

# Safeguarding public health in the wake of hegemonic intellectual property rights – Two means to this end?

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## 1. INTRODUCTION

In a world with an estimated population of 7.6 billion, 2 billion people lack access to medicines that are imperative to their health and survival.<sup>1</sup> Consequently, 15,000 deaths per day (more than half of the 5.6 million children who died before their fifth birthday in 2016) could have been prevented with the provision of essential health services.<sup>2</sup> In total, the World Health Organisation (WHO) estimates that at least 18 million people die needlessly each year from medicinal inaccessibility.<sup>3</sup> The geographical distribution of those unable to access medicines is concentrated in developing countries (DC) and least developed countries (LDCs). As a result, the same disease with a 90% cure rate in America can have a 90% death rate in Africa.<sup>4</sup>

While there are many conclusions that one may draw from these figures, one thing is clear: the inability to access medicines in DCs and LDCs remains a pressing global problem, and one that prevails despite the safeguards present under international law. International human rights law protects the right to health, including access to medicine. Additionally, international intellectual property (IP) law permits compulsory licenses (CLs), offering countries a means to circumvent intellectual property rights (IPRs) to preserve public health, given that the unaffordability of medicines is attributed mainly to patent rights. While it is true that patent rights do not solely inhibit medical accessibility (socio-economic and political factors also play a role) it is also true that patent rights granted under the multilateral legal agreement on 'Trade-Related Aspects of Intellectual Property Rights' (TRIPS)<sup>5</sup> allow pharmaceutical companies to inflate prices well above marginal costs, thereby undermining the right to health.

A CL constitutes a legal measure which, in theory, may be used to effectively fulfil obligations under the right to health. However, historically, external variables such as retaliation from foreign States and pharmaceutical companies, as well as legislative difficulties, have suppressed CL usage. Despite the Doha Declarations<sup>6</sup> reassurance of countries' right to use CLs to uphold public health duties, as well as the adoption of Article 31bis (enabling countries to import medicines under a license) the effective use of CLs remains caught in a web of issues. These issues are in turn exacerbated by the proliferation of bilateral and multilateral free trade agreements (FTAs) with IP provisions surpassing TRIPS requirements. Consequently, the feasibility of using CLs is limited in several countries.

In a turn of events, these issues have led to the increased issuance of voluntary licenses (VLs), whereby countries use the threat of imposing CLs to obtain VLs from pharmaceutical firms. The emergence of VLs has, furthermore, led to the nascence of the Medicines Patent Pool (MPP) -

an entity dedicated to brokering VLs for pharmaceuticals in DCs and LDCs. While VLs can act as a countervailing force against certain of the issues arising from CLs, VLs can themselves entail certain issues impeding accessibility to medicine. In light of these developments, a re-evaluation of how CLs and VLs are used to safeguard public health is necessary.

In this paper, the new private ordering of CLs and FTAs, as well as VLs, are explored. It is argued that countries and pharmaceutical firms now seek to limit the use of CLs through FTAs and investor-state arbitration proceedings. Additionally, it is shown that CLs may be used to strike VLs. While VLs improve medical accessibility and escape the procedural difficulties and resistance obstructing CLs, their focus on HIV/AIDS drugs and geographical exclusions limits its reach. Thus, this paper demonstrates that CLs and VLs should be used as complimentary regimes as, independently, each licensing scheme falls short of comprehensively improving access to medicines and protecting the right to health.

## 2. INTERNATIONAL LEGAL FRAMEWORK: INTELLECTUAL PROPERTY RIGHTS & THE RIGHT TO HEALTH

### 2.1 IP, human rights and access to medicines

We will begin with an outline of the background behind CLs, as well as an outline of the relationship between international IP law and the right to health. The right to health is a universal human right, at least 115 national constitutions.<sup>7</sup> As well as being secured and advanced through international and national human rights law, treaties, and United Nations (UN) resolutions and declarations, this right is protected under Article 25 of the Universal Declaration of Human Rights.<sup>8</sup> Although the Declaration has no binding effect, as it is not a treaty and thus does not impose obligations on signatories directly, it remains an authoritative framework.<sup>9</sup> All WTO Members have ratified at least one international human rights instrument protecting the right to health.<sup>10</sup>

One of the most influential human rights instruments is the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>11</sup> Article 12 of the ICESCR stipulates that the right to health entails "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," including "the creation of conditions which would assure to all medical service and medical attention in the event of sickness."<sup>12</sup> The ICESCR is an international treaty that has been ratified by at least 85% of WTO members who are therefore bound by its terms under the principle of *pacta sunt servanda*.<sup>13</sup> Under



this principle - states must comply with the terms of any international agreement they adopt - states who sign treaties containing provisions regarding the right to health are legally bound to uphold this right.<sup>14</sup> Additionally, human rights treaties are not subject to the principle of *in dubio mitius*, that is, interpreting treaties restrictively to preserve state sovereignty. Instead, human rights treaties are interpreted to afford “effective protection” of the rights conferred.<sup>15</sup>

The extent of which the right to health imposes an obligation on States differs depending on the source. On an international level, however, it is widely acknowledged that, given the legal force of the ICESCR, the *ad minimum* core obligation of the right to health entails access to essential medicines.<sup>16</sup> Thus, the right to health imposes a positive obligation on States to progressively respect, protect and fulfil this right,<sup>17</sup> by which access to essential medicines is recognised as, “one of the fundamental elements in achieving progressively the full realisation” of the right to health.<sup>18</sup>

According to the Committee to the ICESCR, access to medicines comprises four main elements: quality, accep-

tability, availability and accessibility - that is economic and physical accessibility.<sup>19</sup> Put simply, it includes a duty “to prevent unreasonably high costs for access to essential medicines.”<sup>20</sup> It is worth noting that the Committee links essential medicines to those included on the WHO compiled essential recommended medicines list.<sup>21</sup>

The Committee, furthermore, has confirmed that State practice which infringes Article 12 of the ICESCR includes the adoption of laws and policies interfering with any component of the right to health, and failure to consider the State’s legal obligations surrounding the right when agreeing to “bilateral or multilateral agreements with other States, international organisations and other entities, such as multinational corporations.”<sup>22</sup> Foreign States, too, have an extraterritorial obligation to not influence other States in such a way as to hinder that State from complying with ICESCR obligations, such as when negotiating trade agreements.<sup>23</sup> General Comments are not binding, but they are authoritative and instructive as to the object and purpose of the ICESCR.<sup>24</sup>

<sup>1</sup> World Health Organization, “Access to Medicine Index 2018 – Methodology Report,” 6.

<sup>2</sup> UNICEF & United Nations Inter-Agency Group for Child Mortality Estimation, “Child Mortality Estimates: Global and Regional Under-Five, Infant and Neonatal Mortality Rates and Deaths” 19th October 2017.

<sup>3</sup> Statistics obtained from documentary “Fire in the Blood” directed by Dylan Mohan Grey, released on the 12th of February 2013; Devi Sridhar, “Improving Access to Essential Medicines: How Health Concerns can be Prioritised in the Global Governance System,” *Public Health Ethics* 1, no. 2, (2008): 83.

<sup>4</sup> Donald G. McNeil Jr, “As Cancer Tears Through Africa, Drug Makers Draw Up Battle Plan,” *The New York Times*, 7th October 2017.

<sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, 15th April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1197 (1994) (hereinafter “TRIPS”).

<sup>6</sup> WTO, Ministerial Declaration of 20th November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) (hereinafter ‘the Doha Declaration’).

<sup>7</sup> Final Report of the UN Secretary-General’s High-Level Panel on Access to Medicines, September 2016, 16.

<sup>8</sup> UN General Assembly, “Transforming our World: The 2030 Agenda for Sustainable Development,” A/RES/70/1, 25th September 2015; UN Human Rights Council, A/HRC/RES/32/15, 18th July 2016; UN Human Rights Council, “The Right of Everyone to the Enjoyment of the

Highest Attainable Standard of Physical and Mental Health in the Implementation of the 2030 Agenda for Sustainable Development,” A/HRC/35/L.18/Rev.1, 21st June 2017.

<sup>9</sup> Frantzeska Papadopoulou, “TRIPS and Human Rights” in *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS*, ed. Annette Kur and Marianne Levin (Cheltenham: Edward Elgar Publishing, 2011): 261-262.

<sup>10</sup> Papadopoulou, “TRIPS and Human Rights,” 271.

<sup>11</sup> International Covenant on Economic, Social and Cultural Rights, GA Res. 2200A (XXI), 21 UN GAOR Supp. (No.16) at 49, UN Doc. A/6316 (1966); 993 UNTS 3; 6 I.L.M. 368 (1967) (hereinafter ‘ICESCR’).

<sup>12</sup> Article 12(2)(d) of ICESCR.

<sup>13</sup> Article 18 of the Vienna Convention on the Law of Treaties, 115 U.N.T.S. 331, 8 I.L.M. 679, 23rd of May 1969, (hereinafter ‘VCLT’); Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, (Oxford: Oxford University Press, 2007): 102; Frédéric Mégret, “Nature of Obligations,” in *International Human Rights Law* ed. Daniel Moeckli et al., (Oxford: Oxford University Press, 2010): 98.

<sup>14</sup> Christine Chinkin, “Sources,” in *International Human Rights Law* ed. Daniel Moeckli et al., (Oxford: Oxford University Press, 2010): 79.

<sup>15</sup> Hestermeyer, *Human Rights*, 86.

<sup>16</sup> Hestermeyer, *Human Rights*, 136.

<sup>17</sup> Article 2 and 12(1) of ICESCR; A Eide, *The New International Economic Order and the Promotion of Human Rights*, Report on the Right to

Adequate Food as a Human Right, UN Doc E/CN.4/Sub.2/1987/23 (1987) paras 66.

<sup>18</sup> UN Human Rights Council, “Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development,” A/HRC/RES/12/24, 12th October 2009.

<sup>19</sup> Committee on ICESCR, “The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author,” Article 15, para 1(c), General Comment No. 14 (2005), E/C.12/GC/1, 12th January 2006, para 35 (hereinafter ‘the Committee’); Stephen P. Marks, “Access to Essential Medicines as a Component of the Right to Health,” in *Realizing the Right to Health*, ed. Andrew Clapham and Mary Robinson (Zurich: Rüfer and Rub, 2009): 82.

<sup>20</sup> *Ibid.*

<sup>21</sup> Sarah Joseph, *Blame it on the WTO?: A Human Rights Critique* (Oxford: Oxford University Press, 2011): 218.

<sup>22</sup> Committee on ICESCR, General Comment No. 14, para 50.

<sup>23</sup> Committee on ICESCR, “State Obligations under the ICESCR in the Context of Business Activities” General Comment No. 24, E/C.12/GC/24, 10th August 2017, para 28-29.

<sup>24</sup> Nisuke Ando, “General Comments/Recommendations” in *The Max Planck Encyclopedia of Public International Law* ed. Rüdiger Wolfrum (Oxford: Oxford University Press, 2008).

International and national courts also apply and adjudicate on the right to health. The International Court of Justice in its Advisory Opinion in the *Legal Consequences of the Construction of a Wall* cemented the justiciability and legal force of the right to health, along with other rights included under the ICESCR, by confirming the ICESCR's applicability and relevance when evaluating the legality of Israel building a wall in occupied Palestinian territory.<sup>25</sup> Furthermore, several national courts recognise that medicinal access forms part of the right to health.<sup>26</sup> In *Cruz Bermúdez*, the Venezuelan Supreme Tribunal ascertained that the government was obligated to provide HIV/AIDS treatments to *all* patients, as the right to health and the right to access to medicines is protected under the Venezuelan Constitution.<sup>27</sup> Similarly, in *Treatment Action Campaign*, the South African Constitutional Court instructed the State to better provide access to a specific HIV drug due to the government's health duties.<sup>28</sup>

In *Patricia Asero Ochieng*, the Kenyan High Court went one step further and found that the right to health may take precedence over a patent holder's IPRs.<sup>29</sup> In this case, several HIV/AIDS patients claimed a Kenyan law, which failed to distinguish between counterfeit goods and generic medicines, threatened their ability to access essential medicines and violated their right to health.<sup>30</sup> In its reasoning, the court *inter alia* applied the right to health under the Kenyan Constitution, as well as the ICESCR, and affirmed that the State has both a positive obligation towards its citizens to enable medical access and a negative obligation to refrain from acting in a manner that impedes these health services.<sup>31</sup> Although these cases are not binding on an international level, they are persuasive in their elucidation of State practice. Moreover, these cases demonstrate how national courts balance IPRs and the right to health, where the latter is used as justification to enable medical access.

