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Making Trade Policies More Accountable and Human Rights-Consistent: A NGO Perspective of Using Human Rights Instruments in the Case of Access to Medicines

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Introduction

Trade is not only the driving force behind economic globalisation, but also a major influence on the extent to which States can implement economic, social and cultural policies. Indeed, trade rules, including those of the World Trade Organization (WTO), are increasingly curtailing the policy space of States. Without sufficient policy flexibility to adapt trade agreements to national circumstances and development goals, States can find themselves in a position where trade rules undermine their capacity to comply with their human rights obligations. In order to address this problem, it is necessary to understand how trade rules adversely affect the enjoyment of human rights. Moreover, it is important to assess whether international human rights rules and accountability mechanisms can provide solutions capable of reducing the negative impact of trade rules on the enjoyment of human rights.

One of the first trade-related issues to involve clearly recognised human right implications is the effect of intellectual property (IP) rules on access to affordable medicines. IP protection became an international trade issue with the adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1994.² Developing countries, supported by public-interest NGOs and the international media, raised concerns about the public health impacts of the TRIPS Agreement very early on. These concerns resulted in an unprecedented political commitment: the WTO Doha Declaration on TRIPS and Public Health 2001 (Doha Declaration).³ This Declaration reaffirms a State's ability to use all the flexibilities in the TRIPS Agreement to reduce the cost of medicines and fulfil public health obligations.

Despite this political commitment, a State's ability to take measures that ensure access to affordable medicines is being curtailed by IP standards. In particular, IP rules requested in bilateral and regional trade agreements are pushing the boundaries of IP law, achieving a degree of protection of Human Rights that cannot be reached at the multilateral level. This puts States in a situation where they could violate their obligations under international human rights law if they comply with their trade obligations. Also, the fact that these bilateral and regional trade agreements are often negotiated in secret and without proper consultation contravenes the States' obligation to

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² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

³ WTO, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2, 14 November 2001.

ensure access to information and participation in public affairs of all citizens. This lack of transparency also limits independent monitoring of trade negotiations in order to ensure that trade rules are consistent with human rights.

3D → Trade - Human Rights - Equitable Economy (3D) is a public-interest NGO based in Geneva, Switzerland, working to ensure that trade rules are developed and applied in ways that promote an equitable economy.⁴ 3D has consultative status with the United Nations Conference on Trade and Development (UNCTAD), *ad hoc* observer status with the World Intellectual Property Organization (WIPO) and maintains a good working relationship with the Office of the High Commissioner for Human Rights, the World Health Organization (WHO), UNAIDS and other UN institutions.

One of 3D's objectives is to promote the use of human rights rules and mechanisms in order to ensure that States refrain from adopting trade rules or policies that would undermine their compliance with human rights. 3D chose to look at the issue of IP, access to medicines and human rights because many of the public-interest NGOs active on this issue were not using human rights tools to support their work. In 2004 and early 2005, 3D used a number of international human rights mechanisms in order to provide additional arguments to advocates and to decision-makers involved in trade negotiations. The mechanisms used include the UN human rights treaty monitoring bodies, and the special procedures of the UN Human Rights Commission. This work was conducted in close collaboration with public-interest NGOs from the North and South working to achieve fairer trade rules.

This chapter uses 3D's experience of working on the issue of IP, access to medicines and human rights as an illustration of how a policy-focused NGO can use human rights tools to support a human rights-consistent approach to trade. Part one will consider the relationship between international trade rules and human rights obligations by focusing on the case of IP and access to affordable medicines, whilst part two of the chapter will explain how 3D has used international human rights rules and mechanisms to provide tools to advocates who are working to ensure access to affordable medicines and to make trade-related IP policy more accountable and transparent.

Trade agreements and international human rights law: the case of access to medicines

The impact of trade-related IP rules, especially patents, on the ability of States to ensure access to affordable medicines serves as a good illustration of how trade rules affects the enjoyment of human rights. The following sections will explain how the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and subsequent trade agreements risk limiting State policy space to such a degree that a State's ability to comply with their obligations under international human rights law will be dramatically affected.

The impact of trade-related intellectual property rules on the cost of medicines

Multilateral trade agreements: the WTO TRIPS Agreement

The United States (USA) was the first country to link IP standards with trade policy, by using trade sanctions to enforce IP standards in third countries.⁵ In order to consolidate this approach internationally, the USA and Japan proposed the inclusion of IP rules in the Uruguay Round of

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 (last accessed: 15 November 2005).

⁵ J. Watal, *Intellectual Property Rules in the WTO and Developing Countries*, The Hague: Kluwer Academic Publishers, 2001, p. 18.

trade negotiations that led to the creation of the WTO.⁶ Many developing countries fought against the inclusion of IP rules, but were pressurised into accepting them after threats of trade sanctions from the US and promises of trade-offs in agriculture and textiles.⁷ Despite strong resistance from a group of ten developing countries – including India and Brazil⁸ – the TRIPS Agreement was included in the final WTO Agreement adopted in 1994. This marked the beginning of the trend towards systematic inclusion of IP rules in trade agreements.

