

## VENEZUELA BETWEEN DENGUE AND CHIKUNGUNYA: WHO CAN BE HELD ACCOUNTABLE FOR POOR ACCESS TO HEALTH?

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**ABSTRACT:** Access to medicines is a critical focal point when arguing in favour of the patent system and its benefits in terms of innovation, affordability and availability. The general discourse tends to concentrate within the developing and least developing world, however, studies have shown the importance in narrowing the context of discussion or analysis even if within the developing world when addressing the issue of patents and access to medicines. This article aims at analysing the relation between patents and access to medicines in general to thereafter focus in the on-going health crisis in Venezuela due to the outbreak of Dengue and Chikungunya to bring to the spotlight the other factors deterring access to medicines within this context. Extensive parts of this analysis has been already published, thus beyond presenting the reader with the Venezuelan context the goal is to highlight the need to create further incentives to foster R&D together with the need to emphasise the importance of all stakeholders to be held accountable for taking actions addressed to tackle imperative health concerns.

**KEY WORDS:** Public health, access to medicines, Venezuela, Dengue fever, Chikungunya fever, patents, Doha declaration, human rights, TRIPS Agreement and accountability.

**RESUMEN:** El acceso a medicamentos es un punto crítico en la discusión sobre los beneficios del sistema de patentes en términos de innovación, disponibilidad y asequibilidad. La discusión sobre el acceso a medicamentos tiende a enfocarse en la situación en los países en vías de desarrollo y los no desarrollados de forma generalizada. Más sin embargo en varios estudios se ha demostrado el valor y la importancia, en cuanto a la discusión y el análisis se refiere, de poner en contexto ó enfocarse en un determinado espacio geográfico tanto el estudio sobre el impacto de las patentes y el tema sobre acceso a medicamentos. En tal sentido, el presente artículo analizará de forma general la relación entre las patentes y el acceso a medicamentos para posteriormente hacer breve referencia a la actual crisis de salud pública en Venezuela a causa de los brotes de Dengue y Chikungunya. El propósito de este análisis es mostrar al lector la existencia de factores externos, al sistema de patentes, que

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<sup>1</sup> Comprehensive parts of this article has already been published within the doctoral thesis *The Role of Patents in the Latin American Development: models of protection of pharmaceutical patents and access to medicines in Brazil, Chile and Venezuela* by CADILLO CHANDLER, D., (2014).

deterioran y obstaculizan el acceso de medicamentos. Gran parte de este estudio ya ha sido publicado, por lo tanto a parte de introducir al lector de forma breve al contexto Venezolano la meta es resaltar la necesidad de crear incentivos externos al sistema de patentes para fomentar la investigación y desarrollo de nuevos medicamentos por un lado, y por el otro enfatizar la responsabilidad de todas las partes involucradas – Gobiernos, industria, legisladores y gremios profesionales- en tomar las acciones necesarias para garantizar un acceso adecuado tanto a medicamentos como a tratamiento.

**PALABRAS CLAVE:** Salud pública, acceso a medicamentos, Venezuela, Dengue, Chikungunya, patentes, Declaración de DOHA, derechos humanos, ADPIC y responsabilidad social.

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## 1. INTRODUCTION

The patent system as a whole was conceived as a mean to boost technological development by ensuring inventors' rights. Even though the existence of patents can be traced back to 1421,<sup>2</sup> it was until relatively late when intellectual property rights seemed to be colliding with public health concerns. With the creation of the World Trade Organization (hereinafter WTO) in 1994 its member countries also ratified a series of Agreements, among these, the Agreement on Trade Related Aspects of Intellectual Property (hereinafter TRIPS), which linked public health to intellectual property rights by extending protection to all fields of technology.

To understand the relation between both concepts –public health and patents- it is necessary to begin the analysis with the creation of the WTO, the TRIPS Agreement, and the following Declarations i.e. Doha Declaration. Several important aspects need to

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<sup>2</sup> NARD, C., and MORRIS, A., "Constitutionalizing Patents: From Venice to Philadelphia", *Review of Law and Economics*, Volume 2, Number 2, 2006, pp. 223-320, pp. 233.

be taken into consideration when assessing the discourse on access to medicines, namely the underlying human rights aspect embedded in the “right of access to health”, the utilitarian approach to patents and the use of TRIPS flexibilities. The right to health seems to have a particular importance in the context of pandemics such as HIV/AIDS, malaria and tuberculosis. The human right-based approach has an impact on national legislation, since the State is the main guarantor for the fulfillment of this right. For instance, basic health needs are deemed health rights. Thus, Governments need to straighten their priorities within the health sector to ensure not only that sufficient financial resources are allocated but also to comply with their international commitments.<sup>3</sup> In terms of the utilitarian approach to patents, this brings to the spotlight that inventors in nature would not feel compelled to disclose the invention if patent protection would not be available. In principle, patents could be perceived as a reward to the inventor or the fruits of his work that ultimately translate into public disclosure as the price for this protection.<sup>4</sup>

Other element constantly present within the access to medicines discourse is the use of the TRIPS Flexibilities, which will also be defined below since these in-principle allow WTO Country Members to tackle health concerns without breaching intellectual property rights. TRIPS Flexibilities i.e. compulsory licenses have been used by a few countries to address the national supply of HIV/AIDS medication.

The importance of this article beyond presenting the reader with the origins of the discussion and the link between intellectual property rights and access to medicines is mainly to highlight the external factors to the patent system hampering access to medicines. It is also desired to bring to the spotlight within a particular context how the use of these flexibilities or the creation of side incentives could potentially improve peoples’ access to medicines or treatment for tropical illnesses i.e. Dengue or Chikungunya.

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<sup>3</sup> ASHER, J., "The Right to Health: A Resource Manual for NGOs", *The Commonwealth Medical Trust*, August 2004, pp. 22-23.

<sup>4</sup> ALY CROWNE, E., "The Utilitarian Fruits Approach to Justifying Patentable Subject Matter", *John Marshall Review of Intellectual Property Law*, Volume 10, Number 753, 2011, pp. 754-763.

