3D → Trade
→ Human Rights
→ Equitable Economy

3D → Trade - Human Rights - Equitable Economy
Maison des Associations - Rue des Savoises 15
1205 Genève - Switzerland
T +41 22 320 21 21 - F +41 22 320 69 48
www.3dthree.org - info@3dthree.org

Trade-related intellectual property rights, trade in services and the fulfilment of children's rights - Botswana
September 2004

Introduction

1. Botswana has emerged as a model of access to medicines and treatment services in Southern Africa due to its ground-breaking response to HIV/AIDS. Notwithstanding these efforts, it still has one of the highest prevalence rates in the world, with about 34.5% of pregnant women living with HIV/AIDS and an overwhelming 75% of patients in hospital wards suffering from AIDS.[1] Moreover, in 2003 an alarming 25,000 children were living with HIV/AIDS and about 120,000 children had been orphaned by the epidemic.[2] It is therefore vital that Botswana retain the policy flexibility to ensure access to essential medicines and health care services.

2. Botswana, as state party to the Convention on the Rights of the Child (CRC), has an obligation to promote and protect the child's right to the enjoyment of the highest attainable standard of health under article 24 CRC and the child's inherent right to life, survival and development under article 6 CRC. Inherent in the right to health and the right to life is the child's right to sustained and equal access to comprehensive treatment and affordable medicines without discrimination, as interpreted by CRC General Comment No.3 (2003) on HIV/AIDS and CRC General Comment No. 4 (2003) on Adolescent Health.

3. Botswana's first periodic report demonstrates that it has taken bold measures for the implementation of the rights recognized by the CRC. Indeed, steps taken to fulfil the child's right to health and the right to life are commendable; particularly the provision of free antiretroviral drugs (ARVs) and health care services to treat HIV/AIDS under the national ARV therapy programme.[3] However, these positive measures risk being undermined by trade rules, particularly the intellectual property rules and services liberalization measures proposed for inclusion in a bilateral Free Trade Agreement (FTA) between the United States and the Southern African Customs Union (SACU - Botswana, Lesotho, Namibia, South Africa and Swaziland).

4. 3D -> Trade - Human Rights - Equitable Economy is a not-for-profit organization based in Geneva, Switzerland, working to ensure that trade rules are developed and applied in ways that promote an equitable economy.[4] We believe that human rights mechanisms such as the Committee on the Rights of the Child can help attain this objective by reminding States that complying with international trade rules must not undermine human rights obligations.

5. This submission to the members of the Committee on the Rights of the Child first delineates our human rights-based concerns relating to the way Botswana has implemented the WTO Intellectual Property (TRIPS) and Services (GATS) Agreements (section II), and then our concerns about our intellectual property (IP) and services negotiations of the US-SACU Free Trade Agreement (section III). We recommend that Botswana seek all available technical assistance from

[1] UNAIDS, *Stepping back from the edge, the pursuit of antiretroviral therapy in Botswana, South Africa and Uganda*, UNAIDS/04.04E, April 2004.
[2] UNAIDS/WHO *Epidemiological Fact Sheet Update*, Botswana, 2004.
[3] Botswana, *Initial Report to the United Nations Committee on the Rights of the Child*, CRC/C/51/Add.9, 2001, at paragraph 242.
[4] *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 or contact Davinia Ovett, Programme Officer, 3D -> Trade - Human Rights - Equitable Economy, dovett@3dthree.org*

the Office of the High Commissioner for Human Rights (OHCHR) and UNICEF to ensure that these trade rules are negotiated, drafted and implemented in a way that enables Botswana to fulfil its obligations under the Convention on the Rights of the Child.

I. Access to affordable medicines, health care and the child's right to health in Botswana

6. Botswana has taken considerable steps to respect, protect and fulfil the child's right to health according to article 24 CRC and the child's right to life, survival and development according to article 6 CRC. This has particularly been the case in relation to HIV/AIDS. Botswana's landmark national antiretroviral (ARV) therapy programme, which began in 2001, provides free drugs in public sector health services. Pregnant women with HIV/AIDS, all HIV positive children under 12 months and children with AIDS symptoms automatically qualify for free ARV treatment.[5] In June 2004, of the 18,000 people receiving treatment, 12,000 were receiving treatment from the public sector and 6,000 from the private sector.[6] It is therefore important that Botswana retain the power to regulate health service provision to ensure sustained and equal access to treatment.