The TRIPS Agreement is a framework agreement that sets a minimum standard of IP protection to be implemented by all WTO Members. It has raised protection standards beyond that which previously existed in many countries. For example, the TRIPS Agreement requires States to grant patents on all processes and products, including medicines. Moreover, the TRIPS Agreement grants patent owners at least twenty years of exclusive commercial rights to make, use, offer for sale, sell or import their inventions.⁹ This contrasts with the patent terms that existed in many developed and developing countries before the implementation of TRIPS, which ranged from one year in Costa Rica to fifteen years in Brazil.¹⁰ By granting these patent periods, the TRIPS Agreement enables patent owners to keep prices of medicines artificially high for longer than previously, thereby affecting economic access to medicines ('affordability'), an inherent part of the realisation of the right to health¹¹ and the right to life.¹²

In order to remedy these negative effects, developing countries succeeded in including a certain number of legal flexibilities in the TRIPS Agreement, which are capable of reducing the cost of medicines. Firstly, the objective and purpose of the TRIPS Agreement is defined as a balance between public and private interests, and the Agreement specifically says that Members can 'adopt measures necessary to protect public health.'¹³ Furthermore, the TRIPS Agreement allows for 'use without the authorization of the right holder.'¹⁴ This includes the ability of the State to grant compulsory licences or non-commercial government use orders to obtain cheaper generic versions of patented medicines.¹⁵ Other crucial flexibilities include the ability to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans' – such as diagnostic kits for HIV/AIDS,¹⁶ or the regulatory freedom to allow parallel importation of patented medicines from markets where they are sold more cheaply.¹⁷

⁶ Watal, *Intellectual Property Rules*, p.19,

⁷ Watal, *Intellectual Property Rules*, p. 44.

⁸ Argentina, Brazil, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia. See Watal, *Intellectual Property Rules*, p. 19.

⁹ Article 33 of the TRIPS Agreement.

¹⁰ Watal, *Intellectual Property Rules*, p. 114.

¹¹ Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 16 December 1966, 993 U.N.T.S. 3; 6 I.L.M. 368 (1967) as interpreted by General Comment No. 14 (2000), The right to the highest attainable standard of health, UN Doc. E/C.12/2000/4 of 11 August 2000; and Article 24 of the Convention on the Rights of the Child (CRC) of 20 November 1989, 1577 U.N.T.S. 3; 28 I.L.M. 1456 (1989) as interpreted by General Comment No. 3 (2003), HIV/AIDS and the rights of the children UN Doc. CRC/GC/2003/3 of 17 March 2003 and General Comment No. 4 (2003), Adolescent health and development in the context of the Convention on the Rights of the Child, UN Doc. CRC/GC/2003/4 of 1 July 2003.

¹² Article 6 of the International Covenant on Civil and Political Rights (ICCPR) of 16 December 1966, 999 U.N.T.S. 171; 6 I.L.M. 368 (1967) as interpreted by General Comment No. 6 (1982), The right to life, UN Doc. HRI/GEN/1/Rev.7 of 12 May 2004, at 128, and article 6 CRC, as interpreted by General Comment No. 3 (2003) on HIV/AIDS and General Comment No. 4 (2003) on Adolescent Health.

¹³ Articles 7 and 8 of the TRIPS Agreement.

¹⁴ Article 31 of the TRIPS Agreement.

¹⁵ These are licences granted by public authorities to make, use, offer for sale, sell or import cheaper generic versions of medicines without the consent of the patent holder, as long as he is informed and paid adequate remuneration. The requirement to inform can be waived in certain circumstances. The term 'compulsory licence' will be used to describe both compulsory licences and government use orders.

¹⁶ Article 27.3 (a) of the TRIPS Agreement.

¹⁷ Article 6 of the TRIPS Agreement.

Whilst developed countries were required to implement the agreement by 1 January 1995, the TRIPS Agreement granted delays to developing countries and Least Developed Countries (LDCs). Developing countries were required to implement TRIPS by 1 January 2000. Developing countries that did not patent products such as medicines – India being the main one concerned – were given until the 1 January 2005 to comply. Without patents on the final product, the Indian generic industry was able to produce about 70 per cent of bulk medicines used in India and become a leading exporter of generic versions of new medicines.¹⁸ Since the Indian Patent Ordinance, adopted on 1 January 2005, and the subsequent Indian Patents (Amendment) Act 2005, adopted on 23 March 2005,¹⁹ patent protection will now be granted to new medicines for which applications have been filed in India since 1995. It is feared that in the long term the implementation of this legislation will reduce access to new medicines at an affordable price, both within and outside India.²⁰

LDCs have the right to delay implementation of the TRIPS Agreement into national law until 2006 at the earliest, with the option of extending this date if they submit a request to the WTO TRIPS Council.²¹ Furthermore, they may delay implementation and enforcement of patent protection with respect to pharmaceutical products until 1 January 2016.²² The vast majority of LDC Members of the WTO have already passed TRIPS-compliant IP regimes. Nevertheless, a limited number of countries are making express use of the delays for LDCs in relation to pharmaceutical patents. Cambodia incorporated the 2016 deadline into national law and Malawi has invoked the 2016 deadline to suspend IP protection on pharmaceutical products in order to supply its UNICEF antiretroviral programme.²³ The Maldives is the first country, however, to submit a formal request to the TRIPS Council to make use of this extended transition period. The TRIPS Council granted the Maldives an additional delay on 15 June 2005.²⁴

Implementation of the TRIPS Agreement has been a cumbersome and costly process for developing countries, especially for those that did not previously grant patent protection on medicines.²⁵ Moreover, since implementing TRIPS, many developing countries have been strongly dissuaded by economic actors from making use of the flexibilities. Some instances of this are well known: the cases brought against South Africa and Brazil to prevent them from using TRIPS flexibilities to reduce the cost of medicines was front-page news all over the world during 2000 and

¹⁸ S. Musungu and C. Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*, WHO Commission on Intellectual Property Rights, Innovation and Public Health, Study 4C, August 2005, <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> (last accessed: 15 November 2005), at 9.

