



## 1 ISSUE PAPER FOR THE SESSION:

### Intellectual property, access to medicines and human rights

#### Background

According to UNAIDS, by the end of 2012, approximately 9.7 million people were receiving antiretroviral therapy (ART). While only 34 percent of children who needed it had treatment access, 64 percent of adults in need had treatment access.<sup>1</sup> In June 2013, the WHO revised its treatment guidelines, recommending earlier, and in some cases, immediate treatment. As a result, the number of people eligible for ART nearly doubled, to 28.6 million people.<sup>2</sup> In the coming years, pressure to sustain and further accelerate access to ART is only expected to grow, as donor funding becomes more uncertain, and more patients require expensive patent-protected second and third generation antiretroviral treatment. The sustainability of treatment programmes and the development of more effective, less toxic health technologies to treat HIV and related co-infections (particularly tuberculosis and hepatitis C) will depend, to a significant degree, on intellectual property laws and policies.

In the 18 years since the WTO TRIPS Agreement entered into force,<sup>3</sup> developing countries, civil society and development partners have continued to express concerns about the impact of its provisions on access to health and agricultural technologies and learning materials.<sup>4</sup> Flexibilities found in the TRIPS Agreement have been employed on a limited, if growing, number of occasions to increase access to treatment,<sup>5</sup> but those seeking to expand treatment access continue to face many challenges. Ultimately, not enough countries have incorporated or used public health-related TRIPS flexibilities to increase or sustain treatment access. Reasons for this vary, and range from a lack of expertise or resources to adequately implement or use them, to direct

<sup>1</sup> UNAIDS (2013) *AIDS by the numbers*, available: [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2571\\_AIDS\\_by\\_the\\_numbers\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2571_AIDS_by_the_numbers_en.pdf).

<sup>2</sup> Ibid UNAIDS 2013.

<sup>3</sup> The Agreement on Trade related Aspects of Intellectual Property (TRIPS) entered into force with the establishment of the World Trade Organization (WTO) on 1 January 1995.

<sup>4</sup> United Nations Development Programme (1999) Human Development Report pages 57-76 Available: [http://hdr.undp.org/en/media/HDR\\_1999\\_EN.pdf](http://hdr.undp.org/en/media/HDR_1999_EN.pdf). See also, Commission on Intellectual Property Rights (2002) available: [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

<sup>5</sup> MDG Gap Taskforce (2013) The Global Partnership for Development: The Challenge We Face, at 67 Available: [http://www.un.org/en/development/desa/policy/mdg\\_gap/mdg\\_gap2013/mdg\\_report\\_2013\\_en.pdf](http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2013/mdg_report_2013_en.pdf).

pressure from some developed countries not to use flexibilities or to strengthen TRIPS standards through “TRIPS-plus” measures, for instance, through preferential trade agreements or through bilateral investment treaties. Fundamental questions regarding the inability of the TRIPS Agreement to encourage and reward the type of innovation required to develop effective pharmaceutical products for citizens of low and middle income countries remain unresolved.<sup>6</sup>

### **Implementing the recommendations of the Global Commission on HIV and the Law**

The Global Commission on HIV and the Law was an independent body of eminent persons tasked with interrogating the relationship between legal responses, human rights and HIV. Following an extensive process of research and consultation, in July 2012, the Commission released its report, which includes a chapter on intellectual property and access to treatment.<sup>7</sup> If implemented even in part, the intellectual property recommendations of the Commission would contribute significantly to an effective, sustainable response to HIV in a manner consistent with human rights obligations.

According to the Global Commission’s key recommendation on intellectual property:

The UN Secretary General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. Such a body should include representation from the High Commissioner on Human Rights, WHO, WTO, UNDP, UNAIDS and WIPO, as well as the Special Rapporteur on the Right to Health, key technical agencies and experts, and private sector and civil society representatives, including people living with HIV.<sup>8</sup>

Other recommendations include a call for:

- developed countries to refrain from pressuring developing countries to adopt TRIPS-plus measures which may impede treatment access;<sup>9</sup>
- developing countries to seek to include the full extent of TRIPS flexibilities into national laws;<sup>10</sup>

<sup>6</sup> Global Commission on HIV and the Law (2012) “Risks, Rights, & Health”, Page 83-85, available:  
<http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.

<sup>7</sup> Ibid Global Commission Report, pages 76-85.

<sup>8</sup> Recommendation 6.1.

<sup>9</sup> Recommendation 6.2.

<sup>10</sup> Recommendation 6.3.