## 2. WTO AND TRIPS AGREEMENT

The WTO was created in 1994 through the Marrakesh Agreement during the well-known Uruguay Round. The Organization became operational in 1995, and this international organization does not only deal with trade rules between nations, but is also responsible for international trade rule setting.<sup>5</sup>

Annexed to the Marrakesh Agreement Establishing the World Trade Organization, a sum of 12 Agreements became mandatorily ratified by nations if becoming Members of the WTO. Among these, the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (hereinafter TRIPS Agreement) ratified by 158 Members on 2nd February 2013, re-conceptualized intellectual property rights as trade issues<sup>6</sup> when minimum standards of protection were not only established but also extends to all fields of technology, including the pharmaceutical field.<sup>7</sup> This part of the analysis will assess both the content of the TRIPS Agreement relating to patents and public health, and its impact on WTO Member Countries.

Nations, by acceding to the WTO also agreed upon extending the term of protection for a period of 20 years<sup>8</sup> both to products and processes, as they now were contracting parties.<sup>9</sup> This new provision was also binding for developing and least-developed nations that did not provided patent protection neither for the length settled nor for all fields of technology, since the Paris Convention allowed Member Countries to legislate over the fields of technology, which should be subject to patent protection.<sup>10</sup>

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<sup>5</sup> *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3, World Health Organization, Geneva, WHO/EDM/2001.2, pp. 1.

<sup>6</sup> DREYFUSS, R., "TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis", (POGGE, T., RIMMER, M., and RUBENSTEIN, K.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, New York, 2010) pp. 35-55, pp. 35.

<sup>7</sup> Marrakesh Agreement Establishing the the World Trade Organization, Geneva, 15 April 1994, entered into force 1 January 1995, *1867 United Nations Treaty Series* 3, annex 1C – Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), Article 27 (1) (Hereinafter TRIPS Agreement).

<sup>8</sup> Article 33 from TRIPS Agreement.

<sup>9</sup> Article 27(1) from TRIPS Agreement. The non-discrimination principle is embedded within the Agreement since patents cannot be refused on basis of the field of technology.

<sup>10</sup> Paris Convention for the Protection for Industrial Property, as Amended in September 28, 1979, WO020EN, Article 1(4).

To a certain extent some scholars perceive the TRIPS Agreement as an “agent of change in the health sector”<sup>11</sup> since patents for pharmaceutical products and processes were now to be granted. Allegedly in the past, this sector was excluded from patentability due to public or social concerns in terms of countries’ need to ensure access to medicines at a low price, and also to protect the national pharmaceutical industry.<sup>12</sup>

The Agreement, besides extending patent protection to all fields of technology, and stating patentability requirements it however, does not define what an invention is. In this respect, the lack of consensus to provide a universal or single definition has been highlighted, which is not indicative of an omission or having a loophole in the TRIPS Agreement.<sup>13</sup> Allegedly, this is not the only definition not provided by the Agreement, the same Article 27(1) aims at defining inventions by giving their patentability requirements –new, inventive step, and capable of industrial application- but none of these are defined, except for the ‘inventive step’ that can be taken as ‘non-obvious’.<sup>14</sup>

Article 27(2) and (3) also foresee patentability exceptions, namely those “contrary to public order or morality, including to protect human, animal or, plant life or health” animals, and members may also exclude from patentability diagnostic and/or therapeutic and surgical methods.<sup>15</sup>

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<sup>11</sup> CULLET, P., "Patents and medicines: the relationship between TRIPS and the human right to health", *International Affairs*, Number 79, Volume I, 2006, pp. 145.

<sup>12</sup> ROFFE, P., SPENNEMANN, C., and VON BRAUN, J., "From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health", (ROFFE, P., TANSEY, G., and VIVAS-EUGUI, D.) *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, UK-USA, 2006) pp. 9-26, pp. 13.

<sup>13</sup> CORREA, C., "Implementing the TRIPS Agreement in the Patents Field: Options for Developing Countries", *The Journal of World Intellectual Property*, Volume1, Number 1, 1998, pp. 75-99, pp. 76.

<sup>14</sup> Footnote 5 from Article 27(1) of the TRIPS Agreement. See also, CORREA *Ut supra* at 82. Arguably the fact that patentability requirements are not defined, ‘opens some room for flexibility at the national level’ as indicated by CORREA.

<sup>15</sup> Article 27(2) from TRIPS Agreement "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to ... health, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Articles 7 and 8 give the first link to public health within the Agreement, since the need to balance rights and obligations, and the importance to promote social and economic welfare, as well as to protect public health are acknowledged.<sup>16</sup>

Although, the Agreement intends to provide a harmonized intellectual property regime with minimum standards of protection, it also allows Member Countries to tailor their national systems to implement the Agreement.<sup>17</sup> Some developing countries seemed to have implemented stronger IP protection, reportedly as a strategy to attract the pharmaceutical industry to innovate, transfer and disseminate its technology.<sup>18</sup> Nevertheless, exceptions are also foreseen by the Agreement to protect public health, correct anticompetitive practices, and to address national emergencies.

Besides allowing Members to take the necessary measures to protect both public health and public interests, the Agreement in Articles 30 and 31 settles the exceptions for patent protection. Namely, Article 30 entails limited exceptions to these exclusive rights as long as the measures taken do not either unreasonably conflict with the normal exploitation of the patent, or with legitimate interests of the patent owner, taking into account of the legitimate interests of third parties as well.<sup>19</sup>

The other exception foreseen within the Agreement is the compulsory licenses regime, also known within the Agreement's Article 31 as 'Other use without Authorization of the Right Holder.' Accordingly, country members are entitled to enact compulsory licenses to predominantly supply the internal market<sup>20</sup> and after adequately remunerating right holder.<sup>21</sup> In general terms even when a compulsory license has been enacted "the right holder shall be paid adequate remuneration taking into account the economic value of the authorization" as pointed out by Article 31 (h) from the TRIPS

<sup>16</sup> Article 7-8 from the TRIPS Agreement. See also Globalization, TRIPS and access to pharmaceuticals, WHO Policy Perspectives on Medicines No. 3, World Health Organization, Geneva, WHO/EDM/2001.2.

<sup>17</sup> DREYFUSS, R., "TRIPS and Essential Medicines", pp. 37.