¹⁹ The Patents (Amendment) Act 2005, No.15 of 2005, IP/N/1/IND/P/2, http://www.wipo.int/clea/docs_new/pdf/en/in/in018en.pdf (last accessed: 1 October 2005).

²⁰ *Médecins Sans Frontières* (MSF), 'Prognosis: Short-Term Relief, Long-Term Pain. The Future of Generic Medicines Made In India,' Briefing Note, 21 April 2005, at 2, available at: <http://www.msf.fr/documents/sida/2005-04-21-IndiaPatentsAnalysis.pdf> (last accessed: 15 November 2005)

²¹ Article 66.1 of the TRIPS Agreement.

²² WTO, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, Decision of the Council for TRIPS of 27 June 2002, IP/C/25, 1 July 2002.

²³ Musungu and Oh, *The Use of Flexibilities*, at 8.

²⁴ The TRIPS Council extended the delay for the implementation of patents on pharmaceutical products from 1 January 2006 until 20 December 2007, as the Maldives are due to change from LDC status to developing country status on 21 December 2007. If the Maldives were to remain an LDC, then it could make another request to the TRIPS Council to extend the delay until 2016. See WTO, *Maldives – Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement*, Decision of the Council for TRIPS of 15 June 2005, IP/C/35, 17 June 2005.

²⁵ UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, February 2003, (3rd Edition), p. 37. http://www.iprcommission.org/papers/pdfs/final_report/Ch2final.pdf (last accessed: 1 October 2005)

2001.²⁶ In 1997, 39 pharmaceutical companies, supported by the USA and the EU, filed a case against the South African government for passing legislation that allowed parallel imports of patented HIV/AIDS medicines. In 2000, the USA initiated a WTO Dispute Settlement case against the Brazilian government for trying to issue a compulsory licence to supply antiretroviral medicines to its national HIV/AIDS treatment programme.²⁷ Although both these cases were eventually withdrawn due to NGO pressure and media exposure, they demonstrated the need for greater commitment to enabling States to use the flexibilities provided in the TRIPS Agreement to limit the cost of medicines.²⁸

The WTO Doha Declaration on TRIPS and Public Health

The need for a permanent solution and legal clarity in the interpretation of TRIPS flexibilities led a coalition of eighty developing countries – including the Africa Group, Brazil and India – to submit a proposal for a Declaration on TRIPS and Public Health in 2001. This proposal was supported by an access to medicines campaign coordinated by an international coalition of public-interest NGOs from the North and South.²⁹ These included international NGOs such as Consumers International, Health Action International (HAI), *Médecins Sans Frontières* (MSF), Oxfam International; Northern NGOs such as the Canadian HIV/AIDS Legal Network, Consumer Project on Technology (CP-Tech), Act-UP Paris, or Health Gap; and Southern NGOs such as Third World Network, and the Treatment Action Campaign (TAC), South Africa. The strength of the developing country coalition, coupled with NGO advocacy and the political climate prevalent at the time, led to the adoption of the WTO Doha Declaration on TRIPS and Public Health (Doha Declaration) on 14 November 2001. Although the Doha Declaration is a political commitment, it is also an authoritative legal interpretation of the TRIPS Agreement that can be invoked by developing countries if faced with a legal challenge.³⁰

The text of the Doha Declaration says 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.’³¹ Moreover, it expressly ‘reaffirms the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’³² The Doha Declaration then goes on to enumerate a non-exhaustive list of policy flexibilities that can be used to ensure access to affordable medicines. These include the ability to interpret the TRIPS Agreement according to the customary rules of interpretation of international law;³³ the ability to determine the regime and grounds for granting a compulsory licence in order to make, use, offer for sale, sell or import cheaper generic versions of medicines;³⁴ and the ability to determine the regime of parallel importation of cheaper patented medicines from other markets.³⁵

²⁶ Gary G. Yerkey and Daniel Pruzin, ‘United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law,’ *The Bureau of National Affairs*, 26 June 2001, and Nick Mathiason, ‘Drugs: Round One to Africa,’ *The Observer*, 22 April 2001, <http://observer.guardian.co.uk/business/story/0,6903,476408,00.html> (last accessed: 1 October 2005)

²⁷ F. M. Abbot, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO,’ *JIEL* Vol. 5 (2002), 471.

²⁸ S. K. Sell, *Private Power, Public Law: The Globalisation of Intellectual Property Rights*, Cambridge: Cambridge University Press, 2003, p. 157.

²⁹ Sell, *Private Power*, p. 149.

