition of seven new on-patent anti-microbial drugs.[41] The new anti-microbial drugs were research responses to the growing global burden of antimicrobial resistance.[42]

With the significant increase in the list of essential on-patent drugs, the Doha Paragraph 6 system and compulsory licensing have become even more relevant as a legal pathway to secure access. It is important to note that after the epidemic of human immunodeficiency virus (hereinafter "HIV") and acquired immune deficiency syndrome (hereinafter "AIDS") hit the world, it was the utilization of the flexibilities in the TRIPS agreement that helped in creating and sustaining the generic competition that significantly brought down the price of antiretroviral drugs.[43] By the year 2000, HIV and AIDS had triggered enormous suffering and countless deaths globally—affecting developmental gains and threatening global existence.[44] By the year 2008, access to HIV and AIDS drugs has increased by 90%, and about 95% of the drugs are generics. A research carried out to document the use of TRIPS flexibilities between 2001 and 2016 shows 176 instances of possible use.[45] The research found that TRIPS flexibilities are more frequently used than assumed, and it has even assumed more considerable significance.[46] It is interesting to note that the study found that 137 of the instances were channeled at securing access to medicines for the treatment of HIV and AIDS.[47] Can the same global drive be explored for other on-patent essential drugs? The answer should be yes. With the global burden of non-communicable diseases (hereinafter "NCDs") and antimicrobial resistance, more effective drugs are being discovered and approved for the prevention and management of NCDs.[48] These drugs are often patented; hence, the growing need for the use of the Doha Paragraph 6 system. It may be argued that the prices of antiretroviral drugs reduced significantly as a result of the voluntary licenses obtained through the UNITAID Medicine Patent pools.[49] While this may be true, low-income countries cannot keep relying on the whims and caprices of drug charity donations and the voluntary release of

[41] Burrone et al., *supra* note 5, at 576.
[42] Yonghong Xiao et al., *Retrospective Survey of the Efficacy of Mandatory Implementation of the Essential Medicine Policy in the Primary Healthcare Setting in China: Failure to Promote the Rational Use of Antibiotics in Clinics*, 48 INT'L. J. ANTIMICROBIAL AGENTS 409, 410 (2016).
[43] *See* Jorge Bermudez & Ellen F.M. 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 OPEN AIDS J. 37 (2010)
[44] Joshua Salomon, *Global Burden of HIV/AIDS in the Year 2000*, WORLD HEALTH ORG. 5 (2006), https://www.who.int/healthinfo/publications/gbdhivaids.pdf.
[45] Ellen F.M. 't Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-related Aspects of Intellectual Property Rights, 2001-2016*, 96 BULL. WORLD HEALTH ORG. 185, 188 (2018).
[46] *Id.* at 186-87.
[47] *Id.* at 185.
[48] *Id.* at 189.
[49] Burrone et al., *supra* note 5, at 576.

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the patent holder's right. Hence, the need for a sustainable legal pathway to guarantee access through the Doha Paragraph 6 system.

B. High-Drug Prices in Developed Countries

Today the challenge of high costs of drugs is not an issue exclusive to developing countries. Developed countries are also not spared from the conundrum.[50] While it may be argued that developed countries have the purchasing power to pay for high priced drugs, agitations on the need to solve drug pricing problems are becoming more apparent.[51] The German Patent Court, for instance in 2016, granted compulsory licensing for the production of raltegravir which is a more effective anti-retroviral drug.[52] The reason given by the court for the grant is the foreseeable risk of non-availability of the medicine and the need to safeguard the rights of already affected patients to access.[53] In another instance, the Italian government in 2017 gave its citizens the right to import generic versions of Hepatitis C virus drugs citing public health concerns and human rights.[54] The debate on the affordability of Truvada in the US has also been intense. Truvada is a drug for HIV prevention, which was approved in the US in 2012 as pre-exposure prophylaxis with Gilead holding the patent rights.[55] It costed a patient about USD 20,000 annually to use the medication. Health rights activists have been pushing for the introduction of generic manufacturers into the market to break the patent monopoly causing Truvada's price hike.[56] A legal decision against Gilead's patent paved the way for a single generic company, Teva, to launch a generic version of the drug in 2020. As such, since developed countries are even more willing to engage in non-voluntary licenses to address hikes in drug prices, low-income countries who are in most dare need of lower-priced generic medicines should do the same.

C. TRIPS-Plus Agreements- NAFTA 2.0

Despite the remarkable progress made in the use of TRIPS flexibilities for promoting access to medicines, it is worthy of note that most of the

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[50] Syed Shahzad Hasan et al., *High-Cost Medicines: Access, Affordability, and Prices, in* ENCYCLOPEDIA OF PHARMACY PRACTICE AND CLINICAL PHARMACY 20, 21 (Zaheer-Ud-Din Babar ed., 2019).
[51] *See generally* Michael A. Carrier, *Higher Drug Prices from Anticompetitive Conduct: Three Case Studies*, 39 J. LEG. MED. 151 (2019).
[52] 't Hoen et al., *supra* note 45, at 186.
[53] *Id.*
[54] *See generally Epatite C: i generici si possono acquistare all'estero*, ALTROCONSUMO (Apr. 5, 2017), https://www.altroconsumo.it/salute/diritti-in-salute/news/epatite-c#.
[55] Carrier, *supra* note 51.
[56] *See generally* Owen Dyer, *Gilead to Give Up Truvada Exclusivity and Donate Drug to Some in US*, 365 BMJ l2173 (2019).

