



# GLOBAL CONSTITUTIONALISM IN GLOBAL HEALTH GOVERNANCE AND REGIONAL RESPONSES: EXPLORING AFRICAN AND LATIN AMERICAN COMPULSORY LICENSE REGIMES<sup>1</sup>

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## ***Abstract***

This paper discusses conditions under which a regional compulsory license (CL) regime can be feasible and useful for African and Latin (especially) South American regional organizations. We focus on the African Union (AU), the Southern African Development Community for Africa (SADC) and the Union of South American Nations (UNASUR) for Latin America. International legal patenting of medicines and vaccines have in certain instances negatively affected access especially for the most vulnerable. Leaning on global constitutionalism we argue that regional CLs can play a significant role in enhancing the social equity dimensions of international legal patenting of medicines and vaccines. Our paper unveils the meaning of CL with the aim of better understanding the specific needs served by a mechanism that derogates monopoly rights of patent owners. It also considers the current state of affairs in terms of the use of such licenses in countries of the two regions studied (Africa and South America). A canvass is painted of the state of play of regional pharmaceutical policies with emphasis on the role accorded CLs in them. Conditions under which a regional compulsory licensing regime would be deemed successful are articulated with a clear appreciation of the challenges that can undergird their unrestrained use.

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## 1. Introduction: What is the issue and what is Global Constitutionalism (GC)?

*The use of the constitutional vocabulary ... transforms individual suffering into an objective wrong that concerns not just the victim, but everyone ...*<sup>3</sup>

Is it possible to put in place regional compulsory licensing (CL) regimes for Africa (the African Union (AU) and the Southern African Development Community (SADC)) on the one hand, and for the Union of South American Nations (UNASUR), on the other? And why would regional regimes be considered instead of a global compulsory licensing regime? At the heart of these questions is the use of CL under the framework of International Intellectual Property Law (IPL), as sanctioned by the World Trade Organization (WTO). In recent years International IPL has grown like no other area has in the realm of international law. One of the reasons for this is its inclusion in bilateral and regional preferential trade agreements (PTAs).<sup>4</sup> IPL is a key plank of the arsenal that countries need in addressing the issue of access to medicines especially in terms of the use of CLs. This paper considers the regional dimension of using CLs in accessing more effective affordable medicines and vaccines.

The experiences of some West African states in dealing with the Ebola Virus Disease (EVD) have once more highlighted the importance of having health systems that work in an integrated and holistic way. But of equal concern for many is the challenge of accessing safe, effective, quality and above all affordable medicines and vaccines to address the problem especially mindful that the recent Ebola scare has exposed how the security and very existence of countries can be threatened by such diseases.<sup>5</sup> Access to affordable medicines remains a crucial matter. When medications are expensive this affects the population as a whole. However it has the most serious and debilitating impacts on the poorest segments of societies. That is why the issue of access to affordable medicines has rightly been regarded as one of the defining human rights struggles. The acme of this was the tussle surrounding access to anti-retroviral medicines

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<sup>3</sup> Martti Koskenniemi, *Constitutionalism as Mindset: Reflections on Kantian Themes About International Law and Globalization*, 8 *Theoretical Inquiries* (2007), at 35.

<sup>4</sup> Holger Hestermeyer, *The Notion of 'Trade-Related' Aspects of Intellectual Property Rights: From World Trade to EU Law – and Back Again*, *International Review of Intellectual Property and Competition Law (IIC)* (2013), 925-932, at 925.

<sup>5</sup> Alexandra L. Phelan, Lawrence O. Gostin, and Daniel Lucey, *A United Nations Security Council Resolution is Essential to Preventing the Threat to International Peace and Security Posed by Ebola*, *O'Neill Institute* (18 September 2014), at 1.

(ARVs) over the past two decades.<sup>6</sup> A salient aspect of the struggle was over dilution of stringent intellectual property rights (IPR) measures that were supported by brand pharmaceutical companies. Some of these measures that are even stricter than WTO disciplines are currently included in many PTAs. Correa argues that IPR provisions in PTAs between poor and advanced countries do not take account of the socio-economic needs of populations in weaker states. He takes the Free Trade Agreement (FTA) between the United States (US) and Central American States and the DR (CAFTA DR) as a good example. Despite the fact that Central American States only account for 0.36% of the world's pharmaceutical sales, the CAFTA DR with the US contains the most stringent IPR provisions e.g., on test data exclusivity making it hard for generic companies to access prior developed data sets generated by patent holders for marketing approval. The CA states were required by the US to include data exclusivity (that is not in WTO's Agreement on Trade Related Aspects of Intellectual Property or TRIPS) in a manner that may prevent generic companies from obtaining marketing approval of their products for up to 10 years.<sup>7</sup> A challenging element in this and other FTAs is "the lack of proportion between the high costs imposed on developing countries and the low benefit derived by the intended beneficiaries."<sup>8</sup>

All these issues have generated a strong human rights approach toward access to affordable medicines and vaccines. As Correa notes, human rights once regarded as diffused are fast becoming an effective tool with which to deal with the impact of IPRs in the area of health especially in those contexts where the right to health has been constitutionalized.<sup>9</sup> In the case of the European Union (EU)-India FTA parlays, many of the proposed provisions will have negative impacts in terms of access to health and food and the respective human rights.<sup>10</sup> Besides the human rights aspects relating to access, a resource argument can also be provided. Walls, Smith and Drahos argue that ongoing bilateral and regional PTAs, which involve considerable risks to public health have placed serious demands on governments to strengthen

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<sup>6</sup> Allan M. Brandt, How AIDS Invented Global Health, 368(23) *The New England Journal of Medicine* (6 June 2013), 2149-2152, at 2153.

<sup>7</sup> Carlos M. Correa, High Costs, Negligible Benefits from Intellectual Property Provisions in FTAs, *International Review of Intellectual Property and Competition Law (IIC)* (2013), 902-906, at 903.

<sup>8</sup> Correa, High Costs, at 904.

<sup>9</sup> Correa, High Costs, at 905.

<sup>10</sup> N.S. Gopalakrishnan, Principles for Intellectual Property Provisions in Bilateral and Regional Agreements – Reflections on the Ongoing Negotiations of an EU-India FTA, *International Review of Intellectual Property and Competition Law (IIC)* (2013), 920-925, at 923.

administrative regulatory capacities with regard to negotiation, implementation and on-going management of PTAs.<sup>11</sup> The capacities needed are skills-intensive, expensive and need a considerable infrastructure which, poorer countries find hard to afford. Issues to be worried about are not only TRIPS+ provisions but WTO-X ones that are completely outside the WTO framework.<sup>12</sup> They submit that expanding IPR chapter provisions have impact on ever greening of patents. The authors report the case between Eli Lilly and Canada for 500m US dollars under the investor state dispute settlement (ISDS) mechanism of NAFTA for the revocation of patents on two drugs that failed to show substantial benefit, even though the revocation of those patents was upheld in the courts.<sup>13</sup> They call for more collaboration as between developing countries themselves to deal with these issues concluding that: “South-South regulatory learning and diffusion – and indeed, coordinated action – is just as important as North-South learning in this context.”<sup>14</sup>

