High Income Countries Issue Brief:

INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES

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Issue Brief:

Intellectual Property Rights
and Access to Medicines

Prepared for the High-Income Countries Dialogue
of the
Global Commission on HIV and the Law

Oakland (CA), United States of America, 17 September 2011
Contents

Acknowledgements ......................................................................................................................... 1

Abbreviations ................................................................................................................................. 3

1. Introduction ................................................................................................................................. 4

2. WTO, TRIPS and Domestic Flexibility ....................................................................................... 10

3. Post-DOHA Restrictions on Trade: TRIPS Plus and Trade and Investment Agreements; Enforcement of IPR ........................................................................................................... 23

4. Approaches to Overcome IP-Related Barriers to Access to Medicine ..........................32
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## Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACTA</td>
<td>Anti-Counterfeiting Trade Agreement</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>CAMR</td>
<td>Canadian Access to Medicines Regime</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EU</td>
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<td>FTA</td>
<td>Free Trade Agreements</td>
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<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
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<td>ICCPR</td>
<td>International Covenant on Civil and Political Rights</td>
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<td>ICESCR</td>
<td>International Covenant on Economic, Social and Cultural Rights</td>
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<td>ICTSD</td>
<td>International Centre for Trade and Sustainable Development</td>
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<td>IPR</td>
<td>Intellectual Property Rights</td>
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<td>TPP</td>
<td>Trans-Pacific Partnership Agreement</td>
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<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>WTO</td>
<td>World Trade Organisation</td>
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Countries included in the High-Income Dialogue:

Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Iceland, Israel, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom of Great Britain and Northern Ireland, and United States of America (USA/US).
1. Introduction

The human right to essential medicines is a derivative right from the rights to health and to life. Lack of access to medication to treat HIV and co-infections (e.g., tuberculosis, hepatitis C) can have deadly consequences for people and be devastating for communities. In stark contrast, recent evidence indicates that people living with HIV, who are treated with antiretroviral medicines (ARVs), have normal life expectancy even in the developing world. The vast majority of people in high-income countries are able to access ARVs, and medications for co-infections. However, even in high-income countries certain groups of the population may face barriers to accessing medicines, due to systemic and structural factors. Access to medicines in high-income countries implicates several human rights set out in international conventions, including: non-discrimination, equality and equal protection of the law in the International Covenant on Civil and Political Rights (ICCPR), Article 2, 26; International Covenant on Economic Social and Cultural Rights (ICESCR) Article 2; life in ICCPR Article 6(1); the highest attainable standard of physical and mental health in ICESCR Article 12(1), including the treatment of epidemic diseases in ICESCR Article 12(2)(c); and enjoyment of the benefits of scientific progress and its application in ICESCR Article 15(1)(b).

In the developing world, despite significant progress in the past decade, many people living with HIV do not have access to essential medicines, including HIV medicines and medicines used to treat opportunistic and common co-infections. People living with HIV who are taking first-line HIV therapy (many of whom have benefited from generic production and price reductions) will, in the coming years, need to access, patent-protected second-line medications, or newer first-line medicines with fewer side-effects and toxicities. For high-income countries, the lack of access to medicines in the

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2 Médecins Sans Frontières (2010), The Ten Consequences of AIDS Treatment Delayed, Deferred, or Denied, Médecins Sans Frontières.
developing world engages human rights obligations, as well as moral and ethical imperatives, which have been enshrined in international conventions and agreements.\(^5\) State parties to the ICESCR commit to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights in the Covenant by all appropriate means (ICESCR article 2(1)). General Comment 14 to the Covenant clarifies these obligations in the following way: “For the avoidance of any doubt, the Committee wishes to emphasise that it is particularly incumbent on States parties and other actors in a position to assist, to provide ‘international assistance and cooperation, especially economic and technical’ which enable developing countries to fulfill their core and other obligations” (paragraph 45). In addition, State parties recognise the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields (ICESCR article 15(4)). Among the countries participating in the High-Income Country Dialogue, The Netherlands, Norway and the USA have not ratified the ICESCR.

The World Health Organisation (WHO) has identified four key factors affecting access to medicines\(^6\):

- Rational selection of medicines, for example via the WHO Model List of Essential Medicines;
- Affordable prices;
- Sustainable financing;
- Reliable medicine supply systems.

This brief focuses on a determinant of the second factor - the impact of intellectual property rights (IPR) on prices of medicines.\(^7\) A significant determinant of a manufacturer’s price for a given drug lies in whether or not it is patented. Patent protection provides exclusive rights to the patent holder and the patented product cannot be used (produced, marketed) without his consent. This exclusivity drives up drug prices, especially in developing and least developed countries, and has particularly

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negative impacts on access for the poorest of the poor.\(^8\) While access to medicines is multi-causal, reducing drug prices may catalyse action to address other variables, producing considerable increase of access.\(^9\) In the context of the HIV pandemic, a 2002 study estimated that the effect of eliminating patents of ARVs in a cross-section of developing countries would increase access to ARVs by 30%.\(^10\)

In its first section, this brief examines the role of high-income countries participating in the Dialogue, and bodies to which they belong, in creating and regulating IPR regimes that apply to medicines.\(^11\) The second section examines intellectual property protection under the World Trade Organisation’s (WTO) Agreement on *Trade-Related Aspects of Intellectual Property Rights* (TRIPS), and its public health flexibilities that have been reaffirmed by the Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration). The third section of this brief examines restrictions on access to medicines arising out of IPR provisions in free trade and investment agreements, and IPR enforcement, including conditions that undermine the spirit of the public health provisions in TRIPS and the Doha Declaration. The fourth section details legislative and regulatory approaches outside of existing trade treaties, which high-income countries could adopt, in order to increase access to medicines for people living with HIV and AIDS in low- and middle-income countries.

The *International Guidelines on HIV/AIDS and Human Rights* were revised in 2002 in light of the urgent humanitarian and human rights situation posed by the lack of access to HIV prevention, care, treatment and support among people in developing nations. Based on the Third International Consultation on HIV/AIDS and Human Rights, Guideline 6 was revised, as follows:

- States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of quality prevention measures and services, adequate HIV prevention and care information, and safe and effective medication at an affordable price.