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flexibilities stand the risk of being whittled down by the TRIPS-plus agreements being negotiated by developed countries, mainly the US.[57] The newly signed United States-Mexico-Canada Agreement (hereinafter "USMCA") in 2018, which replaces the North American Free Trade Agreement (NAFTA), contains specific provisions on pharmaceutical patents which raises the bar of Intellectual Property Rights protection beyond that of the TRIPS Agreement.[58] These TRIPS-plus provisions place restraints on the potency of TRIPS flexibilities by limiting the grounds upon which they can be invoked. Article 20:46 of the USMCA, for instance, favors the evergreening strategy, which allows the extension of patent term beyond the statutory twenty years, in as much as pharmaceutical patent holders could come up with new uses of the same product; or new methods of using the same product; or new processes of using the same product.[59] About four more TRIPS-plus provisions are contained in the agreement, which includes: patentability requirement, test data protection, patent term adjustments, and regulations on biologics. The elongation of patent terms beyond those stipulated in the TRIPS agreement will delay the market entrance of generic competitors and thereby strengthening the monopoly power of right holders.[60] The USMCA is projected to increase the prices of drugs in Canada by CDN 169 million by 2029, rising each year after that.[61] The impact of the USMCA will not only be felt by the population in the three trading partners, but will also be felt in the low-income countries relying on the parallel importation of high priced patented drugs from the region.[62] As such, discussions on a regional mechanism under Doha Paragraph 6 system is very timely.

D. Introduction of Product Patent Regime in Key Potential Exporting Countries

India and China has been a significant supplier of generics to low-income countries.[63] However, the ability of these countries to sustain their

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[57] Olasupo Owoeye et al., *Patents and the Trans-Pacific Partnership: How TPP-style Intellectual Property Standards May Exacerbate the Access to Medicines Problem in the East African Community*, 33(2) INT'L. TRADE J. 197, 203 (2017).
[58] *See generally* Ronald Labonté et al., *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 GLOBALIZATION & HEALTH 1 (2019).
[59] *Agreement Between the United States of America, the United Mexican States, and Canada 12/13/19 Text*, OFF. U.S. TRADE REPRESENTATIVE [hereinafter USTR], https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between (last visited Mar. 7, 2020).
[60] *Id.* at 3.
[61] *Id.* at 4.
[62] Owoeye et al., *supra* note 57, at 202.
[63] AFRICAN UNION, PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA: BUSINESS PLAN 30 (2012), https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa.

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relaxed intellectual property protection regimes to facilitate the continued production of generics is being threatened.[64] In the wake of the US-China Trade war, the need for China to make adjustments to its intellectual property laws in full compliance with WTO laws has been on the front burner.[65] In response to the ongoing trade war, China has been compelled to amend some of its IP law provisions to align with high-income trading partners' IP protectionist agenda.[66] The build-ups in India shows that things cannot be as it used to, with regard to re-engineering and generic manufacturing.[67] The US in the report released by the US Trade Representative decries the laxity in the Indian Patent Laws, particularly its Section 3(d) which prevents the evergreening rule.[68] The political pressure from the USA and the adoption of the product patent regime by key generic exporters (India and China) will inevitably affect pharmaceutical access in low-income countries.[69] With Africa's reliance on pharmaceutical importation from India and China, the use of Doha paragraph 6 system has become very significant.[70]

IV. A LARGE REGIONAL MODEL FOR THE AFRICAN CONTINENT

The regional framework can be experimented using a large or small model of a coalition of African countries. Of the forty-seven countries categorized as least-developed countries globally, thirty-three are on the African continent.[71] This places African countries in a position of strength to utilize this policy space. With the signing of the African Continental Free Trade Agreement (hereinafter "AfCFTA") in March 2018, a broad continental approach for the utilization of the regional model can be invoked.[72] Under the Doha Paragraph 6 system's regional mechanism, generic drugs produced in or imported by South Africa for instance can be distributed within the African continent, without each African country

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[64] Dianne Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicines*, 91 BULL. WORLD HEALTH ORG. 533, 534 (2013), http://www.who.int/entity/bulletin/volumes/91/7/12-115865.pdf.

[65] *See generally* Tolulope Anthony Adekola, *US-China Trade War and the WTO Dispute Settlement Mechanism*, 18 J. INT'L TRADE L. & POL'Y 125 (2019).

[66] *See* Jyh-An Lee, *Shifting IP Battlegrounds in the U.S.-China Trade War*, 43(2) COLUM. J.L. & ARTS 147, 150 (2020). *See also China to Raise Penalties on IP Theft in Trade War Compromise*, SOUTH CHINA MORNING POST (Nov. 25, 2019, 4:15 PM), https://www.scmp.com/tech/ policy /article/3039232/china-raise-penalties-ip-theft-trade-war-compromise.

[67] *See generally* Olasupo Owoeye, *Regionalism and WTO Multilateralism: The Case for an African Continental Free Trade Area*, 50(6) J. WORLD TRADE 1085 (2016).

[68] USTR, 2015 SPECIAL 301 REPORT, at 49 (Apr. 2015).

[69] Owoeye, *supra* note 9.

[70] *See generally* AFRICAN UNION, *supra* note 63.

[71] UN LIST OF LEAST DEVELOPED COUNTRIES, https://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx (last visited Mar. 13, 2020).

[72] *See* AFRICAN EXPORT-IMPORT BANK, AFRICAN TRADE REPORT 2018: BOOSTING INTRA-AFRICAN TRADE: IMPLICATIONS OF THE AFRICAN CONTINENTAL FREE TRADE AREA AGREEMENT (2018).

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having to go through the same hurdle of issuing a compulsory license for the same drug.

To make the regional model work more effectively in Africa, the African regional coalition must build jointly owned pharmaceutical manufacturing industries in any of its LDCs. The justification for suggesting LDCs as the preferred location is due to the TRIPS council's waiver, which allows LDCs not to grant pharmaceutical patents until 2033.[73] The transition period provides a window of opportunity for LDCs to build local pharmaceutical production capacity and use reverse engineering to exploit patented drugs for research and development. With a regional mechanism in place, the gains of the transition period will not only be useful to individual African LDCs but the entire continent. African regional force will then be placed in the same position India was during its TRIPS transition era. India, whose population is more than that of the African continent put together, was not under obligation to protect product patents and as a result, was able to build viable generic manufacturing capacity.[74] Now, India is fondly called the 'pharmacy store' for developing countries due to its strategic utilization of the transition period.[75] A united African country can follow the same path.