³⁰ C. M. Correa, *Implications of the Doha Declaration on TRIPS and Public Health*, WHO, Health Economics and Drugs EDM Series No.12, June 2002, at 44.

³¹ WTO, *Doha Declaration on TRIPS and Public Health*, 2001, at para. 4.

³² *Ibid.*

³³ *Ibid.*, para 5(a).

³⁴ *Ibid.*, para 5(b) and 5(c).

³⁵ *Ibid.*, para 5(d).

The developing countries that have issued compulsory licences or government use orders since the adoption of the Doha Declaration include Zimbabwe in 2002, Malaysia in 2003, and Indonesia, Mozambique, and Zambia in 2004.³⁶ In March 2005 Brazil began negotiations for voluntary licences with three US pharmaceutical companies in order to manufacture four patented antiretroviral medicines that cost the Brazilian HIV/AIDS national programme three-quarters of its budget. If Brazil did not obtain a voluntary licence, the government announced that it would seek a compulsory licence. Brazil has repeatedly – and successfully – used threats of issuing compulsory licences as a tool to obtain price reductions from patent owners. However, Brazilian and international NGOs fear that voluntary licences cannot guarantee sustained access. In May 2005 Brazilian and International NGOs sent a joint declaration to the Brazilian government requesting compulsory licences.³⁷ The Brazilian Lower House approved a bill granting compulsory licences to local generic manufacturers, in order to allow them to make generic versions of the four patented antiretroviral medicines.³⁸ However, despite Parliamentary and NGO pressure, final approval of the bill was postponed in order to allow for further negotiations for voluntary licences between the Brazilian government and the pharmaceutical companies involved.³⁹

The WTO General Council Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health

Another legal mechanism that could be used by developing countries in order to help reduce the cost of medicines is the WTO General Council Decision of 30 August 2003.⁴⁰ This text is a solution to the problem raised by paragraph 6 of the Doha Declaration concerning the ‘difficulties in making effective use of compulsory licensing’ faced by States with insufficient or no pharmaceutical manufacturing capacity.⁴¹ The reason why such countries cannot make full use of compulsory licensing is due to provisions in the TRIPS Agreement requiring that compulsory licences be ‘predominantly for the supply of the domestic market of the Member authorizing such use.’⁴² This has the effect of restricting the quantity of generic medicines that can be exported to non-producing countries under a compulsory licence. The Decision is a ‘temporary waiver’ to these limitations, thereby allowing States to grant compulsory licences exclusively for export of generic versions of medicines under patent.⁴³

Although it was necessary to find an expeditious solution to the paragraph 6 problem in order to ensure sustained export of new generic medicines once India implemented TRIPS patent rules, the General Council Decision is too complex to have an effective impact on price. The mechanism’s requirements are burdensome for developing countries, such as the requirement of compulsory licences in both the exporting and importing countries.⁴⁴ In view of these hurdles, the mechanism has been criticised as creating a ‘complex, procedural labyrinth that stands between a willing, low-

³⁶ Musungu and Oh, *The Use of Flexibilities*, at iv.

³⁷ Grupo de Trabalho sobre Propriedade Intelectual – GTPI – da Rede Brasileira pela Integração dos Povos – GTPI/REBRIP, *Declaration of Civil Society regarding the Brazilian Negotiations for Voluntary Licence for Aids Drugs*, Rio de Janeiro, 5 May 2005. <http://lists.essential.org/pipermail/ip-health/2005-May/007908.html> (last accessed: 1 October 2005).

³⁸ K. Cortes, ‘Brazil Deputies Suspend Patents on AIDS Drugs’, *Bloomberg*, 1 June 2005.

³⁹ As of date of writing, 1 October 2005.

⁴⁰ WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003.

⁴¹ WTO, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2, 14 November 2001, at 6.

⁴² TRIPS Agreement, article 31(f).

⁴³ P. Vandoren and J. C. van Eeckhaute, ‘The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it Work’, *Journal of World Intellectual Property* 6 (6) (2003), 787.

⁴⁴ C. M. Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WHO Essential Drugs and Medicines Policy, April 2004

cost supplier and a country desperately needing imported generics.⁴⁵ As a result of this, only a limited number of countries – Canada, India and Norway – have passed implementing legislation,⁴⁶ the EU⁴⁷ and Switzerland⁴⁸ have draft implementing legislation under discussion in Parliament, and no developing country has yet made use of the mechanism to import generic medicines.

Bilateral and regional trade agreements and the dangers of TRIPS-plus rules

The emergence of TRIPS-plus rules

Although the TRIPS Agreement does not prevent countries from having higher standards, it allows them to limit themselves to the level imposed by the Agreement.⁴⁹ Nevertheless, developed countries seeking to advance the interests of their industry have begun demanding higher IP protection standards. These stricter IP rules are termed ‘TRIPS-plus rules,’ as they go beyond the TRIPS Agreement and are against the spirit of the Doha Declaration on TRIPS and Public Health. They are increasingly being put forward in IP technical assistance programmes; WTO accession packages, World Intellectual Property Organization (WIPO) treaties, investment agreements and bilateral and regional trade agreements. The emergence of these TRIPS-plus rules has served to legitimise the TRIPS Agreement to a certain degree, by turning it into a reference point and maximum threshold, even though it remains strongly contested by public-interest NGOs from the North and South.