- States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV prevention, treatment, care and support, including ARVs and other safe and effective medicines, diagnostics and related

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\(^9\) Ibid.


\(^11\) Such regimes also apply to regulate intellectual property in medical devices. In the context of the HIV pandemic, diagnostic tests are a significant component of the right to health.
technologies for preventive, curative and palliative care of HIV and related opportunistic infections and conditions.

- States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations.

The commentary to Guideline 6 addresses the role of domestic and international law, and in particular intellectual property law, in access to medications:

*In recognition of the human right to share in scientific advancement and its benefits, States should adopt laws and policies, at the domestic and international levels, ensuring that the outcomes of research and development are of national and global benefit, with particular attention to the needs of people in developing countries and people who are poor or otherwise marginalized (paragraph 42).*

*States should, in light of their human rights obligations, ensure that bilateral, regional and international agreements, such as those dealing with intellectual property, do not impede access to HIV prevention, treatment, care and support, including access to antiretroviral and other medicines, diagnostics and related technologies (paragraph 52).*

*In a preventative vein, which unfortunately has proved prescient, the Commentary calls on States to ensure that their conduct in international forums and negotiations takes into account the needs and situations of developing countries. States are called upon, in light of domestic and international human rights obligations, to: avoid taking measures that would undermine access to HIV prevention, treatment, care and support, including access to antiretroviral and other medicines, diagnostics and related technologies, either domestically or in other countries; ensure that medicines are never used as tools for political pressure; ensure that bilateral, regional and international agreements, such as those dealing with intellectual property, do not impede access; and ensure that, in interpreting and implementing international agreements, domestic legislation incorporates to the fullest extent any safeguards and flexibilities therein that may be used to promote and ensure access (paragraphs 51, 52, 53).*

The Commentary to the *International Guidelines on HIV/AIDS and Human Rights* calls on developed states to contribute to the Global Fund to Fight AIDS Tuberculosis and Malaria (paragraph 44); fulfill commitments to dedicate a fixed percentage of GNP to official development assistance (paragraph 44); policies that promote the purchase of generic medicines, diagnostics and related technologies where these are more economical (paragraph 45); and international and regional cooperation aimed at transferring to developing countries technologies and expertise (paragraph 50).

The scientific, political and economic influence of large multinational pharmaceutical companies cannot be ignored in an examination of the impact of IPR on the right of access to essential medications. The influence of large multinational companies is
recognised implicitly by the existence of the UN Special Rapporteur on the right to health’s *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.*\(^\text{12}\) The Guidelines state that States have the primary responsibility for realising the right to the highest attainable standard of health and increasing access to medicines. Yet they also state that pharmaceutical companies (innovator, generic and biotechnology companies), in addition to the responsibility of enhancing shareholder value, have human rights responsibilities in relation to access to medicines. The Guidelines include the following sections on patents and licensing:

26. *The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing.*

27. *The company should respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) that recognizes a State’s right to protect public health and promote access to medicines for all.*

28. *The company should not impede those States that wish to implement the World Trade Organization Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003) by issuing compulsory licences for exports to those countries, without manufacturing capacity, encompassed by the Decision.*

29. *Given that some least developed countries are exempt from World Trade Organization rules requiring granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.*

30. *As part of its access to medicines policy, the company should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines. The licences, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy set out in Guideline 20. They should also*…

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\(^\text{12}\) (2008), Annex to the Report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN document, A/63/263. For various perspectives on drug companies’ compliance with human rights responsibilities, see various articles with the main title, (2010), *Are Drug Companies Living Up to Their Human Rights Responsibilities?,* PLoS Medicine, vol. 7 (9), [http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000343](http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000343).
include any necessary transfer of technology. The terms of the licences should be disclosed.

31. As a minimum, the company should consent to National Drug Regulatory Authorities using test data (i.e., the company should waive test data exclusivity) in least developed countries and also when a compulsory licence is issued in a middle-income country.

32. In low-income and middle-income countries, the company should not apply for patents for insignificant or trivial modifications of existing medicines.

It is beyond the scope of this brief to examine the human rights responsibilities of pharmaceutical companies. However, it is impossible to ignore the influence of multinational pharmaceutical companies on states pharmaceutical policy and legislation, and their international trade policy.\textsuperscript{13} Increasingly, civil society organisations also attempt to influence such legislation and policies, but do not have at their disposal the vast resources of multinational pharmaceutical companies.

\textsuperscript{13} See, for example, the situation in the USA, where manufacturers of pharmaceuticals, medical devices and other health products spent nearly $182 million on federal lobbying from January 2005 through June 2006; Ismail MA (2007), \textit{Spending on Lobbying Thrives: Drug and Health Products Industries Invest $182 Million to Influence Legislation}, Center for Public Integrity.
The WTO came into existence on 1 January 1995. All of the countries included in the High-Income Country Dialogue are members of the WTO. The TRIPS Agreement is part of the WTO law and governs IPR under the WTO regime. The TRIPS Agreement is the most widely and controversially discussed instrument in the debate about IPR protection and access to treatment.\textsuperscript{14} Both the General Agreement on Tariffs and Trade (GATT) and TRIPS “bear upon crucial elements of the right to health” and, in particular, TRIPS “impacts upon the issues of access to essential drugs and also international cooperation.”\textsuperscript{15} The principal purpose of the TRIPS Agreement was to ensure minimum standards of protection for IPR among WTO members—WTO members agreed to provide mandatory patent protection for inventions in all fields of technology for a \textit{minimum} term of 20 years, in addition to exclusive marketing rights and protection of undisclosed information. “The TRIPS Agreement reduced the discretionary powers of WTO Members to adapt their national IPR regimes to meet specific developmental needs through the imposition of a ‘one size fits all’ IPR minimum standards protection regime.”\textsuperscript{16} In terms of effect on price and access to medicines, TRIPS has negative consequences for drug costs, given the proven impact of generic competition on reducing price.\textsuperscript{17} However, the TRIPS Agreement does recognise the need to balance competing rights and interests: Article 7 states that “the protection and enforcement of IPR should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”


\textsuperscript{15} Hunt, P (2003), \textit{Report of the Special Rapporteur about the right of everyone to enjoy the highest attainable standard of physical and mental health}, submitted to the Commission on Human Rights, E/CN.4/2003/58, paragraph 86. See also Hunt, P (2004), \textit{Report of the Special Rapporteur about the right of everyone to enjoy the highest attainable standard of physical and mental health, addendum}, submitted to the Commission on Human Rights, E/CN.4/2004/49/Add.1.