Another benefit of the regional collective effort is the opportunity it will afford African countries to collectively bargain with patent holders for a substantial reduction in drug prices. It has been reported that Brazil and Thailand were able to substantially reduce the costs of HIV and AIDS drugs by about 75% due to the threat of issuing compulsory licensing against right holders.[76] With the projected regional pharmaceutical industries, member countries can jointly approach patent holders by negotiating voluntary licenses to manufacture generic versions of their on-patent drugs upon payment of adequate remuneration. Pharmaceutical companies will most likely be favorably disposed to negotiating with the regional coalition having regards to the size of the aggregated regional market. With AfCFTA, which has now been signed by fifty-four African countries with twenty-three domestic ratifications, African's collective voice and policy space in global pharmaceutical trade negotiations will undoubtedly be strengthened.[77]

The potential impact of the regional alliance on the international

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[73] Council for Trade-Related Aspects of Intellectual Prop. Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, ¶ 1, WTO Doc. IP/C/73 (Nov. 6, 2015).

[74] *See generally* Prabuddha Ganguli, *Towards TRIPs Compliance in India: The Patents Amendment Act 1999 and Implications*, 21 WORLD PAT. INFO. 279 (1999).

[75] *See generally* Samira Guennif & Shyama Ramani, *Catching Up in Pharmaceuticals: A Comparative Study of India and Brazil*, HAL (2010), http://econpapers.repec.org/RePEc:hal:cepnwp:hal-00632439.

[76] Yu, *supra* note 25, at 349.

[77] *See* AFRICAN CONTINENTAL FREE TRADE AREA (AFCFTA) LEGAL TEXTS AND POLICY DOCUMENTS, https://www.tralac.org/resources/our-resources/6730-continental-free-trade-area-cfta.html (last visited Mar. 16, 2020).

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intellectual property debate is significant. Since the beginning of the Doha round of trade negotiations, the African group, for instance, has been active in putting forward proposals to overhaul the pro-development discussion on the multilateral trading stage.[78] The Cancun Ministerial conference, for example, recorded about two-thirds of the recommendations synthesized in the Chairman's document coming from the African group.[79] The regional mechanism will further provide an opportunity for African countries to reshape the international IP debate.

V. SMALLER MODEL FOR POOLED ACCESS IN SOUTHEAST ASIA

According to the 2017 report of the WHO regional office for Southeast Asia, the procurement and supply chains for access to medicines are still very weak in the region.[80] The report decries the low availability of drugs in most public hospitals and health centers.[81] According to the report, about sixty-five million people in the region are "impoverished because of out-of-pocket health spending, much of which is on medicines, while others even forego treatment".[82] Of particular concern is the limited access to life-saving drugs for the management of non-communicable diseases such as cancer, diabetes, cardiovascular diseases and hepatitis, most of which have on-patent status.[83] Of all the countries in Southeast Asia, Thailand and India have to a certain degree used some of the flexibilities in TRIPS agreement to enhance access to affordable medicines for domestic use and exportation. This paper advances a hypothesis of a five-country regional model in Southeast Asia for the regional framework under TRIPS Amendment. The proposed regional coalition could be comprised of Bangladesh, Myanmar, Nepal and any other developing country in the region. The choice of Bangladesh, Myanmar and Nepal is justified by their status of being the only WTO members with LDC status in the region. Although Timor-Leste and Bhutan are also classified as least developed countries in the region, both countries are not members of the WTO.[84] By this arrangement, drugs imported or produced in Bangladesh under the regional mechanism, for instance, can be collectively used by other members. This will save a lot of cost when going through procedural hurdles.

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[78] Yu, *supra* note 25, at 368.
[79] *Id.*
[80] *See generally* Poonam Khetrapal Singh & Phyllida Travis, *Accelerating Access to Essential Medicines in the WHO South-East Asia Region: Opportunities for Greater Engagement and Better Evidence*, 7 WHO SE. ASIA J. PUB. HEALTH 59 (2018).
[81] *Id.* at 59.
[82] *Id.*
[83] *See* REG'L OFF. FOR SE. ASIA, WORLD HEALTH ORG., IMPROVING ACCESS TO MEDICINES IN THE SOUTH-EAST ASIA REGION: PROGRESS, CHALLENGES, PRIORITIES, at 6, 12 (2017), https://apps.who.int/iris/handle/10665/258750.
[84] *Members and Observers*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mar. 8, 2020).

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Parties to the regional trade agreement can utilize the transition period available to LDCs to facilitate local production of essential medicines for the benefit of parties to the regional arrangement.

Judging by the frail economic strength of Bangladesh, Myanmar and Nepal, it will be burdensome for these countries to drive compulsory licensing separately on a single state basis. The regional approach will facilitate the platform for collective bargaining with pharmaceutical patent holders or potential generic suppliers using the dual compulsory licensing under the Paragraph 6 system through the regional mechanism channel.

VI. THE DOWNSIDES OF THE EAST AFRICAN COMMUNITY REGIONAL PHARMACEUTICAL PLAN

The East Africa Community (hereinafter "EAC") comprises of six countries, which are Burundi, Uganda, Kenya, Rwanda, Tanzania and South Sudan.[85] Five of the regional partners are members of the WTO with South Sudan having an observer status.[86] Kenya is the only developing country while others bear the statuses of Least Developing Countries. The EAC has an existing Free Trade Agreement, which was officially launched in 2010 with the free movement of goods and services. The East Africa community perfectly matches the regional model in TRIPS amendment with more than half of its members classified as least-developed country.[87] The community also shares a similarity in diseases. Collaboration between EAC states cuts across several facets. However, the subject of relevance to this paper is the subregion's alliance for the joint utilization of the flexibilities embodied in the WTO-TRIPS Agreement for access to pharmaceuticals.