TRIPS-plus rules that increase patent protection include extensions of the patent term beyond the twenty years required by the TRIPS Agreement in cases of unreasonable delays, extension of the scope of patent protection to new uses of medicines which allows for the ‘ever-greening’ of patents,⁵⁰ restrictions on the ability of countries to issue compulsory licences to reduce the cost of medicines, and limitations on parallel importation of cheaper patented medicines by contractual means or by requiring regional marketing of a medicine before importation is allowed. Furthermore, the introduction of new rules granting at least five year exclusivity on pharmaceutical test data performed by patent owners will delay the introduction of generic medicines on the market, as they will not be able to use this data to obtain marketing authorization. This is extremely problematic ethically and economically, as generic manufacturers should not have to repeat clinical trials that have already been conducted by the patent owner, just in order to sell a drug on the market.⁵¹

⁴⁵ B. K. Baker, *Process and Issues for Improving Access to Medicines, Willingness and Ability to Utilise TRIPS Flexibilities in Non-Producing Countries*, DFID Health Systems Resource Centre, August 2004, 31.

⁴⁶ By June 2005, Canada, India and Norway have informed the WTO TRIPS Council that they have passed implementing legislation.

⁴⁷ European Commission, *Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, COM (2994), 29 October 2004.

⁴⁸ *Loi fédérale sur les brevets d'invention, avant-projet de révision de la loi sur les brevets 2004*, <http://www.ige.ch/F/jurinfo/documents/j10013f.pdf> (last accessed: 1 October 2005).

⁴⁹ C. M. Correa, *Implementing the TRIPS Agreement: General Context and Implications for Developing Countries*, Third World Network, 1998, at 12.

⁵⁰ The term ‘ever-greening’ refers to the renewal of patent protection for a product whose patent has expired, following the discovery of a new use for the particular invention.

⁵¹ MSF, ‘Access to Medicines at Risk Across the Globe: What to Watch Out For in Free Trade Agreements with the United States’, Briefing Note, May 2004, at 2.

See <http://www.accessmed-msf.org/documents/ftbriefingenglish.pdf> (last accessed: 1 October 2005)

The inclusion of TRIPS-plus rules in bilateral and regional trade agreements

The types of TRIPS-plus rules outlined above are particularly promoted by the US in bilateral and regional trade agreements (known as Free Trade Agreements or FTAs).⁵² The standard of protection achieved in agreements concluded by the USA, such as the US-Chile FTA, the US-Morocco FTA or the US-Dominican Republic-Central American FTA,⁵³ is being used as a benchmark for negotiations with other developing countries.⁵⁴ Indeed, a comparison of the IP standards achieved in each of these FTAs shows a net progression in the degree of protection imposed.⁵⁵ Therefore, even if the text under negotiation in the US-Thailand FTA, or the US-Southern African Customs Union (SACU) FTA⁵⁶ is kept confidential, patterns of previous negotiations point towards a net increase in the standard of IP protection in FTAs.

However, the USA is not the only developed country to pursue TRIPS-plus rules in trade agreements. Indeed, the Member States of the European Free Trade Association (EFTA),⁵⁷ particularly Switzerland, are also seeking to include TRIPS-plus rules in their FTAs with developing countries.⁵⁸ In order to ensure that TRIPS-plus rules are not included in the FTA between EFTA and SACU, NGOs from EFTA countries and from Southern Africa sent an open letter to the negotiators of EFTA Member States requesting ‘no intellectual property provisions in the Free Trade Agreement between the EFTA states and the SACU states.’⁵⁹ The South African Minister of Trade replied to the NGOs saying that SACU would not accept TRIPS-plus provisions on medicines and agriculture in the FTA negotiations with EFTA countries.⁶⁰

TRIPS-plus commitments in bilateral and regional trade agreements are particularly problematic, as they not only apply to the parties to the trade agreement, but are also applicable to all members of the WTO.⁶¹ Indeed, the most-favoured nation (MFN) clause in the WTO Agreements requires that any IP protection standard in a regional trade agreement is applicable to all the members of the WTO.⁶² Therefore, even if the European Union does not promote a TRIPS-plus strategy with regards to pharmaceuticals, the European pharmaceutical industry may still benefit from the

⁵² Section 2101 of the United States Trade Promotion Authority (Trade Act) 2002. ref

⁵³ An agreement between the USA on the one hand, and Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic on the other.

⁵⁴ Oxfam International, ‘Undermining access to medicines: Comparison of five US FTA’s. A technical note’, Oxfam Briefing Note, June 2004, , http://www.oxfam.org.uk/what_we_do/issues/health/undermining_access_ftas.htm (last accessed: 15 November 2005), at 2.

⁵⁵ C. Fink and P. Reichenmiller, ‘Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements’, *World Bank Trade Note* 20 (7 February 2005), at 5.

⁵⁶ SACU is composed of Botswana, Lesotho, Namibia, South Africa and Swaziland.

⁵⁷ EFTA is composed of Iceland, Liechtenstein, Norway and Switzerland.