Yet, steep prices on medicines remain a barrier to accessibility and to the fulfilment of the right to health in DCs and LDCs. It is therefore claimed that high medical prices

infringe the right to health.<sup>32</sup> A counterclaim to this is that, although States have an obligation to ensure that medicines are accessible and affordable, they must not set prices. Under the inventor's 'monopoly' patent rights, this is their prerogative. It is this point that gives CLs their relevance. CLs allow governments to increase affordability, forming part of a State's obligations under the right to health. Due to these obligations, and CLs role in fulfilling them, States have a responsibility "to do all they reasonably can to make sure that existing medicines are available," including, "using CLs", as reaffirmed by the UN Special Rapporteur.<sup>33</sup>

It is worth noting that the ICESCR and other treaties solely impose public health obligations on States, not on the non-State actors who set pharmaceutical prices.<sup>34</sup> However, a 'social contract' between the inventor and society is embedded in patent law: in exchange for sharing their inventions, inventors are entitled to certain exclusive rights. This is aimed at encouraging future innovation, which in turn benefits society.<sup>35</sup> Despite this social contract, as will be shown, inventors fail to conduct R&D for diseases afflicting DCs and LDCs, price drugs well out-of-reach for these citizens and oppose licenses due to their financial interests, thereby failing to 'share' their inventions. Thus, there is a similar normative justification for enabling medicinal access through licensing to be made against inventors.

Notwithstanding this background, medical inaccessibility remains a pressing problem in DCs and LDCs, whereby the right to health is not equally enjoyed around the world. This not only reveals the stark contrast between how the right to health exists on a theoretical level and how it is employed in practice, but also how certain rights protected as human rights and as IPRs may conflict. As patents allow inventors to set prices above marginal costs, IPRs affect the right to health directly.<sup>36</sup> Therefore, to remedy this conflict, the international IP framework permit CLs.

<sup>25</sup> Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion International Court of Justice Report 136, 9th July 2004, paras 113, 130.

<sup>26</sup> Social and Economic Rights Action Centre and the Centre for Economic and Social Rights v Nigeria, Communication No 155/1996, ACHPR/COMM/A044/1, 27th May 2002, para 53f.

<sup>27</sup> Cruz Bermúdez v Ministerio de Sanidad y Asistencia Social, Tribunal Supremo de Justicia de Venezuela, Case no 15.789, Decision No 916 (1999); Hestermeyer, Human Rights, 104.

<sup>28</sup> Minister of Health v Treatment Action Campaign (2002) ZACC 15; 2002 (5) SA 721; 2002

[10] BCLR 1033.

<sup>29</sup> P.A. Ochieng, M. Atieno and J. Munyo v Attorney General, Petition no. 409 of 2009, Judgment of the Kenyan High Court, April 20th 2012; Emmanuel K. Oke, "Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes," Health and Human Rights 15, no. 2 (2013): 103.

<sup>30</sup> *Ibid*, paras 1, 14.

<sup>31</sup> *Ibid*, para 66.

<sup>32</sup> Hestermeyer, Human Rights, 78.

<sup>33</sup> UNGA, "Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Standard of Physical and Mental Health, Paul Hunt," UN Doc. A/61/338 (13 September 2006) para 47.

<sup>34</sup> Article 2 of ICESCR.

<sup>35</sup> Susy Frankel and Jessica C. Lai, "Recognised and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law's Social Contract," in Compulsory Licensing: Practical Experiences and Ways Forward, ed. Reto M. Hilty and Kung-Chung Liu (Heidelberg: Springer, 2014): 150, 159, 161.

<sup>36</sup> Oke, "Incorporating a Right to Health," 98.

## 2.2. Safeguarding of public health: Compulsory Licenses

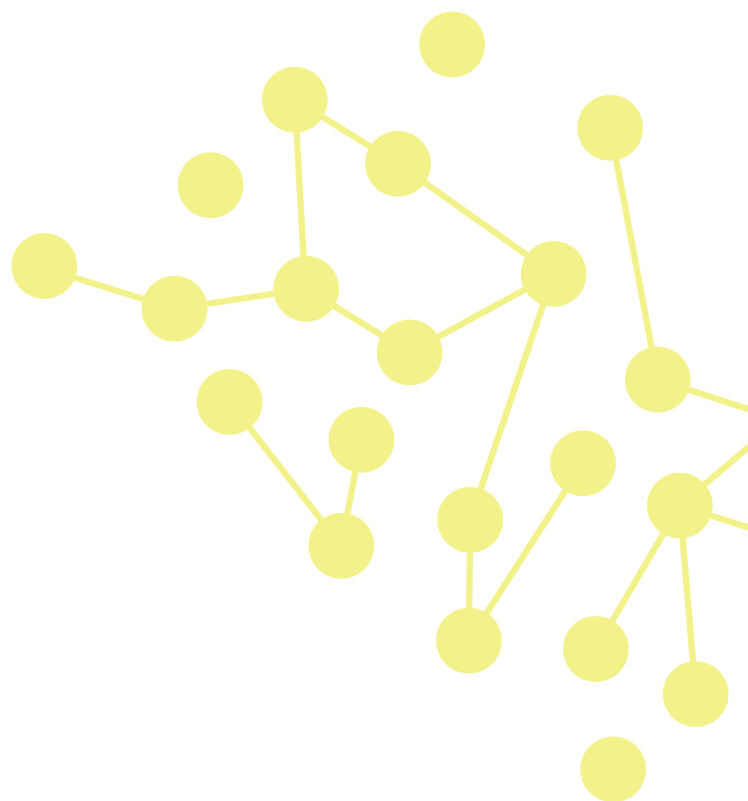
The Paris Convention for the Protection of Industrial Property introduced CLs into international law.<sup>37</sup> Article 5 allows for CLs to prevent abuses that may arise from exclusive patent rights or when the right holder fails to work the patent, otherwise known as ‘the local working requirement.’<sup>38</sup> The Paris Convention remains in force,<sup>39</sup> though TRIPS incorporated Articles 1 to 12 of the Paris Convention upon its ratification in 1995.<sup>40</sup> TRIPS regulates IPRs between WTO members and, in short, sets the *ad minimum* quasi-universal IP protection standards and enforcement measures members must abide by.<sup>41</sup>

The object and purpose of TRIPS under Articles 7 and 8 elucidates how TRIPS seeks to strike a balance between IPRs and public health. Article 7, *inter alia*, provides that the protection and enforcement of IPRs should “contribute to the promotion of technological innovation and transfer and dissemination of technology,” and occur “in a manner conducive to social and economic welfare, and to a balance of rights and obligation.” Article 8(1), *inter alia*, affirms that Members may, “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”

Although neither Article mentions the right to health *per se*, the wording of the Articles arguably lay the basis of the understanding that TRIPS is to be interpreted in a manner allowing Members to uphold their public health obligations. These Articles therefore represent an ‘opening’ where the right to access medicines may be used as an argument to interpret Article 31 liberally.<sup>42</sup> Article 31 permits “other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government.” In other words, Article 31 allows for CLs - a non-voluntary arrangement that allows parties to circumvent patent rights to authorise “domestic entities (public or private) to import, produce, and distribute patented goods.”<sup>43</sup> CLs lead to the decrease of drug prices in that other parties, with production costs nearing zero per-unit level, may enter the market.<sup>44</sup> By solely incurring these production

costs, without astronomical R&D expenditures, such astronomical expenditures are not passed on to the consumer.<sup>45</sup>

Article 31 also enumerates a list of preliminary conditions a party must fulfil to issue a CL. To grant a license, a State must: provide adequate remuneration to the respective right holder; attempt to negotiate a VL with the right holder prior to issuing a CL – this criterion extinguishes in the event of “a national emergency or other circumstance of extreme urgency;” use the patent solely for the purpose of its authorisation; authorise the CL “predominantly for the supply of the domestic market;” construct the CL to be non-exclusive and subject it to judicial review.<sup>46</sup> All CLs must also be assessed by the country on a case-by-case basis and configured according to the situation at hand and the purpose for which it was authorised.<sup>47</sup> While it is worth noting that these conditions are not obligatory if the license is to remedy anti-competitive practices,<sup>48</sup> this article focuses primarily on those grounds for CLs in which the conditions apply.



<sup>37</sup> The Paris Convention for the Protection of Industrial Property, 20th March 1883, as revised at the Stockholm Revision Conference, 14th July 1967, 21 U.S.T. 1583, T.I.A.S. No. 6903, 828 U.N.T.S. 305 [hereinafter ‘the Paris Convention’].

<sup>38</sup> *Ibid*, Article 5(1)-(4).

<sup>39</sup> Paul Champ and Amir Attaran, “Patent Rights and Local Working Under the WTO TRIPS Agreement: An analysis of the U.S. Brazil-Patent Dispute,” *Yale Journal of International Law* 27 (2002): 372.

<sup>40</sup> Article 2(1) of TRIPS.

<sup>41</sup> Frederick M. Abbott, “The Enduring Enigma of TRIPS: A Challenge for the World Economic System,” *Journal of International Economic Law* (1998): 499.

<sup>42</sup> The Panel Report in Canada-Pharmaceutical Patents, WT/DS114/4, 7th April 2000, paras 7.24-7.26 stated that Articles 7 and 8 must be “borne in mind” when interpreting other TRIPS provisions.

<sup>43</sup> Kenneth C. Shadlen, et al., “Globalization, Intellectual Property Rights, and Pharmaceuticals: Meeting the Challenges to Addressing Health Gaps in the New International Environment” in *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (Cheltenham: Edward Elgar Publishing, 2011): 17.

<sup>44</sup> Charles R. McManis and Jorge L. Contreas, “Compulsory Licensing of Intellectual Property: A Viable Policy Lever for Promoting Access to Critical Technologies?” in TRIPS

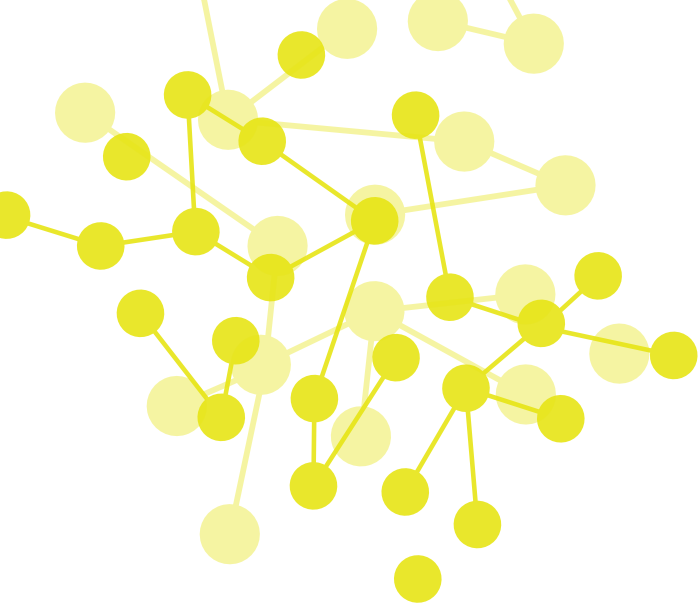
and Developing Countries: Towards a New IP World Order? ed. Gustavo Ghidini, Rudolph J.R. Peritz and Marco Ricolfi (Cheltenham: Edward Elgar Publishing, 2014): 125.

<sup>45</sup> Maura Nuno, “A Fair Return Approach to Pharmaceutical Compulsory,” *Case Western Reserve Journal of International Law* 48, no. 1 (2016): 404.

<sup>46</sup> See Article 31(a)-(k) of TRIPS for full list of requirements.

<sup>47</sup> Articles 31(a)-(c) of TRIPS; Jerome H. Reichman, “Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options” *Journal of Law, Medicine & Ethics* 23, (2009): 252.

<sup>48</sup> Article 31(k) of TRIPS.



In sum, CLs constitute a measure States may employ to safeguard public health. However, after TRIPS took effect in 1995, Article 31 only ostensibly protected public health, while the robust IP standards otherwise imposed by TRIPS nevertheless threatened to thwart access to affordable medicines.<sup>49</sup> Despite the existence of CLs, countries with little or no local manufacturing capabilities were unable produce drugs locally and at the same time prohibited from importing medicines under a license pursuant to Article 31(f). For countries able to produce drugs, the prices offered under a CL were still not affordable.<sup>50</sup> This issue escalated in the wake of the HIV/AIDS epidemic in the late 1990s. During this time, the right to health appeared precarious as IPRs prevailed over individuals' inability to access affordable drugs. This dire situation prompted another round of multilateral trade negotiations, resulting in the Doha Declaration in 2001. The Doha Declaration achieved two pertinent objectives.<sup>51</sup> First of all, it clarified that TRIPS is to be interpreted in light of the obligations surrounding the right to health. To this end, it reaffirmed Members' right to utilise TRIPS flexibilities to circumvent IPRs for improving access to medicines.<sup>52</sup> This is embedded in Paragraph 4 of the Declaration, which states that TRIPS,

*“can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health, and, in particular, to promote access to medicines for all.”*

Second, it made an overture for greater medicinal access by instructing the TRIPS Council to resolve the issue of CLs and LDCs with little or no manufacturing capabilities.<sup>53</sup> On this point, the Council reached a decision on the 30th of August 2003, establishing that LDCs and other countries lacking manufacturing capacities may import drugs under a CL.<sup>54</sup> The Council incorporated this 'Waiver Decision' into TRIPS as amendment 'Article 31bis' in January of 2017.<sup>55</sup> However, the Doha Declaration only *prima facie* resolved the issues with CLs. Issues remained with Article 31bis and, as the Declaration failed to mediate the tensions that had been stirring between WTO Members since negotiating TRIPS, these tensions continued to dissuade the use of CLs.<sup>56</sup> Thus, the procedural and political difficulties of employing CLs survived into the post-Doha era,

only now inhibiting both Articles 31 and 31bis,<sup>57</sup> including the further requirements contained in the latter.