<sup>18</sup> WANIS, H., "Agreement on Trade-Related Aspects of Intellectual Property Rights and Access to Medication: Does Egypt Have Sufficient Safeguards Against Potential Public Health Implications of the Agreement", *The Journal of World Intellectual Property*, Volume 13, Number 1, 2010, pp. 24-46, pp. 25-26.

<sup>19</sup> Article 30 from TRIPS Agreement "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

<sup>20</sup> Article 31 (f) from the TRIPS Agreement.

<sup>21</sup> Article 31 (h) from TRIPS Agreement.

Agreements, however the Agreement also foresees an exception to this rule settled within the same Article part (k) from where it could be inferred that the aforementioned compensation does not necessarily will take place in the terms initially foreseen within Article 31(h) since the amount of the compensation may need to be taken into consideration when correcting anti-competitive practices.<sup>22</sup> The original Agreement – draft- brought along a gap in members’ ability to take measures to address public health or national emergencies given to Article’s 31 (b) requirement to pursue voluntary license from patent holders before actually enacting compulsory licenses.<sup>23</sup>

Following the TRIPS Agreement, countries began lobbying for further clarification in terms of the flexibilities. Two particular cases seemed to have played an important role in the move towards recognizing public health concerns in the years to come. During 1997 the South African Government modified its National Drug Policy in a manner favorable to compulsory licenses and parallel imports in their aim to tackle the HIV/AIDS crisis, but both the United States of America’s government and the U.S. pharmaceutical industry strongly opposed to such implementation arguing that it was an abrogation to patent rights and subsequently a breach to TRIPS.<sup>24</sup> The USTR placed South Africa within the Special 301 reports watch list for two years in a row (1998-1999) and later on also withheld trade benefits for a selection of products that were already approved within the Generalized System of Preferences (GSP) as a method of pressure with South Africa to back down from implementing the revised National Drug Policy.<sup>25</sup> Given the media attention, and the work of activists the U.S. Government

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<sup>22</sup> Article 31 (k) from TRIPS Agreement.

<sup>23</sup> Article 31 (b) from TRIPS Agreement. See Also, MITHELL, A.D., and VOON, T., "The TRIPS Waiver as a recognition of public health concerns in the WTO", (POGGE, T., RIMMER, M., and RUBENSTEIN, K.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, New York, 2010) pp. 56-76, pp. 59-61. The Agreement in its final version included a waiver to the requirement for the party pursuing a compulsory license to obtain authorization from the right holder for such use in cases of national emergency, or other circumstances of extreme urgency. Regardless of the waiver, the right holder must be notified as soon as possible about the measure.

<sup>24</sup> FISCHER, WILLIAM, W., and RIGAMONTI, CYRILL, "The South Africa AIDS Controversy A Case Study in Patent Law and Policy", *The Law and Business of Patents* (Harvard Law School, Updated 2005) 3-5 < [cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf](http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf)> accessed 10 March 2014.

<sup>25</sup> *Idem* pp. 7. During 1998 the South African Pharmaceutical Association brought their complain about the revised National Drug Policy before the High Court of South Africa, the industry challenged the constitutionality of the legislation, allegations that were later on dismissed by the High Court. (Fischer, W. et al).

shifted their policy towards South Africa in a manner consistent with South Africa's need to achieve greater access to essential medicines.<sup>26</sup>

Later on during 2000, the U.S Government called for consultations with Brazil due to the implementation of the working requirement within its IP legislation, which, if unfulfilled, would suffice as for the government to enact compulsory licenses and/or parallel trade to satisfy the internal market.<sup>27</sup> These two cases portrayed the conflict of interests, sometimes still prevalent, between the interests of the pharmaceutical industry on the one hand and on the other with the duty to implement the TRIPS Agreement in a manner consistent with the each country's national needs (i.e. to supply the internal market to grant access to essential medicines).

Thus far it has been established that the TRIPS Agreement does not only settle minimum standards of protection, but also foresees exceptions to patent rights. More attention shall be given to both the Doha Declaration, and other flexibilities conceived to address public health concerns among other national interests. Thus far, TRIPS flexibilities can be summarized as compulsory licenses, parallel imports, and early working exceptions or Bolar exception. And these have been defined as:

- Compulsory Licences can be understood as “the authorization given by the State to a third party to exploit a patented invention, generally against a remuneration to the patent holder, and these may be granted according to national laws on several grounds, such as emergency, public interests, non-working of the invention, anticompetitive practices and dependency of patents.”<sup>28</sup>
- Parallel imports refer to the situation “when a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner).”<sup>29</sup>

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<sup>26</sup> *Idem* pp. 8-9. Also See DICEY, V., "AIDS drug imperialism", *The Monthly Journal of the Socialist Party*, Number 32, 1999 <[www.socialismtoday.org/42/aids.html](http://www.socialismtoday.org/42/aids.html)> accessed 15 January 2013.

<sup>27</sup> ROFFE, P., et al. "From Paris to Doha", pp. 17, Also See WTO Dispute DS199 <[www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds199\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm)> accessed 14 March 2014.

<sup>28</sup> CORREA, C., "Public Health and Intellectual Property Rights", *Global Social Policy*, Volume 2, Number 3, 2002, pp. 261-278, pp. 268.

<sup>29</sup> WTO Glossary <[www.wto.org/english/thewto\\_e/glossary\\_e/parallel\\_imports\\_e.htm](http://www.wto.org/english/thewto_e/glossary_e/parallel_imports_e.htm)> accessed 14 March 2014.



- Regulatory exception or ‘Bolar exception’ “allows manufacturers of generic drugs to use the patented invention, without the patent owner's permission and before the patent protection expires, for the purpose of obtaining marketing approval from public health authorities. Generic producers are thus able to market their versions almost as soon as the patent expires.”<sup>30</sup>

It has been suggested that developing and least-developed countries have taken advantage of TRIPS’ options and safeguards, for instance, in determining when intellectual property rights have been exhausted either at a national or an international level depending on each Member’s preference.<sup>31</sup> TRIPS- Agreement flexibilities, as these set of exceptions became known, were object of further negotiations and clarifications in the Doha Round since these link intellectual property rights with public health concerns. The flexibilities deemed necessary given that IP protection was now available for medicines as well.

