

## **IMPLEMENTATION OF THE CONVENTION ON THE RIGHTS OF THE CHILD IN EL SALVADOR**

### **The impact of international trade agreements regulating intellectual property rights on access to medicines and the fulfilment of children's rights<sup>1</sup> February 2004**

#### **Introduction**

1. In El Salvador a high proportion of childhood deaths are a result of infectious diseases that can be treated. Yet, these lives are lost for lack of access to affordable medicines. El Salvador, as a State party to the Convention on the Rights of the Child (CRC), has an obligation under article 4 CRC to take all appropriate measures for the implementation of the rights recognized by the Convention.
2. Access to affordable medicines is a fundamental element of the child's right to the enjoyment of the highest attainable standard of health under article 24 CRC, as interpreted by the CRC General Comment No.3 (2003) on HIV/AIDS and General Comment No. 4 (2003) on Adolescent health. Hence, it is imperative that the government of El Salvador ensure that its intellectual property (IP) laws governing the manufacture, import and distribution of pharmaceuticals are implemented in a way that enables El Salvador to fulfil its public health obligations.
3. El Salvador, as party to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), must ensure a minimum standard of IP protection. The TRIPS Agreement, as interpreted by the Doha Declaration on TRIPS and Public Health of November 2001<sup>2</sup> is flexible enough to permit national legislation that enables parties to fulfill their public health obligations.
4. However, this flexibility is being undermined by regional and bilateral trade agreements that contain more stringent IP requirements (termed "TRIPS plus" provisions). Indeed, El Salvador may have already dramatically curtailed its ability to implement the TRIPS flexibilities and fulfill its human rights obligations by signing the Central American Free Trade Agreement (CAFTA) on the 16<sup>th</sup> December 2003 and risks losing even more policy flexibility if the negotiations for the regional Free Trade Agreement of the Americas (FTAA) scheduled to conclude in 2005 enshrine even stricter IP protection.
5. This briefing outlines which flexibilities in the TRIPS Agreement can be used by El Salvador to ensure access to affordable medicines, and warns of the dangers raised by bilateral and regional trade agreements. It delineates issues of concern from a human rights perspective to be raised with the El Salvadorian government and recommends that trade-related intellectual property rules should not be developed or implemented in ways that prevent El Salvador from fulfilling its obligations under the CRC.

#### **I. Access to medicines, health and children's rights in El Salvador**

6. Article 66 of the Constitution of El Salvador affirms that the State will provide free assistance to patients who lack the resources if treatment is needed to prevent the spread of infectious diseases. However, according to the Ministry of Public Health and Social Welfare (MSPAS), about one quarter

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<sup>1</sup> 3D would like to thank Cecilia Oh and David Vivas for their helpful comments on an earlier draft of this briefing.

<sup>2</sup> WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 Nov. 2001.

of the population of El Salvador and 35% of the poorest members of society do not have access to treatment, due to the fact that treatment is too far away and unaffordable.<sup>3</sup>

7. This situation could be partially alleviated if the government of El Salvador actively acquired and promoted the use of generic drugs – generics being cheaper than drugs subject to patents<sup>4</sup>. Unfortunately, El Salvador has so far taken no measures to promote the acquisition of generic drugs or stimulate the local manufacture of generic drugs

8. Another concern is the fact that public expenditure on prescription drugs has decreased since 1996. Indeed, in 1999 only 10.8% of MSPAS expenditure was on prescription drugs whilst in 1996 it was 17.04%.<sup>5</sup> Without a comprehensive national drug policy that promotes generic drugs, El Salvador will not be able to fulfill its constitutional obligations or its obligation to ensure children's right to the highest attainable standard of health under article 24 CRC.

## **II. The framework agreement: the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)**

### **A. TRIPS, public health and access to medicines**

9. The WTO TRIPS Agreement provides a framework for IP laws that aims to raise standards of IP protection in developing countries. El Salvador, for example, had to increase its minimum term of patent protection for pharmaceuticals (and other inventions) from fifteen to twenty years when complying with the TRIPS Agreement patent provisions in January 2000. Nonetheless, the TRIPS Agreement does seek to accommodate the public interest, particularly in relation to public health and access to medicines. This is further emphasized by the Doha Declaration on TRIPS and Public Health (Doha Declaration) which stresses that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, access to medicines for all.”