\textsuperscript{16} UNDP (2010), \textit{Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the in the WTO TRIPS Agreement},

\textsuperscript{17} Cohen-Kohler J et al (2008), \textit{Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards}. Health Economics, Policy and Law, vol. 3 (3), at pp. 229–256.
To this end, the TRIPS Agreement contains an important public health-related exception to mandatory patent protection, which has been articulated over a number of years through successive rounds of WTO member negotiations:

- Article 8 of the TRIPS Agreement provides that WTO members may, in formulating or amending their laws and regulations, 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, provided that such measures are consistent with the provisions of this Agreement.

- In the 2001 Doha Declaration on the TRIPS Agreement and Public Health, WTO members, recognised:
  
  - The gravity of public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
  - A concern about the effect of intellectual property protection on prices of new medicines that members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement (this is known as “paragraph 6” of the Doha Declaration).

The Declaration reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose, including:

- The right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- The right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- The right to establish its own regime for exhaustion of IPR without challenge.

A 2003 WTO General Council decision established a regulatory system to give effect to paragraph 6 of the Doha Declaration. Essentially, the system permits members to issue compulsory licences for the domestic production of generic versions of medications for export, despite the fact that valid patent protection is in effect. Important features of the system include:

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Creation of two classes of members—eligible importing members, and exporting members.
Waiver of the exporting members’ obligations under TRIPS article 31(f) to issue compulsory licences predominantly for domestic markets.
Notification requirements for intention to issue a compulsory licence.
Conditions that must be attached to a compulsory licence.
Notification of the granting of a compulsory licence.
Adequate remuneration for the patent-holder.
Reasonable measures to address risk of trade diversion and prevent re-exportation.
Annual review and reporting by the WTO Council for TRIPS.

In 2005, the WTO General Council put forward for members’ acceptance a protocol amending the TRIPS Agreement to include the paragraph 6 regulatory system. The original deadline for members to accept the amendment, 1 December 2007, has been extended twice because the two-thirds majority of members required to amend the TRIPS Agreement has not yet been achieved. Among High-Income Dialogue Countries, the following countries have accepted the protocol: Canada, Israel, Norway, Switzerland, the USA, and the EU on behalf of member states. The current deadline for depositing acceptance is 31 December 2011.

Accepting the protocol is distinct from implementing the paragraph 6 system in members’ domestic legal frameworks. All countries considered in the High-Income Dialogue have incorporated patent protection into their domestic legislation, in accordance with the TRIPS Agreement. Therefore, domestic legislative amendment is required to give effect to the paragraph 6 compulsory licensing regime. Canada, Norway, the EU and Switzerland have enacted domestic implementing legislation permitting compulsory licensing for export in accordance with the paragraph 6 system.

20 See WTO website (updated 15 March 2011), http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. The other members that have passed domestic implementing legislation are: Albania, China, Croatia, Hong Kong, India, Japan, Philippines, Republic of Korea, and Singapore.
21 WTO (2009), Amendment of the TRIPS agreement—Second extension of the period for the acceptance by Members of the protocol amending the TRIPS Agreement, decision of 17 December 2009, WT/L/785.
22 Canada amended the Patent Act and Food and Drugs Act, and enacted the Use of Patented Products for International Humanitarian Purposes Regulations; see WTO document IP/N/1/CAN/P/5-7 and an explanatory note in IP/C/W/464.
25 In Switzerland, the consolidated version of the Federal Law on Patents for Inventions of 1 July 2008 and the Ordinance on Patents for Invention provide the legal basis to act as an exporting Member. See WTO documents IP/N/1/CHE/P/9 and IP/N/1/CHE/4.
UNAIDS, WHO and UNDP have recently recommended that high-income countries with pharmaceutical manufacturing capacity consider implementing the paragraph 6 system in an administratively efficient and effective manner.  

Despite the significant resources invested by civil society, governments and the WTO in realising the paragraph 6 regulatory system, it has only been used once. In 2007, a Canadian generic pharmaceutical manufacturer provided fixed-dose HIV ARVs to Rwanda.  

In general, it has been observed that “despite the TRIPS legality of both compulsory licensing and generic export, TRIPS and its associated political economy are significantly curtailing generic manufacture and export and hence the availability of more affordable medicines and this strongly influences drug prices and ergo access.”

Due to the partial, uneven implementation by developed countries, questions have been raised about both the efficacy and its legitimacy of the TRIPS flexibilities brought about by paragraph 6 of the Doha Declaration.

Academic analysis and commentary, debate among WTO members, and civil society advocacy has focused on the limitations and obstacles to the current paragraph 6 regulatory system, on attempts to use the system that have not come to fruition, and on the domestic legislative framework for compulsory licensing in Canada, including the export of medications to Rwanda by a Canadian generic pharmaceutical manufacturer.

A number of limitations in the current paragraph 6 regulatory system, and its use in practice, have been identified, including:

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1. The need for a strong political commitment to act on the part of potential importer country governments in the face of the opposition of developed country WTO Members and interested industry groups within them.

2. The concerns of potential importer country governments about possible backlash from foreign direct investors and retributions from originator pharmaceutical companies.

3. The relative ease of reaching accommodations with foreign patent holders rather than challenging them through the compulsory licensing process.

4. For potential importer countries, the implementation of compulsory licensing is complex and requires a sufficient local administrative infrastructure, which is often prohibitively expensive.31

5. Onerous anti-diversion measures (specific labeling and marketing) that act as a disincentive to generic manufacturers.

6. Developing nations lack the infrastructure and distribution capabilities necessary to provide the infected with ARVs.

7. The system provides only a minimum standard, which has resulted in exporter countries passing domestic legislation that exceeds what is required to comply with the paragraph 6 agreement (known as “TRIPS plus”).