⁵⁸ J. Reinhard, ‘Deprive Doha of all substance: How through bilateral agreements EFTA states impose to developing countries intellectual property rules on medicines that are beyond the WTO obligations and that restrict access to medicines’, Lausanne: *Déclaration de Berne*, November 2004, at 1. http://www.evb.ch/cm_data/depriveDoha.pdf (last accessed: 1 October 2005).

⁵⁹ *Déclaration de Berne* and MSF-Switzerland, ‘Open letter to the trade and foreign ministers of EFTA’s states’, *Lausanne*, 4 November 2004. <http://www.evb.ch/en/p25009520.html> (last accessed: 1 October 2005).

⁶⁰ *Déclaration de Berne* and *Liechtensteinische Gesellschaft für Umweltschutz* (LGU), ‘Southern African Countries have taken a firm stand against EFTA demands on Intellectual Property Rights in Free Trade Agreement’, Press Release, Lausanne, 4 March 2005. <http://www.evb.ch/en/p25009521.html> (last accessed: 1 October 2005)

⁶¹ J. Reinhard, ‘Deprive Doha’, at 6.

⁶² P. Roffe, ‘Bilateral agreements and a TRIPS-plus world: the Chile-USA Free Trade Agreement’, UNCTAD-ICTSD TRIPS Issues Papers, Ottawa: QIAP, 2004, 18.

TRIPS-plus rules applicable in the countries that have signed FTAs with the US or EFTA Member States.⁶³

Although FTAs have made explicit reference to the need to respect public health, as well as uphold the Doha Declaration and the General Council Decision,⁶⁴ these assertions have limited weight if the implementation of the TRIPS-plus rules in the agreement nullifies the flexibilities reaffirmed by the Doha Declaration. Hence, if developing countries agree to sign on to TRIPS-plus rules they may find themselves in a situation where they may no longer have the regulatory flexibility to ensure access to affordable medicines and fulfil their human rights obligations.

International human rights law as a benchmark and framework for trade agreements: ensuring access to affordable medicines for all

Access to affordable medicines as an obligation under international human rights law

All State parties to the TRIPS Agreement are also parties to at least one of the core international human rights treaties, including the International Covenant on Civil and Political Rights (ICCPR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the Convention on the Rights of the Child (CRC). International human rights law not only provides a legal basis upon which to develop legislative measures and administrative policies regulating accessibility of medicines, it also provides a framework by which to assess the trade measures adopted by States and non-State actors in relation to IP rules and access to affordable medicines.⁶⁵

International human rights bodies,⁶⁶ scholars,⁶⁷ and human rights advocates, such as the Canadian HIV/AIDS Legal Network,⁶⁸ have looked at the relationship between the TRIPS Agreement and human rights. Notwithstanding their clear demonstrations of the impact of strict IP rules on the State's ability to ensure access to affordable medicines and comply with human rights obligations, public-interest NGOs participating in the access to medicines campaign and decision-makers have only rarely referred to human rights⁶⁹ or used human rights mechanisms⁷⁰ to support their policy positions.

⁶³ See 3D → Trade - Human Rights - Equitable Economy, *Denmark and Italy., Trade-related intellectual property rights, access to medicines and human rights*, Geneva, October 2004 http://www.3dthree.org/pdf_3D/3DCESCRDenmarkItalyBriefOct04en.pdf (last accessed: 1 October 2005)

⁶⁴ The US-Morocco FTA, for example, includes a side-letter of 15 June 2004.

⁶⁵ A.E. Yamin, 'Not Just a Tragedy: Access to Medications as a Right Under International Law', *Boston University International Law Journal* 21 (2003), 103.

⁶⁶ Sub-Commission on the Promotion and Protection of Human Rights Resolution 2000/7 and 2001/21 and High Commissioner for Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, UN Doc. E/CN.4/Sub.2/2001/13 (2001).

⁶⁷ See for instance P. Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health', 79 *International Affairs* I (2003) 139-160.

⁶⁸ See for instance R. Elliot, *TRIPS and Rights: International Human Rights Law, Access to Medicines and the Interpretation of the WTO Agreement on Trade-Related Aspects of Intellectual Property*, Toronto: Canadian HIV/ AIDS Legal Network, November 2001. <http://www.aidslaw.ca/Maincontent/issues/cts/briefs/TRIPS-human-rights-briefPDF.pdf> (last accessed: 1 October 2005).

⁶⁹ Exceptions include HAI and Consumers International – Asia Pacific, who have used right to health arguments to support their advocacy work on IP and access to affordable medicines.

⁷⁰ Brazil is unique in having used human rights mechanisms to support its positions on IP and health issues. Brazil sponsored the Commission on Human Rights resolutions on access to medication and the resolutions on the right to health which have consistently raised concerns about the impact of trade-related IP rules on the cost of medicines.

The main internationally-recognised human rights that ensure access to medicines are: the right to life and the right to health.⁷¹ These human rights contain obligations which States must take into account in their entire policy making, including trade policy.⁷² Other human rights of particular relevance are those that encourage greater transparency and accountability, notably the right to access information and the right to participate in public affairs.⁷³ These human rights are very important to stress as trade negotiations – particularly those that take place bilaterally – are notoriously untransparent.