### **3. DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

Following the TRIPS Agreement WTO Members began pushing for further clarification in terms of the use of TRIPS flexibilities, and also for international recognition of public health concerns. As part of the analysis it is important to address the structure, content and importance of the Doha Declaration on the TRIPS Agreement and Public Health, and the Decision implementing paragraph 6 from the Doha Declaration and its following amendment.

In 2001 during the Fourth Ministerial Conference in Doha, public health concerns were recognized by WTO Member States in the ‘Declaration on the TRIPS Agreement and Public Health’ (hereinafter Doha Declaration or Declaration) and also in

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<sup>30</sup> WTO Agreement and Public Health: a joint study by the WHO and the WTO Secretariat (WTO Secretariat, 2002) 44. <[www.wto.org/english/res\\_e/booksp\\_e/who\\_wto\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf)> accessed 14 March 2014.

<sup>31</sup> Deere, C., *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Clarendon Press: Oxford, 2008) pp. 75.

the Doha Ministerial Declaration.<sup>32</sup> The Doha Declaration is structured in seven paragraphs that assess the Agreement's provision relevant to public health concerns, bringing also to the spotlight the need to modify the compulsory license regime as first established. In this respect, HIV/AIDS, tuberculosis, and malaria are recognized as some of the epidemics' afflicting the most; hence further R&D is needed.<sup>33</sup>

The Doha Declaration is considered as a milestone for the debate between TRIPS and access to medicines, since it makes the agreement both development and public health-friendly in terms of interpretation.<sup>34</sup> The Declaration is said to include similar language as the one found in the Submission by the African group<sup>35</sup> before the Ministerial Conference, together with other developing and least developed countries, which have been perceived as a relevant issue to facilitate both the interpretation and the implementation of the Agreement since protecting public health still is a major concern.<sup>36</sup>

Paragraph 5 of the Declaration does not only honor the commitments within the Agreement, but also recognizes and clarifies to a certain extent the use of compulsory licenses, parallel imports and the leeway given to Member Countries to determinate what constitutes a national emergency.<sup>37</sup> However, Doha Declaration as it was adopted, is said to contain stronger language than the one originally used within the drafts prior to the final version. Working groups, had reported to have had disagreed in two key issues, namely the use of "access to medicines" instead of "public health", and with paragraph 4th choice of words in allowing member countries to take measures to

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<sup>32</sup> *Doha Declaration on the TRIPS Agreement and Public Health*, World Trade Organization, WTO Doc. WT/MIN(01)/DEC/2, (1 November 2001) , and Also see, *Doha Ministerial Declaration*, World Trade Organization, WTO Doc. WT/MIN(01)/DEC/1, (14 November 2001).

<sup>33</sup> Paragraph 1, Doha Declaration WT/MIN(01)/DEC/2

<sup>34</sup> NAGAH, A., "TRIPS and Public Health: What should African Countries Do?", *African Trade Policy Centre*, Working Paper N° 49 (January 2007) pp. 3.

<sup>35</sup> Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/296 (June 2001) at 22 <[commerce.nic.in/wto\\_sub/trips/sub\\_Trips-ipcw296.htm](http://commerce.nic.in/wto_sub/trips/sub_Trips-ipcw296.htm)> accessed 10February 2013.

<sup>36</sup> YU, P. K., "The Objectives and Principles of the TRIPS Agreement", *Houston Law Review*, Volume 46, Number 979, 2009 <[www.peteryu.com/correa.pdf](http://www.peteryu.com/correa.pdf)> accessed 10January 2013.

<sup>37</sup> Paragraph 5 (a)-(d) Ministerial Conference, Forth Session, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 20 November 2001 (Hereinafter Doha Declaration).

protect public health without breaching the Agreement.<sup>38</sup> Developing nations requested the phrase “Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health”<sup>39</sup> to be included within the final document, but instead during the negotiations the phrase “...the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” was approved for the final draft.<sup>40</sup>

Another important issue addressed within the Doha Declaration referred to the difficulties in making effective use of compulsory licenses by Members’ with no or insufficient manufacturing capability. In this regard, in paragraph 6 the Council for TRIPS was instructed to find a solution to the problem and report back to the General Council by 2002.<sup>41</sup>

Least developed countries had the prerogative to fully implement the Agreement, specifically patent protection for pharmaceutical products, by 2016.<sup>42</sup> This provision within the Doha Declaration is consistent with Article 65 (4) from the TRIPS Agreement,<sup>43</sup> however, both the ambiguity embedded within paragraph 7th in terms of the so called ‘mailbox provision’ and whether or not countries had to either grant ‘exclusive marketing rights’ or implement the mailbox provision before the end of the transitional period, have been highlighted by scholars as important issues to clarify.<sup>44</sup>

In light of the TRIPS Agreement’s Article 70 (9) Member Countries that did not provide patent protection for pharmaceutical products but granted marketing

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<sup>38</sup> WATAL, J., "From Punta del Este to Doha and beyond: Lessons from the TRIPS negotiation process", *The WIPO Journal*, Volume 3, Number 1, 2011, pp. 24-35, pp. 30.

<sup>39</sup> Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, General Council Council for Trade-Related Aspects of Intellectual Property Rights IP/C/W/312, WT/GC/W/450 (4 October 2001) at 1 <[www.wto.org/english/tratop\\_e/trips\\_e/mindecdraft\\_w312\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm)> accessed 10 January 2013.

<sup>40</sup> Paragraph 4 from Doha Declaration.

<sup>41</sup> Paragraph 6 from Doha Declaration.

<sup>42</sup> Paragraph 7 from Doha Declaration.

<sup>43</sup> Article 65(4) from TRIPS Agreement "To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years."