8. When negotiating regional and bi-lateral free-trade and investment agreements with low- and middle-income countries, some high-income countries have circumvented the system by including in agreements intellectual property protections that undermine the TRIPS flexibilities permitted under the Doha Declaration and subsequent WTO decisions.

The following recommendations have been made for improving the efficacy paragraph 6 regulatory system to provide access to medications and diagnostic technology:

* Compulsory licences could be leveraged regionally rather than on a per-country basis.32

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31 The costs of such implementing infrastructure have been estimated as US Dollars 1.5mn: Martin G et al (2007), Balancing intellectual monopoly privileges and the need for essential medicines, Globalization and Health, vol. 3, at p.4.

• Governments implementing the system in national law should employ all options for maximum flexibility in its use.  

• Developing country governments should pursue programmes of cooperation that permit them to take advantage of economies of scale in purchasing, as well as in the production and distribution of pharmaceutical products.

• A tiered approach to the TRIPS Agreement applying it only in countries at an economic level that is deemed appropriate (e.g. only developed economies) and waiving the requirement that the TRIPS Agreement be applied in least developing and developing countries.

• Waivers for developing countries (whose transition period has ended under TRIPS Article 65) and extending transition periods for least-developed countries (an option that is contemplated in TRIPS Article 66).

• An index that can be used to determine the circumstances in which patent obligations should be waived for developing countries whose obligations are already in force or to extend transition periods further for least-developed countries.

Even before the 2001 Doha Declaration, a coalition of Canadian civil society organisations and other activists, had been urging the Canadian government through various means (letters, public presentations, meetings with government officials) to make the necessary legislative changes to allow Canadian generic pharmaceutical manufacturers to supply developing countries. The Jean Chrétien Pledge to Africa Act (amending the Patent Act and Food and Drugs Act) was introduced in Parliament in November 2003, passed by Parliament in May 2004, came into force in May 2005, and was followed in June 2005 by the publication of related regulations. Together these

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34 Ibid.
36 Ibid.
39 An Act to amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa), S.C. 2004, c. 23.
42 Use of Patented Products for International Humanitarian Purposes Regulations, S.O.R./2005-143; Food and Drug Regulations (1402 – Drugs for Developing Countries), S.O.R./2005-141; Medical Devices
legislative changes established the Canadian Access to Medicines Regime (CAMR). The key features of CAMR are:

1. Three categories of countries eligible to import under the regime, including both WTO member and non-member countries, and least-developed countries (Schedules 2, 3, 4 to the Patent Act).
2. A list of eligible medications and products (primarily from the World Health Organisation's Model List of Essential Medicines), and a process to request medications and products not on the list.
3. If the product is patented in the importing country, a compulsory licence must be granted by the importing country's government to authorise its import.
4. A requirement that the generic manufacturer provides the patent holder within a certain timeframe the information required by law, and attempts to negotiate a voluntary licence with the patent-holder.
5. Information to be included by importing countries in notifications to the WTO or the Canadian government.
6. Non-governmental organisations can act as purchasers of licensed pharmaceutical products with the permission of the importing country's government.
7. Health Canada product review (safety, quality, efficiency) using the same process as products for the Canadian market, with a special stream to expedite review.
8. Manufacturer must conclude a sales agreement with an eligible importing country and submit an application for authorisation to Canada’s Commissioner of Patents.
9. A formula for determining royalty fees payable by the manufacturer to the patent-holder.
10. A limit on the duration of a compulsory licence (valid for two years, but can be extended an additional two years if the original amount of product has not been shipped).
11. Before export, the pharmaceutical company must establish a website providing the following information:
   a) the name of the licensed product and, if applicable, the strength, dosage form and route of administration;
   b) its distinguishing characteristics, to distinguish the product from those marketed in Canada;
   c) the identity of the importing country;
   d) the amount to be manufactured and sold for export;
   e) information identifying every known party who will be handling the product while it is in transit from Canada to the importing country; and

Regulations (Developing Countries), S.O.R./2005-142.

f) the export tracking number and number of the bill of lading for each shipment.

12. A process whereby Health Canada will remit to the manufacturer the fees normally associated with the regulatory review process.

13. A process whereby patent holders may challenge a compulsory licence in court if the cost of the generic product is more than 25% of the cost of its equivalent patented version in Canada.

14. An obligation to review the regime and report to the Canadian Parliament.

To date, CAMR has been used once, to permit the generic production for export to Rwanda of HIV ARVs to treat 21,000 people living with HIV for one year.\(^44\) CAMR was considered to be the start of a feasible solution to drug access for developing countries; it was the first detailed domestic law, and as such sets a precedent for other jurisdictions; royalties payable to the patent-holders are clearly defined and affordable; and the period of time for negotiation of a voluntary licence is clearly defined. Canadian government representatives to the WTO\(^45\) and representatives of name-brand pharmaceutical companies have stated that CAMR “has worked”, is “expeditious”, “functioned well”, and is “efficient and effective” at achieving its objectives\(^46\).

Nevertheless, the preponderance of analysis and commentary has pointed to significant shortcomings in CAMR, both in its design and in practice. The following limitations with CAMR have been identified\(^47\):


\(^{46}\) See for example, the testimony of Grant Perry (Vice-President, Public Affairs/Reimbursement, GlaxoSmithKline Canada) and Russell Williams (President, Canada's Research-Based Pharmaceutical Companies (Rx & D)) to the House of Commons Standing Committee on Industry, Science and Technology, *Consideration of Bill C-393, An Act to amend the Patent Act (drugs for international humanitarian purposes)* and to make a consequential amendment to another Act, Meeting No. 40, 26 October 2010.

1. Onerous, time- and resource-consuming bureaucratic, administrative and legal requirements for use by importing countries.
2. Unnecessarily restrictive conditions placed on potential importing countries that are neither WTO members nor least-developed countries.
3. Requirement that the government of the importing country approves the importation.
4. A limited list of products, which had to be amended to add the fixed-dose combination ARV proposed for export to Rwanda.
5. Requirement for the generic manufacturer to enter into negotiation with the patent holder (in the case of fixed-dose combinations of HIV ARVs, there may be numerous patent holders).
6. Unnecessary application of the regulatory review process that applies to drugs marketed for sale in Canada.
7. Arbitrary duration of the compulsory licence — i.e., two years plus the possibility for renewal for another two years.
8. Restrictions of the quantity of medicines that can be provided under the compulsory licence, as set out in the sales agreement.