7. Botswana currently uses ten patented drugs in the national ARV therapy programme.[7] In order for Botswana to scale-up the programme and achieve the national treatment target of 55,000 people by 2005, it is important to cut the price of ARV drugs and other essential medicines. The use of generic drugs – that are equivalent and interchangeable with patented ones – would reduce the cost of ARV treatment per patient, thereby allowing the treatment of more people.[8] Hence, it is important that Botswana use all the policy flexibilities at its disposal to reduce the price of drugs, notably for the prevention of mother-to-child transmission of HIV and the treatment of children living with HIV/AIDS.

II. WTO Agreements, public health and children's rights

A. TRIPS and access to medicines

8. Trade-related intellectual property (IP) rights can affect access to affordable medicines, which is a crucial element of fulfilling the child's right to health and the right to life, survival and development. Of all IP rights, patent rules can have the most direct effect on the price of drugs. For example, TRIPS grants patent owners at least twenty years of exclusive commercial rights to make, use or sell their inventions. This keeps prices of patented drugs artificially high, which in turn affects the affordability of medicines for the most vulnerable and marginalized groups.

9. Botswana was required to implement minimum standards of IP protection according to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). As a developing country it was granted a delay until January 2000 and officially notified the WTO TRIPS Council of its compliance in June 2001.[9] The TRIPS agreement contains various flexibilities which aim to reduce the adverse effects of IP rights on the cost of drugs. The WTO Doha Declaration on TRIPS and Public Health of November 2001 (Doha Declaration) reaffirms these flexibilities to "protect public health and, in particular, access to medicines for all." Botswana has incorporated some of these TRIPS flexibilities in its current IP laws, particularly the

[5] UNAIDS, note 1 above.
[6] WHO, *Summary Country Profile for HIV/AIDS Treatment Scaling-Up*, July 2004.
[7] UNAIDS, note 1 above
[8] MSF/WHO/UNAIDS, *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries, The Experience of Médecins Sans Frontières*, 2003.
[9] WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification of laws and regulations under article 63.2 TRIPS*, WTO IP/N/1/BWA/1, February 2002.

compulsory licensing and government use measures.[10] It has also crucially excluded from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans" which would mean that HIV/AIDS diagnostic kits cannot currently be patented in Botswana[11] and are therefore available at a low cost.

10. Botswana should be encouraged to implement and fully use the TRIPS flexibilities reaffirmed by the Doha Declaration, of which the following main flexibilities:

- **Compulsory licensing and government use:** the ability of the relevant authorities to grant and define when to issue a license to manufacture, use or sell a generic equivalent version of a patented drug without the consent of the patent holder, as long as the patent holder is compensated.
- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the re-sale of their products. This enables the importation of patented drugs from countries where they are sold more cheaply (termed "parallel importation").
- **Exceptions to patent rights:** the ability to allow the manufacture and testing of a drug prior to the expiry of the patent, in order to obtain regulatory approval for making a generic drug once the patent expires (termed "bolar provision").
- **Prohibition of anti-competitive practices:** the ability to penalize pharmaceutical patent owners that abuse their dominant position in contractual relationships and engage in prohibitive pricing.

11. Another mechanism that Botswana should use to seek to reduce the price of medicines is the solution provided by the WTO General Council Decision of 30th August 2003 (General Council Decision). This temporary waiver to the TRIPS Agreement aims to allow States with insufficient drug manufacturing capacity to fully benefit from compulsory licensing. Botswana should be encouraged to pass implementing legislation allowing it to use this compulsory licensing mechanism as soon as possible, to ensure that it has all the tools at its disposal to ensure access to affordable medicines for the most vulnerable groups.