In this study we lean on the concept of Global Constitutionalism (GC) to make a case for using the mechanism of regional CL in pushing for better access to affordable medicines and vaccines. In many instances individual countries find it hard to negotiate better pharmaceutical terms with large research or brand pharmaceutical companies that use patents to retain monopoly rights over vital medications, which they often tend to over price. The idea of GC considers ways of incorporating critical precepts of constitutional law for application in the international legal order. Peters defines global constitutionalism as “an academic and political agenda that identifies and advocates for the application of constitutionalist principles in the international legal sphere in order to improve the effectiveness and the fairness of the international legal order.”<sup>15</sup> For her, states are not goals in themselves but are tools to meet the needs of humanity.<sup>16</sup> Some of the underlying precepts of GC are: a) humanization of sovereignty, b) importance of majoritarian decision-making as partly replacing the principle of state consent, c)

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<sup>11</sup> Helen L Walls, Richard D Smith and Peter Drahos, Improving Regulatory Capacity to Manage Risks Associated with Trade Agreements, 11(14) *Globalization and Health* (2015), 1-5, at 1.

<sup>12</sup> Walls et al., Improving Regulatory Capacity, at 1.

<sup>13</sup> Walls et al., Improving Regulatory Capacity, at 2.

<sup>14</sup> Walls et al., Improving Regulatory Capacity, at 4.

<sup>15</sup> Anne Peters, The Merits of Global Constitutionalism, 16(2) *Indiana Journal of Global Legal Studies* (Summer 2009), pp. 397-411, at 397.

<sup>16</sup> Peters, The Merits, at 398.

formal acceptance of universal treaties as the basis on which to build such constitutionalization and d) increasing legalization and juridification of settlement of international disputes.<sup>17</sup>

To be clear, in this study we use GC as distinct from global or international constitutionalization. We understand global constitutionalization as the process of granting or denying law-making authority to a centralized authority.<sup>18</sup> So global constitutionalization does not necessarily improve the fairness of the international legal order: some global constitutionalization does, others not. The example above of the WTO having been granted the authority to make International IPL serves as illustration: many would argue that this global constitutionalization did not improve the fairness of the international legal order. Thus GC appears as the critical twin of global constitutionalization: an approach that “uncovers legitimacy deficits” and “suggests remedies”.<sup>19</sup>

Many strictures have been leveled at GC. Some of the criticisms of GC include firstly, artificial construction of social legitimacy. For some critics “constitutionalist reconstruction might fraudulently create the illusion of legitimacy of global governance.”<sup>20</sup> Second, the constitutionalist reading of the law is too idealist and fails to mirror the realist world which governments have to deal with. Third, advocates tend to be scholars and not politicians. Fourth the concept suffers from “oversell and vagueness.” Fifth, if all international law is constitutional then actually nothing ends up being constitutional. Sixth, GC may be anti-pluralist and too European-biased or Eurocentric. Finally, GC pretends to be too apolitical and above politics.<sup>21</sup>

To all these strictures, Peters’ response is a firm rebuttal. For her, “the idea is not to create a global, centralized government, but to constitutionalize global, polyarchic, and multilevel governance”.<sup>22</sup> In her opinion, GC must indeed take more fully into account the needs and interests of developing countries and their populations. For those who still doubt the enforcement power of international law she notes: “The constitutionalist approach helps to

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<sup>17</sup> Peters, *The Merits*, at 399.

<sup>18</sup> Jeffrey L Dunoff and Joel P Trachtman. A Functional Approach to International Constitutionalization: in, *Ruling the World? Constitutionalism, International Law and Global Governance*. New York, Cambridge University Press, 2009. Pp. 3-35, at 4.

<sup>19</sup> Peters, *The Merits*, at 397.

<sup>20</sup> Peters, *The Merits*, at 400.

<sup>21</sup> Peters, *The Merits*, at 400-407.

<sup>22</sup> Peters, *The Merits*, at 404.

overcome the narrow focus on sanctions and on top-down enforcement.”<sup>23</sup> She also alludes to Neil Walker for whom constitutional discourse has a “responsibilising potential.”<sup>24</sup> Furthermore, in this conception of GC, regional constitutionalization is not excluded, and can be a necessary complement to global constitutionalization in order to improve the fairness of the international legal order. Again, International IPL is a case in point.

Given the challenges ushered by globalization in the realm of health, going beyond the state has not only become fashionable but imperative. This is so as pathogens respect few if any boundaries.<sup>25</sup> One would then expect that regional and global actors be increasingly involved in a more structured manner in dealing with the myriad of health challenges that defy borders. Yet in the important actors that mark this field, regional organizations are still not considered to be key actors in the global health system which some have noted is constituted of national governments; the United Nations (UN) system, multilateral development banks (MDBs), global health initiatives, philanthropic organizations, global civil society organizations (CSOs) and non-governmental organizations (NGOs), industry, professional associations and even academic institutions with no mention of regional organizations.<sup>26</sup> We argue that regional organizations are indeed an important level of responding to the global challenges related to health and especially in the arena of accessing affordable vital medicines and vaccines. They can even be more effective in their actions if pooled initiatives can be fostered including through the use of regional CLs. In the paragraphs that follow the following questions are answered: what is a Compulsory License (CL) and what needs are meant to be addressed by CLs (2)? What is the lay of the land on the use of CLs in countries of the two regions studied (3)? What is the state of regional pharmaceutical policies and what is the role for CLs in them (4)? What are the conditions under which a regional CL for the African and Latin American (UNASUR) regions can work (5)? What are the problems in using the regional CL approach (6)? In concluding we allude to some insights and policy implications (7). In answering these questions the authors use the

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<sup>23</sup> Peters, *The Merits*, at 405.

<sup>24</sup> See Peters, *The Merits*, at 410 and Neil Walker, *The EU and the WTO: Constitutionalism in a New Key*, in: *The EU and the WTO: Legal and Constitutional Issues* (Grainne de Burca and Joanne Scott eds., 2001), at 53.

<sup>25</sup> Lawrence O. Gostin and Devi Sridhar, *Global health and the law*, 370(18) *The New England Journal of Medicine* (1 May 2014), 1732-1740, at 1732.

<sup>26</sup> Julio Frenk and Suerie Moon, *Governance Challenges in Global Health*, 368(10) *The New England Journal of Medicine* (7 March 2013), 936-942, at 938.



principal regional pharmaceutical and medicines policy documents of the AU, UNASUR and SADC. Secondary literature review was conducted and useful correspondences were exchanged with health and pharmaceutical policy officials in some of the regional organizations.