In 2008, the Canadian HIV/AIDS Legal Network made the following call for reform to CAMR, based on the WTO TRIPS flexibilities and Canada’s legal obligations under international human rights treaties:

Canada has implemented the mechanism negotiated at the WTO in August 2003; so far, Canada’s model has not worked, but neither has the August 30th Decision yet worked at all for any country. As the first country to implement the WTO Decision with any sort of detailed legislative framework, and the jurisdiction in which the most concerted efforts have been made to date to use the mechanism as implemented domestically, Canada is in a position to set a positive global precedent by acknowledging that the system has not worked and by putting in place a more effective mechanism. Canada has the clear legal right to use the flexibility that it retains under TRIPS Article 30 to legislate, as a set of “limited exceptions” to exclusive patent rights, the simpler, streamlined mechanism for compulsory licensing for export that has been described above — a regime that avoids the cumbersome requirements of seeking first a voluntary licence, and failing that a compulsory licence, for every single contract that is limited to a predetermined quantity of a particular drug for one specific country, over a period of two years at most. Canada also has an ethical duty to take action to improve access to medicines in developing countries, learning from what has not worked to date, and similarly has a legal obligation under international human rights treaties it has ratified that oblige it to take steps, individually and through international assistance and cooperation, to prevent, treat, and control epidemic and other diseases as part of achieving fully the

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right of everyone to the highest attainable standard of health.

Academics and legal practitioners have also pointed out the practical economic realities that can stymie the regulatory system established under domestic legislation implementing compulsory licensing:

Policy implementations by both the exporting and the importing country must account for the business realities faced by generic manufacturers, in order to make participation in end-to-end compulsory license regimes attractive for prospective participants. For example, if bureaucratic red tape on either end is prohibitive, the high costs of participation may thwart the common objective of all stakeholders. Also, if compulsory license terms are artificially short, such that generics cannot factor long-term revenues into their decision calculi, even where essential medicines will undoubtedly be necessary in the long run, generics may decide not to participate to the detriment of all.

The government of Canada concluded, based on a review of CAMR, “that the case for making legislative or regulatory changes to CAMR has not yet been made out.” Nonetheless, it recognised that the regime could better address underlying economic barriers and committed to undertaking further analysis of harnessing of economies of scale through the pooling of purchasing power by multiple developing countries suffering from the same public health problem. The government committed to intensifying its outreach activities to promote CAMR to potential importer countries and to establishing an expert committee, as provided for in the *Patent Act*, to advise Ministers on what products should be eligible for export under CAMR.

A private member’s bill (Bill C-393) amending CAMR was introduced into the lower chamber of the bi-cameral Canadian Parliament on 25 May 2009. The bill was passed

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by the House of Commons, but died in the Senate when the Parliament was dissolved before a federal general election. A key feature of Bill C-393 was the “single licence” solution to address the realities of the way international pharmaceutical markets work in practice, and the limitations of the CAMR system identified above. It would have permitted a pharmaceutical producer to apply to the Commissioner of Patents to obtain a single licence that would have authorised it to produce patented medicines to eligible countries. Thus the need for a pharmaceutical producer to apply for a compulsory license on a case-by-case, country-by-country basis, only after concluding sales agreements with a country, would have been avoided. Frederick Abbott described the practical, market-based advantages of the single-licence system over the original CAMR:

The single license mechanism would allow Canadian producers to submit proposals or bids in response to requests from developing countries requiring medicines to meet public health needs. Canadian producers would be in a position to commit to supplying the medicines in the event that they are the successful bidder. Similarly, the single license mechanism would permit Canadian producers to respond to direct purchase requests from developing countries, or to seek contracts from developing countries (so at to allow the producers to realise production efficiencies), without fear that ultimately they would not be able to meet their contract commitments.

Significantly, the provisions of Bill C-393 did not limit the number of importer countries/purchasers to which the compulsory licence could be issued. It also did not establish the maximum quantity of medication that could be produced, nor expressly limit the duration of the licence. According to Abbott, Bill C-393 was consistent with Canada’s obligations under the TRIPS Agreement and the 30 August 2003 Waiver Decision.

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52 Abbott F, *Prepared Testimony before House of Commons Standing Committee on Industry, Science and Technology regarding Bill C-393*, An Act to amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act, Meeting No. 40, 26 October 2010, at p 4.

53 See also Canadian HIV/AIDS Legal Network (2011), *Bill C-393: Key features and compliance with Canada’s WTO obligations*. 20
A European Community regulation implementing paragraph 6 of the Doha Declaration came into force on 29 June 2006. Key features of the regulation include:

1. No restrictions with regard to the pharmaceutical products and illnesses covered.
2. Identification of three categories of eligible importing countries (least-developed countries; WTO members that have filed notifications of their intention to use the system; non-WTO low income countries that have filed notifications of their intention to use the system).
3. Anyone may apply for a compulsory licence to the competent authorities of the member state.
4. Compulsory licence is not time limited or limited as to the number if importing countries are covered.
5. Competent patent authority shall notify the patent-holder without delay of the application for a compulsory licence, give the patent-holder an opportunity to comment on the application, and provide the competent authority with any relevant information regarding the application.
6. 30 day mandatory negotiation period between the patent-holder and applicant (which does not apply in the event of national emergency, nor in cases of public, non-commercial use).
7. Before export, the pharmaceutical company must establish a website providing information:
   a) the name of the licensed product and, if applicable, the strength, dosage form and route of administration;
   b) its distinguishing characteristics, to distinguish the product from those marketed domestically;
   c) the identity of the importing country;
   d) the amount to be manufactured and sold for export;
   e) information identifying every known party who will be handling the product while it is in transit from Canada to the importing country; and
   f) the export tracking number and number of the bill of lading for each shipment.
8. Maximum remuneration to be paid by the licensee to the patent-holder of 4%.
9. Measures and enforcement powers to prevent re-importation to the EU.
10. Purely formal or administrative requirements necessary for the efficient processing of the application may be prescribed under national law, which requirements shall not add unnecessarily to the costs or burdens placed upon the applicant.