In order to collectively take advantage of the regional mechanism under TRIPS reforms, the EAC adopted two policy documents, which are: The East African Community Regional Pharmaceutical Manufacturing Plan of Action (hereinafter "EACRPMPoA") 2012-2016 and the East African Community Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislations 2013 to which the EAC Health Protocol on Public Health-Related WTO-TRIPS Flexibilities is annexed.[88] The documents mainly elaborate on how the EAC can incorporate the flexibilities of TRIPS into their domestic laws for optimal utilization of TRIPS flexibilities. Even though the community has made some progress in the area

[85] *About East African Community*, EAST AFRICAN COMMUNITY, http://www.eac.int/overview-of-eac (last visited Mar. 8, 2020).
[86] *Id.*
[87] Owoeye et al., *supra* note 57, at 208.
[88] Olufemi Soyeju & Joshua Wabwire, *The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework*, 17 WORLD TRADE REV. 145, 146 (2018).

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of public health since its formation, several health challenges persist which continues to require urgent attention.[89]

The EACRPMPoA (2012-2016) provides a five-year road map for the region detailing how the region can build a regional pharmaceutical manufacturing capacity that can guarantee access to quality and affordable drugs while serving both regional and international markets. The EAC through its policy direction attempts to reduce over-reliance on the importation of drugs from more than 70% to 50%, cut dependence on pharmaceutical imports from outside EAC from more than 70% to less than 50% and increase the ability of product portfolio in EAC firms to cater for about 90% of diseases.[90] The target was that at least five companies in the EAC would be able to produce more advanced pharmaceutical formulations after the end of the five-year roadmap.[91] In 2016, which was the end of the plan, there was an assessment of the policy direction, and indeed the deficiencies in Article 31 *bis* 3 resurfaced.

The EAC was not able to achieve its target due to inadequate local manufacturing capacity and lack of technical expertise and technology transfer. The inhibiting factors that hampered the effectiveness of the regional collective effort can be linked to the nature of the obligations of developed countries expressed in Paragraphs 5 and 6 of the annex to the TRIPS Agreement as amended.

To justify this claim, figure 1 was used in the EACRPMPoA (2017-2027) document to analyze the five main levels of pharmaceutical manufacturing. The figure reveals that the majority of stakeholders in the EAC pharmaceutical sector still operates at level 1, which is branded by overdependence on the importation of finished drugs for local supplies. EAC local manufacturers cannot manufacture Active Pharmaceutical Ingredients (hereinafter "API") and as such, are confined to the production of finished pharmaceutical products. As shown in figure 1, local firms are trapped in Levels 2 and Levels 3. The manufacturing of API requires high-level expertise and access to the requisite technology, which are not available.[92]

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[89] For instance, according to the United Nations Office on Drugs and Crime (UNODC), "Eastern Africa is the second most affected region by HIV and AIDS in the world after Southern Africa." In a document released by the EAC in 2015 on essential facts and figures within the community, HIV prevalence rates in 2014 were 5% in Tanzania, 7% in Uganda, 6% in Kenya, and 3% in Rwanda. For Tuberculosis (TB), the 2014 world report on TB reveals that Kenya (9,400 mortality cases), Uganda (30,000 mortality cases) and Tanzania (4,500 mortality cases) remain "high burden" countries. The free movement of persons within the regional community has increased the prevalence of infectious diseases within the region. According to the WHO, the recent outbreak of Ebola virus in DR Congo remains a threat to the East African Community. In 2019, Uganda, which is a member of the community, has already been hit with the deadly virus. The community also continues to battle with Malaria Tuberculosis and many other non-communicable diseases.

[90] E. AFRICAN CMTY., 2ND EAC REGIONAL PHARMACEUTICAL MANUFACTURING PLAN OF ACTION 2017-2027, at 7 (2017).

[91] *Id.* at 18.

[92] *Id.* at 19.

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Even if APIs are produced, the cost of its production gulps a substantial amount of the total cost of pharmaceutical products, which cannot be recouped judging by the strength and purchasing power of the regional market.[93]

There is also little or no technical cooperation with developing countries in the aspect of research and development, particularly in the area of biotech products in the EAC.[94] The EAC pharmaceutical manufacturers, even after the life span of the five-year pharmaceutical plan, can only produce simple generic formulations as opposed to higher value medicinal products.[95] Pharmaceutical companies in EAC have similar drug portfolios and as such, compete with themselves at the very bottom. They focus mainly on the production of anti-bacteria, vitamins, cold preparations, vitamins and analgesics. Innovative drugs for anti-cancer drugs and immune suppressants, for instance, are primarily imported due to lack of local manufacturing capacity.

Having shown the shortcomings of the regional coalition as evidenced in the drawbacks of the EACRPMPoA, the legitimacy question of the TRIPS agreement resurfaces. The cons show clearly the vacuum left in the obligation of developed countries under TRIPS agreement and the hitches in the objective of TRIPS Agreement. Article 7 of TRIPS emphasizes that the agreement "should contribute to the promotion of technological innovation and the transfer and dissemination of technology." From the practical evidence expressed in the EAC regional framework, this objective has not materialized.[96] The realities of the seemly futile effort of the EAC regional effort question the substance of the objectives of the WTO, which recognized "the need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development."[97] While low-income countries continue to be deficient in technological innovation and overall development, developed countries continue to shop for greater protection of knowledge goods through TRIPS-plus bilateral and regional agreements.[98] The resolution of the G7 in France in August 2019 alludes to the resolve of developed countries to further their drive for more efficient IP protection in the WTO, a position they have

[93] *Id.* at 17.
[94] *Id.* at 19.
[95] *Id.*
[96] *Id.*
[97] WTO, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.
[98] Labonté et al., *supra* note 58, at 12.