One example of these difficulties can be seen in the requirement for the importing country to notify the TRIPS Council of its intent to issue a CL, specifying the product name, the quantities to be imported, the measures taken to prevent re-export.<sup>58</sup> The exporting country must inform the Council of its intent to grant a CL, specifying the product, export quantities and the final destination, and with the products displaying distinct features signalling that they are produced under the CL.<sup>59</sup> Additionally, all information must be published and publicly available online.<sup>60</sup> Notwithstanding these requirements, the grounds for issuing CLs remain at the discretion of States themselves and primarily a matter of national law.

### 2.3. Also a matter of national law

Paragraph 5(b) of the Doha Declaration manifests that each member retains “the freedom to determine the grounds upon which such licenses are granted,” provided that the Article 31 requirements are adhered to. As Article 31 and 31bis are not self-executing for all countries - these countries must enact ancillary legislation to implement CL provisions in their respective jurisdictions. This gives countries leeway to determine autonomously the scope of the procedural conditions and the grounds for issuances, which differ from state to state as a result.<sup>61</sup>

How grounds to issue CLs vary between states is confirmed in a study of 41 DCs. Its results reveal that: 39 countries include failure to exploit a patent to meet public demand after 3-4; 33 countries allow for public non-commercial use; 29 countries permit dependent patents; 24 countries to remedy anti-competitive practices; 22 countries mention national security, healthy emergencies or to develop a vital economic sector, and 2 countries provide no specific provisions.<sup>62</sup> Hence, these findings reveal how the basis for granting a CL varies depending on national laws.

Grounds also vary due to bilateral and multilateral FTAs signed between States. As a result of these agreements, the grounds for which some countries may issue CLs are restricted and countries expected to use TRIPS flexibilities adopted stronger IP standards prior to the TRIPS deadline.<sup>63</sup> This is discussed in further detail in section 3.1. In 2013, the TRIPS Council, pursuant to Article 66.1, extended the transition period deadline for LDCs to implement the TRIPS minimum standards to July of 2021.<sup>64</sup> As of now, only 20 African countries are among the 87 countries to have ratified Article 31bis, despite the continent containing the greatest number of LDCs.<sup>65</sup> This may be one of several reasons for why Article 31bis, thus far, has not been employed as extensively as envisaged. Meanwhile, use under Article 31 appears more prevalent than putatively reported.<sup>66</sup>

## 3. COMPULSORY LICENSES: HISTORIC USES AND CONTEMPORARY CHALLENGES

### 3.1 Background

To date, it is reported that the governments of 24 countries have granted at least 34 CL requests from third parties to

access medicines under Article 31 following the Doha Declaration, and that 51 CLs have been issued for government use.<sup>67</sup> Countries who have used CLs include developed countries such as the U.S and Italy, as well as DCs<sup>68</sup> and LDCs<sup>69</sup> such as Ecuador, Brazil, Indonesia, India, Thailand, Malaysia, Kenya, Mozambique, South Africa, Eritrea, Zimbabwe, Cameroon, Zambia and Ghana.<sup>70</sup> In several of these instances - particularly in African states - it remains ambiguous whether any local production occurred post-grant.<sup>71</sup> Article 31bis has been used successfully once - the Canada-Rwanda license - whereas the India-Nepal attempt failed. When successfully granted, CLs have reduced prices and increased medicinal access in all these cases.

To cite an example, in 2003, when the Malaysian government granted CLs for two HIV/AIDS medications, the price decreased from \$365 per patient per month to \$115. Zimbabwe also reported a 50% price reduction in one HIV/AIDS drug following a CL. After India's licence, the drug became available at approximately one-tenth of the original price.<sup>72</sup>

Due to a lack of information publicly available, assessing the impact of CLs in LDCs carries difficulties. CLs in India, Thailand and Brazil have procured medicines for

millions of patients.<sup>73</sup> For example, Brazil's CL for Efavirenz provided treatment for 75,000 additional patients,<sup>74</sup> while Thailand's CL for Efavirenz increased patient access from 4539 to 29,360, and its CL for Lopinavir/Ritonavir, from 69 to 6200.<sup>75</sup>

But affordability does not guarantee accessibility, as citizens' wages and States infrastructure, governance and health distribution abilities also impact access.<sup>76</sup> The health sector in DCs and LDCs is particularly susceptible to corruption, which manifests in both the public and private sector, thereby affecting drug allocation.<sup>77</sup> The devastating effects of health care corruption on health outcomes and public health obligations notably prompted, and were reflected in, a UN Special Rapporteur report in 2017.<sup>78</sup> Enforcing measures to combat corruption is thus necessary for the results of CLs to be enjoyed equally. Price reductions caused by CLs also accrue government savings, which may be used to strengthen health systems against corruption. For example, after its license, Brazil saved approximately \$30 million annually for its health procurement budget.<sup>79</sup> However, the emergence of FTAs greatly threatens the feasibility of using, and even initiating CLs.

<sup>49</sup> Reichman, "Comment," 248.

<sup>50</sup> Ibid.

<sup>51</sup> For a more detailed historical account see Ellen FM 't Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha" *Chicago International Law Journal* (2002): 27.

<sup>52</sup> Paragraph 4 of the Doha Declaration.

<sup>53</sup> Paragraph 6 of the Doha Declaration.

<sup>54</sup> General Council, "Decision of 30 August 2003 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," WT/L/540 and Corr.1, 1st September 2003.

<sup>55</sup> WTO News Items, "WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines," 23rd January 2017; General Council, "Decision of 6 December 2005 on Amendment of the TRIPS Agreement," WT/L/641, 8th December 2005.

<sup>56</sup> Frederick M. Abbott, "The Trips-Legality of Measures taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO" in *The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec* ed. Daniel L. M. Kennedy and James D. Southwick (Cambridge: Cambridge University Press, 2002): 313.

<sup>57</sup> Amir Attaran, "Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution," *Emory International Law Review* 17, (2003): 746 - 748; Carlos M. Correa, "TRIPS Agreement and Access to Drugs in Developing Countries," *Emory International Law Review* 17, no. 2 (2003): 36.

<sup>58</sup> Article 31bis para 2(a)(i) of TRIPS; Article 3 in Annex to TRIPS.

<sup>59</sup> Ibid, para 2(b)(ii)-(iii)-(c).

<sup>60</sup> Ibid.

<sup>61</sup> Kenneth C. Shadlen, et. Ad., "Globalization, Intellectual Property Rights, and Pharmaceuticals," 17.

<sup>62</sup> Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, (Oxford: Oxford University Press, 2009): 92-93; WIPO, "Survey on Compulsory Licenses Granted by WIPO Members to Address Anti-Competitive Uses of Intellectual Property," CDIP/4/4/REV.Study/INF/5, 4th October 2011, Table 2.

<sup>63</sup> Deere, *The Implementation Game*, 20.

<sup>64</sup> WTO Decision of the Council for TRIPS, "Extension of the Transition Period under Article 66.1 for LDC Members," IP/C/64 12th June 2013.

<sup>65</sup> For a complete list, see: <http://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/LDC-Map.aspx> (accessed Mar. 25, 2018).

<sup>66</sup> Ellen FM 't Hoen, et. ad., "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2006" *Bull World Health Organ* 96, (2018): 185.

<sup>67</sup> Ellen FM 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Amsterdam: Health Action International, 2016): 54, 58.

<sup>68</sup> As identified by the UN in the report, "World Economic Situation and Prospects 2018," 106 - 130.

<sup>69</sup> As identified by the UN Committee for Development Policy, "List of LDCs as of June 2017."

<sup>70</sup> Donald Harris, "TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing," *Journal of Intellectual Property Law* 18, no. 2 (2011): 388.

<sup>71</sup> Hiroko Yamane, *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines*, (UK: Hart Publishing, 2011): 313-316; Deere, *The Implementation Game*, 83.

<sup>72</sup> Dipika Jain and Jonathan J. Darrow, "An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India," *Health Matrix* 23, no. 3 (2013): 442.

<sup>73</sup> Petra Moser and Alessandra Voena, "Compulsory Licensing: Evidence from the Trading with the Enemy Act," *American Economic Review* 102, no. 1 (2012): 396.

<sup>74</sup> Dr. Pedro Canisio Binsfield, Ministry of Health of Brazil "The Use of Compulsory License as Patent Related Flexibility - The Brazilian Experience in Health," Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of Several Patent-Related Flexibilities," February 2012, 20.

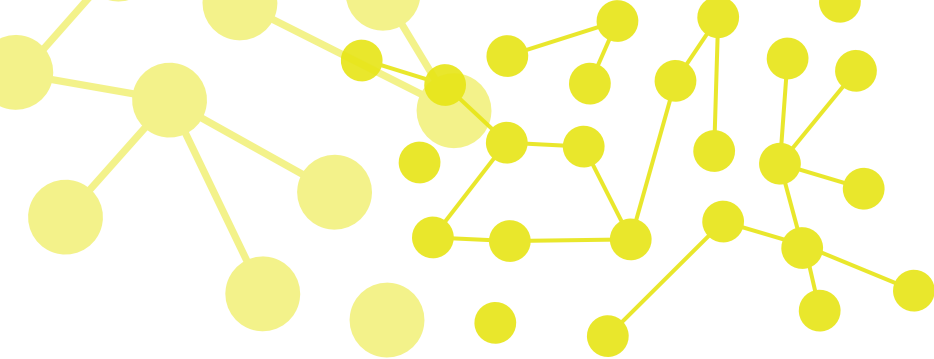
<sup>75</sup> Hein and Moon, *Informal Norms*, 100-107.

<sup>76</sup> Richard A. Epstein & F. Scott Kieff, "Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents," *The University of Chicago Law Review* 78, no. 1 (2011): 81-82.

<sup>77</sup> Saskia Mostert, et al., "Corruption in Health-Care Systems and its Effect on Cancer Care in Africa," *Lancet Oncology* 16, no. 8 (2015): 394-404.

<sup>78</sup> Report of the UN Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, UN General Assembly, A/72/137, UN 72nd Session, 14th July 2017.

<sup>79</sup> Public Interest, "Post-TRIPS Examples" 2.



### 3.2. Bilateral and multilateral trade agreements

Bilateral and multilateral FTAs between countries commonly include conditions surpassing TRIPS requirements - so-called 'TRIPS-plus provisions' - that restrict the grounds on which countries may issue CLs.<sup>80</sup> Article 1(1) of TRIPS permits States to enter into FTAs with IP standards exceeding those under the treaty, provided these agreements do "not contravene" TRIPS provisions. As CLs are an option available to countries and not a requirement, these agreements do not conflict with TRIPS *per se*.<sup>81</sup>

Provisions limiting CL grounds are present in FTAs between the EU and Columbia, Peru, South Korea and Moldova.<sup>82</sup> Moreover, the EU has proposed similar restrictions during FTA negotiations with India, Thailand, Vietnam and Myanmar.<sup>83</sup> These provisions are additionally included in FTAs between the US and other countries. For instance, the US-Jordan FTA confines CL use in Jordan to failure to work patents, to remedy anti-competitive behaviour and for public health emergencies and public non-commercial use.<sup>84</sup> US FTAs with Chile,<sup>85</sup> Morocco,<sup>86</sup> Bahrain,<sup>87</sup> and the signatories of the Central American-Dominican Republic FTA,<sup>88</sup> (Guatemala, El Salvador, Honduras, Costa Rica, Nicaragua and the Dominican Republic), allow patent owners to essentially consent to a CL before it may take effect, by requiring patentee consent or acquiescence for a party to bring a patented product to market.<sup>89</sup>

FTAs indirectly, but intentionally, restrict CLs by including clauses that: prolong patent rights; impose 'non-reliance principles'; include stringent market provisions,<sup>90</sup> and extend data exclusivity periods.<sup>91</sup> Consequently, generic manufacturers cannot utilise the clinical trial and safety data in the original patent application, and the data originator must authorise and give market approval for products subject to a CL.<sup>92</sup>

Moreover, evidence suggests that FTAs increase drug prices and decrease access.<sup>93</sup> After the US-Jordan FTA, prices increased by 20%.<sup>94</sup> It is estimated that the U.S-Colombia FTA will increase medical expenditures in Colombia by \$919 million by 2020<sup>95</sup> and that the U.S-Peru FTA will limit medical access for 700,000 people.<sup>96</sup> Thus, TRIPS-plus provisions may hinder the market entry of medicines irrespective of a CL, and impair affordability and accessibility.