12. It is important that the technical assistance provided to Botswana in drafting IP legislation make use of all the TRIPS flexibilities reaffirmed by the Doha Declaration and the flexibilities granted to developing countries in the General Council Decision. There is concern that technical assistance provided by the World Intellectual Property Organization (WIPO) does not promote these flexibilities and favours IP rules that go beyond the TRIPS Agreement (termed TRIPS-plus rules).[12] Therefore, it is necessary that Botswana seek technical assistance from the Office of the High Commissioner for Human Rights (OHCHR) to ensure that IP implementing legislation does not undermine Botswana's human rights obligations.

B. GATS and health-related services

13. The WTO General Agreement on Trade in Services (GATS) is the first multilateral agreement to set a framework for the liberalization of trade in services. Although GATS does not dictate the level at which WTO Members should liberalize, it does commit countries to successive rounds of negotiations on trade in services "with a view to achieving a progressively higher level of liberalization." The GATS liberalizes services according to four "modes of supply." Although all modes affect health service provision, the third mode - commercial presence of foreign providers in another country - could have the most far-reaching impact on the enjoyment of the child's right to health and the child's right to life. Indeed, it is feared that increasing foreign direct investment in health-related services such as hospitals or health insurance could lead to a two-tiered health

[10] Botswana, *Industrial Property Act*, 1996, sections 30, 31 69 respectively.
[11] Botswana, *Industrial Property Act*, 1996, section 9(f), as amended by *Industrial Property (Amendment) Act*, 1997.
[12] Sisule Musungu and Graham Dutfield, *Multilateral agreements and a TRIPS-plus world: the World Intellectual Property Organisation (WIPO)*, QUNO TRIPS Issues Papers 3, 2003.

system that discriminates against the poor and most vulnerable groups, such as children living with HIV/AIDS.[13]

14. Although the GATS preamble recognizes WTO Member's right to regulate "in order to meet national objectives" it subjects all domestic measures to a "necessity test" even in service areas where no commitments have been made. Therefore, if Botswana decided to introduce regulations on health insurance prohibiting discrimination against people living with HIV/AIDS similar to South Africa's, this measure would only be allowed if it were "least trade restrictive." It is therefore important that Botswana obtain technical assistance from the Office of the High Commissioner for Human Rights to ensure that these GATS rules do not undermine its human rights obligations to ensure the availability, accessibility, acceptability and quality of health-related services.[14]

15. The GATS requires countries to make liberalization commitments and list all the limitations on liberalization they wish to keep. Once commitments are made it is very difficult to reverse them, as other service commitments need to be granted to WTO members as compensation. Botswana has not made commitments on health services or financial services such as health insurance. Liberalizing these sectors without proper knowledge of impacts could undermine the enjoyment of the right to health. Therefore, Botswana should not make any commitments in health-related sectors in the current round of GATS negotiations. If it is planning to do so, it is essential that it first conduct an impact assessment of the effect of service liberalization on the fulfilment of its obligations under the Convention on the Rights of the Child and other human rights treaties.

III. Threats to public health and children's rights in Botswana raised by bilateral trade agreements: the US-SACU Free Trade Agreement

16. Botswana is currently involved in a number of trade negotiations at the regional level. In July 2004 the Southern African Development Community (SADC), of which Botswana is a member, began negotiations with the European Union for an Economic Partnership Agreement (EPA). Also, as member of the Southern African Customs Union (SACU) it began negotiations in May 2003 for a bilateral trade agreement with the European Free Trade Association (EFTA - Iceland, Liechtenstein Norway and Switzerland). Both these agreements cover trade in services and intellectual property rights and risk impacting on Botswana's obligations under the Convention on the Rights of the Child.

17. However, the agreement that is of most immediate concern is the US-SACU Free Trade Agreement (FTA). FTA negotiations began in June 2003 and are scheduled to end by late 2004. The proposed agreement is the first US FTA with sub-Saharan Africa and will be used as a benchmark for other trade agreements in the region. The US is proposing that the FTA build on previous agreements such as the US-Morocco FTA and the Dominican Republic - Central American FTA (CAFTA).[15] There are a number of issues of concern in the proposed FTA agreement, as outlined in the 3D's submission to the Committee on the Rights of the Child pre-session working group in May 2004.[16] However, the areas posing the greatest threat to the child's right to health and right to life are the IP and services provisions. It is feared that the agreement