11. Mandatory review of the regulation, three years after the entry into force of this Regulation, and every three years thereafter, the Commission shall present a report to the European Parliament, the Council, and the European Economic and Social Committee on the operation of this Regulation including any appropriate plans for amendments.

To date, no applications for a compulsory licence have been filed pursuant to the EU regulation.

In 2007 the Swiss Parliament introduced amendments to the Law on Patents for the purposes of implementing the paragraph 6 regulatory system. The amendments, which entered into force on 1 July 2008, are accompanied by amendments to the patent ordinance. Key features of the Swiss regime include:

1. Any person can make an application for a compulsory licence to a judge.
2. No restrictions with regard to the pharmaceutical products (medications, active ingredients or diagnostic kits) or illnesses covered.
3. Only the quantity of products necessary to respond to the beneficiary country may be produced under a compulsory licence, and the entirety of the production must be exported.
4. A judge determines the extent and duration of the licence.
5. Provisions for labeling and identification of products produced are placed on the licensee.
6. 30 days mandatory negotiation period between the patent-holder and the applicant (which does not apply in the event of national emergency, nor in cases of public, non-commercial use).
7. A federal commission empowered to regulate other conditions of the licence, in particular information and notifications that a judge must review in deciding an application for a compulsory licence.
8. A federal commission empowered to determine the compensation owed to the patent-holder, taking into account the economic value of the licence in the importing country and the level of development and the humanitarian and health need.
9. Notification of WTO, labeling, and publication of information requirements.
10. Powers granted to customs authorities to prevent interference with valid Swiss patents.

To date, no applications for a compulsory licence have been filed pursuant to the Swiss legislation.

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55 Law on Patents, LBI, RS 232.14, RO 1955 893. See amended article 40(c), (d) and (e) as per RO 2008 2551 2567; FF 2006 1, in force 1 July 2008.
Adoption of the WTO decision on the paragraph 6 regulatory system alone is not sufficient to address concerns about the negative effects of intellectual property protections on access to medications. For while the adoption, and acceptance by numerous member countries and domestic implementation by some member countries, has set the framework for generic production of medications, some of the same countries have, at the same time, moved to increase patent protection for medications in bi-lateral and regional free trade and investment agreements. As legal scholar and IPR expert Frederick Abbott has noted:

The adoption of the Decision shows that the WTO can address important issues of social concern. But adoption standing alone does not show that the WTO can do so effectively. Effective implementation of the Decision is threatened by newly negotiated bilateral and regional agreements.

From a human rights perspective, recent history has shown that developed countries still need to remain cognisant of their international assistance and cooperation obligations to respect, protect, and fulfill human rights when partaking in international organisations and in adopting multilateral, regional, or bilateral agreements. The UN Special Rapporteur on the right to the highest attainable standards of health has recommended that countries should be “cautious about enacting ‘TRIPS plus’ legislation without first understanding the impact of such legislation on human rights, and


recommended that high-income countries “should not pressure a developing country to implement ‘TRIPS plus’ legislation, unless reliable evidence confirms that such legislation will enhance enjoyment of the right to health in the developing country.”60 This recommendation has recently been echoed by the UN Human Rights Council, and in a UN policy, both of which documents call on governments to ensure that their free-trade agreements with middle- or low-income countries comply with the spirit and principles of the Doha Declaration. 61

Free trade agreements (FTA) negotiated by high-income, industrialised countries have required commitments beyond those specified by TRIPS. Trade agreements negotiated by the USA and the EU have faced particular criticism.62 Such TRIPS plus commitments include63:

- Extending patent terms beyond 20 years for delayed marketing approval.
- Limiting parallel imports of patented drugs, restricting grounds for compulsory licensing.
- Imposing “data exclusivity” rules.
- Defining “innovation” for the purposes of determining patent protection to include minor “me-too” molecular variations.


• Facilitating elimination of reference pricing.
• Introducing the pro-evergreening “linkage” of safety and quality regulatory assessments of proposed new generic market entrants with patent checks.
• Border measures (searches, seizures) for alleged patent infringement.
• Criminal sanctions for patent infringement.
• Requiring that countries join the Patent Cooperation Treaty, which Treaty enables companies to apply for a patent in multiple countries through simplified procedures.

According to the International Centre for Trade and Sustainable Development (ICTSD), the introduction of data exclusivity for pharmaceutical products has the worst impact and represents about 90% of the medicine cost increases predicted under FTAs. Under data exclusivity provisions, generic manufacturers cannot rely on clinical test data generated by the patent-holding pharmaceutical for a period of up to ten years, and would have to repeat such studies at considerable expense to bring a product to market. Without data exclusivity provisions, generic manufactures can obtain approval for drugs based on relatively cheap tests for bioequivalence to demonstrate that their product has essentially the same bio-pharmaceutical properties as the original. In addition to the extra cost involved, data exclusivity can delay the entry of generic manufacturers into the market by many years.64

With the negotiations of the WTO Doha Development Round stalled, FTAs have been proliferating. During the period 2001-2010, 72 FTAs with intellectual property clauses have been announced to the WTO. Of specific concern are the FTAs between developed countries and markets, most notably the US) and the EU with low and middle income countries.