## **2. What is a Compulsory License (CL) under WTO's TRIPS and what needs are meant to be addressed by CLs?**

CLs as opposed to voluntary licenses (VLs) are permits granted to applicants allowing them to produce patented products without the authorization of the patent holder. Under the World Trade Organization (WTO) Annex 1C Agreement on Trade Related Aspects of Intellectual Property (Art 33) a patent term is for 20 years. CLs are recognized under Art 31 of TRIPS under strict conditions, which are more robust than those in Art 5(A) of the Paris Convention.<sup>27</sup> CLs are often used by governments especially in cases of non-working of the patent, in instances where the manufactured products are inadequate to meet the public's needs and above all in cases of emergency. They are vital to meet drug shortages and availability of cheap products. They further the public's interests of poor countries and are regarded as a Robin Hood tool for developing countries.<sup>28</sup> The current CL norms in TRIPS (although not qualified in TRIPS as CLs) owe their presence in the text to the deft negotiation skills of Indian negotiators.<sup>29</sup>

The provision that allows for use of CL under TRIPS only allows such use under very strict conditions. For instance, Art 31(a) is to the effect that "authorization of such use shall be considered on its individual merits." CLs can be granted only where the prospective licensee has made efforts to obtain authorization from the patentee on "reasonable commercial terms and conditions" and that these efforts have not been successful within a reasonable period of time (Art 31(b)). Art 31(d) TRIPS then provides a proportionality rule by stating that the scope of the license must be limited to the purpose for which it was granted. In Art 31(d) CLs must be non-exclusive: it means that the patentee can continue to exploit the invention and directly

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<sup>27</sup> Charles R. McManis and Jorge L. Contreras, *TRIPS and Developing Countries – Towards a New World Order?* (Gustavo Ghidini, Rudolph J.R. Peritz & Marco Ricolfi, eds., 2014 (Edward Elgar)). Also listed in Social Science Research Network (SSRN) as: American University, WCL Research Paper No. 2014-16, at 119.

<sup>28</sup> Enrico Bonadio, Compulsory Licensing of Patents: The Bayer/ Natco Case, *10 European Intellectual Property Review* (2012), 719-728, at 727-728.

<sup>29</sup> Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, *Journal of Law, Medicine and Ethics* (Summer 2009), 247-263, at 248.

compete with the licensee. Under Art 31(e) CLs must be non-transferable. The use must be authorized predominantly for the supply of the domestic market of the country authorizing such use under Art 31(f) and not for example for re-export. Under Art 31(g) CLs should expire when the circumstances which led to them cease to exist. Pursuant to Art 31(h) the patentee must receive adequate remuneration.<sup>30</sup>

The evolution of the use of Art 31 TRIPS has been very uneven, at best. The discussions on CL came to a head in the late 1990s and in the run-up to the WTO Doha conference that was held in 2001. These efforts culminated in the adoption of the Doha Declaration, paragraph 6 of which sought to address the issue of production for (predominantly) domestic consumption in the use of the Art 31(f) exception. Efforts have been made that have resulted in the codification of the responses to the Doha Declaration paragraph 6 demands into a WTO TRIPS amendment in 2005. In recent years, there has been increase in access especially of ARVs in poor countries due to more effective philanthropic activities, bilateral aid and public private partnerships.<sup>31</sup> Beall and Kuhn look at the impact that the Doha Declaration has had on the issuance of CLs. They find that the use of CLs or the threat of their use has been an important negotiating tool for poor countries leading to drug discounts and use of VLs. They also note that CLs have been used more by upper middle income countries (UMICs) than by least developed countries (LDCs) and low income countries (LICs). So for them, CLs have little direct impact for the poorest countries especially as most of the drugs are not even patented in LDCs and LICs.<sup>32</sup> Unlike LDCs and LICs, UMICs have the production and distribution capacities to administer CLs and they may also have the weight to withstand retaliatory actions.

CLs were not commonly used before 2001.<sup>33</sup> Between 2001 and 2006 there was a high level of CL applications. From 2006 onward there has been a slump in CL activities. Beall and Kuhn find no CL use for high-impact diseases with patented treatments such as malaria, multi-drug resistant tuberculosis and sepsis. They conclude that: “the efforts put forth during the Doha conference in regard to pharmaceutical CLs will have a negligible long-term impact on the

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<sup>30</sup> See Art 31 and Art 31bis of TRIPS and also see Bonadio, *Compulsory Licensing of Patents*, at 724-726.

<sup>31</sup> Reed Beall and Randell Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9(1) *PLoS Medicine* (January 2012), 1-9.

<sup>32</sup> Beall and Kuhn, *Trends*, at 6.

<sup>33</sup> Beall and Kuhn, *Trends*, at 7.

regular use of CLs or on global access to pharmaceuticals.”<sup>34</sup> As such advocates who pushed for the Doha Declaration reforms have had little success in engaging trade as a positive, proactive force for addressing health gaps. This is attributable to the fact that some developing countries lack the requisite capacities to negotiate the terms of use under the CL regime of the WTO. As such using more tailored regional approaches that are consistent with WTO disciplines but more reflective of regional realities is advised.

### **3. What is the lay of the land on use of CLs in countries of the two regions?**

CLs received ample attention following the attacks of 11 September in 2001. Love reports how in 2001 the Secretary of the US Department of Health and Human Services (DHHS) Tommy Thompson used the threat to activate §28 USC 1498 to authorize imports of generic Ciprofloxacin, for stockpiles against a possible anthrax attack.<sup>35</sup> In Canada, on 18 October 2001, Health Canada equally set aside the Bayer patents for Ciprofloxacin and authorized generic manufacture for purposes of building a stockpile as protection against an attack of certain strains of anthrax. Also on 14 May 2004 Canada passed BILL C-9: an Act that amended the Patent Act and the Food and Drugs Act.<sup>36</sup> So while CLs are often invoked mainly in the context of developing countries, they have also been used and are used in the developed world as well. Many countries in the regions studied have issued CLs in the past.

#### **3.1 In Latin America**

In Argentina, on 18 October 2005 Health Minister Gines Gonzalez Garcia announced that the government would issue CL for Tamiflu but the patents for Tamiflu had not been granted for

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<sup>34</sup> Beall and Kuhn, Trends, at 7.

<sup>35</sup> James Packard Love, Recent examples of the use of compulsory licenses on patents, *2 Knowledge Ecology International Research Note* (8 March 2007), at 3.

<sup>36</sup> Love, Recent examples, at 5. For Europe CLs have been used in: the United Kingdom (UK), Germany (in 2000 Roche asked and obtained in 2001 Blood Screening HIV Probe owned by Chiron and as *quid pro quo* Roche promised to forfeit its demand for a CL), Belgium (Brussels modified its laws in 2005 with introduction of a new CL for public health purposes). Use in Asia has been mainly in: India, Indonesia (5 October 2004: Indonesia issued government use CL to manufacture generics of HIV/AIDS drugs lamivudine and nevirapine until the end of patent terms respectively in 2011 and 2012. Production was started by PT Kimia Farma with royalty rates at 0.5% of net selling value), Malaysia (29 September 2004: the Malaysian Minister of Domestic Trade and Consumer Affairs issued a two-year government use CL to import from India didanosine (DDL) and zidovudine (AZT) and Combivir. A royalty of 4% of value of the generic product was proposed), Thailand (29 November 2006: the Thailand Ministry of Health announced a government use CL to import from India and locally manufacture Efavirenz until 2011 and at proposed royalty of 0.5 of the price of the generic product). Korea and Taiwan also issued CLs.