[13] Commission on Human Rights 60th Session, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Report of the Special Rapporteur, Paul Hunt, Mission to the World Trade Organization*, E/CN.4/2004/49/Add.1, 1 March 2004.
[14] Commission on Human Rights, 54th Session*, Liberalization of trade in services and human rights, Report of the High Commissioner,* E/CN.4/Sub.2/2002/9, 25 June 2002.
[15] See 3D's submission to the Committee on the Right of the Child at its 36th Session, *El Salvador: The impact of international trade agreements regulating intellectual property rights on access to medicines and the fulfilment of children's rights,* February 2004, <www.3dthree.org/en/page.php?IDpage=23&IDcat=5>
[16] See 3D's submission to the Committee on the Rights of the Child's pre-session working group, *Botswana: International trade, health and children's rights*, May 2004, <www.3dthree.org/en/page.php?IDpage=23&IDcat=5>

will contain strict IP rules that will undermine access to affordable medicines and services liberalization commitments that will undermine the State's obligation to ensure "sustained and equal access to comprehensive treatment" according to the CRC General Comment No. 3 (2003) on HIV/AIDS.

A. TRIPS-plus conditions and the price of drugs

18. The US-SACU FTA negotiations stalled in mid-2004 due to disagreements over IP, services and investment provisions. SACU members fear that the IP rules could undermine their ability to use the flexibilities permitted by the TRIPS Agreement and reaffirmed by the Doha Declaration. It would be important for SACU countries to take advantage of this time to conduct human rights impact assessments of the proposed IP rules.

19. The following clauses in previous FTA negotiations go beyond the requirements of the TRIPS Agreement (termed TRIPS-plus rules). Due to the fact that IP clauses in previous FTAs will be used as a benchmark for the SACU negotiations, it is important to understand how they will limit the flexibilities permitted by TRIPS[17]:

- **Extension of the patent term for unreasonable delays:** "adjustments" of three to five years for "unreasonable delays" in granting a patent is included in agreements such as the CAFTA. Such provisions effectively extend the patent term beyond the TRIPS twenty year period.
- **Compulsory licensing restrictions:** limitations on the export of drugs under compulsory license were proposed by the US in the current Free Trade Agreement of the Americas (FTAA) negotiations. This would undermine the mechanism of the WTO General Council Decision of 30th August 2003.
- **Parallel import restrictions:** the US-Morocco FTA allows patent holders to restrict parallel imports by contractual means, whilst the FTAA proposal requires the sale of a drug in a whole region before allowing parallel imports (termed "regional exhaustion"). This would be contrary to the spirit of the Doha Declaration which allows Members the freedom to decide their own regime.
- **Exclusive rights over test data:** owners of patented drugs that have not yet been marketed or registered in a country are granted exclusivity over test data on safety and efficacy for a period of five years in the US-Chile FTA and CAFTA. This protection also extends to off-patent drugs, meaning that patients need to wait five extra years before generic drug manufacturers can use the data to make generic versions of the drug. There are no such rights in the TRIPS Agreement.
- **Marketing authorization:** CAFTA grants drug regulatory authorities' new responsibilities in assessing the patent status of a drug before granting marketing authorization for a generic. This may be harmful, as these regulatory authorities do not have the experience to make decisions on patents. Moreover, CAFTA requires that generic manufacturers get the consent of patent owners to use the safety and efficacy data in order to obtain marketing authorization. Since generic manufacturers cannot afford to re-do these tests, this could effectively undermine compulsory licensing permitted by TRIPS.

B. Trade in services and access to health care services

20. As noted below, the FTA is being negotiated in secret, contrary to basic human rights principles. Little is therefore known about the services negotiations. However, the United States' trade objectives for the US-SACU FTA give an indication of the scope of the services commitments requested. These objectives indicate that the US will focus on obtaining "disciplines to address discriminatory or other barriers to trade" which includes domestic regulation and also

[17] Oxfam, *Undermining access to medicines: Comparison of five US FTA's*, Briefing Note, June 2004.

aim to obtain market access for sectors such as financial services.[18] This could have dramatic effects on the child's right to access health care services, as health insurance providers are likely to discriminate against certain vulnerable groups, such as people living with HIV/AIDS, if there is insufficient regulation of the market. It is also important to note that if Botswana makes any specific commitments to open up health-related services under this US-SACU FTA, it will be obliged to grant this privilege to all other members of the WTO under the non-discrimination requirements of the WTO Agreements. Therefore, it is crucial that Botswana resist pressures to liberalize the health insurance segment of its financial services sector. If it does nevertheless plan to, it should first undertake an impact assessment to ensure that services commitments under the US-SACU FTA, or any other trade agreement it is currently negotiating, do not undermine its obligations under the Convention on the Rights of the Child and other human rights treaties.