For instance, the FTA signed between the US and countries in Central America65, as well as the Dominican Republic (the US-CAFTA-DR), has introduced test data exclusivity, patent linkage and patent term extension. In its brief submitted before the Committee on Ways and Means at the US House of Representatives, the international humanitarian organisation Médecins sans Frontières expressed grave concerns about the possible impact of this FTA on access to medicines, and brought the example of Guatemala, where test data exclusivity threatened to block access to generic ARV equivalent, thereby potentially increasing cost of treatment up to 22 times.66

According to another study, the estimated economic impact of the TRIPS-plus provisions in the US-Colombia means that by 2020, Colombia would need to spend an additional

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65 Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua.
US$ 919 million for medicines, or alternatively, would have to reduce medicine consumption by 40%.67

The Trans-Pacific Partnership Agreement (TPP), based on an agreement originally concluded in 2005 between Brunei, Chile, New Zealand and Singapore, and now negotiated also between Australia, Malaysia, Peru, the US, and Vietnam has also been harshly criticised. Provisions on IPR protection have been negotiated largely under pressure from the US government and they have raised serious concerns about the public health impact of the TPP. The draft text of the provisions has so far not been officially released and all commentaries by scholars and public health activists rely on unofficially leaked texts.68 The main concerns about the likely public health impact of the IPR provisions proposed by the US are related to the extension of patent terms and broadening patentability, restricting patent opposition, introduction of test data exclusivity and patent linkage, as well as of TRIPS-plus IPR enforcement requirements. In addition, the TPP contains pharmaceutical price regulation provisions, which, according to some commentators, envision creating systems for administrative and judicial appeals to contest public reimbursement rates for medicines to “appropriately recognise the value” of pharmaceutical patents. If adopted, these provisions are likely to create an imbalance in favor of originator pharmaceutical manufacturers without considering the public health interest.69

Médecins sans Frontières has released an issues brief analysing the likely negative impact of the proposed IP provisions in the TPP, also stressing that the US proposals back off from recently established US policies and commitments regarding access to medicines, thereby reversing the pro-public health policy shift achieved in 2007 and re-introducing concepts that have been criticised and that are likely to have a substantial negative impact on public health.70 Public Citizen, a non-governmental organisation for protecting consumer interests and access to medicines, also stresses the inconsistency of the proposed IP provisions with US policies, as well as agreements previously reached between the US and developing countries negotiating the TPP, such as Peru.71

FTAs negotiated by the EU have also been criticised from the access to medicines perspective. The most notable example is the negotiated EU-India FTA, India being the largest global producer of generics that supplies around 80% of the generic ARV medicines worldwide. The proposed EU-India FTA is likely to have an adverse impact on the Indian generic pharmaceutical industry’s ability to remain the major supplier of affordable HIV medications for the developing world. Médecins sans Frontières and others have expressed grave concern over the potential impact that such provisions will have on access to medicines. 72 While the proposed FTA is unlikely to impact the supply and price of generic ARVs already on the market, TRIPS plus commitments such as data exclusivity in particular, could prevent generic competition to newer generation ARVs released after the FTA is concluded. The European Commission (EC), which is in charge of the FTA negotiations on behalf of the EU has acknowledged that it is seeking to have a provision requiring India to introduce data exclusivity into its drug regulatory framework. 73

While recent reports suggest that the despite initial assurances by negotiators in India and the EU that the FTA would not adversely impact public health, the Prime Minister’s office is re-considering TRIPS plus commitments including data exclusivity. An EU-India FTA with TRIPS plus commitments could critically damage successful efforts to scale up treatment access, thereby reversing a decade of hard-won success in saving lives. 74

TRIPS-plus provisions are included in other negotiated FTAs such as the EU-Central America Regional Association Agreement, the EU-Andean Community Regional Association Agreement, and the EU-MERCOSUR Regional Association Agreement. In Eastern Europe and the Caucasus TRIPS-plus IPR protection and enforcement provisions are included in the negotiated association agreements with Armenia, Azerbaijan, Georgia, Moldova and Ukraine.

TRIPS-plus enforcement provisions, particularly regarding border measures and criminalisation of IPR infringement are characteristic for the IPR initiatives pursued and promoted by industrialised nations. During their June 2007 Summit in Heiligendamm, Germany, G-8 countries adopted a Declaration, which clearly promotes a harsher IPR system, through harmonisation of the global patent system to improve acquisition and protection of patent rights worldwide, as well as stronger enforcement of IPRs in developing countries. The six points on IPR protection, described in this Declaration included the adoption of customs and border measures, technical cooperation with developing countries for the adoption of so-called “anti-counterfeit” IPR enforcement

73 EU-India FTA negotiations and access to medicines, Questions and answers http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf.
provisions, promoting the adoption of criminal sanctions for IP infringements, and the development of a special Task Force to combat counterfeiting and piracy.75

The measures proclaimed in the G-8 IP enforcement initiative are in line with the enforcement-related acquis adopted in the EU. Directive 2004/48/EC of the European Parliament and the Council on the enforcement of IPR, known as the “Enforcement Directive" provides a TRIPS-plus standard that includes provisionary and precautionary measures such as seizures, injunctions, payments of damages and costs, and also the possibility for censoring EU Member States by the European Court of Justice for provisions in national laws that make IPR protection “unnecessarily complicated or costly”. The EC initially proposed supplementing the Enforcement Directive by introducing a section on criminal sanctions for IPR infringements. After serious controversies, in September 2010 the EC announced its decision to withdraw the proposed amendment.

Council Regulation (EC) No 3295/94 of 22 December 1994 known as the Customs Regulation, succeeded by Customs Regulation 1383/2003, which came into force in 2004 also includes TRIPS-plus IPR enforcement measures at the border. Border measures against goods in transit that are suspected to infringe IPR have already been used to seize generic medicines that did not infringe IPR and were of good quality. In 2009, customs officials of the Netherlands seized 49kg of abacavir sulphate tablets, manufactured by WHO pre-qualified generic manufacturer Aurobindo, claiming that the medicines were “counterfeit” and infringed patent rights. The shipment, funded by UNITAID, was passing through Amsterdam airport in transit, on its way to Nigeria, where the medicines were to be distributed by the Clinton Foundation.76 ICTSD has reported about numerous other seizures of legitimate, good quality generic medicines by customs officials in the EU and other European countries (e.g. Norway).77

The proposed plurilateral Anti-Counterfeiting Trade Agreement (ACTA) is another international initiative establishing international standards for IPR rights enforcement that exceed the standards of the TRIPS Agreement. Negotiations of ACTA are carried out in secrecy and clearly dominated by the US. IPR Watchdog Knowledge Ecology International reported that major transnational corporations based in the US have formed an advisory committee that was consulted during the ACTA negotiations.78

75 See official 2007 Summit website, http://www.g-8.de/Webs/G8/EN/Homepage/home.html
78 Knowledge Ecology International (2009), Who are the cleared advisors that have access to secret ACTA documents?, http://www.keionline.org/blogs/2009/03/13/who-are-cleared-advisors.
ACTA aims to establish a new international legal framework for IPR enforcement and to create its own governing body outside the WTO Council on TRIPS. Leaked and subsequently officially released drafts, as well as the text that is described as “final” indicate that ACTA focuses strongly on copyright infringement on the Internet, includes anti-counterfeit measures, but also TRIPS-plus measures related to patent rights. The Agreement foresees civil remedies, border measures and criminal sanctions for certain IPR violations. Renowned academics and legal scholars, as well as international access to knowledge organisations have subjected ACTA to strong criticism. The European Parliament also has adopted a Declaration calling the EC and the Council to grant access to the ACTA negotiation information and documents.