Argentina as was later revealed.<sup>37</sup> Also in Chile in December 2004 Essential Inventions requested a CL to supply Glivec to the country.<sup>38</sup> Ecuador has also had experience with CLs. In 2003 Acromax a local manufacturer applied for a CL from the patent office for a the fixed dose combination of Lamivudine (3TC) and AZT (sold under the trade name Combivir by Glaxo or GSK) but the request was rejected and GSK granted Ecuador preferential prices on their HIV/AIDS medicines.<sup>39</sup>

In South America, Brazil is the jurisdiction in which CLs for patented pharmaceutical medicines and vaccines have been most widely invoked. Art 68 of Brazil's Patent Law required local working else CL could be issued. Just before former US President Bill Clinton left office the US challenged Brazil and threatened to take it to the WTO's Dispute Settlement Body in January 2001. It withdrew the threat in June 2001. Basically the law required that CL could be issued if the manufacturer did not produce the patented product locally in Brazil. In early 2001 the Brazilian government reached a settlement with Merck for price discounts for Efavirenz in return for not issuing a CL. A similar deal was reached with Roche for Viracept in August 2001 when Brazilian health minister Jose Serra had threatened use of CL. On 5 September 2003 the government again issued a decree that it will import or manufacture generic ARVs without the consent of the companies. The ARVs in question were Lopinavir, Efavirenz and Nelfinavir. The health ministry wanted a discount of 40% but brand companies could only offer 6.7%. However, Brazil and Merck reached an agreement in November 2003.<sup>40</sup> In 2005 Health Minister Humberto Costa signed a decree declaring the patent of Kaletra appropriate for CL for public interest but an agreement was reached with Abbott with price discount of 46%.<sup>41</sup> A similar threat for the manufacture of Viread owned by Gilead was also made but both sides reached a deal in 2006 leading to a price discount of about 50% for Brazil.<sup>42</sup> The same case obtained for CL on Gleevec owned patents whereby an agreement was reached for a discount of more than

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<sup>37</sup> Love, Recent examples.

<sup>38</sup> Love, *ibid.*

<sup>39</sup> Love, *ibid.*

<sup>40</sup> Love, *ibid.*

<sup>41</sup> Love, *ibid.*

<sup>42</sup> Love, *ibid.*

65%.<sup>43</sup> This shows how Brazil has deftly used unilateral threats of CLs to obtain better deals in terms of affordable medicines for its citizens. What is the situation in Africa?

### 3.2 Africa

In Africa CL is “fairly common” but “not widely publicized.”<sup>44</sup> Cameroon, Ghana, Guinea, Eritrea all considered CL for ARVs in 2005. All these were CLs for importation of medical products. So too was that of Swaziland of 20 April 2004 issued on grounds of public emergency by the Ministry of Health and Social Welfare.<sup>45</sup> The authorization was for procurement of ARVs at the best affordable prices “irrespective of any patent or other Intellectual Property protection applicable in Swaziland...”<sup>46</sup>

That of Mozambique of 5 April 2004 was for the local production by Pharco Mocambique Lda of ARV fixed dose combinations and royalties were not to exceed 2% of sales. On 21 September 2004 Zambia also issued CL for local manufacture of ARV fixed dose combination by Pharco Ltd with royalty of 2.5%. As early as 2002, Zimbabwe had issued a CL to deal with the aids emergency. The CL was for use or import of aids medicines. Local production was through Indian assistance via Varichem Pharmaceuticals Ltd.<sup>47</sup>

In South Africa the situation is one whereby private persons have been active in pushing for use of legal mechanisms against brand companies that abuse their market positions. On 7 March 2001 Cipla (an Indian generics producer) requested the South African Department of Trade and Industry to issue CL to patent holders for 8 ARVs including nevirapine and efavirenz. Hazel Tau of Treatment Action Campaign (TAC) filed a complaint to the South African Competition Commission against GSK and Boehringer Ingelheim on grounds of excessive pricing of nevirapine, ritonavir, lamivudine and combivir in September 2002. On 16 October 2003 the Competition Commission found against GSK on unfair competition and excessive pricing. Nonetheless, in December 2003 the South African Competition Commission reached a deal with

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<sup>43</sup> Love, *ibid.*

<sup>44</sup> Love, *ibid.*

<sup>45</sup> Love, *ibid.*

<sup>46</sup> Love, *ibid.*

<sup>47</sup> Love, *ibid.*

GSK and a similar settlement was reached with Boehringer Ingelheim.<sup>48</sup> In 2014 the South African health minister Aaron Motsoaledi made clear his plans of reforming the country's patent laws to make it harder for pharmaceutical companies to obtain patent extensions based on demonstrably minor changes.

#### **4. What is the state of Regional Pharmaceutical Policies and what Role for CLs in them?**

Many regional organizations now include sustainable development and poverty reduction as part of their objectives. Some of them such as UNASUR and SADC have developed important normative instruments that focus on health in the reduction of social inequities. Within the ambit of health the regional entities have focused on developing regional strategies to ensure access to affordable pharmaceutical products including medicines and vaccines. The discussions surrounding regional approaches to the access challenges are not new. Abbott and Reichmann have suggested that developing states engage in pooled procurement.<sup>49</sup> Bird and Cahoy propose that there be collective bargaining arrangements steered by regional trade associations.<sup>50</sup> These regional approaches could be building blocks of a proposed WHO Convention on International Tiered Pricing and Compulsory Licensing.<sup>51</sup> As noted, increasingly there are efforts being made by some regional organizations to develop pharmaceutical and medicines policies. Within these policies there is often the recognition that CLs are tools to ease access to more affordable medicines.

The advantages of using a regional CL unlike a national one are as follows. First, use of regional CLs means dispersed and more diluted effects of threatened retaliatory actions. There are risks that in using unilateral (national as opposed to regional and collective) CLs as Thailand did the US may retaliate. The United States Trade Representative (USTR) placed Thailand under the 2007 Special 301 "Priority Watch List Surveillance" and threatened to terminate Thailand's

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<sup>48</sup> Love, *ibid*.

<sup>49</sup> Frederick M Abbott and 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 *Journal of International Economic Law* (2007), 957.

<sup>50</sup> Robert Bird and Daniel R. Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach, 45(2) *American Business Law Journal* (2008) 283-330.

<sup>51</sup> Gorik Ooms, Lisa Forman, Owain D. Williams and Peter S Hill, Could international compulsory licensing reconcile tiered pricing of pharmaceuticals with the right to health? 14(37) *BMC International Health and Human Rights* (2014).

Generalized System of Preferences (GSP) privileges to export certain products to the US at low or no tariffs.<sup>52</sup> Participating in the application of regional CLs for vital medicines dilutes the risks of such retaliation even if it does not entirely eliminate it. Second, regional and collective CLs can engender the maximization of production and distribution economies of scale. Finally such regional CLs are also less burdensome from the perspective of patent holders or companies that would prefer to deal with unique applications rather than a multiplicity of petitions.