C. Trade negotiation procedures: limited access to information and participation

21. The US-SACU FTA negotiations have been as secretive and expedient as other recent US bilateral trade negotiations with Central America, the Andean Community and Thailand. Although Botswana officially set-up a National Committee on Trade Policy Negotiation on the 12 March 2004, which includes an NGO representative, there has been limited access to information about the trade negotiations and no clear mechanism for wider consultation with groups representing children's rights or people living with HIV/AIDS. Botswana must therefore be reminded that this is inconsistent with the fundamental obligation to give prime consideration to the best interests of the child according to article 3 CRC, the obligation to ensure the child's freedom to seek, receive and impart information according to article 13(1) CRC and the obligation to ensure access to information on children's physical health under article 17 CRC.

Conclusion

22. Botswana has shown strong political commitment to fulfilling the child's right to health and the child's right to life, survival and development. In order to sustain this commitment, it is necessary that Botswana refrain from entering into trade agreements that would undermine its obligations under the Convention on the Rights of the Child and other human rights treaties. It is also crucial that Botswana undertake impact assessments of the human rights effect of proposed IP rules and services liberalization before negotiating and implementing trade agreements. Furthermore, it is important that Botswana take measures to consult and ensure access to information to groups representing children and other vulnerable groups, according to its obligations under the Convention on the Rights of the Child.

September 2004

(See issues of concern on next page)

[18] Treatment Action Campaign (TAC)/ Aids Law Project (ALP), *Memorandum on the United States/ Southern African Customs Union Free Trade Agreement Negotiations*, 3 February 2004.

Botswana: issues of concern on trade, health and the CRC

Right to the highest attainable standard of health (Article 24 CRC) and obligation to review the treatment provided to the child (Article 25 CRC)

Question: Has the government of Botswana assessed the possible impacts on children's rights, and particularly the child's right to health, of proposed intellectual property and services provisions of the US-SACU Free Trade Agreement (FTA)?

Recommendation: The government of Botswana should undertake human rights impact assessments before negotiating or implementing trade agreements, in order to ensure that they do not undermine the State's obligations to ensure access affordable medicines and health care services, as required by Article 24 CRC.

Best interests of the child (Article 3 CRC)

Question: Has the government of Botswana considered the best interests of the child under Article 3(1) CRC when negotiating the US-SACU FTA, particularly in relation to intellectual property rules and trade in services?

Recommendation: The government of Botswana should systematically consider the best interests of the child when negotiating trade agreements and when implementing trade-related obligations into national law.

Respect for the views of the child (Article 12 CRC), obligation to receive and impart information (Article 13(1) CRC), and access to information on children's physical health (Article 17 CRC)

Question: Has the government of Botswana 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 US-SACU FTA?

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

Technical Assistance (Article 4 CRC)

Question: Has the government of Botswana requested technical assistance under article 4 CRC to ensure that its trade-related obligations are developed and implemented in ways that help it ensure the realization of the rights set out in the CRC, for instance to carry out a human rights impact assessment of new or proposed trade obligations?

Recommendation: The government of Botswana should seek technical assistance from UNICEF and the Office of the High Commissioner for Human Rights (OHCHR), to ensure that any new or proposed trade-obligations are developed and implemented in a way that promotes the best interests of the child and is consistent with other obligations under the CRC.

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

Question: Are Botswana's trade officials aware of the principles and provisions of the CRC?

Recommendation: The government of Botswana should ensure that the principles and provisions of the CRC are widely known to its trade officials, in particular those responsible for negotiating the US-SACU FTA.