### **B. TRIPS flexibilities enabling access to affordable medicines**

10. The Doha Declaration encourages States to use all flexibilities in the TRIPS Agreement and expressly enumerates the following four flexibilities:

- **Interpretation:** The Doha Declaration encourages States to interpret and implement the TRIPS Agreement in a way that balances public and private interests, by adopting measures to protect public health. Since El Salvador is currently involved in a radical overhaul of its health system, it could use this opportunity to promote a public health-focused IP regime that contributes to fulfilling the right to the highest attainable standard of health under article 24 CRC.
- **Compulsory licensing:** The Doha Declaration reminds States of their right to grant “compulsory licenses” to local generic manufacturers without the consent of the patent holder, and determine the grounds for granting such licenses.<sup>6</sup> Although no developing country has yet issued a compulsory license under the TRIPS Agreement, in 2001 Brazil threatened to use one for the AIDS drug Viracept and succeeded in convincing the pharmaceutical group Roche to dramatically reduce their prices for the drug. El Salvador has retained the ability to grant compulsory licenses in its 1993 Intellectual Property Promotion and Protection Law, but has never made use of it. It should be encouraged to use it as a bargaining tool and as a useful measure to obtain cheaper patented medicines.

<sup>3</sup> See Ministerio de Salud Publica y Asistencia Social de El Salvador, Propuesta de Reforma Integral de Salud: [http://www.mspas.gob.sv/avance\\_reforma.asp](http://www.mspas.gob.sv/avance_reforma.asp)

<sup>4</sup> Generic drugs are equivalent to patented drugs, and are usually made without a license from the patent holder.

<sup>5</sup> See PAHO, El Salvador Profile of Health Systems and Services, 2001.

<sup>6</sup> Compulsory licensing allows public authorities to issue a license to manufacture or import a generic drug without the consent of the patent holder, as long as the patent holder is compensated.

- **Definition of national emergencies or other circumstances of extreme urgency:** The Doha Declaration reminds States that the obligation to consult the patent holder when granting a compulsory license may be waived if the grant of the license was due to a situation of national emergency or other circumstance of extreme urgency. The Doha Declaration encourages States to define these situations and expressly states that national emergency or circumstances of extreme urgency can include public health crises such as HIV/AIDS, tuberculosis, malaria and other epidemics.
- **Exhaustion of patent rights:** the TRIPS Agreement does not determine when intellectual property rights have been exhausted.<sup>7</sup> It therefore gives States the freedom to define when a patent holder loses exclusive rights over the re-sale of a product. This freedom is a crucial policy tool for developing countries, as it enables the importation of cheaper patented drugs from countries where patent rights have already ended (termed “parallel importation”). The 1993 Intellectual Property Promotion and Protection Law of El Salvador does not prohibit parallel importation, but El Salvador currently has no policy on the subject. Therefore, it should be encouraged to draft a drug policy that makes active use of parallel imports to decrease the price of patented drugs.

### C. TRIPS safeguards and access to affordable medicines

11. The TRIPS Agreement also contains safeguards that could stimulate generic production and help El Salvador reduce the price of patented medicines:

- **Exceptions to patent rights:** article 30 of the TRIPS Agreement permits States to limit the rights of patent holders as long as the limitations do not conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder or third parties. This provision could be used by States to allow local generic drug manufacturers the right to import, manufacture and test a medicine prior to the expiry of a patent, to ensure that the manufacture of generic equivalents is not delayed once a patent runs out. El Salvador would benefit from implementing this exception, as it would accelerate the availability of affordable off-patent drugs, of particular importance to the most vulnerable groups who cannot afford more expensive medicines.
- **Prohibition of anti-competitive practices:** article 40 of the TRIPS Agreement gives States the authority to prohibit anti-competitive practices of patent owners. This provision gives states the ability to penalize pharmaceutical patent owners that abuse their dominant position in contractual relationships and engage in prohibitive pricing. In view of this ability, the South African Competition Commission in October 2003 held the pharmaceutical companies GlaxoSmithKline South Africa and Boehringer Ingelheim responsible of excessive pricing of HIV/AIDS drugs, unlawful refusal to issue voluntary licenses to generic drug manufacturers and unreasonable restriction of HIV/AIDS drugs. If El Salvador was given the technical assistance necessary to implement competition rules prohibiting anti-competitive behaviour and abuse of rights it would gain another bargaining tool that would help it make low-cost drugs available in the face of influential pharmaceutical lobbies.