<sup>44</sup> FREDERICK, A., "WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries", *Study Paper 2a*, United Kingdom Commission on Intellectual Property Rights, (February 14, 2002) pp. 1-69, pp. 11 <[ssrn.com/abstract=1924420](http://ssrn.com/abstract=1924420)> accessed 15 January 2013.

approvals for a new product through its national health agency, had to grant exclusivity for a period of 5 years.<sup>45</sup> However, on the 8<sup>th</sup> July 2002 the General Council decided to waive exclusive marketing rights for Least Developed Country members.<sup>46</sup>

Allegedly the terminology ‘exclusive marketing rights’ was unusual in the legal jargon and became introduced with the TRIPS Agreement, presenting Member Countries with a new challenge. Exclusive marketing rights, after following the Oxford dictionary’s definition, strictly mean that a product that obtained a marketing approval in a country making use of the transitional period can only be commercialized in that country by the applicant. However this is not to prevent third parties from producing, exporting, and commercializing the product in foreign markets.<sup>47</sup>

#### **4. FROM THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH TO THE TRIPS AGREEMENT AMENDMENT**

Despite WTO Members’ having received the Declaration as a positive step towards ensuring adequate use of TRIPS flexibilities, the interpretation of paragraph 6 became worrisome as little information about its procedure was provided.<sup>48</sup> Hence, different positions and interests preceded long negotiations before reaching consensus over the implementation of Paragraph 6 from the Doha Declaration.

Furthermore, on the 30<sup>th</sup> of August 2003 in the General Council, WTO Member States’ adopted Decision WT/L/540 that settled rules to issue compulsory

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<sup>45</sup> Article 70(9) from TRIPS Agreement "Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member."

<sup>46</sup> General Council, Decision of 8 July 2002, Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, World Trade Organization, WTO Doc. WT/L/478, 12 July 2002.

<sup>47</sup> UNCTAD-ICTSD, "Resource Book on TRIPS and Development: An Authoritative and practical guide to the TRIPS Agreement", (Cambridge University Press, July 2005) at 774 <[www.iprsonline.org/unctadictsd/ResourceBookIndex.htm](http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm)> accessed 20 January 2013.

<sup>48</sup> LALITHA, N., "Doha Declaration and Public Health issues", *Journal of Intellectual Property Rights*, Number 13, 2008, pp. 401-413, pp. 405.

licenses to export patented medicines to countries with no manufacturing capacity.<sup>49</sup> This Decision is considered to have broken new ground in clarifying the relationship between TRIPS and public health, and also because it ratified country members' 'freedom' to issue compulsory licenses to address public health emergencies.<sup>50</sup>

The aforementioned Decision contains three waivers besides establishing the notification system, and also settling the conditions to benefit or to be fulfilled before intending to make use of compulsory licenses under Paragraph 6 from Doha Declaration. This Decision basically waives 'the obligation in 31(f) that compulsory licenses shall be used predominantly to supply the internal market, and the obligation in 31(h) for the Importing Country to pay adequate remuneration to the right holder, and the obligation in 31(f) allowing re-export of important pharmaceuticals among members or a regional trade agreement if half of its members are least developed countries.'<sup>51</sup>

Thus far, it has been established that the scope of Decision WT/L/540 are pharmaceutical products as defined in paragraph 1 (a). The same text defines both eligible Importing Members<sup>52</sup> and Exporting Members.<sup>53</sup> However, it is not enough to become either an Importing or an Exporting Member by notifying the TRIPS Council if the conditions settled in the Decision is not met.

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<sup>49</sup> General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision 30 August 2003', World Trade Organization, WTO Doc. WT/L/540 (1 September 2003). (Hereinafter Decision WT/L/540) <[www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)> accessed 20 January 2013. Note that the TRIPS Agreement in Article 31(f) did not foresee compulsory licences for export purposes; therefore countries with no manufacturing capacity were not able to obtain pharmaceutical products produced under compulsory licence's scheme in a foreign country.

<sup>50</sup> VANDOREN, P., and VAN EECKHAUTE, J., "The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", *The Journal of World Intellectual Property*, Volume 3, Number 6, 2003, pp. 779-793.

<sup>51</sup> Kommerskollegium National Board of Trade, *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems* (2008) pp. 1-100, pp 23.

<sup>52</sup> Paragraph 1(b) from Decision WT/L/540 defines eligible importing Member as "any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;"

<sup>53</sup> Paragraph 1(c) from Decision WT/L/540 defines eligible exporting Member as "a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member."

In this respect, the notification submitted by an eligible importing Member shall (i) specify the means and expected quantities of the products(s) needed,<sup>54</sup> (ii) confirmation that the eligible importing Member-other than least-developed country Member- has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question,<sup>55</sup> and (iii) the confirmation that the country intends to grant a compulsory license or that this has already been granted one given that the product is patented within the territory.<sup>56</sup>

On the other hand, the compulsory license issued by the Exporting Member shall contain (i) only the amount necessary to meet the needs of the eligible Importing Member, therefore it can only manufacture the highlighted amount under this license which also needs to be exported in its totality;<sup>57</sup> (ii) products produced under the license shall be clearly identified as being produced under the system, taking into consideration that labeling, packaging, and shaping needs to be different from the products commercialized outside the system, prices cannot increase due to strict labeling and marking rules;<sup>58</sup> and (iii) the licensee shall post on a website<sup>59</sup> both the quantities being supplied to each destination, and the distinguishing features of the products, before the shipment begins.<sup>60</sup>

As of today, Canada and Rwanda are the only countries making use of the system set out by paragraph 6 from the Doha Declaration.<sup>61</sup> Accordingly, 33 countries have opted out to use the system as importers, and 11 agreed to use it exclusively in

<sup>54</sup> Paragraph 2(a)(i) from the Decision WT/L/540.

<sup>55</sup> Paragraph 2(a)(ii) from the Decision WT/L/540.

<sup>56</sup> Paragraph 2(a)(iii) from the Decision WT/L/540.

<sup>57</sup> Paragraph 2(b)(i) from Decision WT/L/540.

<sup>58</sup> Paragraph 2(b)(ii) from Decision WT/L/540.

<sup>59</sup> Footnote 7 from Decision WT/L/540 allows the licensee to post the aforementioned information in a website maintained by the WTO as well.

<sup>60</sup> Paragraph 2(b)(iii) from Decision WT/L/540.

<sup>61</sup> See Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health from Rwanda in WTO Doc. IP/N/9/RWA/1 (19 July 2007), and from Canada in WTO Doc. IP/N/10/CAN/1 (8 October 2007).

<docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?Query=(%20@Symbol=%20ip/n/9/\*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICchanged=true#>, and <docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?Query=(%20@Symbol=%20ip/n/10/\*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICchanged=true#> accessed 1 February 2013.

cases of extreme urgency.<sup>62</sup> To effectively make use of the mechanism set out in Paragraph 6 exporting Members' need to adapt their patent legislations as to grant compulsory licenses for exporting purposes, since it is not enough to have the WTO Decision allowing Members to grant these kind of licenses.

Allegedly, one of the reasons behind developing and less-developed Members' impossibilities in making use of the system relates to the implementation of the aforementioned system within its national laws.<sup>63</sup> Despite the mechanism representing an effective flexibility to tackle access to medicines, scholars have identified its complexities as a drawback in itself for the system. For instance a potential eligible importing Members are able to purchase generics from India at reasonable prices without having to enact a compulsory license to carry out with such import, and also because of both implementation issues and confusing rules in terms of the adequate remuneration that needs to be paid.<sup>64</sup> This notification system was intended to be temporal until the amendment to the agreement became permanent in 2005.<sup>65</sup> In 6 December 2005 the General Council passed the Amendment of the TRIPS Agreement, as to integrate Article 31*bis* into the Agreement that comprised the notification system, and the terms for compulsory licenses to work.<sup>66</sup>

For the amendment to come into force, it is necessary for two thirds of the Members to ratify it. Thus far only 71 countries have ratified it from a total of 120

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<sup>62</sup> CORREA, C., "Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", *Health Economics and Drugs*, Series N° 016 (Universidad de Buenos Aires, April-2004) pp. 1-49, pp. 11-12 <[apps.who.int/medicinedocs/en/d/Js6159e/](http://apps.who.int/medicinedocs/en/d/Js6159e/)> accessed 20 February 2013.

<sup>63</sup> HESTERMEYER, H., *Human Rights and the WTO: The Case of Patent and Access to Medicines* (Clarendon Press: Oxford, 2007) pp. 270.

<sup>64</sup> Ibid HESTERMEYER, pp. 271-272.

<sup>65</sup> Paragraph 11 from Decision WT/1/540 "This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1)"

<sup>66</sup> General Council, 'Amendment of the TRIPS Agreement- Decision of 6 December 2005', World Trade organization, WT Doc. WT/L/641 (8 July 2005) <[www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm)> accessed 20 January 2013.

Country Members.<sup>67</sup> Nevertheless, the waivers of the Decision have been in use since 30 August 2003.<sup>68</sup>

## 5. IPRS AND PUBLIC HEALTH IN VENEZUELA: BRIEF ANALYSIS

The IPR situation in Venezuela by no means seems to be an easy topic to address in first place. Just a few authors have written about the national legal framework and its disparities. The whole system seems to be in the edge of a cliff still debating on whether or not patents are detrimental for the access to medicines in Venezuela.

The current legal framework does not provide patent protection for pharmaceutical products. It has been argued by highly ranked officials how patents are a big detrimental to both access to medicines and universal coverage granted by the Constitution,<sup>69</sup> thereafter it seems to be justified the rejection and silence in granting pharmaceutical patents since 2002.

Venezuela came in compliance with its international duties by implementing Andean Community Decision 313, and later on 344 that adequate IPR standards to those settled in at the TRIPS Agreement. However, it can also be seen how the legislator's will collided with the President's in 2000 when direct implementation was achieved by publishing the aforementioned Decision within the country's Official Journal without formal parliamentary approval. At that time, the Venezuelan Constitution did not foresee direct and preferred implementation, as did the following one amendment in 1999.

The differences between the scheme under Andean Community Law and the current national legal framework are evident, portraying the country's distance from complying with its international duties, for instance with the TRIPS Agreement. Until 2008 when SAPI enacted in its Official Journal an official communication disregarding Decision 486, the public in general understood as integral part of the national system

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<sup>67</sup> *Member accepting amendment of the TRIPS Agreement*, World Trade organization. <[www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm)> accessed 20 January 2013

<sup>68</sup> Kommerskollegium National Board of Trade, 'The WTO Decision on Compulsory Licensing', at 23.

<sup>69</sup> SAMÁN, E., "Patentes y Salud Pública", *Aporrea* (30 Septiembre 2007) <[www.aporrea.org/tecnologia/a41884.html](http://www.aporrea.org/tecnologia/a41884.html)> accessed 10 March 2013



those provisions settled in the aforementioned framework. Furthermore, the fact that there are just a few Supreme Court rulings addressing the issue but there is no formal ruling solving the constitutionality of SAPI's decision in 2008 is rather interesting.

Going beyond the legal body per se, it is an interesting fact that after almost six years from the date when Venezuela withdrew from the Andean Community, there is not a single "proyecto de ley" (legislative project) presented for discussion before the National Assembly. One important difference between frameworks is the compulsory licensing regime, which to certain extent may leave the country in a delicate position when facing national health emergencies.

Admittedly compulsory licenses are not the only legal mechanisms to protect public health, as in Venezuela "price control policies" seem to be one of the preferred mechanisms to guarantee access to affordable medicines. In reality ensuring access to medicines might prove challenging considering the inexistence of a comprehensive list of illnesses covered by the country. Some illnesses are protected in Venezuela, and medication and treatment may be provided at affordable prices or even for free but there is general misinformation about the issue. It is important to mention that Venezuelans are heavily dependent on private insurances to cover their health care needs due overload and inefficiency of public health care providers regardless of statistics showing significant governmental investment in the public health care sector.

Thus far the Venezuelan public health system has been reshaped into a "mission" based one when addressing primary, secondary and specialized attention. As highlighted above, inside the neighborhood mission it is said to provide attention in rural areas, but further solving capabilities lead to create Barrio Adentro II –Inside the neighborhood II- through the newly named Integral Diagnostics Centers –CDI-, and Centers with High Technology – CAT. All of these aim to accelerate social integration while safeguarding universal human rights contained within 1999's Venezuelan political constitution –health, education, place to live, and work.<sup>70</sup> These missions originated from cooperation between the Cuban and Venezuelan Governments, and

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<sup>70</sup> ALVARADO, C., *et al.* "Cambio Social y Política de Salud en Venezuela" Sección Especial: Reformas Progresistas en Salud, *Medicina Social* Volume 3, Number 2, 2008, pp. 121.

began operating at first as a pilot program in a few neighborhoods from the Metropolitan District where Cuban health practitioners treated those needed.<sup>71</sup>

On the one hand, health services are perhaps more accessible in rural areas, but on the other hand, rampant inequalities keep on emerging within the health sector. The fact that access to health care provided by Barrio Adentro is highly politicized, together with neglecting the existent public health care infrastructure are factors taking a toll on the private health care sector. Private health care providers' are reported to be over flooded, given lack of faith on the public sector and reluctance in receiving medical care from foreign doctors are two of the reasons leading patients to chose the aforementioned sector.<sup>72</sup> Allegedly, private health care is only in reach for 3% to 4% from the total population who can afford to pay it, the rest of the cases or people seeking attention from them does it through private insurance policies either individual or employment related, which is a clear indication of access inequalities.