#### **4.1 Latin America with focus on UNASUR in South America**

At the 67<sup>th</sup> World Health Assembly in Geneva in May 2014 UNASUR member states took a common position on ten issues. Amongst these were access to vaccines and medicines.<sup>53</sup> In May 2014 the 7<sup>th</sup> South American Health Council Technical Group on Universal Access to Medicines (GAUMU) meeting was held.<sup>54</sup> In the GAUMU meeting held in Buenos Aires in May 2014 update was presented of the Common Initiative Fund projects including medicines price database and mapping of regional capacities in medicines production. These are led by the *Instituto Sudamericano de Gobierno en Salud* (ISAGS) and GAUMU. In 2013 ISAGS (as part of its annual functioning plan) and GAUMU decided to undertake a mapping of medicines policies in Latin America. The rationale of the project was stated as follows:

A diagnosis of the medicines policies of certain selected Regional Blocs such as UNASUR, MERCOSUR,<sup>55</sup> CAN,<sup>56</sup> CARICOM<sup>57</sup> and ALBA<sup>58</sup> – always making use of already consolidated information regarding the sub-regional progress in implementing referred scattered information to the current capacities of UNASUR member countries – may serve to enhance strategic decisions regarding medicine production and consequently improve care in health systems ... Understanding the building blocks of a medicines policy that enables the coordination of incentives and stimuli to advance regional productive sovereignty, to strengthen the Bloc and to produce effective, quality and safe medicines ...<sup>59</sup>

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<sup>52</sup> Reichmann, Compulsory licenses, at 258.

<sup>53</sup> ISAGS, UNASUR Common Positions Make Global Health Agenda Move Forward, *ISAGS Report*, Rio De Janeiro, June 2014, at 1.

<sup>54</sup> ISAGS, Technical Groups of the South American Health Council Make Advancements on Projects, *ISAGS Report*, Rio De Janeiro, May 2014, at 2.

<sup>55</sup> MERCOSUR: Common Market of the South.

<sup>56</sup> CAN: The Andean Community.

<sup>57</sup> CARICOM: The Caribbean Community.

<sup>58</sup> ALBA: Bolivarian Alliance for the Peoples of Our America.

<sup>59</sup> Thiago Botelho Azeredo, Mapping of the Productive Capacity of Medicines; Medicines Policies of Regional Blocs: UNASUR, MERCOSUR, CAN, CARICOM and ALBA and Mapping of Bilateral Cooperation in Production and/ or Purchase of Medicines in countries of South America, Rio De Janeiro, May 2014. The report is available at 2015 ISAGS: [http://www.isags-unasur.org/it\\_biblioteca.php?cat=7&bb=247&lg=3](http://www.isags-unasur.org/it_biblioteca.php?cat=7&bb=247&lg=3), at 7

The regulatory canvas of the medicines reality in Latin America is such that MERCOSUR, CAN and CARICOM have normative medicines policies. UNASUR and ALBA have facultative initiatives that are non-binding. The relevant policy document for UNASUR is Resolution 9 of 24 November 2009 adopted by the Health Council in Guayaquil.<sup>60</sup> The picture is different for the other Latin American blocs: MERCOSUR has the Medicines Policy of MERCOSUR (Agreement RMS/MERCOSUR N°005/00 of December 2000); CAN, the Andean Medicines Policy (Resolution REMSAA 30/455 of March 2009) and in the Caribbean there is the Caribbean Pharmaceutical Policy.<sup>61</sup> It can be deduced that non-members have signed up for some of the regional medicines policies: Chile and Bolivia (MERCOSUR), Chile and Venezuela (CAN). For UNASUR the opposite obtains whereby Resolution 9 of 2009 does not include the signatures of all the member countries.<sup>62</sup>

Three main goals are included in national medicines policies replicated at the regional level: ensuring equitable access to medicines; ensuring the quality safety and efficacy of medicines in circulation; and promoting the rational use of medicines. UNASUR Resolution 9 is unique as it has no specified goal as such but notes that access to affordable medicines is important in enabling human rights to health.<sup>63</sup> The strategic areas of intervention for most of the regional blocs in Latin America are: a) universal access, b) quality, efficacy and safety regulation, c) rational use and d) research and development (R&D). Even though the documents of UNASUR and ALBA are not normative policy texts as per the categorization of the WHO they also have elements that can be classified according to the strategic areas of intervention.<sup>64</sup>

Strategic areas covered under UNASUR's Resolution 9 on access to affordable medicines include the promotion of comprehensive policies to secure access to affordable and quality essential medicines, vaccines and other technologies, and the inclusion of TRIPS advantages and allowing for the use of CLs, management of intellectual property, and fostering of health production

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<sup>60</sup> UNASUR, Resolución 09/2009, *Promover el desarrollo de políticas integradas que aseguren acceso a medicamentos esenciales, vacunas y otras tecnologías sanitarias, promoviendo investigación y desarrollo basados en las necesidades sanitarias*, Guayaquil, Ecuador, Unión de Naciones Suramericanas, 2009.

<sup>61</sup> Azeredo, Mapping, at 12.

<sup>62</sup> Azeredo, Mapping, at 12.

<sup>63</sup> Azeredo, Mapping, at 14.

<sup>64</sup> Azeredo, Mapping, at 15.



complex, amongst others.<sup>65</sup> While others do, the UNASUR Resolution 9 does not focus on quality, efficacy, safety/ regulation (for example, putting in place pharmaco-vigilance systems). It also includes nothing on rationale use.<sup>66</sup> But these elements are included in the texts of the other Latin American regional blocs for the most part.<sup>67</sup> On R&D, the Health Council Resolution 9 has clauses that aim at fostering R&D in the pharmaceutical sector.<sup>68</sup>

## **4.2 Africa**

The optimal scenario in the case of Africa is to have a single framework CL regime which can be applied to all AU countries. Within this structure sub regional entities such as SADC can also align their CL practices so that they are coherent with this AU/NEPAD<sup>69</sup> framework. As it is only a framework it entails that the nature of the demands will vary from one sub region to the next. It will also be vital that various countries are aligning their obligations in regimes such as those of OAPI<sup>70</sup> and ARIPO<sup>71</sup> to the AU's framework CL. SADC is only used here as an example of a sub-regional organization. The goal is to indicate convergences between SADC and the AU. The main insight to be drawn here is that through initiatives such as the African Medicines Regulation Harmonization (AMRH) Program of NEPAD there is room for more alignment between the AU and regional economic community (REC) regimes as such alignment is already taking place.

### **4.2.1 The African Union (with NEPAD's AMRH Program)**

Africa faces many health challenges. Chan notes that there have been gains nowhere near enough and that the people of Africa bear the greatest burden of ill health and disease and this

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<sup>65</sup> Azeredo, Mapping, at 18. In UNASUR on four countries have ratified the TRIPS Amendment of 2005: Argentina (20 October 2011), Brazil (13 November 2008), Chile (26 July 2013) and Colombia (7 August 2009). See WTO, Members Accepting Amendment of the TRIPS Agreement, (27 April 2015) at [https://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm)

<sup>66</sup> The strategy of selection of medicines is revisited and reinforced through the definition of national and regional Lists of Essential Medicines (LEM), in addition to the elaboration of Therapeutic Formularies, Clinical Protocols and Therapeutic Guidelines for the directing prescription and dispensing activities.

<sup>67</sup> Azeredo, Mapping, at 18-19.

<sup>68</sup> Azeredo, Mapping, at 20.

<sup>69</sup> NEPAD: New Partnership for Africa's Development.