### D. Import of generic medicines under compulsory license to countries that lack or have insufficient manufacturing capacity

12. The WTO General Council Decision of 30<sup>th</sup> August 2003 (hereinafter General Council Decision) provides a solution for States that lack or have insufficient national pharmaceutical manufacturing capacity. The General Council Decision is a waiver to TRIPS provisions on compulsory licensing that limit the export of generic drugs. The General Council Decision is available to States with insufficient

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<sup>7</sup> Exhaustion of patent rights means that once a patent holder sells or authorizes the sale of a product in a market it no longer has control over the re-sale of the product in that market.

drug manufacturing capacity to meet their needs. Since States decide themselves if they have insufficient capacity, El Salvador could qualify as eligible for the waiver. Hence, in applying its IP legislation and in negotiating new rules (see section II below) it is necessary that El Salvador retain the policy flexibility to invoke the General Council Decision, as incorporated into a future TRIPS amendment, particularly in response to a public health crisis.

## II. Threats to cheap medicines in bilateral and regional trade agreements

### A. Bilateral trade agreements: the Central American Free Trade Agreement (CAFTA)

13. On the 16<sup>th</sup> December 2003, El Salvador signed a bilateral trade agreement with the United States termed the Central American Free Trade Agreement (hereinafter CAFTA) and is now in the process of ratification. The other parties to the agreement are Costa Rica, Guatemala, Honduras and Nicaragua. Prior to the signing of the agreement no official study was made of the potential impacts of CAFTA on public health in El Salvador. Furthermore, the CAFTA text was kept secret during the whole negotiations and was only made public *after* signature, on 29 January 2004. In addition, consultation of civil society groups in El Salvador during the negotiations was largely limited to members of the business community. This is inconsistent with the obligation to give prime consideration to the best interests of the child under article 3 (1) CRC, the obligation to respect the views of the child under article 12 CRC, the obligation to ensure the child's freedom to seek, receive and impart information under article 13(1) CRC and the obligation to ensure access of the child to information on his or her physical health under article 17 CRC. It is also inconsistent with the general human rights obligation that allows participation of individuals and groups in decisions that affect them.

14. Moreover, of serious concern is the fact that the CAFTA text includes various "TRIPS Plus" provisions which contradict the commitments made in the Doha Declaration. These provisions delay the date at which generic medicines can be manufactured and/or marketed. This risks putting El Salvador in a situation where it is forced to violate its obligations under article 4 CRC to undertake all appropriate measures to implement the rights set out in the Convention, as it will have to implement legislation that further curtails its capacity to make affordable medicines available, and thus its ability to realize the right to an adequate standard of health under article 24 CRC.

- **Extension of the patent term for unreasonable delays:** CAFTA allows the extension of the patent term for pharmaceuticals beyond the twenty years required by the TRIPS Agreement by allowing an "adjustment" for "unreasonable delays" of three to five years experienced during the granting of a patent. In practice, this is tantamount to extending the patent term to up to twenty-five years.
- **Marketing authorization:** CAFTA gives patent owners the right to prohibit the marketing of a generic medicine for a period of five years. This is another method by which patent owners can achieve a de facto extension of the patent term to twenty-five years.
- **Exclusive rights over test data:** CAFTA allows owners of medicines that have not yet been marketed in El Salvador to have exclusivity over test data on safety and efficacy for a period of five years. This provision of CAFTA gives patent holders rights over data that has never been confidential and has the damaging effect of delaying the manufacture of cheaper generic versions by five years even for off-patent drugs.

### B. Regional trade agreements: the Free Trade Agreement of the Americas (FTAA)

15. El Salvador is also a party to the negotiations to establish a Free Trade Agreement of the Americas (FTAA) covering 34 countries from across the Americas. Negotiations under the FTAA were officially launched in 1998 and currently aim to conclude by 2005. Unlike CAFTA, a draft of the FTAA text has

been openly circulated and various civil society groups have been consulted. Nevertheless, negotiations still remain secretive and consultations are very limited, in violation of the best interests of the child under article 3 CRC, the obligation to respect the views of the child under article 12 CRC the obligation to ensure the child's freedom to seek, receive, and impart information under article 13(1) CRC and the obligation to ensure access of the child to information on his or her physical health under article 17 CRC.