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always clamored for since TRIPS' founding moments.[99] The newly signed agreement between the United States of America, Mexico and Canada, also contains far-reaching provisions that will reduce the potency of TRIPS flexibilities and availability of generic drugs in less developed countries.[100]

VII. REGIONAL MECHANISM AND THE DILEMMA OF DEVELOPED COUNTRIES' OBLIGATION UNDER TRIPS AGREEMENT

To ensure the effectiveness of the regional mechanism enshrined in Article 31 *bis* 3 of TRIPS reforms, the combined provisions of paragraphs 5 and 6 of the annexes to the amended TRIPS Agreement oblige developed countries to render technical, financial and technological assistance to the regional framework. As lofty as the gains of the regional collective effort are, access to the requisite technology, and technical expertise may hamper the effort's effectiveness. The obligations of developed countries to the regional mechanism are rooted in the objective of TRIPS Agreement expressed in Article 7 of TRIPS Agreement.[101]

A. Article 67 Obligation

Paragraph 5 of the annex to TRIPS specifically accentuated the obligation of developed countries in Article 67 of TRIPS Agreement for the provision of technical cooperation.[102]

For emphasis, Article 67 of TRIPS Agreement states thus:

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[99] *Europa-G7 Leaders' Declaration — Biarritz, France, 26 August, 2019*, EUROPEAN COUNCIL, https://www.consilium.europa.eu/en/press/press-releases/2019/08/26/g7-leaders-declaration-biarritz-26-august-2019/.

[100] Labonté et al., *supra* note 58, at 3.

[101] Jayashree Watal & Leticia Caminero, *Least-developed Countries, Transfer of Technology and the TRIPS Agreement* 3 (WTO Econ. Res. & Stat. Div., Working Paper No. ERSD-2018-01, 2018), https://www.econstor.eu/bitstream/10419/176766/1/1016547994.pdf; TRIPS Agreement art. 7:

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

[102] Annex to the TRIPS Agreement ¶ 5:

> With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31 bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations [emphasis added].

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> In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

The text of Article 67 cites instances of the technical cooperation expected from developed countries. The textual examples significantly relate to the preparation of laws and regulations for the protection and enforcement of IP rights. It, therefore, implies that the attainment of coherence in the domestic IP laws of members of the regional coalition depends on developed countries' fulfilment of their obligations under Article 67. However, the concern with Article 67 is that there is no framework for the enforcement of compliance with developed countries' obligations.[103] Although developed countries are indulged to submit reports annually to the TRIPS council on the technical and financial assistance rendered to less-developed countries within a given year, non-compliance with the requirement cannot give rise to a cause of action under the WTO dispute settlement system.[104] Hence, the obligation has no teeth.

The fact that the technical and financial assistance has to be mutually agreed by developed countries and less-developed countries poses the "risk of a dependency."[105] By implication, developed countries will possess a stronger bargaining power in the negotiations leading to mutually agreed assistance. The provision for "mutual agreement" is, therefore, capable of placing the recipients of the benefit (less-developed countries) in a position of political and economic weakness, since "he who pays the piper dictates the tune."

B. Article 66.2- Technology Transfer

Paragraph 6 of the Annex to the TRIPS Agreement recognizes the

[103] Jayashree Watal & Leticia Caminero, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement, in* INTELLECTUAL PROPERTY AND DEVELOPMENT: UNDERSTANDING THE INTERFACES: LIBER AMICORUM PEDRO ROFFE 199, 228 (Carlos Correa & Xavier Seuba eds., 2019).
[104] *See generally* Kirsten M. Koepsel, *How Do Developed Countries Meet Their Obligations Under Article 67 of the TRIPS Agreement,* 44(2) J. L. TECH. 167 (2004).
[105] Abbott & Reichman, *supra* note 10, at 973.

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imperative of local manufacturing capacity building and the need to promote the transfer of technology to the regional coalition. The provision stresses the need to pay special attention to the undertaking of developed countries under Article 66.2 of the TRIPS Agreement.

The provision of Article 66.2 of the TRIPS Agreement; on the other hand, obliges developed countries to provide incentives to institutions within their territory to promote the transfer of technology to LDCs.

Article 66.2 states:

> Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to the least-developed country. Members to enable them to create a sound and viable technological base.

Article 66.2 is a fundamental part of the regional mechanism in the TRIPS amendment. However, it is important to note that the provision of Article 66.2 does not impose the duty of the transfer of technology on developed countries but rather stipulates that incentives should be provided by developed countries to institutions within their region for the institutions or agencies to transfer technology to LDCs.[106] This suggests that developed countries are not expected to intervene directly with the transfer of technology. Developed countries' obligations only stop at giving incentives to private institutions that will carry out the assignment. It is therefore doubtful if, by the enormous power allotted by TRIPS Agreement to individual rights holder in the transfer of technology, the development agenda for less-developed countries can be realized. Private institutions and agencies are profit-oriented; hence, even if they transfer technology, tension will most likely arise in the long run between their private interests and public needs.

Furthermore, the TRIPS Agreement provides that the council for TRIPS should monitor the implementation and compliance with the obligations set out in the TRIPS Agreement.[107] This is to be done by a review of an annual report to be submitted by developed countries with regard to their compliance with Article 66.2 obligations. However, the submission of this report is discretionary.[108] Besides, there seems to be some loopholes in the feedback mechanisms of the reporting system. While some developed countries indeed turn out comprehensive reports every year, there is no

[106] Watal & Caminero, *supra* note 103, at 203.
[107] TRIPS Agreement art. 20.
[108] U.N. Conference on Trade & Dev., *Dispute Settlement, World Trade Organization, 3.14 TRIPS*, at 5, U.N. Doc. UNCTAD/EDM/Misc.232/Add.18 (2003), https://unctad.org/en/Docs/edmmisc232add 18_e n.pdf.

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feedback mechanism from LDCs on whether the programs and activities reported have an impact on the developmental agenda of the targeted beneficiaries.[109] With the absence of a robust feedback mechanism, the issue of whether or not the incentives will fulfil the mandate of facilitating the building of a viable technological base will technically remain uncertain.