In terms of public health, admittedly, within the last fourteen years significant investments within the health care sector have been registered. However, by the country implementing a new system instead of boosting the existing one, more challenges arose and the situation within the sector also deteriorated. Misinformation and inequalities are characterizing public health care in Venezuela. Access to medicines is provided to a limited number of diseases; despite the Government taking part in the Andean Sub regional Group to purchase medicines.

Parliamentarist Ismael García became very critical of the government policies in general, but regarding health care, he finds no reason for such a poor performance within the sector when considerable investments have been made to raise the level. He is also of the opinion that running a parallel system (Barrio Adentro), importing foreign doctors, discriminating national doctors and institutions are just to mention some of the hypothesis leading the current system to fail.<sup>73</sup>

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<sup>71</sup> *Ibíd.* pp. 120.

<sup>72</sup> DÁVILA, E., "Medicina Privada ¿Un negocio poco lucrativo?", *VenEconomía Mensual: Insutria y Comercio*, Number 25, 2008, pp. 1.

<sup>73</sup> MÉNDEZ CEGARRA, A., 'El Sector Salud en Venezuela, tanto público como privado, anda de mal en peor' <[ismaelgarcia.net/home/index.php/el-sector-salud-en-venezuela-tanto-publico-como-privado-anda-de-mal-en-peor/](http://ismaelgarcia.net/home/index.php/el-sector-salud-en-venezuela-tanto-publico-como-privado-anda-de-mal-en-peor/)> accessed 15 June 2012

Rapid price increase in private health services due high demand, lead to price regulations on behalf of the Government as to ensure access. Accordingly, this measurement where both the private health sector and the Government agreed upon evaluating and determining singular fees for services and attention provided in clinics and hospitals, came after significant social pressure in recent months.<sup>74</sup>

Other relevant challenge, relates to lack of resources to ensure quality, both financial and human resources are needed to boost public and private health sector. With the wiki leaks scandal a few years ago, something regarding the national health care system was also leaked. An important international journal, points out the most important information contained in a cable sent from the Embassy from the United States of America in 2008, addressing the exodus of Venezuelan doctors to foreign countries offering better labor conditions than the ones found at home among other things.<sup>75</sup>

The lack of financial resources within the public health care sector has never been a secret either; the Bermudez vs. Ministerio de Sanidad y Asistencia Social (Ministry of Health) case is a vivid example of how priorities are managed in Venezuela. This case highlighted not only the incompetence of the Government to offer a decent health care but also demonstrated that pharmaceutical patents did not have anything to do when denying access to health care. In this case the Supreme Court failed in favor of an HIV patient who did not receive adequate treatment even when he had the right to access public health care.<sup>76</sup> It was the first time that a Court recognized a lack of budget to provide a proper public health in the country. The Courts' ruling was deemed to create social concern towards health care needs.<sup>77</sup>

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<sup>74</sup> Efe Agencia, 'Acuerdo del Gobierno y La Patronal Médica: Venezuela: Congelan las tarifas en salud privada', *Los Tiempos*, 17 August 2011

<sup>75</sup> PEREGIL, F., "Ábrelo y di ahhh: Sistema venezolano de salud", *El País*, 9 March 2011. <[www.elpais.com/articulo/internacional/Abrelo/di/ahhhh/Sistema/venezolano/salud/elpeuint/20110309elpeuint\\_14/Tes](http://www.elpais.com/articulo/internacional/Abrelo/di/ahhhh/Sistema/venezolano/salud/elpeuint/20110309elpeuint_14/Tes)> accessed 6 June 2012

<sup>76</sup> CRUZ BERMÚDEZ, et al v Ministerio de Sanidad y Asistencia Social, Sala Político Administrativa, Corte Suprema de Justicia, República de Venezuela, Expediente Número 15.789 (1999)

<sup>77</sup> TORRES, M., "The Human Right to Health, national Courts and Access to HIV/AIDS Treatment: A case study from Venezuela", *Chicago Journal of International Law*, 2002, pp. 105

Besides the current legal uncertainty surrounding the country in general, other issues collide with constitutional rights like access to proper health care and the emerging “right to health”.<sup>78</sup>

## 6. BETWEEN DENGUE AND CHIKUNGUNYA: FINAL CONSIDERATIONS

The Pan American Health Organization highlighted within 2013’s report that countries in the Americas have reported more than 2.3 million cases of dengue. Among these Dengue fever cases ‘37,692 cases of severe dengue and 1,280 deaths, for a mortality rate of about 0.05%’.<sup>79</sup> Venezuela alone has reported up to 32,168 cases of Dengue fever in 2014.<sup>80</sup>

Dengue fever is not new to Venezuela, however, the recent outbreak calls for questioning the Government’s effectiveness in both containing and also in providing adequate treatment to its citizens. Different news outlets have documented the undergoing health crisis within the country, where insufficient resources undermines hospitals and health practitioners ability to treat patients and in some cases to even identify the illnesses due to the lack of medical supplies. It has been suggested that about 95% of the hospitals in Venezuela have in stock only 5% of total medical supplies needed to treat patients in general.<sup>81</sup>

The international pharmaceutical industry seems to be responsible for importing about 60% of the medicines commercialised in Venezuela. Given the current debt from the Government to this industry, that allegedly rounds up to 4 billion dollars,

<sup>78</sup> GATHII THUO, J., "The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties", *Harvard Journal of Law & Technology*, Volume 15, Number 2, 2002, pp. 292-317, pp. 305.