**16.** The CAFTA agreement sets a dangerous benchmark for the FTAA negotiations, as it creates a new, higher, level of IP protection that the United States is hoping the FTAA will meet or even surpass. The CAFTA provisions extending the patent term for pharmaceuticals and providing exclusive rights over test data are also included in the draft FTAA text. Other worrisome FTAA proposals that go beyond TRIPS requirements include:

- **Compulsory licensing restrictions:** the draft FTAA aims to limit the scope of compulsory licensing permitted by the TRIPS Agreement to government use only. Also of concern is the fact that a proposed limitation on exports of drugs under compulsory license would render the WTO General Council Decision of 30<sup>th</sup> August 2003 inoperable. This would remove the possibility currently open to El Salvador to import drugs manufactured under compulsory license to face a public health crisis.
- **Exhaustion of patent rights:** contrary to the TRIPS Agreement which grants States the power to determine when the marketing of a patent leads to exhaustion of patent rights, the draft FTAA aims to provide a minimum principle of "regional exhaustion." This provision would curtail access to parallel imports of cheaper medicines, as the exclusive right of patent holders over marketing would not end until after the drug has been marketed in the whole region of the Americas.

## Conclusion

El Salvador has a duty under the Convention on the Rights of the Child to ensure children's access to affordable medicines. In order to fulfill this obligation it must retain sufficient policy flexibility to enforce intellectual property rights in a way consistent with its human rights obligations.

The WTO TRIPS Agreement, as interpreted by the Doha Declaration on TRIPS and Public Health provides sufficient flexibility to El Salvador to encourage generic drug competition and reduce the prices of medicines. However, El Salvador has not yet made use of these flexibilities and may even have curtailed its future ability to use them by signing CAFTA. Therefore, it is essential that the Committee on the Rights of the Child remind El Salvador of its human rights obligations in relation to access to medicines and recommend that El Salvador use all the policy tools at its disposal to permit the realization of the rights set out in the CRC.

For information on 3D's work in general, or on 3D's project on the impact of trade-related intellectual property rules on access to medicines and human rights, please visit [www.3dthree.org](http://www.3dthree.org) or contact:

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## **El Salvador: issues of concern on access to medicines and the CRC**

### **Right to the highest attainable standard of health (article 24 CRC)**

*Question:* Has the government of El Salvador implemented the flexibilities and safeguards in the TRIPS Agreement and Doha Declaration on TRIPS and Public Health in a way that enables it to fulfill its obligation to ensure access to affordable medicines, inherent in the right to the highest attainable standard of health under article 24 CRC?

*Recommendation:* The government of El Salvador should ensure that its intellectual property laws do not violate the obligation to ensure access to affordable medicines enshrined in the right to health under article 24 CRC.

### **Best interests of the child (article 3 CRC)**

*Question:* Has the government of El Salvador considered the best interests of the child under article 3(1) CRC when implementing the TRIPS Agreement and negotiating the intellectual property provisions of the Central American Free Trade Agreement (CAFTA) and Free Trade Agreement of the Americas (FTAA)?

*Recommendation:* The government of El Salvador should systematically consider the best interests of the child under article 3(1) CRC when negotiating trade-related intellectual property rights and implementing them into national law.

### **Respect for the views of the child (article 12 CRC), Obligation to receive and impart information (article 13(1) CRC), Access to information on children's physical health (article 17 CRC)**

*Question:* Has the government of El Salvador ensured the respect for the views of the child under article 12 CRC, fulfilled its obligation to receive and impart information to the child under article 13(1) and ensured access to information on the children's health under article 17 CRC, when negotiating the Central American Free Trade Agreement (CAFTA) and the Free Trade Agreement of the Americas (FTAA)?

*Recommendation:* the government of El Salvador should make its negotiating positions public, consult widely and encourage participation of civil society groups representing children's interests whilst negotiating or implementing trade policy.

### **Technical Assistance (Article 4 CRC)**

*Question:* Has El Salvador requested technical assistance under article 4 CRC to ensure that its trade-related intellectual property rights are developed and implemented in ways that help it ensure the realization of the rights set out in the CRC?

*Recommendation:* The government of El Salvador should seek technical assistance under article 4 CRC, particularly from UNICEF and the Office of the High Commissioner for Human Rights (OHCHR), to ensure that trade-related intellectual property rights are developed and implemented in a way that facilitates access to affordable medicines in a manner consistent with the obligations of the CRC.

### **Making the principles and provisions of the Convention widely known (Article 42 CRC)**

*Question:* Are El Salvador's trade policy officials aware of the principles and provisions of the CRC?

*Recommendation:* The government of El Salvador should ensure that the principles and provisions of the CRC are widely known to its trade negotiators.