The potency of the TRIPS amendment, particularly the obligation of developed countries is limited just as the scope of Articles 7 and 8 of the TRIPS Agreement.[110] In any WTO dispute settlement proceeding, the question as to whether the measure complained is mandatory or discretionary is cardinal. From the existing WTO jurisprudence,[111] a binding obligation must be complied with, while a discretionary rule "may not" be complied with.[112] Although this may not be the applicable principle on a case-by-case basis, it has since been established under the GATT system that discretionary obligations are not actionable, except when such discretion has been abused in a manner inconsistent with the WTO rules.[113] For commitments like those of Articles 66.2 and 67 to be challenged, the discretion granted by the TRIPS Agreement must have been abused.[114] It is, therefore, not clear how developed countries can abuse an obligation they have discretion to either grant or refuse.

VIII. FINDING REGIONAL SOLUTIONS TO REGIONAL PROBLEMS

The regional mechanism undoubtedly provides a window of opportunity for the facilitation and stimulation of local production in low-income countries. This space of possibility makes it practicable for poor countries to collectively achieve the kind of generic pharmaceutical production base that was fostered in India.[115] The question now is whether India had to rely on Articles 66.2 and 67 of TRIPS to achieve their feat as the biggest generic manufacturers in the world? The Answer is No. India navigated its way within the ambits of its patents to create a competitive pharmaceutical market.[116] Of course, doubters may argue that LDCs in Africa and Southeast

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[109] *Id.*
[110] Watal & Caminero, *supra* note 103, at 200.
[111] *See generally* Panel Report, *Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Doc. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted Aug. 27, 2018).
[112] U.N. Conference on Trade & Dev., *supra* note 108, at 5-6.
[113] *Id.*
[114] Watal & Caminero, *supra* note 101, at 3.
[115] *See generally* Harunrashid Kadri & Medha Saykhedkar, *Post-TRIPS Patenting Trends in India with Special Reference to USA: A Comparative Analysis*, 16 J. INTELL. PROP. RTS. 217 (2011).
[116] *See generally* Feroz Ali Khader, *Book Review: Indian Patent Law and Practice, Kalyan C. Kankanala, Arun K. Narasani and Vinita Radhakrishnan (OUP, 2010)*, 7 INDIAN J.L. & TECH. 121 (2011).

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Asia lack comparative advantage when compared to India and China in this area, and will undoubtedly require assistance to fix their technical, technological and financial deficiencies. One, however, should not underestimate the strength that comes in a collective resolve to drive and maintain the supply of essential life-saving drugs for the public good.[117] The potential comparative advantage that may come with poor countries' unique utilization of their reserve of traditional knowledge and biogenetic diversity when local production capacity is built should not be underrated.[118]

With a strong political will and support from other intergovernmental organizations, such as United Nations Development Programme (UNDP), WHO, private sector or the Global Fund, sustainable access to essential medicines can be achieved.[119] With a regional alliance, the compensation needed for patent holders to recoup their invest R&D can be collectively paid, sourced or negotiated. Patent owners are compensated under a pooling formula "which mimics the lost R&D cost recovery from the foregone sales".[120] If China and India could do it, it is also possible and achievable from a collective front.

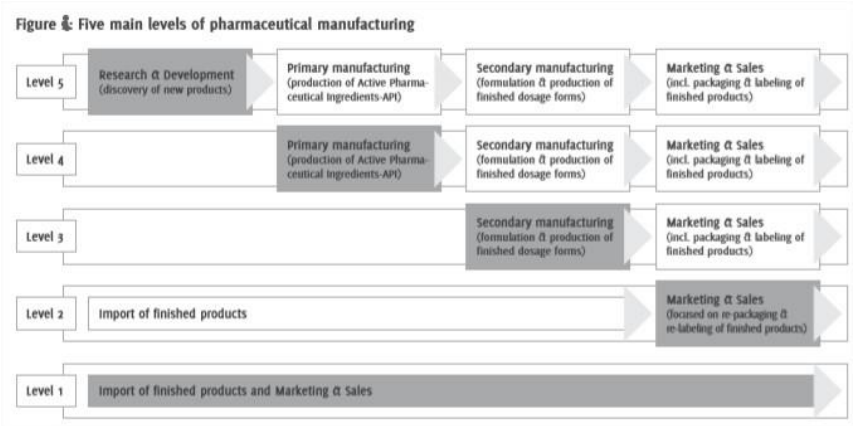
IX. CONCLUSION

Article 31*bis* 3 of the TRIPS Agreement as amended indeed provides a viable pathway for low-income countries to deliver newer and effective medicines to their population through a single regional market framework. The ongoing effort in the East Africa Community indicates remarkable progress to facilitate not just the joint procurement of generic drugs, but also the local production of pharmaceuticals. While the building of viable local pharmaceutical manufacturing capacity through the regional mechanism is critical to the striking of the needed balance in the asymmetries existing between developed and less-developed countries, the enormous reliance placed by TRIPS reforms on the obligation of developed countries under Articles 66.2 and 67 of TRIPS could impede its effectiveness. It is recommended that the regional models hypothesized in this paper should look within their regional alliance or outside the scope of the undertaking of developed countries in the TRIPS agreement for solutions to their technical, financial and technological deficits in order to facilitate the delivery of access to medicine to the most vulnerable populations.

[117] Abbott & Reichman, *supra* note 10, at 978.
[118] *Id.* at 974.
[119] *Id.* at 972.
[120] *Id.* at 979.

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FIGURE1: EACRPMPoA (2017-2027)



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REFERENCES

Books

MERCURIO, BRYAN & DARIA KIM (eds.) (2017), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS.

MUSUNGU, SISULE F. ET AL. (2004), UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS.

OWOEYE, OLASUPO (2019), INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN AFRICA.

Articles

't Hoen, Ellen F.M. et al. (2018), *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-related Aspects of Intellectual Property Rights, 2001-2016*, 96 BULLETIN OF THE WORLD HEALTH ORGANIZATION 185.

Abbas, Muhammad Z. & Shamreeza Riaz (2018), *WTO "Paragraph 6" System for Affordable Access to Medicines: Relief or Regulatory Ritualism?*, 21 THE JOURNAL OF WORLD INTELLECTUAL PROPERTY 1.