At the ACTA signing ceremony in October 2011 in Tokyo, Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the US signed the treaty. The EU, Mexico, and Switzerland have confirmed their preparations to sign ACTA, which is open for signatures until 31 March 2013.

A group of Parliamentarians from 24 countries, representing a range of economic development, recently noted that the global consensus of the Doha Declaration is under threat as some governments are negotiating for bilateral and regional trade and investment agreements that create obligations for developing countries that exceed the standard set out by TRIPS, and that undermine the Declaration. They called on countries to oppose, and refrain from pursuing or adopting provisions in bilateral and regional trade and investment agreements that would undermine access to medicines and other pharmaceutical products.

All countries included in the High-Income Country Dialogue are WHO members and, as such, have the right to participate in the World Health Assembly, the government body of the WHO. In 2008 the World Health Assembly adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The Global Strategy and Plan of Action “provide[s] a medium-term framework based on the recommendations of the Commission on Intellectual Property, Innovation and Public Health, and to secure, inter alia, an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and

estimating funding needs in this area.” The Global Strategy and Plan of Action includes the following principles:

- The promotion of technological innovation and the transfer of technology should be pursued by all states and supported by IPR (Article 19).
- IPR do not and should not prevent Member States from taking measures to protect public health (Article 20).
- International negotiations on issues related to IPR and health should be coherent in their approaches to the promotion of public health (Article 21).
- IPR are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain (Article 25).

Element 5 of the Global Strategy and Plan of Action addresses the “application and management of intellectual property to contribute to innovation and promote public health a crucial need to strengthen innovation capacity as well as capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health”. The strategy recognises that WHO member governments have a role to play in every aspect of element 5. The actions to be taken in relation to element 5 include:

- Encourage and support the application and management of intellectual property in a manner that maximises health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific research and development needs of developing countries (5.1a).
- Strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the TRIPS Agreement, including the flexibilities recognised by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS Agreement (5.1e).
- Consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement, including those recognised by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003 (5.2a).
- Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the TRIPS Agreement, without prejudice to the sovereign rights of Member States (5.2b).
- Take into account in trade agreements the flexibilities contained in the TRIPS Agreement and including those recognised by the Declaration on the TRIPS
Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003 (5.2c).

- Consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003 (5.2d).
There are numerous legal and regulatory mechanisms available to low- and middle-income countries to increase access to medicines using public health flexibilities in the WTO TRIPS Agreement. The focus of this brief is on the laws, policies and practice of high-income countries. It has been suggested that high-income countries need to find ways of regulating and incentivising the pharmaceutical industry to pay greater attention to the medicines that are needed by developing countries. High-income countries also have a role to play in exploring and developing incentive mechanisms that would delink cost of research and development from price of products.

WTO members, during the 2010 annual review of the Doha Declaration paragraph 6 system, examined alternatives to its use to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines. A number of alternatives identified are relevant to high-income countries given their resources and their international legal and human rights obligations:

- Take measures to expand research and development of innovative drugs and production capacity for both innovator and generic drugs in developing countries. (paragraph 193).
- Governments that own patents should consider contributing them to the Medicines Patent Pool. For example, the US, through the National Institutes of

83 See UNDP (2010), Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the in the WTO TRIPS Agreement.
84 Mok E (2010), International assistance and cooperation for access to essential medicines, Health and Human Rights, vol. 12 (1), at p. 73.
85 Global Fund Partnership Forum (2011), Sao Paulo Parliamentary Declaration on Access to Medicines and other Pharmaceutical Products. See also World Health Assembly (2008), Global strategy and plan of action on public health, innovation and intellectual property, adopted 24 May 2008, WHA61.21, which calls on governments to “explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionally affect developing countries (5.3a).
Health, had been the first patent holder to share its patents with the newly established Medicines Patent Pool Foundation (paragraph 194). [Note that The Medicines Patent Pool has recently been criticised by access to medicines advocates after Gilead Sciences Inc. and the Medicines Patent Pool concluded a licensing agreement for four HIV ARVs.\(^87\) The advocates characterised the agreement as “a serious setback for the global movement on access to medicines”.]

- Provide technical and financial assistance to low- and middle-income countries to develop domestic capacity to manufacture pharmaceuticals. For example, although not a high-income country, the Brazilian Government helped Mozambique set up a small manufacturing unit for the production of first-line ARVs. While the initial supply was initially intended for the local market, Mozambique might in the future also supply other neighboring markets (paragraph 208).

In order to facilitate the prompt introduction (“spring boarding”) of generic medicines following the expiration of patents, governments may enact “Bolar exceptions”, whereby competing companies can make applications for the development and approval of a generic product before the patent expiration date. A WTO Dispute Settlement Body established a panel to examine the Bolar provision in the *Canadian Patent Act*. The panel concluded that Canada was in violation of their obligation under TRIPS by stockpiling pharmaceuticals during the six months prior to the expiry of the patents, but were not in violation in allowing development and submission of information required to obtain marketing approval for products without the consent of the patent holder.\(^88\)

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“Every day, stigma and discrimination in all their forms bear down on women and men living with HIV, including sex workers, people who use drugs, men who have sex with men, and transgender people. Many individuals most at risk of HIV infection have been left in the shadows and marginalised, rather than being openly and usefully engaged... To halt and reverse the spread [of HIV], we need rational responses which shrug off the yoke of prejudice and stigma. We need responses which are built on the solid foundations of equality and dignity for all, and which protect and promote the rights of those who are living with HIV and those who are typically marginalised.”

- UNDP Administrator Helen Clark

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