- countries to proactively use areas of law other than intellectual property, such as competition and procurement law, to increase access to treatment;<sup>11</sup>
- WTO Members to grant an indefinite extension of TRIPS transition periods to least-developed countries (LDCs);<sup>12</sup> and
- countries to invest in alternative mechanisms to bridge the innovation gaps for diseases predominately affecting low- and middle-income countries.<sup>13</sup>

The recommendations of the Commission were informed by evidence and submissions which pointed at the failure of the current intellectual property regime to address the interests of countries, especially developing countries, in relation to treatment access.<sup>14</sup>

Aiming to accelerate the implementation of the Report's recommendations, UNDP and UNAIDS organized a strategy meeting in New York on 4-5 September 2013. Participants included former Commissioners Michael Kirby, Jon Ungphakorn and J.V.R. Prasada Rao, the Secretary General's special envoys Michel Kazatchkine (Eastern Europe and Central Asia) and Edward Greene (Caribbean), government representatives from South Africa, Ecuador, and Nigeria, and civil society representatives from low-, middle- and high-income countries. Participants highlighted a number of recent developments which they felt were supportive of the Commission's recommendations, notably the Resolution of the UN Human Rights Council in June 2013 which called for the use of TRIPS flexibilities to increase access to medicines and the WTO TRIPS Council decision to extend the transition period for LDCs to implement the TRIPS Agreement until July 2021. Meeting participants also noted the increased use of TRIPS flexibilities in the past year, such as the issuing of compulsory licenses in Indonesia, Ecuador and India, as well as the affirmation by the Supreme Court of India that the public health sensitive patentability criteria found in Section 3(d) of the Indian Patent Law is within the ambit of the TRIPS Agreement. A background paper prepared by Fred Abbott and Amy Kapczynski<sup>15</sup> suggested a number of human rights- and intellectual property-based options to advance the Commission's recommendations and served as a starting point for the group's deliberations.

These options include:

#### WTO

- Advocating for a review of the TRIPS Agreement, with a view to

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<sup>11</sup> Recommendation 6.3.4.

<sup>12</sup> Recommendation 6.4.

<sup>13</sup> Recommendation 6.6.

<sup>14</sup> See Global Commission working papers

<http://www.hivlawcommission.org/index.php/working-papers> and submissions

<http://www.hivlawcommission.org/index.php/submissions>.

<sup>15</sup> Abbott and Kapczynski 2013 "Draft Background Paper with Human Rights and Intellectual Property Options to Advance the Report of the Global Commission on HIV and the Law"

- safeguard public health related TRIPS flexibilities
- Initiating a discussion among potential WTO Members on the feasibility of an automatic compulsory licensing mechanism for essential health technologies.

#### WHO

- Actively supporting ongoing initiatives at the WHO to de-link the costs of R&D from the price of health commodities.

#### Human Rights Institutions

- Calling on the UN Secretary General to establish an independent high level body to recommend a new intellectual property regime for pharmaceutical products consistent with international human rights law.
- Advancing a case for the suspension of the TRIPS Agreement as it applies to health technologies on the grounds that it may potentially violate the right to health, as previously postulated by the Special Rapporteurs on the right to health and cultural rights.
- Advocating for the mandatory application of TRIPS flexibilities in line with the principle of the progressive realization of human rights including the articulation of the human rights norms that would oblige states to apply the TRIPS flexibilities if required.

The post-2015 development agenda was also identified as an opportunity to advance some of the Commission's recommendations on intellectual property and access to treatment. As a first step, a letter signed by the UNDP Administrator, the UNAIDS Executive Director and the UN High Commissioner was sent to the UN Secretary General in October 2013, requesting him to convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products as envisaged by the Report of the Global Commission.

#### **Potential key messages and recommendations**

1. There is a looming crisis in treatment sustainability as more people need to take up effective treatment for HIV, tuberculosis and hepatitis C. This crisis will be heightened even further as the need grows for newer, less toxic and more effective, and/or second and third-line treatment, all of which will be under patent and prohibitively expensive. All the organizations in the Joint Programme who are working on access to treatment should unite to support the implementation of the intellectual property recommendations of the Global Commission on HIV and the law.

2. UNAIDS, UNDP and OHCHR should actively support human rights-based initiatives to implement the recommendations of the Global Commission on HIV and the law and should co-convene a meeting of human rights experts in 2014 to further explore avenues to advance the intellectual property recommendations of the Global Commission in human rights institutions.
3. The UNAIDS-Lancet Commission should endorse the intellectual property findings and recommendations of the Global Commission on HIV and the Law

**This issue paper was prepared by Tenu Avafia and edited by Ralf Jürgens to facilitate discussion at the Reference Group's December 2013 meeting.**

**Please see the Summary and Recommendations report of the Reference Group's Fifteenth Meeting for an overview of the discussion at the meeting and the Reference Group's recommendations.**