Abbott, Frederick M. & Jerome H. Reichman (2007), *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10(4) JOURNAL OF INTERNATIONAL ECONOMIC LAW 921.

Adekola, Tolulope Anthony (2019), *Public Health-Oriented Intellectual Property and Trade Policies in Africa and the Regional Mechanism Under Trade-Related Aspects of Intellectual Property Rights Amendment*, 173 PUBLIC HEALTH 1.

Adekola, Tolulope Anthony (2019), *US-China Trade War and the WTO Dispute Settlement Mechanism*, 18 JOURNAL OF INTERNATIONAL TRADE LAW AND POLICY 125.

Atif, Muhammad et al. (2019), *Essential Medicine List, Policies, and the World Health Organization, in* ENCYCLOPEDIA OF PHARMACY PRACTICE AND CLINICAL PHARMACY 239 (Zaheer-Ud-Din Babar ed.).

Bermudez, Jorge & Ellen 't Hoen (2010), *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 THE OPEN AIDS JOURNAL 37.

Bond, Eric W. & Kamal Saggi (2020), *Patent Protection in Developing Countries and Global Welfare : WTO Obligations Versus Flexibilities*, 122 JOURNAL OF INTERNATIONAL ECONOMICS 103281.

Burrone, Esteban et al. (2019), *Patent Pooling to Increase Access to Essential Medicines*, 97 BULLETIN OF THE WORLD HEALTH ORGANIZATION 575.

臺灣大學學術期刊資料庫

Carrier, Michael A. (2019), *Higher Drug Prices from Anticompetitive Conduct: Three Case Studies*, 39 JOURNAL OF LEGAL MEDICINE 151.

Dyer, Owen (2019), *Gilead to Give Up Truvada Exclusivity and Donate Drug to Some in US*, 365 BMJ l2173.

Eden, Tim et al. (2019), *Are Essential Medicines Available, Reliable and Affordable in Low-Middle Income Countries?*, 19 JOURNAL OF CANCER POLICY 100180.

Ganguli, Prabuddha (1999), *Towards TRIPs Compliance in India: The Patents Amendment Act 1999 and Implications*, 21 WORLD PATENT INFORMATION 279.

Guan, Wenwei (2016), *IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment*, 29 LEIDEN JOURNAL OF INTERNATIONAL LAW 411.

Hasan, Syed Shahzad et al. (2019), *High-Cost Medicines: Access, Affordability, and Prices*, *in* ENCYCLOPEDIA OF PHARMACY PRACTICE AND CLINICAL PHARMACY 20 (Zaheer-Ud-Din Babar ed.).

Houston, Adam R. & Reed F. Beall (2019), *Could the Paragraph 6 Compulsory License System Be Revised to Increase Participation by the Generics Industry? Lessons Learned from an Unheralded and Unsuccessful Attempt to Use Canada's Access to Medicines Regime*, 12(2) MCGILL J. L. & HEALTH 227.

Kadri, Harunrashid & Medha Saykhedkar (2011), *Post-TRIPS Patenting Trends in India with Special Reference to USA: A Comparative Analysis*, 16 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS 217.

Khader, Feroz Ali (2011), *Book Review: Indian Patent Law and Practice, Kalyan C. Kankanala, Arun K. Narasani and Vinita Radhakrishnan (OUP, 2010)*, 7 INDIAN JOURNAL OF LAW AND TECHNOLOGY 121.

Khetrapal Singh, Poonam & Phyllida Travis (2018), *Accelerating Access to Essential Medicines in the WHO South-East Asia Region: Opportunities for Greater Engagement and Better Evidence*, 7 WHO SOUTH-EAST ASIA JOURNAL OF PUBLIC HEALTH 59.

Koepsel, Kirsten M. (2004), *How Do Developed Countries Meet Their Obligations Under Article 67 of the Trips Agreement*, 44(2) THE JOURNAL OF LAW AND TECHNOLOGY 167.

Labonté, Ronald et al. (2019), *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 GLOBALIZATION AND HEALTH 1.

Lee, Jyh-An (2020), *Shifting IP Battlegrounds in the U.S.-China Trade War*, 43(2) COLUMBIA JOURNAL OF LAW & THE ARTS 147.

Marks, Victoria A. et al. (2017), *On Essentiality and the World Health Organization's Model List of Essential Medicines*, 83(3-4) ANNALS OF GLOBAL HEALTH 637.

臺灣大學學術期刊資料庫

Mendoza-Ruiz, Adriana et al. (2017), *Pharmaceutical Policy in Colombia*, *in* PHARMACEUTICAL POLICY IN COUNTRIES WITH DEVELOPING HEALTHCARE SYSTEMS 193 (Zaheer-Ud-Din Babar ed.).

Nicol, Dianne & Olasupo Owoeye (2013), *Using TRIPS Flexibilities to Facilitate Access to Medicines*, 91 BULLETIN OF THE WORLD HEALTH ORGANIZATION 533.

Owoeye, Olasupo (2015), *International Patents Law and Public Health: Revisiting the TRIPS Compulsory Licensing Regime and the Doha Paragraph 6 System*, 37(12) EUROPEAN INTELLECTUAL PROPERTY REVIEW 782.

Owoeye, Olasupo (2016), *Regionalism and WTO Multilateralism: The Case for an African Continental Free Trade Area*, 50(6) JOURNAL OF WORLD TRADE 1085.

Owoeye, Olasupo (2014), *Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa*, 92 BULLETIN OF THE WORLD HEALTH ORGANIZATION 214.

Owoeye, Olasupo et al. (2019), *Patents and the Trans-Pacific Partnership: How TPP-style Intellectual Property Standards May Exacerbate the Access to Medicines Problem in the East African Community*, 33(2) THE INTERNATIONAL TRADE JOURNAL 197.

Russo, Giuliano & Geoffrey Banda (2015), *Re-Thinking Pharmaceutical Production in Africa; Insights from the Analysis of the Local Manufacturing Dynamics in Mozambique and Zimbabwe*, 50 STUDIES IN COMPARATIVE INTERNATIONAL DEVELOPMENT 258.