<sup>70</sup> OAPI: Organisation Africaine de la Propriété Intellectuelle. It is based in Yaoundé, Cameroon. It is composed of 17 member states.

<sup>71</sup> ARIPO: African Regional Intellectual Property Organization. ARIPO was formed in 1976, following the Lusaka Agreement. It is headquartered in Harare: Zimbabwe and composed of 19 member states.

can be attributed to various reasons of climate, history and geography.<sup>72</sup> Normative policy efforts have been made by Africa's political leaders to cooperate in dealing with the numerous challenges in health. The main text in this respect is the African Health Strategy. The African Health Strategy of 2007 states its goal as follows: "The goal of this Africa Health Strategy is to contribute to Africa's socio- economic development by improving the health of its people and by ensuring access to essential health care for all Africans, especially the poorest and most marginalized by 2015."<sup>73</sup> Specifically on access it is made clear that "Universal access to essential health care must be supported with adequate supply of commodities including essential medicines ..."<sup>74</sup> The local production of pharmaceuticals and other essential commodities is also underscored.<sup>75</sup> In this respect reference is made to the Pharmaceutical Manufacturing Plan for Africa (PMPA) in the following terms:

Support should be given to the Pharmaceutical Manufacturing Plan for Africa which is aimed at realising the economic production at volume of quality generic medicines and other commodities, with countries showing solidarity and removing the tariff and non-tariff barriers to its success.<sup>76</sup>

The PMPA of 2007 is an important document.<sup>77</sup> It makes clear that TRIPS and the Doha Declaration shall be fully maximized.<sup>78</sup> It is noted in the PMPA that the nature of the needs and the nature of the markets in Africa vary. For instance, Egypt, Morocco and Tunisia can provide between 60% and 95% of their domestic essential medicines needs at the national level.<sup>79</sup> It is highlighted that TRIPS flexibilities and national patent laws also have an impact.<sup>80</sup> Production is largely in the hands of the private sector as governments handle regulations.<sup>81</sup> There is need to decide on priority medicines (diseases) and also need to harmonize Essential Medicines Lists.<sup>82</sup> Also, intra-regionally, decisions have to be made on which countries or country will produce

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<sup>72</sup> Margaret Chan, On the Road to Health Equality, *Harvard International Review* (8 September 2014), at <http://hir.harvard.edu/2014/09/on-the-road-to-health-equality/>

<sup>73</sup> African Union, African Health Strategy, 2007-2015, at [http://www.nepad.org/system/files/AFRICA\\_HEALTH\\_STRATEGY\(health\).pdf](http://www.nepad.org/system/files/AFRICA_HEALTH_STRATEGY(health).pdf), at paragraph 26.

<sup>74</sup> African Union, African Health Strategy, at paragraph 64.

<sup>75</sup> African Union, African Health Strategy, at paragraph 66.

<sup>76</sup> African Union, African Health Strategy, at page 14.

<sup>77</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, CAMH/MIN/7(III) 2007, at <http://sa.au.int/en/sites/default/files/Pharmaceutical%20manufacturing%20plan%20for%20Africa-English.pdf>

<sup>78</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 1.

<sup>79</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 7.

<sup>80</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 10.

<sup>81</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 14.

<sup>82</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 17.

what commodity.<sup>83</sup>

In 2012 a Business Plan for the PMPA was adopted.<sup>84</sup> The adoption of this Business Plan was in view of implementing the PMPA agreed by African leaders in 2007.<sup>85</sup> It is made clear that non-communicable diseases (NCDs) will overtake communicable diseases (CDs) as the leading cause of death in Africa by 2030. Donors will be reducing their assistance given the financial crisis that peaked in 2008. So it is important to identify how Africa can improve its own capacities for reliable and quality affordable medicines in the area so as not to be reliant on handouts. At the 5<sup>th</sup> meeting of the Conference of African Ministers of Health held in Namibia in 2011 ministers reiterated the need for a Business Plan to implement the PMPA that had been endorsed by AU leaders in Ghana in 2007. They resolved that the goal of the Business Plan should be the development of sustainable supply of affordable, quality essential medicines to improve public health outcomes and contribute to industrial development and economic growth (innovation). While there is aspiration to meet the highest international production standards, it is recognized that this will take time to develop. It is vital that national regulators with oversight of the pharmaceutical manufacturing system have an eye for Good Manufacturing Practices, Good Distribution Practices and Good Warehousing Practices while also paying close attention to pharmaco-vigilance and marketing surveillance.<sup>86</sup>

Manufacturing capacities vary across countries from about 200 production facilities in Nigeria to none in many. About 38 of the 54 countries have some sort of pharmaceutical manufacturing taking place.<sup>87</sup> Regulatory capacities also vary with countries like Algeria, South Africa and Tunisia having very strong regulatory institutions. While there is acknowledgement that local manufacturing needs to grow national governments and regulatory institutions have not done much to reduce high tariffs experienced by some African importers for needed production raw materials. In some cases the import tariffs are about 25%. This is revealing of signs of

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<sup>83</sup> African Union, Pharmaceutical Manufacturing Plan for Africa, at para. 20.

<sup>84</sup> African Union, Pharmaceutical Manufacturing Plan for Africa Business Plan (hereinafter, PMPA Business Plan) (AU Commission-UNIDO Partnership, Addis Ababa, 2012). This came as sequel to a report of the AU and NEPAD. In this report of 2010 their recommendations included aspects of implementing innovation in the countries; ensuring access; manufacturing and capacity building for R&D: see African Union, NEPAD and Council on Health Research for Development (COHRED), Strengthening Pharmaceutical Innovation in Africa : Designing Strategies for National Pharmaceutical Innovation : Choices for Decision Makers and Countries (2010), at 9.

<sup>85</sup> African Union, PMPA Business Plan, at 1.

<sup>86</sup> African Union, PMPA Business Plan, at 2.

<sup>87</sup> African Union, PMPA Business Plan, at 2.

incoherence across government departments in many countries.<sup>88</sup> With the exception of South Africa, Egypt and Ghana few countries are involved in production of active ingredients and the majority mainly deal with packaging.<sup>89</sup> Apart from problems of incoherence and human capacities, there are also issues of cost and inadequate oversight. Other challenges are the underutilization of TRIPS advantages for developing countries; the lack of linkages between industry and academia in Africa and also the lack of linkages between African manufacturers and international ones.<sup>90</sup> The Business Plan sets out a road map with suggestions on how to address some of these problems. Some of the proposals include advocating for the extension of TRIPS flexibilities beyond 2016, expanding Africa's capacity to produce active pharmaceutical ingredients and to help RECs develop tailored strategies to respond to some of the challenges.<sup>91</sup> It is also recommended that the PMPA is implemented in harmony with the AMRH Program of NEPAD.<sup>92</sup> The AU proposes to create a consortium alongside the AMRH initiative to help implement the Business Plan over five years with a cost of 54 million US dollars.