NGOs, scholars and politicians have led harsh criticisms against FTAs in this respect.<sup>97</sup> Former French President Chirac at the 2004 International AIDS Conference in Bangkok stated that, "making certain countries drop these measures (TRIPS flexibilities) in favour of bilateral trade negotiations would be immoral blackmail."<sup>98</sup> Although countries 'willingly' sign FTAs, they financially rely on trade benefits and preferential market treatment.<sup>99</sup> As such, developed countries use FTAs to advance stronger

IP standards outside TRIPS and arguably arrange for a *quid pro quo*; restriction of TRIPS flexibilities in exchange for preferential trade treatment.<sup>100</sup> Given the implications of FTAs, the UN Special Rapporteur discourages TRIPS-plus standards and warns *all* States to be "mindful of actions which may infringe upon the right to health."<sup>101</sup>

Signing FTAs that increase drug prices and limit access may violate States' obligations under the right to health and lead to situations where such obligations conflict with the right to health.<sup>102</sup> Tribunals which arbitrate FTA disputes have notably rejected the argument that human right obligations can legally affect how States execute their trade obligations.<sup>103</sup> In *Suez v Argentina*, the tribunal reinforced that respecting human right duties fails to justify non-compliance with trade obligations, as States "must respect both of them equally."<sup>104</sup> Hence, States must fulfil their trade and human right obligations simultaneously, even when they are at odds. By dichotomising these two obligations, States' duty to ensure medicinal access may have no influence in FTA arbitrations should CLs be challenged. This may engender conflicting decisions between national courts, FTA tribunals and the WTO, which not only creates legal uncertainty for States but could promote forum shopping.<sup>105</sup>

Clauses permitting health exceptions in FTAs are ambiguous, weakening "their use as a defence."<sup>106</sup> Certain FTAs or FTA side letters explicitly refer to the Doha Declaration,<sup>107</sup> which may allow for FTAs to be interpreted and implemented in a manner supportive of CLs given the purpose of the Declaration.<sup>108</sup> However, this depends on how the legal value of the side letters is interpreted, as well as the language present in FTAs.<sup>109</sup> If language from the Declaration is 'transplanted,' this provides a stronger case than if it is merely referenced.<sup>110</sup> Whether countries will challenge FTAs likewise depends on their willingness to do so in light of the possibility of backlash, retaliation, or the removal of trade concessions. Thus, as FTAs may effectively force countries to choose between trade benefits or health measures, FTAs will likely have grave implications for public health and pose a serious challenge to the viability of CLs.

### 3.3. Investor-state arbitration proceedings

Trade agreements also allow firms to sue countries for alleged TRIPS violations,<sup>111</sup> as they include a clause permitting Investor-state arbitration proceedings (ISAPs), where a foreign company may bring suit against a country for TRIPS breaches that affect their IP investments in an independent tribunal, as firms are ineligible to use the WTO Dispute Settlement Mechanism (DSM).<sup>112</sup>

To cite an example, in *Eli Lilly v Canada*, Eli Lilly raised a claim under the North American Free Trade Agreement

(NAFTA) by alleging that Canada's invalidation of its patents diverged from NAFTA requirements.<sup>113</sup> Patentability criteria under NAFTA notably mirror those of TRIPS.<sup>114</sup> Canada revoked Eli Lilly's patents as they failed to comply with Canada's promise doctrine, that the invention achieves what it promises to do in its patent application; a TRIPS flexibility.<sup>115</sup> The Tribunal unanimously dismissed Eli Lilly's claims, but on evidentiary grounds, not because TRIPS flexibilities do not apply in investment disputes.<sup>116</sup> It is therefore possible for firms to initiate action against a country using CLs by claiming the license compromises their IP investments.<sup>117</sup>

This development invites two problems. First, it may curb countries' rights to procure medicines through the use of TRIPS flexibilities, and discourage countries from granting CLs lest they have to pay substantial financial damages.<sup>118</sup> Eli Lilly notably claimed \$500 million in remuneration.<sup>119</sup> Although a case involving CLs has yet to arise, leaked documents addressed to the Colombian Ministry of Trade revealed that Novartis threatened to initiate ISAs when Colombia considered issuing a CL for Glivec in 2016, by claiming that the CL violated the Swiss-Colombian

bilateral investment treaty.<sup>120</sup> Colombia consequently abandoned the CL.

Second, it may create conflicting WTO and Investor-State tribunal (IST) decisions on TRIPS flexibilities.<sup>121</sup> ISTs are not bound by WTO rulings, nor by previous Tribunal decisions which are often contradictory, inconsistent and without possibility of appeal.<sup>122</sup> In other words, a CL may be reinforced by the WTO panel, yet the country may be required to reimburse the firm by an IST. Damages awarded by the two judicial bodies also differ, as WTO reports usually instruct the country to amend the conflicting law in question, whereas ISTs require financial compensation.<sup>123</sup> The lack of balance between actors in investor-state disputes is also recognised by developed countries and caused Belgium to challenge this procedure, which is permitted under the EU-Canada Comprehensive Economic and Trade Agreement (CETA), to the Court of Justice of the EU.<sup>124</sup> Given these circumstances, a UN Trade and Development Conference report found that these "disputes pose particular challenges for host States and especially DCs."<sup>125</sup>

<sup>80</sup> Bryan Mercurio, "TRIPS-Plus Provisions in FTAs: Recent Trends," in *Regional Trade Agreements and the WTO Legal System* ed. Lorand Bartels and Federico Ortino (Cambridge: Cambridge University Press, 2006): 231.

<sup>81</sup> Henning G. Ruse-Khan, "The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?" *Journal of Intellectual Property Law* 18, no. 2 (2011): 349-350.

<sup>82</sup> Health Action International and MSF, "Empty Gestures: The EU's Commitments to Safeguard Access to Medicines," *Review of the European Union's Trade & Investment Policy* (2015): 4, 13.

<sup>83</sup> *Ibid.*; European Commission, "Overview of FTA and other Trade negotiations," Updated March 2018.

<sup>84</sup> Article 1.2 of U.S.-Jordan, FTA, 24th October 2000, 41 I.L.M. 63; Carlos M. Correa, "Multilateral Agreements and Policy Opportunities," in *Intellectual Property Rights: Legal Economic Challenges for Development* ed. Mario Cimoli, et. al., (Oxford: Oxford University Press, 2014): 431.

<sup>85</sup> Article 17.10(b) of U.S.-Chile, FTA, 6th June 2003, 42 I.L.M. 1026.

<sup>86</sup> Article 15.10(4) of U.S.-Morocco FTA, 15th June 2004, 44 I.L.M. 544.

<sup>87</sup> Article 14.9(4) of U.S.-Bahrain FTA, 14th September 2004, 44 I.L.M. 544.

<sup>88</sup> Ch 15 of U.S.-Dr.-Central America-Dominican Republic FTA, (CAFTA-DR), FTA, 5th August 2004, 19 U.S.C.

<sup>89</sup> Harris, "TRIPS After Fifteen Years," 394.

<sup>90</sup> Yamane, *Interpreting TRIPS*, 504-505.

<sup>91</sup> Ruse-Khan, "The International Law Relation," 32.

<sup>92</sup> Sam F. Halabi, "Multipolarity, Intellectual Property, and the Internationalization of Public Health Law," *Michigan Journal of International Law* 35, no. 4 (2014): 752; WHO, "Guide for the Application," 19.

<sup>93</sup> Lisa Forman, "The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries," *Maryland Journal of International Law* 31, no. 1 (2017): 13.

<sup>94</sup> Oxfam International, "All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines," (2007): 2.

<sup>95</sup> UN Development Programme and UNAIDS Issue Brief, "The Potential Impact of Free Trade Agreements on Public Health," (2012): 4.

<sup>96</sup> Forman, "Trade Rules, Intellectual Property," 342.

<sup>97</sup> Pedro Roffe and Christoph Spenneman, "The Impact of FTAs on Public Health Policies and TRIPS flexibilities," *International Journal of Intellectual Property Management* 1, No. 1 (2006): 76-77.

<sup>98</sup> Message from M Jacques Chirac, President of the Republic, Read by M Xavier Darcos, Delegate for Cooperation, Development and Francophony, 15th International AIDS Conference, Bangkok, 13th July 2004; Yamane, *Interpreting TRIPS*, 505.

<sup>99</sup> Roffe and Spennemann, "The Impact of FTAs," 79; Ruse-Khan, "The International Law Relation," 349.

<sup>100</sup> *Ibid.*

<sup>101</sup> UN Special Rapporteur 2009 Report, para 108.

<sup>102</sup> General Comment 14 of ICESCR; Simon M. Walker, *The Future of Human Rights Impact Assessment of Trade Agreements*, (Intersentia Publishing, 2009): 66, 68; Forman, "Trade Rules, Intellectual Property," 342-343.

<sup>103</sup> Urbaser S.A et al., v Argentine Republic, ICSID Case No. ARB/07/26, 8th December 2016, para 1210.

<sup>104</sup> Suez et al., v Argentine Republic, ICSID Case No. ARB/03/19 30th July 2010, para 262.

<sup>105</sup> Ho and Gathii, "Regime Shifting," 4, 10.

<sup>106</sup> Halabi, "Multipolarity, Intellectual Property," 751.

<sup>107</sup> U.S FTA with Chile;

<sup>108</sup> Ruse-Khan, "The International Law Relation," 354.

<sup>109</sup> Christoph Spenneman, Interview, 14th May 2018: Appendix A.

<sup>110</sup> *Ibid.*, 357-358.

<sup>111</sup> Christopher Gibson, "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation," *American University International Law Review* 25, no. 3 (2010): 359, 394-399.

<sup>112</sup> Article 22 of *Understanding on Rules and Procedures Governing the Settlement of Disputes*.

<sup>113</sup> *Eli Lilly and Company v Government of Canada*, ICSID Case No. UNCT/14/2, 16th March 2017.

<sup>114</sup> NAFTA, Can-Mex.-U.S., December 17, 1992, 32 I.L.M., 289 (1993), Article 1709.

<sup>115</sup> *Eli Lilly and Company v Canada*, para 303, 307.

<sup>116</sup> Cynthia M. Ho, "A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings," *UC Irvine Law Review* 22, no. 395 (2016): 102-104.

<sup>117</sup> *Ibid.*

<sup>118</sup> WTO, "Intellectual Property and Public Interest," para 7.

<sup>119</sup> *Eli Lilly v Canada*, para 467(i).

<sup>120</sup> For documents, see: [https://www.publiceye.ch/fileadmin/files/images/Gesundheit/Zwangslizenzen/ISDS\\_Threat\\_Novartis\\_aga-inst\\_Colombia.pdf](https://www.publiceye.ch/fileadmin/files/images/Gesundheit/Zwangslizenzen/ISDS_Threat_Novartis_aga-inst_Colombia.pdf) [accessed Mar. 23, 2018]; Ho, "A Collision Course," 174-175.

<sup>121</sup> Ho, "A Collision Course," 102-104.

<sup>122</sup> *Ibid.*

<sup>123</sup> *Ibid.*, 397.

<sup>124</sup> European Parliament, "CETA Ratification Process: Latest Developments," October 2017, [http://www.europarl.europa.eu/RegData/etudes/ATAG/2017/608726/EPRS\\_ATA\(2017\)608726\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/ATAG/2017/608726/EPRS_ATA(2017)608726_EN.pdf); Koninkrijk België, "CETA: Belgian Request for an Opinion From the European Court of Justice," [https://diplomatie.belgium.be/sites/default/files/downloads/ceta\\_summary.pdf](https://diplomatie.belgium.be/sites/default/files/downloads/ceta_summary.pdf). [Both accessed May 7, 2018].

<sup>125</sup> UNCTD, "Investor-State Disputes: Prevention and Alternatives to Arbitration," at 3-4.





Over 3000 of these agreements exist, with Investor-State disputes increasing over time and, correspondingly, WTO disputes declining.<sup>126</sup> Ho affirms that ISAPs impair TRIPS flexibilities' potential to protect public health and "indicate an intent to shift from the WTO/TRIPS regime to the use of investment disputes to effectuate policy changes in domestic and global laws."<sup>127</sup> However, as ISAPs on CLs have yet to arise, determining conclusively the extent that ISAPs will influence CLs is subject to dispute. That being said, the reasoning for the decision in *Eli Lilly v Canada* and the financial damages claimed gives serious cause for concern. Paying \$500 million in damages may devastate a DC or LDC's health resources and prevent the procurement of medicines, as well as justify non-compliance with obligations under the right to health due to a lack of

financial means.<sup>128</sup> Thus, if a tribunal finds that a CL amounts to expropriation under an FTA, by restricting or discharging IPRs considered an investment, and whereby private actors may claim compensation,<sup>129</sup> a chilling effect on use under both Article 31 and 31bis may arise and curtail the right to access affordable medicines.<sup>130</sup>

It is worth mentioning that, on the 20th of March 2018, the EU announced that negotiations for the establishment of a multilateral court designated to adjudicate disputes under EU investment treaties is underway.<sup>131</sup> This Court may create a more democratic process in resolving such disputes by appointing judges, following Court procedures and allowing appeals.<sup>132</sup> However, until this court comes into being, an assessment of how it will impact IS-APs and CLs can only be limited.