Sell, Susan K. (2001), *TRIPS and the Access to Medicines Campaign*, 20(3) WISCONSIN INTERNATIONAL LAW JOURNAL 481.

Soyeju, Olufemi & Joshua Wabwire (2018), *The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework*, 17 WORLD TRADE REVIEW 145.

Sun, Haochen (2004), *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15(1) EUROPEAN JOURNAL OF INTERNATIONAL LAW 123.

Sundaram, Jae (2015), *Analysis of TRIPS Agreement and the Justification of International IP Rights Protection in the WTO's Multilateral Trading System, with Particular Reference to Pharmaceutical Patents*, 24(2) INFORMATION & COMMUNICATIONS TECHNOLOGY LAW 121.

Watal, Jayashree & Leticia Caminero (2019), *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, *in* INTELLECTUAL PROPERTY AND DEVELOPMENT: UNDERSTANDING THE INTERFACES: LIBER AMICORUM PEDRO ROFFE 199 (Carlos Correa & Xavier Seuba eds.).

臺灣大學學術期刊資料庫

Willow, Dawn (2006), *The Regulation of Biologic Medicine : Innovators' Rights and Access to Healthcare*, 6(1) CHICAGO-KENT JOURNAL OF INTELLECTUAL PROPERTY 32.

Xiao, Yonghong et al. (2016), *Retrospective Survey of the Efficacy of Mandatory Implementation of the Essential Medicine Policy in the Primary Healthcare Setting in China: Failure to Promote the Rational Use of Antibiotics in Clinics*, 48 INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS 409.

Yu, Peter K. (2008), *Access to Medicines, BRICS Alliances and Collective Action*, 34 AMERICAN JOURNAL OF LAW & MEDICINE 345.

Case

Panel Report, Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WTO Doc. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R (adopted August 27, 2018).

Treaty

Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

WTO -related Documents

Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (November 6, 2015).

REGIONAL OFFICE FOR SOUTH EAST ASIA, WORLD HEALTH ORGANIZATION, (2017), IMPROVING ACCESS TO MEDICINES IN THE SOUTH-EAST ASIA REGION: PROGRESS, CHALLENGES, PRIORITIES, https://apps.who.int/iris/handle/10665/258750.

World Trade Organization (2002), Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755.

World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, https://ww.wto.org/english/thewto_e/minist_e/min01e/mindecle.htm.

Internet Sources

About East African Community, EAST AFRICAN COMMUNITY, http://www.eac.int/overview-of-eac.

臺灣大學學術期刊資料庫

AFRICAN CONTINENTAL FREE TRADE AREA (AFCFTA) LEGAL TEXTS AND POLICY DOCUMENTS, https://www.tralac.org/resources/our-resources/6730-continental-free-trade-area-cfta.html.

Agreement Between the United States of America, the United Mexican States, and Canada 12/13/19 Text, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between.

Epatite C: i generici si possono acquistare all'estero, ALTROCONSUMO (April 5, 2017), https://www.altroconsumo.it/salute/diritti-insalute/news/epa tite-c#.

Europa-G7 Leaders' Declaration — Biarritz, France, 26 August, 2019, EUROPEAN COUNCIL, https://www.consilium.europa.eu/en/press/press-releases/2019/08/26/g7-leaders-declaration-biarritz-26-august-2019/.

Members and Observers, WORLD TRADE ORGANIZATION, https://www.wto.org/english/thewto_e/whati s_e/tif_e/org6_e.htm.

UN LIST OF LEAST DEVELOPED COUNTRIES, https://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx.

WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines, WORLD TRADE ORGANIZATION (January 23, 2017), https://www.wto.org/english /news_e/news17_e/trip_23jan17_e.htm.

Other Sources

AFRICAN EXPORT-IMPORT BANK (2018), AFRICAN TRADE REPORT 2018: BOOSTING INTRA-AFRICAN TRADE : IMPLICATIONS OF THE AFRICAN CONTINENTAL FREE TRADE AREA AGREEMENT.

AFRICAN UNION (2012), PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA: BUSINESS PLAN, 30 (2012), https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa.

China to Raise Penalties on IP Theft in Trade War Compromise, SOUTH CHINA MORNING POST (November 25, 2019, 4:15 PM), https://www.scmp.com/tech/policy/article/3039232/china-raise-penalties-ip-theft-trade-war-compromise.

EAST AFRICAN COMMUNITY (2016), EAST AFRICAN COMMUNITY REGIONAL PHARMACEUTICAL MANUFACTURING PLAN OF ACTION (2012-2016).

EAST AFRICAN COMMUNITY (2017), 2ND EAC REGIONAL PHARMACEUTICAL MANUFACTURING PLAN OF ACTION 2017-2027.

Guennif, Samira & Shyama Ramani, *Catching Up in Pharmaceuticals: A Comparative Study of India and Brazil*, HAL (2010), http://econpapers.repec.org/RePEc:hal:cepnwp:hal-00632439.

Salomon, Joshua (2006), *Global Burden of HIV/AIDS in the Year 2000*, WORLD HEALTH ORGANIZATION, https://www.who.int/healthinfo/publiccations/gbdhivaids.pdf.

臺灣大學學術期刊資料庫

THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2015 SPECIAL 301 REPORT (April 2015).

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, *Dispute Settlement, World Trade Organization, 3.14 TRIPS* 5, U.N. Doc. UNCTAD/EDM/Misc.232/Add.18 (2003), https://unctad.org/en/Docs/edmmisc232add 18_e n.pdf.

Watal, Jayashree & Leticia Caminero (2018), *Least-developed Countries, Transfer of Technology and the TRIPS Agreement* (World Trade Organization Economic Research and Statistics Division, Working Paper No. ERSD-2018-01), https://www.econstor.eu/bitstream/10419/176766/1/1016547994.pdf.

臺灣大學學術期刊資料庫