The right to life

The right to life is a supreme right under international human rights law that cannot be derogated from even in times of a public emergency.⁷⁴ This is set out in Article 6 of the ICCPR as well as in other human rights treaties such as Article 6 of the CRC. The Human Rights Committee (HRC), which is the UN human rights treaty body that monitors the application of the ICCPR, provides an authoritative interpretation of the right to life in General Comment No.6 (1982).⁷⁵ In this General Comment, the HRC expressly states that the right to life ‘cannot be understood in a restrictive manner.’⁷⁶ Accordingly, State parties are required to ‘adopt positive measures’ which include ‘all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.’⁷⁷ Access to affordable medicines therefore emerges as an inherent element of the right to life.

This has been confirmed by the HRC in its consideration of State party reports. For example, in its consideration of the report of Uganda in May 2004 the HRC recommended that ‘while the Committee takes note of the measures taken by the State party to deal with the widespread problem of HIV/AIDS, it remains concerned about the effectiveness of these measures and the extent to which they guarantee access to medical services, including antiretroviral treatment, to persons infected with HIV (article 6). The State party is urged to adopt comprehensive measures to allow a greater number of persons suffering from HIV/AIDS to obtain adequate antiretroviral treatment.’⁷⁸ This recommendation demonstrates that State parties have an obligation to take comprehensive legal and administrative measures to ensure access to affordable medicines in order to comply with their obligations under the right to life.

The right to health

Access to affordable medicines is also an integral part of the right to health. This right is protected by a number of international treaties, most notably Article 12 of the ICESCR and Article 24 of the CRC. The Committee on Economic, Social and Cultural Rights (CESCR), the UN body that

⁷¹ The right to life: Article 6 of the ICCPR and Article 6 of the CRC. The right to an adequate standard of physical and mental health: Article 12 of the ICESCR and Article 24 of the CRC.

⁷² Even States such as the USA that have signed and not ratified the ICESCR or CRC are bound by a good faith legal obligation to refrain from acts that could defeat the object and purpose of these rights. See Article 18 of the 1969 Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331.

⁷³ The right to seek, receive and impart information: Article 19 ICCPR, Article 12 of the ICESCR, Articles 13(1) and 17 of the CRC. The right to participate in public affairs: Article 25 of the ICCPR. The right to respect the views of the child: Article 12 of the CRC.

⁷⁴ Cf. Human Rights Committee General Comment No. 29: States of emergency and rights derogation (Article 4), CCPR/C/21/Rev.1/Add.11 of 31 August 2001, para. 7. , reprinted in *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, UN Doc. HRI/GEN/1/Rev.6 (2003) at 186.

⁷⁵ Cf. Human Rights Committee General Comment No. 6: The right to life (Article 6), *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, UN Doc. HRI/GEN/1/Rev.6 (2003) at 127.

⁷⁶ *Ibid.*, at para. 5.

⁷⁷ *Ibid.*

⁷⁸ HRC, Uganda, Concluding Observations, UN Doc. CCPR/CO/80/UGA (2004).

monitors the application of the ICESCR, has provided the most detailed exposition of the right to health. This can be found in the General Comment No. 14 (2000) on the right to health.⁷⁹ The General Comment clearly explains that the normative content of the right to health includes *accessibility* of health facilities, goods, and services on a non-discriminatory basis.⁸⁰ Accessibility includes affordability for all, in a way that ‘poorer households should not be disproportionately burdened with health expenses as compared to richer households.’⁸¹ Access to affordable health goods includes ‘appropriate treatment for prevalent diseases, illnesses, injuries and disabilities’ and ‘the provision of essential drugs.’⁸² The Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Mr Paul Hunt, has emphasised that ‘whether publicly or privately provided, the essential medicine must be affordable for all, not just the well off. Clearly, the affordability of essential medicines raises crucial issues, such as drug pricing, compulsory licensing, parallel importing, and the reduction of import duties.’⁸³

Although the right to health can be realised progressively over a period of time, the State has an immediate obligation to take ‘deliberate, concrete and targeted’ steps towards the full realisation of the right to health.⁸⁴ These include measures to *respect, protect and fulfil* their obligations.⁸⁵ The requirement to *respect* means that States should refrain from interfering with the enjoyment of the right to health. This could be interpreted as meaning that States should not sign on to TRIPS-plus rules that would limit access to affordable medicines. The obligation to *protect* requires States to adopt measures that will prevent third parties from threatening the enjoyment of the right to health. This may include the State taking measures to ensure that third parties, such as the pharmaceutical industry, do not adversely affect the cost of medicines by imposing high prices. Finally, the obligation to *fulfil* requires the State to implement national policies and legislative measures that ensures the realisation of the right to health. This could involve the implementation and use of the mechanisms such as compulsory licences or parallel imports to ensure access to affordable medicines for all.

Finally, the right to health also includes the obligation on States not to take steps that constitute retrogression from realisation of the right. The State has the burden of proving whether these measures were introduced after careful consideration.⁸⁶ This imposes an obligation on States to undertake human rights impact assessments of the TRIPS-plus rules in bilateral and regional trade agreements before they sign on to them, in order to ensure that they do not pass measures that violate the right to health. This has recently been reaffirmed by the CHR Resolution on access to medicines which ‘calls upon States to conduct an impact assessment of the effects of international trade agreements with regard to public health and to the progressive realization of the right of everyone to the highest attainable standard of health.’⁸⁷

⁷⁹ CESCR, General Comment No. 14: The right to the highest attainable standard of health, UN Doc. E/C.12/2000/4 (11 August 2000).