In sum, while CLs can protect the right to health and enable medicinal access, the proliferation of FTAs with ISAPs constitutes a significant barrier to their effective use. Against this background, CLs seem an infeasible way of increasing medicinal access. However, following Article 31bis, CLs are indeed frequently 'used' - in another sense - to improve public health. Thus, issuing or threatening to issue a CL has proliferated the issuance VLs.<sup>133</sup>

#### 4. DEFINING VOLUNTARY LICENSES

VLs - also known as 'social licenses' - of patented pharmaceuticals are private contractual agreements between right holders and second parties, which stipulate the terms and conditions for the entry of particular medicines in a designated market.<sup>134</sup> Two types exist. First, 'out-licensing', where the right holder licenses an already developed drug or the technology to produce the respective drug. Such arrangements typically grant second parties with the production, marketing and distribution rights of an invention, whereby the right holder is rewarded with royalty payments from net sales.<sup>135</sup> The second type is 'in-licensing', where the right holder licenses a compound at a pre-clinical or clinical stage, which the generic manufacturer develops and introduces to the market in exchange for royalties.<sup>136</sup>

<sup>126</sup> UNCTD, "Investor-State Disputes: Prevention and Alternatives to Arbitration," at 3-4..

<sup>127</sup> Ibid; Ho, "A Collision Course," at 109; James Gathii and Cynthia Ho, "Regime Shifting of IP Law Making and Enforcement From the WTO to the International Investment Regime," *Minnesota Journal of Law, Science and Technology* 18, (2017): 5, 16.

<sup>128</sup> Hestermeyer, *Human Rights*, 111-112.

<sup>129</sup> Christoph Spenneman, Interview, 14th May 2018: Appendix A; Carlos M. Correa, "Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses," *Michigan Journal of International Law* 26, no. 1 (2004): 345-348.

<sup>130</sup> Yamane, *Interpreting TRIPS*, 504-505.

<sup>131</sup> Council of the EU, "Multilateral Investment Court: Council Gives Mandate to the Commission to Open Negotiations," Press

Release 144/18, 20th March 2018.

<sup>132</sup> Christoph Spenneman, Interview, 14th May 2018: Appendix A; EU Council, Declassified Version of Note from General Secretariat of the Council to Delegations Regarding "Negotiating Directive for a Convention Establishing a Multilateral Court for the Settlement of Investment Disputes," 12981/17, 1st March 2018, para 9, 10.

<sup>133</sup> Harris, "TRIPS After Fifteen Years," 395.

<sup>134</sup> Peter Beyer, "Developing Socially Responsible Intellectual Property Licensing Policies: Non-exclusive Licensing Initiatives in the Pharmaceutical Sector," in *Research Handbook on Intellectual Property Licensing* ed. Jacques de Werra (Cheltenham: Edward Elgar Publishing, 2013): 228.

<sup>135</sup> K. D. Raju, "Compulsory v Voluntary Licensing: A Legitimate Way to Enhance Access to

Essential Medicines in Developing Countries" *Journal of Intellectual Property Rights* 22, (2017): 27.

<sup>136</sup> Tahir Amin, "Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?" *I-MAK*, (2007): 3.

<sup>137</sup> GSK Public Policy Position, "IP & Access to Medicines," provided by GSK via email, <https://www.gsk.com/media/2958/ip-atm-developing-countries-policy.pdf> (accessed May 14, 2018).

<sup>138</sup> AstraZeneca, Novo Nordisk, Bayer, Merck KGaA, Pfizer, Sanofi, Sankyo, Takeda, Astellas, Eisai, Eli Lilly and Novartis have yet to license their patents; Peter Beyer and WHO, "Enhancing Access to Medicines through Licenses" WIPO Regional Seminar for Certain African Countries on the Implementation and

VLS are not subject to the conditions under Article 31 of TRIPS. Instead, terms such as royalties, exclusivities and geographical preferences are negotiated between the parties: a generic firm, State or the MPP; and the patentee, typically a pharmaceutical company. Of the top 20 pharmaceutical companies globally, Gilead, GSK,<sup>137</sup> Boehringer Ingelheim (BI), Bristol-Myers Squibb, Merck Inc., Johnson & Johnson, Hoffman La Roche and Abbvie license their products voluntarily.<sup>138</sup> A reported total of at least 47 VLS for different drugs have been granted; 19 attributed to Gilead.<sup>139</sup> VLS primarily arise through the MPP or from bilateral agreements.

#### 4.1. Bilateral Voluntary Licensing Agreements

Bilateral VL agreements are negotiated between the parties directly. The know-how and rights to manufacture and distribute the drug are transferred to generic companies, who sell the medicine under the original label or another brand name. As a result, local manufacturers may access drug technology that is otherwise unavailable, as well as acquire the competency to produce medicines of safe quality.<sup>140</sup> For example, Gilead licenses a multiple compound used to treat Hepatitis C. The license is non-exclusive, non-sublicensable, non-transferable and demands a 12% royalty of net sales for products sold in Malaysia, Thailand and Ukraine, and 7% for products sold in the other permitted countries. The licensee must also purchase active pharmaceutical ingredients (APIs) from Gilead approved suppliers, although local manufacturers produce the product.<sup>141</sup> VLS are also negotiated through the MPP, an organisation attempting to bridge the gap between pharmaceutical companies and the governments of DCs and LDCs, as well as generic manufacturers.

#### 4.2. The Medicines Patent Pool

The UN-funded MPP is the only patent pool dedicated to licensing pharmaceuticals in DCs and LDCs.<sup>142</sup> The MPP aims to improve access to HIV/AIDS, tuberculosis and malaria treatments.<sup>143</sup> The WIPO defines the model of patent pools as “an agreement between two or more patent owners to license one or more of their patents to one

another or to third parties.”<sup>144</sup> In short, the MPP obtains licenses from patent-holders and then sub-licenses manufacturing and distribution rights to generic companies. A significant advantage of MPP licenses is their data exclusivity waivers, which guarantees that generics may be registered in licensed territories.<sup>145</sup>

A total of 17 product licenses with 20 generic manufacturers were signed by the MPP between 2011-2018.<sup>146</sup> For example, in 2014, ViiV Healthcare and the MPP signed an agreement to license Dolutegravir, a 1st line HIV drug, in both adult and paediatric formulations. The adult license permits the sale of Dolutegravir in 92 named countries, and the paediatric license, in 121 named countries without royalties.<sup>147</sup> If a generic firm sells the drug in 10 other countries, a 5-10% royalty prevails.<sup>148</sup> Brazil is excluded and most South American countries may only sign paediatric licenses. Notwithstanding the implications of such geographical limitations, which are discussed in section 4.4.4, the license proved beneficial in terms of price and access.

#### 4.3. Findings in relation to price & medicinal access

Outcomes demonstrate that drug prices fall precipitously following VLS. This is confirmed in the 2016 Final Report by United Nations Secretary-General’s High-Level Panel on Access to Medicine, which found that these agreements have reduced treatment costs in several countries.<sup>149</sup> Due to the VL between Gilead and Strides, the price of Tenofovir in India dropped from \$200 per patient, per year to \$26.<sup>150</sup> As a result of the price decline initiated by another Gilead VL, access to an HIV/AIDS drug increased from 30,000 persons in 2006 to 8.7 million in 2015.<sup>151</sup> Gilead’s VLS also stimulate competition within the market and cause non-licensees to decrease prices.<sup>152</sup> The level of competition initiated by VLS is notably decisive of how much prices decline post-license.<sup>153</sup> As bilateral VLS are primarily confidential, data on their effect on price and access is limited. In contrast, licenses signed through the MPP are publicly available.

Use of Several Patent-Related Flexibilities, 29th – 31st January 2013: 11; Access to Medicine Index, “Access to Medicine Index 2016 Overall Ranking,” 8-11, 63-77.

<sup>139</sup> Raju, “Compulsory v Voluntary Licensing,” 27.

<sup>140</sup> Amin, “Voluntary Licensing,” 12.

<sup>141</sup> For license, see: <http://www.gilead.com/-/media/files/pdfs/other/form%20ar%20hcv%20license%20agmt%20gild%2011202017.pdf?la=en> [accessed Mar. 1, 2018].

<sup>142</sup> UNAIDS Press Statement, “UNAIDS Welcomes First VL to the MPP and Pharmaceutical Company,” 12th July 2011.

<sup>143</sup> MPP, “Annual Report 2016: Expanding for Better Treatment Options.” <https://annual-report-2016.medicinespatentpool.org> [accessed Apr. 1, 2018].

<sup>144</sup> WIPO, “Patent Pools and Antitrust – A Comparative Analysis” Prepared by the Secretariat, March 2014: 3.

<sup>145</sup> T Hoen, Boulet and Baker, “Data Exclusivity,” 4.

<sup>146</sup> Data obtained from MPP, <https://medicine-spatentpool.org/who-we-are/our-model/> [accessed Apr. 2, 2018].

<sup>147</sup> AmfAR, “HIV Treatment Clinical Brief: Dolutegravir,” September 2017.

<sup>148</sup> AmfAR, “HIV Treatment Snapshot: Dolutegravir, May 2017.

<sup>149</sup> UN High-Level Panel on Access to Medicines Report, 8, 22.

<sup>150</sup> Murphy Halliburton, India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime [Cornell: Cornell University Press, 2017]: 96.

<sup>151</sup> Tanoubi Ngangom, “Voluntary Licensing: Access to Markets for Access to Health,” Observer Research Foundation Report (2016): 7.

<sup>152</sup> Information obtained from article provided by Gilead via email: Kasturi Rangan and Katharina Lee, “Gilead Sciences, Inc. Access Program,” Harvard Business School, 3rd February 2010: 15.

<sup>153</sup> Michael A. Friedman, Henk den Besten and Amir Attaran, “Out-licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries,” *The Lancet* 361, (2013): 241.

TABLE 2: INFORMATION ON ALL MPP SUB-LICENSES.<sup>154</sup>

Patented Drug	Disease	Patentee	Countries Included	Persons with Disease Covered	# of Sublicensees (Generic Firms)
Abacavir	HIV	ViiV	121	99.3%	1
Atazanavir	HIV	Bristol Myers	122	89 %	6
Bictegravir	HIV	Gilead	116	89.8%	8
Cobicistat	HIV	Gilead	116	89.8%	7
Daclatasvir	Hepatitis C	Bristol Myers	112	65.4%	10
Dolutegravir (Adult)	HIV	ViiV	92	94	14
Dolutegravir (Pead.)	HIV	ViiV	121	99 %	13
Elvitegravir	HIV	Gilead	109	88.4%	4
Emtricitabine	HIV	Gilead	112	92.2%	11
Lopinavir	HIV	Abbvie	Africa	Africa	7
Lopinavir (Pead.)	HIV	Abbvie	125	98.8%	1
Darunavir	HIV	U.S NIH	N/A	N/A	N/A
Raltegravir (Paed.)	HIV	Merck Sharp	92	98%	2
Ravidasvir	Hepatitis C	Pharco	19	N/A	Not yet finalised
Solid Drug	HIV	U. of Liverpool	137	N/A	Not yet finalised
Sutezolid	Tuberculosis	John Hopkins	238	N/A	Not yet finalised
Tenofovir Alafenamide	HIV	Gilead	116	89.8%	11
Tenofovir Disoporsil	HIV	Gilead	112	89 %	3

The MPP boasts VLs for 17 products, and 80 sub-licenses with 19 manufacturers.<sup>155</sup> Following MPP sub-licenses, HIV and Hepatitis C drugs experienced an average 89% price drop.<sup>156</sup> As a result, the MPP distributed more than 4.7 billion dosages of lower-priced HIV/AIDS drugs between 2011-2018, and reached 99% of children and 87%-91% of adults living with HIV in DCs and LDCs.<sup>157</sup> 125 countries have received essential medicines.<sup>158</sup> In total, the MPP serviced approximately 10.9 million patient years from January of 2012 to June 2016.<sup>159</sup> A study estimates that, by 2027, a cumulative 36 million patient years will access lower cost drugs due to MPP VLs.<sup>160</sup> Moreover, the study found that the direct savings generated by the MPP is expected to reach \$2.3 billion by 2028, “equivalent to more than 24 million people living with HIV receiving first-line antiretrovirals (ARVs)” in DCs and LDCs “for 1 year at average prices today.”<sup>161</sup>

VLs can therefore benefit the national economy by boosting savings and stimulating the local generic industry. Local production, in turn, helps concoct new drug formulations or processes by improving the proprietor’s invention, which may depress the price further. This incentivises future licensing discussions and builds goodwill between generic firms and pharmaceutical companies; relations which may otherwise be strained.<sup>162</sup> It is also worth noting that VLs do not instigate adverse reactions from foreign States or pharmaceutical companies.<sup>163</sup> However, a downside to VLs is, as Table 2 displays, that they remain focused on HIV/AIDS drugs, with less frequent use in relation to other medications.