<sup>79</sup> Pan American Health Organisation, *CHA.01 Neglected Tropical Vector Borne Diseases/CHA.01.03b Dengue (Statistics & Maps)* (2013).

<[www.paho.org/hq/index.php?option=com\\_content&view=article&id=4494%3Adescripcion-situacion-epidemiologica-actual-dengue-americas&catid=1221%3Acha-01-03b-dengue-statistics-maps&Itemid=40687&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=4494%3Adescripcion-situacion-epidemiologica-actual-dengue-americas&catid=1221%3Acha-01-03b-dengue-statistics-maps&Itemid=40687&lang=en)> accessed 25 September 2014

<sup>80</sup> El Universal, Health, *Venezuela registers 32,168 events of dengue fever* (29 July 2014) <[www.eluniversal.com/nacional-y-politica/140729/venezuela-registers-32168-events-of-dengue-fever](http://www.eluniversal.com/nacional-y-politica/140729/venezuela-registers-32168-events-of-dengue-fever)>

<sup>81</sup> CNN, *Escasez de insumos médicos pone en crisis el sistema de salud de Venezuela* (4th July 2014) Available at <[cnnespanol.cnn.com/2014/07/07/escasez-de-insumos-medicos-pone-en-crisis-el-sistema-de-salud-de-venezuela/](http://cnnespanol.cnn.com/2014/07/07/escasez-de-insumos-medicos-pone-en-crisis-el-sistema-de-salud-de-venezuela/)>

and the difficulties in obtaining foreign currency seems to be compromising not only access to medicines but also access to other medical supplies which only 50% of these are only available.<sup>82</sup> Venezuela's current economical situation is challenging even for the food sector where severe food shortages have also been highlighted by several international news outlets. In past months the medical community in Venezuela petitioned for humanitarian aid and also requested to the President of the nation to declare the current national health care system in 'national emergency' since the lack of supplies in general –including medicines- affected both the private and health care sectors.<sup>83</sup>

High prices were one of the reasons hampering access to medicines in Venezuela, as highlighted in the past by governmental officials, thus the Ley de Costos y Precios Justos was sanctioned by the Parliament in 2011 and later on published within Official Journal N° 39.715 (Gaceta Oficial N° 39.715) intending to tackle the high prices and price disparities prevalent in the market. Under the framework of the said regulation about nine thousand medicines were price regulated amid price speculation allegations. This legislation has been recently reformed in Official Journal N° 40.340 from 23 January 2014. Even though the legislation has been expected to tackle high medicines prices to improve access to affordable medicines the situation of availability of medicines does not seem to have improved since 2011, if anything it seems to have worsened.

The current health situation in Venezuela denotes how patent protection could not be considered as even a relevant factor deterring access to either medicines or public health. Scholars have highlighted price control and money control policies as causes deterring access to medicines, besides human resources and poor infrastructure. In terms of intellectual property rights and the use of TRIPS flexibilities, Venezuela seems to be in disadvantage in comparison with other developing countries. Not only minimum standards of protection are not foreseen within the current IP framework but also the

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<sup>82</sup> VINOGRADOFF, L., "La sanidad agoniza en Venezuela por la escasez de medicines", *ABC.es Internacional* (12 September 2014) <[www.abc.es/internacional/20140622/abci-sanidad-agoniza-venezuela-201406212012.html](http://www.abc.es/internacional/20140622/abci-sanidad-agoniza-venezuela-201406212012.html)>

<sup>83</sup> Univision Noticias, 'Piden declarar emergencia humanitaria en Venezuela por falta de medicamentos' (19<sup>th</sup> August 2014) <[noticias.univision.com/article/2063295/2014-08-19/america-latina/venezuela/piden-declarar-emergencia-humanitaria-en-venezuela-por-falta-de-medicamentos](http://noticias.univision.com/article/2063295/2014-08-19/america-latina/venezuela/piden-declarar-emergencia-humanitaria-en-venezuela-por-falta-de-medicamentos)>

flexibilities i.e. compulsory licenses are absent from the current framework. The current framework foresees expropriation of intellectual property rights as a corrective measure in cases of national emergency. However, how could the expropriation of a patent right help in improving both affordability and availability of medicines in the country if the major challenge relates to access to foreign currency needed not only to import the finalised product but also to import raw material to manufacture medicines in the country. Perhaps if Venezuela would have implemented TRIPS adequately and also became an importing Member under the system set out in Paragraph 6 of the Doha Declaration, then Venezuela could import medicines manufacture under compulsory licenses to supply the internal market. Nonetheless it is important to highlight at the moment only Canada and Rwanda are using the notification system for the aforementioned purpose.

Venezuela's political Constitution envisages both health and intellectual property right within the fundamental rights chapter. Thus efforts in providing universal coverage would indicate the country's 'determination' in providing adequate health care for all, however the reality indicates otherwise. Consistent and effective public health policies together with adequate IPR protection could benefit Venezuela. For instance, if a new IP law reform were to take place this should include the use of TRIPS flexibilities to address national health emergencies. Thus, in doing so Venezuela even though still under a money control policy would be able to import medicines or could simple enact a compulsory license to tackle health epidemics if availability could not be achieved first through i.e effective bulk procurement of medicines.

Admittedly, nor the patent system neither current public health policies can be held accountable for the recent Dengue and Chikungunya fever outbreak. However, the Government can be held accountable for not addressing the effective implementation of the aforementioned policies, and also for not effectively preventing the spread of the diseases. It was until 29 September 2014 that the Ministry of Health launched a National plan to fight both Dengue and Chikungunya, this plan is based on fumigation and extermination of larvae and mosquitos growing in dwellings.

The current patent system as is in Venezuela does not seem to correlate to poor health care or even access to medicines in general or at least not in the current

circumstances. Nevertheless, if the country were implement the minimum standards of intellectual property protection settled within TRIPS it should also take into consideration both the flexibilities and the provisions related to health within TRIPS as to tailor such implementation in a manner favourable to the country's needs.<sup>84</sup>

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<sup>84</sup> See Cadillo Chandler, D. M., *The Role of Patents in the Latin American Development*, 273 Economic and Society (Edita, Helsinki-Finland, 2014)

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