The AMRH was created in 2009 mainly by NEPAD and the Pan African Parliament (PAP) with support of other partners such as the WHO and the Bill and Melinda Gates Foundation (BMGF). Its goal is to promote harmonization of medicines regulation in Africa.<sup>93</sup> The partners include the WHO, the World Bank and the BMGF as key actors. In 2010 a trust fund was created for it and in 2011 the World Bank and the BMGF signed an administration agreement for the financing of the AMRH.<sup>94</sup> African RECs were selected as platforms through which the AMRH will be organized mainly because the secretariats of the extant RECs have the coordinating infrastructure in place to realize registration harmonization.<sup>95</sup> The consortium managing the initiative issued a call for proposals for RECs to develop their medicines registration harmonization projects. The East African Community (EAC) was the first to submit for the Medicines Registration Harmonization (MRH) project. The project for the EAC was launched in

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<sup>88</sup> African Union, PMPA Business Plan, at 2.

<sup>89</sup> African Union, PMPA Business Plan, at 3.

<sup>90</sup> African Union, PMPA Business Plan, at 3.

<sup>91</sup> African Union, PMPA Business Plan, at 4.

<sup>92</sup> African Union, PMPA Business Plan, at 4.

<sup>93</sup> WHO, WHO Support for Medicines Regulatory Harmonization in Africa: focus on East African Community, 28(1) *WHO Drug Information* (2014), at [http://www.who.int/medicines/publications/druginformation/DI\\_28-1\\_Africa.pdf](http://www.who.int/medicines/publications/druginformation/DI_28-1_Africa.pdf), pp. 11-15, at 11.

<sup>94</sup> WHO, WHO Support, at 11.

<sup>95</sup> WHO, WHO Support, at 12.

Arusha in March 2012. The EAC (MRH) goals do not mention CL but they aim to have joint assessments of product dossiers (according to harmonized strict standards) and to conduct joint inspections on manufacturing sites.<sup>96</sup>

The AMRH is timely and could benefit from ideas such as those on a regional CL. This is because efforts are under way now to create an African Union Model Law on Medical Products Regulations and Harmonization. The specific aim is to ensure that drugs circulating on the continent are of good quality and are properly manufactured, stored and distributed.<sup>97</sup> The Model Law will promote local production of pharmaceuticals. The overall goal is to domesticate the law when AU leaders are presented with a draft in January 2016 for approval.

#### **4.2.2 SADC**

The pharmaceutical program as elucidated in SADC's Pharmaceutical Business Plan is in line with goals of the SADC Health Policy of 1997 and Health Protocol of 1999 (that entered into force in 2004).<sup>98</sup> The goal is to ensure availability of essential medicines.<sup>99</sup> One of the strategies amongst many to be used in pursuance of this goal is joint procurement of safe, effective, quality and affordable medicines. It makes clear that CLs can be used as TRIPS flexibilities for RECs (half the members of which should be LDCs).<sup>100</sup> The Common TRIPS flexibilities for LDCs include: a) The decision (IP/C/25) of 27 June 2002 of WTO TRIPS Council which was a waiver that extended the period for the application of Arts 5 and 7 of TRIPS for LDCs in terms of patent protection until at least January 2016. This is a commitment that had been reflected in Para 7 of the Doha Declaration of 2001. b) The General Council Decision of 8 July (WT/L/478) which was also a waiver was basically an exoneration relating to the obligations of LDCs in terms of exclusive rights. c) The Decision of 30 August 2003 of the General Council addressing the issue faced by poor countries with no or limited capacity to manufacture pharmaceuticals when

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<sup>96</sup> WHO, WHO Support, at 12.

<sup>97</sup> AMRH, Major Policy Decision on African Health and Medicine Regulation Reviewed in Central Africa, 10 March 2015 at <http://amrh.org/major-policy-decision-on-african-health-and-medicine-regulation-reviewed-in-central-africa.html>. A similar meeting was held for West Africa in Ghana: AMRH, Improving Access to Good and Quality Medicines in West Africa, 15 February 2015, at <http://amrh.org/improving-access-to-good-and-quality-medicines-in-west-africa.html>

<sup>98</sup> SADC, SADC Pharmaceutical Business Plan 2007-2013 (adopted in 2007), at [https://www.unido.org/fileadmin/user\\_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf](https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf), at 3.

<sup>99</sup> SADC, SADC Pharmaceutical Business Plan, at 4.

<sup>100</sup> SADC, SADC Pharmaceutical Business Plan, at 12.

using CLs: without this waiver it would be hard for SADC countries to (predominantly) import large consignments of medicines through the use of a CL. A General Council Decision of 6 December 2005 (WT/L/641) endorsed a Protocol amending the TRIPS Agreement, which included Art 31bis, fully incorporating the Decision of 2003 as part of the TRIPS Agreement.<sup>101</sup> As part of the constellation of the African Group at the WTO SADC States pushed hard for these advantages regarded a key plank of the Pharmaceutical Business Plan.<sup>102</sup>

All SADC countries allow for the grant of patents directly through their national laws or indirectly through the Patent Cooperation Treaty and ARIPO's Harare Protocol on Patents.<sup>103</sup> New use patents are broadly allowed in the region but Malawi, Namibia and Zambia specifically prohibit patenting of new use pharmaceutical patents. Most SADC states are LDCs and could be taking advantage of the flexibilities especially that of 2002 on wider time horizons but they do not do so as they often have national patent laws. Madagascar, Mozambique and Tanzania do not allow for parallel importation because they have national exhaustion. But Botswana, Mauritius, Namibia, South Africa and Zimbabwe have international exhaustion.<sup>104</sup> All the national patent laws allow for use of CL for failure to meet the needs of the domestic market, anti-competitive behavior, failure to grant voluntary licenses (VLs) on reasonable terms and also in emergencies.<sup>105</sup> CLs and government use licenses are common amongst the states in the region. Of the 15 SADC members (that are also all WTO members), only Botswana, Mauritius and Zambia have ratified the 2005 TRIPS amendment and taken steps at the national level, to integrate conditions of the amendment including conditions for re-exportation and notification.<sup>106</sup> With a low level of ratifications from SADC it means the region as such cannot take collective advantage of the system introduced by the amendment. It is argued that using this system has direct positive fallout on pooled procurement. Evidence of the use of the TRIPS

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<sup>101</sup> SADC, Pharmaceutical Patents, TRIPS Flexibilities and Access to Medicines in the Southern African Development Community (SADC), 18 September 2012, at 6.

<sup>102</sup> SADC, Pharmaceutical Patents, at 6.

<sup>103</sup> SADC, Pharmaceutical Patents, at 9.

<sup>104</sup> SADC, Pharmaceutical Patents, at 9.

<sup>105</sup> SADC, Pharmaceutical Patents, at 10.