#### 4.4. Focusing on particular diseases

A study conducted in 2007 found that all but one of the 32 VLs from 2003 to 2005 in India and Africa concerned HIV/

AIDS.<sup>164</sup> A 2017 review ascertained that out of the total 47 VLs granted, 40 concerned HIV/AIDS drugs, 3 Cancer, 2 Hepatitis B&C,<sup>165</sup> 1 Avian Flu and 1 for Tamiflu.<sup>166</sup> Of the 18 patents currently licensed through the MPP, 15 are for HIV drugs.<sup>167</sup> These results confirm that VLs remain predominantly directed towards HIV/AIDS. The focus on HIV/AIDS is due to the severity of the disease, but it may also be owed to downstream effects from CLs, which tend to concentrate on HIV/AIDS drugs (Table 1), albeit not to the same degree as VLs. Omitting licensing possibilities for other diseases is a shortcoming of VL schemes, as the WHO estimates that Non-communicable diseases (NCDs) kill 38 million people in low- and middle-income countries annually.<sup>168</sup> Cancer notably accounts for 5.3 million of the deaths in DCs, which means it now claims more people than malaria, tuberculosis and HIV/AIDS combined.<sup>169</sup> Persons living with HIV/AIDS are also increasingly dying from hepatitis C and tuberculosis co-infections. Cryptococcal meningitis, a co-infection, accounts for 15% of all AIDS-related deaths, whereby 181,000 of the 223,100 infected annually die.<sup>170</sup>

The MPP is looking to expand into NCDs in the future, but as they follow the WHO essential medicines list (according to which non-profit organisation UNITAID determines which medicines it will fund), they are prevented from broadening their medicinal scope.<sup>171</sup> Global funding for diseases other than HIV/AIDS, tuberculosis and malaria is, in general, scarce and firms remain reluctant to license drugs for other diseases. However, efforts to widen VLs’ medicinal scope are experiencing some progress. One recent bilateral VL concerned drugs for Hepatitis C and certain cancers.<sup>172</sup> UNITAID currently has an open call for cervical cancer proposals and is seeking to expand further into NCDs.<sup>173</sup> The MPP also confirmed the feasibility of expanding into other essential

medicines on the 24th of May 2018, and announced in 2017 that it will continue working with the WHO to determine which products should be prioritised for in-licensing for another three years.<sup>174</sup> As the WHO expanded its list to include several cancer medicines in 2017, VLs may include more cancer drugs, although there remains a dearth of WHO recommendations for other NCDs, cardiovascular and endocrine medicines.<sup>175</sup> Given the focus on VLs for HIV/AIDS treatments, and the MPP's observation of the WHO list, CLs remain a useful tool to enable access to medicines for diseases excluded from VLs. CLs are, furthermore, crucial as certain terms and conditions constrain the potential for VLs.

#### 4.5. Terms & Conditions

VL agreements, irrespective of the number of parties involved, share similar factors which may impede access to medicines. This is due to terms and conditions which impose certain restrictions, demand high royalties, include geographical constraints, and lack transparency.

##### 4.5.1. Lack of transparency

A preliminary issue facing VLs is the lack of transparency in agreements. As most licensing contracts signed through the MPP are now publicly available on their website, this issue pertains to bilateral VL agreements. Bilateral VL agreements are often confidential, notwithstanding the snippets of information shared through press releases. This presents two significant difficulties. First, as previously mentioned, it encumbers the process of assessing the impact certain licenses have in relation to medi-

cal prices and access. Second, it disadvantages local manufacturers and governments as they may accept less favourable terms than other parties.

To help parties negotiate prices, it is suggested that they consult the annual medicine price list published by Clinton Health Access Initiative (CHAI), a non-profit organisation furthering the cause of improving health access by decreasing medical prices.<sup>176</sup> This list includes drug information and the price offered by four different pharmaceutical companies, as CHAI partners with firms such as Pfizer and Cipla,<sup>177</sup> and brokers "market access agreements," also known as price reduction schemes. It is worth noting such international procurement schemes may achieve lower prices for HIV/AIDS drugs than CLs,<sup>178</sup> and that generic drugs produced in India are frequently sold at a lower price than those offered through a VL.<sup>179</sup> The CHAI price list may therefore help governments decide whether a CL or VL (or neither) is the best option.

Checking the MPP online database 'MedsPal,' which presents information on 6,800 national patents and licenses in more than 110 countries, can also assist parties when discussing royalties by providing bargaining power if the patent soon expires.<sup>180</sup> Reviewing MPP sublicenses is likewise an option as it exposes parties to current terms and conditions, and can function as a template when discussing bilateral VLs. Another alternative is conferring with regional patent offices to inquire about information on existing licenses. For example, the African Regional IP Organisation, an intergovernmental body that facilitates collaboration on IP matters among 19 African States.<sup>181</sup> Cooperation between countries is vital, so parties conclude VLs with fair conditions.

<sup>154</sup> Information obtained from sublicenses published on MPP website, <https://medicinespatentpool.org/what-we-do/global-licence-overview/licences-in-the-mpp/>. (accessed Apr. 2, 2018).

<sup>155</sup> MPP, "Update on Progress of MPP Sub-Licenses," January 2018, <https://medicinespatentpool.org/uploads/2017/09/Update-on-Progress-of-MPP-Sub-licenses-January2018.pdf> (accessed Apr. 2, 2018).

<sup>156</sup> *Ibid.*

<sup>157</sup> Data obtained from MPP, <https://medicinespatentpool.org/who-we-are/our-model/> (accessed Apr. 4, 2018).

<sup>158</sup> Elizaveta Osipchuk, "Working Competition and Biotechnology Patent Pools," *Stockholm Intellectual Property Law Review* 1, no. 1 (2018) (forthcoming): 13.

<sup>159</sup> Information obtained in a PowerPoint presentation supplied by the MPP.

<sup>160</sup> Sandeep Juneja, et al., "Projected Savings through Public Health Voluntary Licenses of HIV Drugs Negotiated by the Medicines Patent Pool [MPP]," *PLOS ONE* (2017): 11.

<sup>161</sup> *Ibid.*, 1, 10.

<sup>162</sup> Halliburton, *India and the Patent*, 98.

<sup>163</sup> Frederick M. Abbott, and Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World*, (Cheltenham: Edward Elgar, Publishing, 2009): 144.

<sup>164</sup> Amin, "Voluntary Licensing," 7 – 10.

<sup>165</sup> Gilead, "Expanding Chronic Hepatitis C Treatment in Low- and Middle-Income Countries,"

(2017) <http://www.gilead.com/-/media/files/pdfs/other/hcv-access-fact-sheet-011217.pdf> (accessed Mar. 18, 2018).

<sup>166</sup> Raju, "Compulsory v Voluntary," 27.

<sup>167</sup> MPP, *Products Licenses*, <https://medicinespatentpool.org/what-we-do/global-licence-overview/licences-in-the-mpp/> (Accessed Apr. 20, 2018).

<sup>168</sup> WHO, "Background Paper: Non-Communicable Diseases in Low- and Middle-Income Countries" Regional High-Level Consultation in the Eastern Mediterranean Region on the Prevention and Control of Non-Communicable Diseases in Low- and Middle Income Countries," 25-26 October 2010: 2.

<sup>169</sup> Angelica Kershaw, "Pharma Industry Embraces Medicines Patent Pool's Voluntary Licence," *IHS Market*, 18th August 2016.

<sup>170</sup> WHO, "Guidelines for the Diagnosis, Prevention and Management of Cryptococcal Disease in HIV-Infected Adults, Adolescents and Children," Policy Brief, March 2018, 1.

<sup>171</sup> Maica Trabanco, Interview, 28th March 2018: Appendix A.

<sup>172</sup> Raju, "Compulsory v Voluntary," 23, 27.

<sup>173</sup> Draurio Barreira, Interview, 22nd May 2018: Appendix A.

<sup>174</sup> Nicole Homb, Interview, 21st May 2018; Maica Trabanco, Interview, 28th March 2018: Appendix A.

<sup>175</sup> WHO, "WHO Model List of Essential Medicines, 20h List," March 2017, as amended August

2017; WHO, "Executive Summary: The Selection and Use of Essential Medicines," Report of the 21st WHO Expert Committee on the Selection and Use of Essential Medicines, 27.31st March 2017; WHO, "WHO Model List of Essential Medicines, 19th List," April 2015, as amended November 2015.

<sup>176</sup> CHAI, "2017 Antiretroviral (ARV) CHAI Reference Price List," December 2017, [https://clintonhealthaccess.org/content/uploads/2017/12/2017-CHAI-ARV-Reference-Price-List\\_FINAL.pdf](https://clintonhealthaccess.org/content/uploads/2017/12/2017-CHAI-ARV-Reference-Price-List_FINAL.pdf) (accessed Feb. 20, 2018).

<sup>177</sup> CHAI Press Release, "American cancer Society and Clinton Health Access Initiative Announce Collaborations with Pfizer and Cipla to Increase Access to Lifesaving Cancer Treatment in Africa," Published June 20th, 2017.

<sup>178</sup> Reed F. Beall, Randall Kuhn and Amir Attaran, "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement" *Health Affairs* 34, no. 3 (2015): 1.

<sup>179</sup> Amin, "Voluntary Licensing," 5.

<sup>180</sup> Data obtained from MPP MedsPal Database, [www.medsPal.org](http://www.medsPal.org) (accessed Mar. 10, 2018).

<sup>181</sup> See: <http://www.aripo.org> (accessed Apr. 9, 2018); See also WHO, "WHO Support for Medicines Regulatory Harmonization in Africa: Focus on East African Community," *WHO Drug Information* 28, no. 1 (2014): 11-13.

#### 4.5.2. Restrictions

Due to the lack of transparency, second parties may unknowingly allow for more restrictive provisions than neighbouring countries. As a result, agreements contain varying terms and conditions. Common restrictions include designating suppliers from which ingredients must be sourced and stringent obligations in case of improvements.<sup>182</sup> Capping the number of patients to be treated is also mentioned as a limitation present in VLs,<sup>183</sup> as well as Gilead's 'anti-diversion programme' which requires patients to disclose sensitive personal information such as, name, address and citizenship to receive treatment.<sup>184</sup> This may prevent persons who are refugees, homeless or without stable living arrangements to access medicines.<sup>185</sup>

Furthermore, requiring licensees to purchase materials from certain suppliers may prevent prices from falling further. Gilead, for example, attaches supplier specifications to all its licenses.<sup>186</sup> Although this protects medicinal quality, it increases opportunity costs by imposing higher production expenses when other companies sell equivalent ingredients at a lower price for the identical quality. This also forces several manufacturers to import ingredients, which may carry additional VAT costs.<sup>187</sup> More seriously, controlling the sourcing of APIs can curb generic competition in the long-run.<sup>188</sup>

In addition to this, if manufacturers improve products, numerous agreements require the licensee to sublicense back the new formulation indefinitely and royalty free. Of the 18 sub-licensing agreements signed through the MPP, 16 include such a condition. For instance, in the MPP sub-license for Viiv's drug 'Abacavir,' clause 8.1. stipulates that if, during the agreement, the licensee "makes, develops, acquires, reduces to practice, becomes entitled to or secures control over any Improvements it shall communicate such improvements to Licensor and Viiv."<sup>189</sup> Moreover, it obliges the licensee to grant Viiv and the Licensor a "perpetual, irrevocable, worldwide, royalty-free, non-exclusive license to use any Improvement, Improvement Patent and related know-how."<sup>190</sup> Such a perpetual and royalty free 'grant-back' may discourage manufacturers from signing licenses or innovating, which benefits both parties.<sup>191</sup> Given this, a royalty-bearing grant-back should be sought and is present in at least one MPP sublicense: the agreement regarding the combination drug 'Lopinavir/Ritonavir' for the paediatric population. The sublicense provides that AbbVie retains the sole right to purchase the potential new formulation from the sublicensee or to license the new product until the termination or expiration of the original agreement, while paying a 4% royalty of net sales.<sup>192</sup> Similarly to brand companies, generic manufacturers should be rewarded for their innovation and willingness to share technology in the form of royalties.

#### 4.5.3. Royalties

Royalties in VLs reportedly reach an average of 5%,<sup>193</sup> albeit increasing when agreements cover greater territory or new products.<sup>194</sup> This is significantly higher than CLs, whose rate ranges from 0.5% to 4%. Although royalties in licenses not related to CLs and VLs primarily remain undisclosed, a survey reviewing agreements between the top 15 pharmaceutical companies estimates that they average

anywhere between 0-25%,<sup>195</sup> depending on the drug's stage of development.<sup>196</sup> A 5% rate may therefore represent a reduction compared to other licensing deals. However, manufacturers often incorporate the 5% rate in their price.<sup>197</sup> As a result, patient expenses, which are usually paid for out-of-pocket due to a lack of health care, increase.<sup>198</sup> Costs furthermore accumulate as HIV/AIDS patients may require several treatment stages of ARVs, as well as inhibitors and medicines for co-infections.<sup>199</sup>

One plausible means of lowering royalties is to threaten right holders with CLs or attempt to sublicense through the MPP. Post MPP negotiations decreased the royalties of several pre-existing bilateral VL agreements with Gilead for the drug Tenofovir from 5% to 3%.<sup>200</sup> Although less common, certain MPP licenses have resulted in agreements forgoing royalties and permitting free technology transfer, as well as assistance if necessary.<sup>201</sup> If this occurs, generic firms should be wary of the licensor attaching other restrictive clauses to offset such lenient conditions. However, this solution is futile for countries that are excluded from MPP licenses or VLs altogether.

#### 4.5.4. Geographical exclusions

Excluding certain countries from agreements or imposing geographical constraints on where manufacturers may sell products restricts access to medicines in those regions. DCs deemed middle-income, which by definition still constitute DCs, are primarily precluded from VLs<sup>202</sup> as they are profitable markets for pharmaceutical companies.<sup>203</sup> By doing so, pharmaceutical companies may charge higher prices on medicines in these areas.<sup>204</sup> Brazil, Colombia, Mexico, Venezuela and China are, for example, routinely excluded.<sup>205</sup> Consequently, the lowest prices of medicines are inaccessible to these countries, despite housing 75% of the world's impoverished.<sup>206</sup> MPP licenses include 55-80% of middle income countries.<sup>207</sup> As a result, ARVs licensed through the MPP are currently unavailable to 7 million people living with HIV/AIDS.<sup>208</sup> The MPP notably discloses that negotiating the geographical scope with patent holders carries the greatest difficulties.<sup>209</sup> This demonstrates that the financial interests inciting the adverse reactions to CLs also influence how VLs are administered.

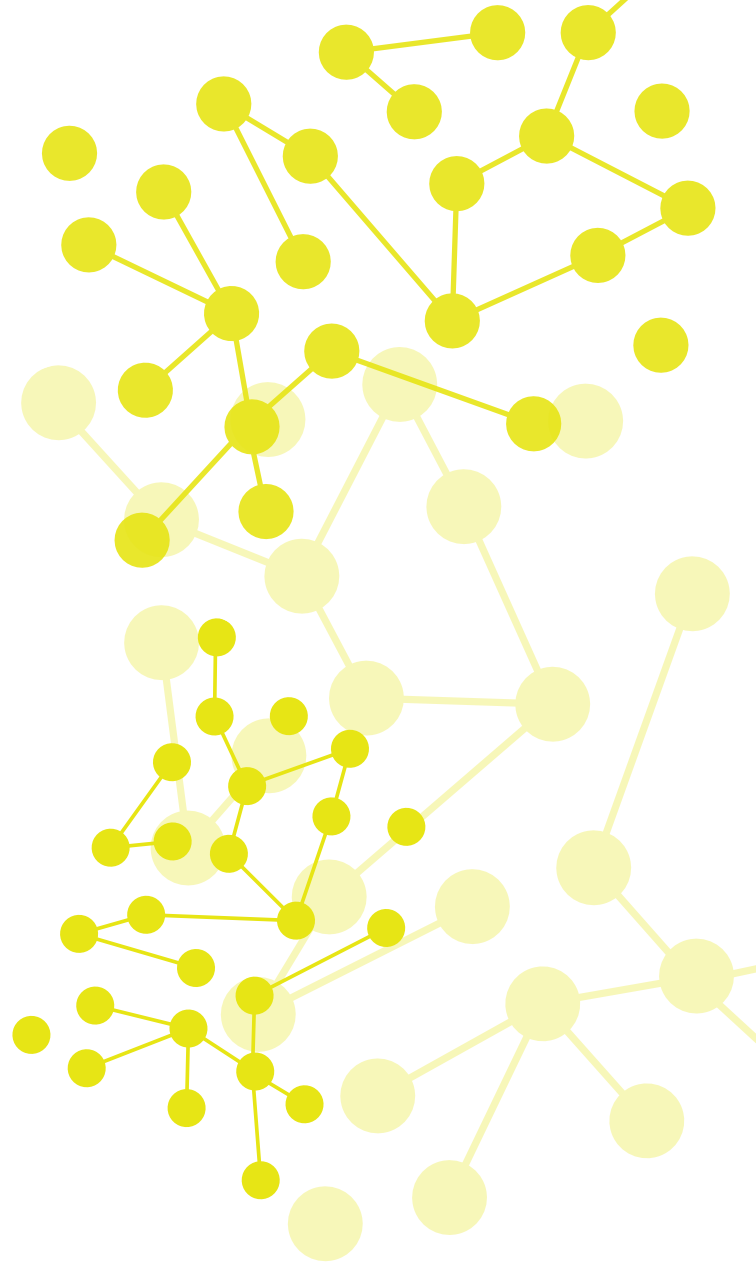
Countries tackle the issue of geographical exclusion differently. South Africa challenged, as well as resolved, its exclusion through national competition law. The South African *Competition Commission* found that GSK and BI had abused their dominant position by pricing their patented HIV/AIDS drugs exorbitantly.<sup>210</sup> The parties entered into a settlement agreement that required the two companies to voluntarily license their patents to generic manufacturers.<sup>211</sup> In the case of *GSK v Competition Commission*, this agreement was reinforced.<sup>212</sup> As a result, firms licensing their patents through bilateral VLs or the MPP increasingly include South Africa in their geographical scope.<sup>213</sup>

Threatening with a CL is also used to leverage patent holders to expand their geographical scope. For instance, Gilead included Malaysia, Ukraine, Belarus and Thailand in a VL only after the Malaysian Cabinet approved a CL for the reference drug.<sup>214</sup> Granting a CL likewise ensures that

a country attains access to the drug in case of unwavering exclusion. Additionally, certain MPP sublicenses allow for generics produced under a VL to be supplied to countries excluded from the license, if they issue a CL or there is no patent infringement.<sup>215</sup>

As of now, this opportunity has never been put to practice, despite its potential to improve medicinal access. Employing this measure successfully requires the consolidation of several factors. The same drug would need to be unavailable in both countries, and the countries would need to cooperate and facilitate export and import. While the structure of the license notably mimics that of Article 31bis, it escapes its legislative, procedural and administrative hurdles, and can procure a more favourable price. This is because the VL/CL combination involves several countries, helping to achieve economies of scale. Keeping this in mind, this license may provoke resistance from the patentee as its products would be reaching a country that may have been intentionally excluded. The country issuing a CL, likely to be a middle-income DC, may thus encounter similar international opposition as when granting a 'regular' CL.

Nevertheless, the possibility of executing this VL/CL license through the MPP and the criticism these exclusions elicit exerts pressure on pharmaceutical firms to extend their geographical reach. Indeed, the general trend demonstrates that companies are progressively including middle-income countries.<sup>216</sup> However, as VLs also preclude upper-middle-income countries, they fail to improve medicinal accessibility and affordability in these regions. CLs therefore remain necessary for countries prevented from the enjoying the benefits of VLs.



<sup>182</sup> Ibid; AmfAR, The Foundation for AIDS Research, "Improving Voluntary Licensing Agreements for Better Drug Access," 16th November 2017.

<sup>183</sup> Germán Velásquez, Carlos Correa and Robert Weissman, "Cost-Containment Mechanisms for Essential Medicines, Including Antiretrovirals, in China," WHO Health Economics and Drugs No. 13, [2002]: 7.

<sup>184</sup> For more information, see MSF Briefing: [https://www.msfaccess.org/sites/default/files/HepC\\_Gilead\\_anti-diversion\\_ENG\\_2014\\_0.pdf](https://www.msfaccess.org/sites/default/files/HepC_Gilead_anti-diversion_ENG_2014_0.pdf) [accessed Apr. 10, 2018].

<sup>185</sup> Ibid.

<sup>186</sup> Amin, "Voluntary Licensing," 14.

<sup>187</sup> Osewe, Nikrumah and Sackey, *Improving Access to HIV/AIDS*, 35.

<sup>188</sup> AmfAR, "Improving Voluntary."

<sup>189</sup> MPP, "License Agreement for Abacavir – Paediatrics," February 2013: 7.

<sup>190</sup> Ibid.

<sup>191</sup> Beyer, "Developing Socially Responsible," 240; Article 40 of TRIPS notably also provides that grant-back provisions may be deemed anti-competitive.

<sup>192</sup> MPP, "License Agreement for Lopinavir, Ri-

tonavir (LPV/R) Paediatrics" November 2014: 7.

<sup>193</sup> Amin, "Voluntary Licensing," 4.

<sup>194</sup> Beyer and WHO, "Enhancing Access to Medicines through Licenses," 15.

<sup>195</sup> Nigell Borshell and Adrian Dawkes, "Pharmaceutical Royalties in Licensing Deals: No Place for the 25 Per Cent Rule of Thumb," *Journal of Commercial Biotechnology* 16, [2010]: 10.

<sup>196</sup> Sharon Finch, "Royalty Rates: Current Issues and Trends," *Journal of Commercial Biotechnology* 7, [2001]: 6.

<sup>197</sup> Amin, "Voluntary Licensing," 14.

<sup>198</sup> Striner, "Learning From Practice," 559.

<sup>199</sup> WHO Fact Sheet, "What's New in HIV Treatment," November 2015: 1-2.

<sup>200</sup> Juneja, et al., "Projected Savings," 9.

<sup>201</sup> Ibid; Amin, "Voluntary Licensing," 4.

<sup>202</sup> MSF, "Untangling the Web of Antiretrovirals Price Reductions" 17th edition July 2014; See for example, Gilead, "Scaling Up Antiretroviral Treatment Sustainably" November 2016, 4, <http://www.gilead.com/-/media/files/pdfs/other/hiv%20access%20backgrounder%20us%20112816.pdf> [accessed Feb. 27, 2018].

<sup>203</sup> Beyer, "Developing Socially Responsible," 238.

<sup>204</sup> MSF, "Johnson & Johnson/Tibotec AIDS Drug Licenses Leave Out Too Many Patients," Press Release 28th January 2011.

<sup>205</sup> AmfAR, "HIV Treatment Snapshot: Dolutegravir," May 2017; Halliburton, India and the Patent, 112.

<sup>206</sup> Ibid.

<sup>207</sup> Information obtained in PowerPoint presentation supplied by the MPP.

<sup>208</sup> Halliburton, India and the Patent, 112.

<sup>209</sup> Maica Trabanco, Interview, 28th March 2018: Appendix A.

<sup>210</sup> Beyer, "Developing Socially Responsible," 232.

<sup>211</sup> Ibid.

<sup>212</sup> GlaxoSmithkline v Competition Commission, Case 61/CAC/Apr06, Competition Appeal Court, 12/06/2006.

<sup>213</sup> MSF, "Untangling the Web of Price Reductions," 11-12.

<sup>214</sup> MPP Press Release, "The MPP and Gilead Sciences Sign License for Bictegravir," 4th October 2017.

<sup>215</sup> T Hoen "Medicine Procurement" 189.

<sup>216</sup> Beyer, "Developing Socially Responsible," 238, 242.

## 4.6. Additional factors to consider

As VLs are predominantly regulated by the pharmaceutical industry, remedying the aforementioned terms and conditions presents a challenge and is up to individual countries. Assessing the circumstances from which VLs emerge is therefore vital to evaluate how VLs may improve or impede access. This will help decipher whether VLs represent a means to alleviate public health problems by counteracting the issues of CLs or are a means to retain control over patented inventions.

### 4.6.1. Prolonging patent lives & security?

It is claimed that companies voluntarily license base compounds protected by weak or soon-to-expire patents to strategically elude patent revocations.<sup>217</sup> What is noticeable is that patents may be placed in the MPP after Patent Offices reject patent applications.<sup>218</sup> Likewise, bilateral VLs may be signed after patent applications fail. To cite an example, Gilead signed VLs with seven Indian generic companies only after the Indian Patent Controller rejected Gilead's patent application for the Hepatitis C medicine Sofosbuvir in 2015.<sup>219</sup> This creates the impression that certain VLs serve the purpose of facilitating for companies to retain market power by signing agreements, which secure financial rewards with potential competitors otherwise eligible to enter the market independently, as opposed to resolving medicinal inaccessibility.<sup>220</sup>

Products not yet patent protected may also be licensed, which may indicate certain VLs merely arise as attempts to evade patent opposition.<sup>221</sup> For example, in 2007, Gilead agreed to license Tenofovir, an HIV/AIDS drug awaiting patent registration, with 11 Indian manufacturers.<sup>222</sup> The license granted the manufacturers with rights to produce and distribute Tenofovir in ninety-five countries in exchange for a 5% royalty, along with two additional conditions.<sup>223</sup>

First, that the product not be sold in certain countries, such as Brazil and China; and second, that all materials had to be purchased from Gilead approved suppliers. These restrictive conditions caused Cipla to reject Gilead's licensing offer and submit a pre-grant opposition to the patent office in India, who rejected Gilead's patent application due to evergreening in 2009.<sup>224</sup> As a result, generic versions of Tenofovir became available at \$700 per patient, per year, a significant reduction from its previous price of \$5,718 per patient in DCs annually.<sup>225</sup> These ex-

amples therefore suggest that companies may license questionable patents, and that an intention behind VLs is to obviate legal challenges.

Conversely, ex ante estimating a patent application's success is an intricate task with uncertainty involved.<sup>226</sup> This uncertainty weakens claims that VLs are merely negotiated as a defence measure. VLs also involve 'viable' products with newly acquired patent protection. MedsPal shows that the expiry date of patents licensed varies anywhere from 2018 to 2032.<sup>227</sup> It is therefore implausible that licensors generally only licence patents they predict to fail. Indeed, while revoked or failed patents may grant more advantageous terms for generic manufacturers, opposing patents or seeking revocations may prolong medicinal inaccessibility, as these proceedings often experience delays and appeals, and are costly.<sup>228</sup> Additionally, using an inventor's know-how also saves firms from having to develop their own technology, enabling the product to become available more quickly. Thus, it may prove more beneficial overall to exploit the information provided by VLs.