<sup>106</sup> Botswana (18 June 2014), Mauritius (16 April 2008) and Zambia (10 August 2009): see WTO, Members Accepting Amendment of the TRIPS Agreement, (27 April 2015) at [https://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm)

flexibilities by SADC member states is sparse.<sup>107</sup> Only Zimbabwe has successfully used unilateral CLs while South Africa has made use of VLs through competition laws.<sup>108</sup>

The AMRH treated in 4.2.1 also launched a specific initiative for SADC. The meeting in view of this took place in Gaborone from 16-18 June 2014.<sup>109</sup> The meeting was held with the World Bank, the WHO, SADC Secretariat and the SADC Troika. It was aimed at finalizing the work plans and terms of reference in view of submitting them for approval to SADC organs of policy making. The SADC Medicines Regulatory Harmonization project will be aimed at ameliorating public health through access to quality, affordable and safe essential medicines mainly through the means of a harmonized registration system.<sup>110</sup> The project was launched in November 2014. The activities include finalizing the common technical document (CTD) format via the backing of the Southern African Regional Program on Access to Medicines and Diagnostics (SARPAM). An Information Management System is envisaged to be in place. Also a Quality Management System is to be set for the project in all member states.<sup>111</sup>

It is worthwhile to elaborate more on SARPAM, a project funded by the UK's Department for International Development (DfID) with the goal of partnering with SADC states to enhance access to affordable medicines.<sup>112</sup> The SARPAM team does this through ameliorating efficiency and more competition in the pharmaceutical sector. SARPAM has a cluster or partnership of action (PACT) on pooled procurement which aims to: pool regional information resources through information and work sharing and pool financial resources, for countries to be able to negotiate purchase contracts jointly. In November 2012, Health ministers adopted the SADC Strategy on Pooled Procurement of Essential Medicines and Health Commodities. Through the work of SARPAM governments have been encouraged to publish figures at times revealing how some of them are over-charged by companies with rates of up to 25%. This has helped governments make better and informed decisions.

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<sup>107</sup> SADC, Pharmaceutical Patents, at 12. SADC states have not used the pooled or collective procurement option that is so much alluded to in the region: correspondence with a SADC health official, 27 April 2015.

<sup>108</sup> SADC, Pharmaceutical Patents, at 12.

<sup>109</sup> AMRH, SADC Gears Toward Launching their Medicines Regulatory Harmonization Project, 13 *AMRH Newsletter*, 2014, at <http://amrh.org/wp-content/uploads/2014/10/Newsletter-Issue-13-of-29-Oct.pdf>, at 2.

<sup>110</sup> AMRH, SADC Gears Toward, at 3.

<sup>111</sup> AMRH, SADC Gears Toward, at 3.

<sup>112</sup> SARPAM, The Southern African Regional Program on Access to Medicines and Diagnostics at <http://www.sarpam.net/>

## **5. What are the Conditions under which a Regional CL for Africa and UNASUR can Work?**

For CLs to work at the regional level they need to meet a number of conditions. First, it is vital that they be in line with the strict terms included in Art 31 of the TRIPS Agreement and now the Art 31bis. The limitations and safeguards in these clauses are useful minimal standards to curb abuse of CLs. Second, there is need for common pharmaceutical/ medicines policies that are normatively robust and respected by the states. Such a normative framework on pharmaceutical/ medicines policies will provide for a common wavelength on which all the members can operate even as they manifest specific country needs and realities. Third there is need for shared good manufacturing practices, good distribution practices and good surveillance critical mass in place. Regional efforts are needed to ensure that there is at least minimal alignment and convergence in the protocols used by various states to ensure access and delivery of quality medicines and vaccines on cross-country basis as needed. Fourth, pooled procurement must actually happen and not exist only on paper.<sup>113</sup> The underutilization of the TRIPS Amendment which many states and other stakeholders clamored for corroborates the fact that progressive norms only make sense and are effective when used. Even in the various regions where there are mature policies on pooled procurement this only happens on paper. Fifth, regional organizations in which more than 50 percent of the membership is composed of LDCs are the most favourable to take advantage of regional CLs. This specific element is underscored in the TRIPS Amendment. Sixth it is vital that states aspiring to benefit from regional CL regimes align REC and alternate IP (e.g., ARIPO/OAPI) regime obligations with the broader regional ones. Finally the existence of a continent wide board or panel that reviews the merits of specific CL applications and use is recommended.

## **6. What are the Problems in Using the Regional CL Approach?**

Many problems can be identified. To begin, different countries within the regions have different disease profiles. This means one-size-fits-all mechanisms such as regional CLs may

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<sup>113</sup> Correspondence with a SADC secretariat health official, 27 April 2015.



eventually be detrimental to some countries. For many years certain countries including those in SADC have focused on CDs. Indeed, there has been disproportionate attention paid to CDs and not NCDs. The WHO devotes only 8% of its budget to NCDs compared to 39% for infectious diseases and polio eradication.<sup>114</sup> By aligning with regions prioritizing CDs it is probable that a country that prefers to address NCDs may not find its interests amply reflected in an eventual regional CL application. Moreover, the negotiations for the use of CLs can be highly skills-intensive and costly. This entails that in certain cases governments have to use very limited human resources to navigate national, global and now regional norms on CLs making the administrative and substantive tasks cumbersome. Furthermore, the existence of multiple regional organizations within the regions studied, raises issues of duplication of CLs for given countries that belong to more than a single regional outfit. It is true that such a problem can be mitigated in the case of Africa for instance where a broader AU CL framework would increase the propensity for convergence. Finally, regional CLs may mean longer time horizons to act in given instances meanwhile prompt unilateral/ national actions could have otherwise been preferred and be more effective.

## **7. Conclusions**

The recent efforts to address the Ebola outbreak in West Africa have been a loud reminder of the significance of questions and unresolved issues surrounding access to medicines and vaccines. In this paper we attended to global constitutionalism and the use of regional CLs as a means to ensure that the most vulnerable have access to affordable, effective, quality and safe medicines and vaccines. We argued that in Africa and Latin America regional organizations have prioritized access to affordable pharmaceuticals as a crucial element in the implementation of their health policies. In looking closely at UNASUR for Latin America and the AU (alongside SADC) for Africa we argued that despite some of the challenges that are associated with a regional CL, there are clear benefits of using such a regional access tool. Optimally important conditions to be met include alignment with other regional and WTO TRIPS disciplines (alongside its flexibilities for LDCs and LICs) and intra-regional alignment. As African leaders

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<sup>114</sup> Lawrence O. Gostin Healthy living needs global governance, 511 *Nature* (10 July 2014), 147-149, at 148.

debate the priorities for the new African health strategy and as they also prepare to receive the draft African Union Model Law on Medical Products Regulations and Harmonization due in January 2016 closer attention is needed to ways of making a regional CL regime work better in securing affordable, quality, safe and effective medicines and vaccines for citizens.

This conduces back to the notion of global constitutionalism, which as Peters notes constitutionalizes “global, polyarchic, and multilevel governance”.<sup>115</sup> There is room to relate the regional CL regimes to the international one to foster better linkages and allow for mutual improvements that ease better access for quality affordable medicines and vaccines especially to the vulnerable and those afflicted by poverty. The regional pharmaceutical regimes being developed in South America and Africa (AU and SADC) provide useful opportunities for synergies that will allow a maximization of optimal access channels to vital and affordable medicines for countries in need. This is very important in a context of addressing diseases such as a Ebola that reveal the acute distortions and weaknesses not only in national health systems of affected countries but also in the perverse patent incentives built in the international IPL regime that at times, complicates access. Tying the notion of GC and regional CLs is a good fit in addressing access to affordable medicines and vaccines that is now considered a fundamental issue of justice.

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<sup>115</sup> Peters, *The Merits*, at 404.