India may be an exception, given their vigorous patent opposition procedure which is less time consuming than fellow countries and permits third parties to file pre-grant observations.<sup>229</sup> In one instance, this process led to GSK rescinding a patent application and thereby allowing Indian generic manufacturers to offer Abacavir to DCs and LDCs for \$330 per patient, per year. This is a price 31% lower than its expected rise following the potential patent (as a data point, Abacavir is sold in Mexico for \$2,600 per patient, per year).<sup>230</sup> Pre-grant oppositions can, as with the tactic of threatening right holders with CLs, be used as a method to increase VLs or reduce prices.<sup>231</sup> Licensees should therefore perform sufficient due diligence on the patent subject to a potential VL, as it may help to negotiate better terms, determine whether to avoid the license altogether, or issue a CL.

### 4.6.2. Merely a means to avoid compulsory licenses?

Whether VLs as used by pharmaceutical companies as a form of corporate social responsibility, or whether they are merely a means of avoiding CLs, is subject to speculation. VLs accord inventors with greater control over compensation, and when they are to be issued, than CLs. This, in turn, entails that manufacturers and countries retain less control over whether they are to be included in an agreement, which medicine is to be supplied and, most

<sup>217</sup> Amin, "Voluntary Licensing," 4-5.

<sup>218</sup> Halliburton, India and the Patent, 134.

<sup>219</sup> Gilead Press Release, "Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries," September 15th 2014.

<sup>220</sup> WHO, "Cost-Containment -Mechanism" 7.

<sup>221</sup> Beyer, "Developing Socially Responsible," 236; Amin, "Voluntary Licensing," 13.

<sup>222</sup> Lalitha, "TRIPS Flexibilities," 114.

<sup>223</sup> Ibid.

<sup>224</sup> Ibid.

<sup>225</sup> Ibid.

<sup>226</sup> Ramanujam and Goyal, "One View of Compulsory Licensing," 404.

<sup>227</sup> Data obtained from MPP MedsPal Database, see: [www.medsPal.org](http://www.medsPal.org) (accessed Mar. 10, 2018).

<sup>228</sup> Amin, "Voluntary Licensing," 12.

<sup>229</sup> Tahir Amin, "Re-visiting the Patents and Access to Medicines Dichotomy: An Evaluation of TRIPS Implementation and Public Health Safeguards in Developing Countries," in The

Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines ed. Obijofor Aginam, John Harrington and Peter K. Yu (Cheltenham: Edward Elgar Publishing, 2013): 118.

<sup>230</sup> Ibid.

<sup>231</sup> Yibeltal Assefa, et al., "Access to Medicines and Hepatitis C in Africa: Can Tiered Pricing and Voluntary Licensing Assure Universal Access, Health Equity and Fairness?" *Globalization and Health* 13, no. 73 (2017): 8.

<sup>232</sup> Beall and Kuhn, "Trends in Compulsory," 6.



importantly, when that medicine will be supplied. Meanwhile, CLs grant extensive power to licensees with regards to royalties, products and timing, and are unfavourable to patent holders compared to VLs. The emergence of VLs is thus cited as the reason for lower CL use in recent years.<sup>232</sup> A study of all CLs from 2001 to 2016 found that of the 19 proposed CLs that were ultimately not issued, 5 resulted in bilateral VLs.<sup>233</sup>

VLs may indicate companies' willingness to cooperate with countries to increase access to medicines. This reasoning is supported by the fact that VL negotiations have been a preliminary requirement to issue a CL since the ratification of TRIPS in 1995, and VLs only recently proliferated. Additionally, countries increasingly sign VLs with the MPP without threatening or issuing CLs. Companies are also progressively taking independent steps to alleviate public health issues, such as participating in price reduction schemes with NGOs.<sup>234</sup> Alternatively, the underlying reason for the correlation between lower CL use and the increase of VLs could simply be that it offers firms a means to escape a CL. One criticism of VLs is that such a 'friendly measure' helps companies refute the necessity of CLs more convincingly.<sup>235</sup> In other words, VLs may represent pharmaceuticals companies choosing the carrot to keep the stick, CLs, at bay.

This criticism hinges on the fact that VLs frequently arise after countries threaten with a CL. For example, Gilead included Malaysia in a VL only after Malaysia issued a CL,<sup>236</sup> despite Malaysia attempting to acquire a VL through the MPP and with the patent holder directly.<sup>237</sup> Roche similarly signed a sublicense with a company and selected 12 other potential generic manufacturers after Taiwan issued a CL for Tamiflu.<sup>238</sup> Also, in Kenya, GSK and BI granted a

VL for HIV/AIDS drugs only after Cosmo, a local manufacturer, applied for a CL.<sup>239</sup> Cosmo attempted to negotiate a VL before its CL application. Upon signing the agreement, both companies dropped the price of their drug below Cosmo's in the same market.<sup>240</sup> Not only does this imply that the companies acted in bad faith and in an ethically unsound manner, but it undermines the credibility of VLs and discourages parties from seeking such a license.

Hence, inventors unwillingly grant *voluntary* licenses *voluntarily*. By averting CLs and agreeing to VLs, firms maintain market control and their influence on royalties. Correspondingly, achieving favourable terms is reported as an obstacle while negotiating VLs.<sup>241</sup> LDCs, for instance, have less bargaining power given their small market size. Meanwhile, Brazil, who has a large pharmaceutical market, monitors which diseases require intervention and then uses CLs as a bargaining chip by threatening with issuances to depress prices.<sup>242</sup> Issuing or threatening with CLs is thus a method of spurring VLs. However, this 'tactic' leads to superfluous negotiations and needlessly protracts the process at the expense of the patient. Indeed, it may be idealistic to expect patentees to voluntarily share information without the threat of a less favourable outcome. However, VLs present firms with an opportunity to increase revenue by entering untapped markets.<sup>243</sup> It is estimated that the African market may generate \$30 billion in revenue for pharmaceutical companies.<sup>244</sup> As generic manufacturers have stable supply chains in DCs and LDCs, companies can widen their market reach with VLs in these regions with little investment.<sup>245</sup> Therefore, threats should not be necessary, as VLs achieve a middle ground by offering incentives for all parties involved.

<sup>233</sup> 't Hoen, "Medicine Procurement," 186.

<sup>234</sup> McNeil Jr, "As Cancer Tears Through Africa."

<sup>235</sup> Ho, Access to Medicine in the Global Economy, 365 – 366.

<sup>236</sup> Gilead Press Release, "New License Agreement with the MPP for Access to Bictegravir," 4th October 2017.

<sup>237</sup> Director-General of Health Malaysia, "Implementation of the Rights of Governments for Sofosbuvir Tablet to Increase Access for Hepatitis C Treatment in Malaysia," 20th September 2017.

<sup>238</sup> Amanda Mitchell, "Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Option for Accessing Medical Patents," California Law Review 95, no. 2 (2007): 544.

<sup>239</sup> Osewe, Nikrumah and Sackey, Improving Access to HIV/AIDS, 33.

<sup>240</sup> Olulomire Ogunye, et. al., "AIDS, Africa and ARVs: Domestic Production as the Solution to the treatment Gap," in Global Challenges: Science and Society, 2009: 14.

<sup>241</sup> 't Hoen, Boulet and Baker, "Data Exclusivity," 3.

<sup>242</sup> Singhai and Singhai, "A Study of," 23.

<sup>243</sup> Daniel D. Kim, "Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing," American University Intellectual Property Brief 8, no. 1. (2016): 68, 104.

<sup>244</sup> Ngangom, "Voluntary Licensing: Access," 8.

<sup>245</sup> Ibid.



Procuring agreements with threats also raises ethical concerns and fails to alleviate tensions between pharmaceutical firms and countries. Cooperation between these parties is not only essential to preserve public health and increase access to medicines in a sustainable manner, but to motivate firms to undertake R&D for diseases afflicting DC and LDCs. Despite these implications, VLs do contribute to remedying medicinal inaccessibility and, as stated by Ho, “serve as an example of how the alternative solutions, although not completely satisfying, nevertheless promote more access to medicines.”<sup>246</sup>

## 5. CONCLUDING THOUGHTS

Affordability is a key factor to improve access to medicines in DCs and LDCs, and to protect the right to health. Both VLs and CLs serve as a means to reach this end, albeit through vastly different routes and with different results. Which license ultimately engenders the better price for the public depends upon a plethora of factors, including the license duration, the product itself, the technology licensed, whether it is for import or local manufacturing, costs of APIs, exclusivities, generic availabilities, royalty rates and so on. CLs allow for competitors who reach production costs nearing zero per-unit level, and who price correspondingly, to penetrate the market. For VLs, prices vary depending on whether it is an agreement between a patentee and one generic manufacturer, several manufacturers, or through the MPP. If the VL is non-exclusive, thereby involving several generic firms, the resulting spurring of competition can depress prices significantly. However, if the VL is with one manufacturer, in the absence of competition, drug costs remain mostly intact. The amount of competition in the market is thus a determining factor as to which license achieves a more favourable price.

However, as shown, the process of acquiring the rights to use a pharmaceutical patent is likewise crucial to the success of the license in procuring access to medicines.

This relates to both the administrative and legislative procedure of obtaining a license, as well as the aftermath. Middle-income DCs may encounter resistance both internationally and domestically when issuing CLs, whereas LDCs have yet to report similar occurrences. VLs are not accompanied by such social, economic or trade-related consequences and may therefore, for political reasons, be preferential depending on the country.

Procedurally, both licensing options may meet obstacles. Constraints present under TRIPS and in national laws inhibit the process of issuing a CL under both Article 31 and 31bis. Although several licenses were indeed successful and experienced no issues, an advantage of VLs is nevertheless that the process includes fewer procedural difficulties and is less strenuous and time-consuming than CLs. VLs also meet minimal resistance from pharmaceutical companies and foreign States, diminishing the threat of litigation and political pressure. However, several countries struggle to obtain VLs and sign licenses only after threatening to issue or issuing a CL or, alas, are never included in the geographical scope of the license. The geographical exclusions present in several VLs reinforces the relevance of CLs and the necessity of using both licensing options.

The type of treatment to be licensed is equally important and particularly germane to HIV/AIDS, as persons are required to consume multiple medicines with enhancers or boosters. MPP sublicenses allow parties to combine products encompassing several patents, saving parties from seeking a license for each patent individually, and saving patients from purchasing several different drugs. CLs increasingly include the ARV cocktail, but this is contingent on what is patented in each respective country. This issue continues to be relevant as future drugs may contain the ARV compound, as well as boosters, and compounds able to treat co-infections and HIV/AIDS simultaneously, or several lines of HIV/AIDS treatments. Global populations are increasingly becoming resistant to 1st line

<sup>246</sup> Ho, *Access to Medicine in the Global Economy*, 367.

<sup>247</sup> Ravinda K Gupta, John Gregson and Silvia Bertagnolio, “HIV-1 Drug Resistance Before Initiation or Re-Initiation of First-Line Antiretroviral Therapy in Low-Income and Middle-Income Countries: A Systematic Review and Meta-Regression Analysis” [2018] *Lancet Infectious Disease* 18 346, 346-350.

drugs and, as India enforced the TRIPS standards in 2005, there are fewer generics available.<sup>247</sup> The inability to secure 2nd and 3rd line HIV/AIDS drugs may therefore develop into an issue tantamount to the level of medicinal inaccessibility present during the first AIDS epidemic 'outbreak.' Securing treatments for NCDs, tropical diseases and furthermore must also be prioritised. As the results of CLs and VLs of HIV/AIDS drug demonstrate, these licenses significantly improve access to medicine for citizens of DCs and LDCs. Should similar efforts be employed for other diseases, medicines could become more readily available and so public health issues capable of being remedied from the outset; not in hindsight where the consequences of omission are the needless deaths and suffering of millions of persons, annually.

In conclusion, although CLs enable medicinal access, the extent of which Articles 31 and 31bis succeeds in protecting the right to health by increasing access to medicines in DCs and LDCs is limited by the resistance of foreign States and pharmaceutical companies, in addition to FTAs procedural difficulties which impair the possibilities of issuing CLs. VLs escape the restrictions of FTAs, as well as the threat of foreign retaliation and procedural inefficiencies hindering CLs. However, VLs remain focused on HIV/AIDS drugs and frequently exclude middle-income DCs. VLs should therefore not supersede CLs, despite its advantageous process, as the extent to which VLs improve access to medicines is confined to its stated geographical limits and to a limited range of diseases. For countries and diseases excluded, VLs fail to remedy the issue of inaccessible medicines in DCs and LDCs. Given this, CLs should be used by States to counteract these deficiencies. In this way, CLs and VLs should be used in a complimentary manner to offset each other's limitations, to cover the range of diseases in question, and to reach the citizens in all countries of need, thereby maximising medicinal access and protecting the right to health.



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Katarina is from Norway and holds an LLB Honours degree from Edinburgh University and an LLM in European Intellectual Property Law from Stockholm University. Currently, she is pursuing an advanced LLM in Law and Digital Technologies at Leiden University. In the future, she hopes to work with increasing medicinal access in developing and least developed countries through the intellectual property framework.