⁸⁰ *Ibid.*, at 12.

⁸¹ *Ibid.*

⁸² *Ibid.*, at 16.

⁸³ Commission on Human Rights (CHR), *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Report of the Special Rapporteur of the Commission on Human Rights on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, UN Doc. E/CN.4/2004/49/Add.1 (1 March 2004), at 37 (c).

⁸⁴ *Ibid.*, at 30.

⁸⁵ CESCR, General Comment No. 14.

⁸⁶ *Ibid.*, at 32.

⁸⁷ CHR Resolution 2005/23, *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, 51st meeting, 15 April 2005, at para. 14.

Children's rights

The 'best interests of the child' is one of the key underlying principles of human rights law relating to children. Article 3(1) of the CRC requires State parties to give prime consideration to the best interests of the child in all decision-making, including the conduct of 'public or private social welfare institutions, courts of law, administrative authorities or legislative bodies.' The Committee on the Rights of the Child (CRC), the UN treaty body that monitors the application of the CRC, has looked at the issue of access to medicines in the context of pandemics such as HIV/AIDS. It has expressly stated that the best interests of the child should be 'fundamental to guiding the action of States in relation to HIV/AIDS. The child should be placed at the centre of the response to the pandemic, and strategies should be adapted to children's rights and needs.'⁸⁸

General Comment No.3 (2003) on HIV/AIDS encourages a 'holistic child rights-based approach' that includes consideration of the right to life (Article 6 of the CRC),⁸⁹ the right to health (Article 24),⁹⁰ the right to non-discrimination (Article 2),⁹¹ the right of the child to have his/her interests as a primary consideration (Article 3)⁹² and the right of the child to have his/her views heard (Article 12).⁹³ This interpretation of children's rights and obligations of States is particularly groundbreaking in its integrated approach. In relation to treatment and care, State parties are required to ensure that 'children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs, goods and services on a basis of non-discrimination.'⁹⁴ The Committee goes on to add that 'comprehensive treatment and care includes anti-retroviral and other drugs, diagnostics and related technologies for the care of HIV/AIDS, related opportunistic infections and other conditions.'

A similar approach is taken by the CRC in General Comment No.4 (2003) relating to adolescent health and development. In the interpretation of State obligations relating to adolescent health, the Committee requires States to 'ensure that appropriate goods, services and information for the prevention and treatment of STDs [sexually transmitted diseases], including HIV/AIDS, are available and accessible' for all and without discrimination.⁹⁵ These obligations, coupled with the obligations under the General Comment on HIV/AIDS could be interpreted as requiring States to take into account the best interests of the child and obligations under the CRC in all IP negotiations that will affect access to affordable medicines and the enjoyment of children's rights.

These obligations under the CRC are also reinforced by {suggest this might be 'also reinforce', as ICCPR came before CRC} Article 24 of the ICCPR which requires States to ensure that every child benefits from 'measures of protection as are required by his status as a minor.' The HRC has interpreted this in General Comment No. 17 (1989) as meaning that 'every possible economic and social measure should be taken to reduce infant mortality.'⁹⁶ Therefore, the obligations under the ICCPR could be interpreted as requiring States to ensure that they grant compulsory licences for generic medicines and undertake parallel imports of patented medicines that are cheaper in other countries in order to obtain sufficient quantities of medicines capable of reducing infant mortality, at an affordable price.

⁸⁸ CRC, General Comment No. 3: *HIV/AIDS and the rights of the child*, UN Doc. CRC/GC/2003/3 of 17 March 2003, at para. 8.

⁸⁹ *Ibid.*, e.g. para. 11

⁹⁰ *Ibid.*, e.g. para. 5 and 6.

⁹¹ *Ibid.*, e.g. paras. 5, 6, 7., 8 and 9.

⁹² *Ibid.*, e.g. para. 10.

⁹³ *Ibid.*, e.g. para. 12.

⁹⁴ *Ibid.*, at 28.

⁹⁵ CRC, General Comment No.4: *Adolescent health and development in the context of the Convention on the Rights of the Child*, UN Doc. CRC/GC/2003/4 (1 July 2003), at para. 30.

⁹⁶ General Comment No. 17: *Rights of the child* (Article 24) : . 07/04/89. Thirty-fifth session, 1989, at para.3.

International cooperation and assistance

Article 2(1) of the ICESCR, as interpreted by the Committee on Economic, Social and Cultural Rights (CESCR) in General Comment No. 3 (1990) requires State parties to take ‘deliberate, concrete and targeted’ steps ‘through international assistance and cooperation, especially economic and technical’ towards full realisation of Covenant rights.⁹⁷ This obligation is echoed by Article 4 of the CRC, as interpreted by General Comment No.5 (2003), which states that members of international organizations, including the WTO, ‘should ensure that their activities related to international cooperation and economic development give primary consideration to the best interests of children and promote full implementation of the Convention.’⁹⁸ States also have an obligation to ensure that their actions as members of international organizations take due account of the right to health.⁹⁹ This can be interpreted as meaning that States should take into account the right to health when they negotiate IP rules in all trade agreements and implement these rules domestically.

International cooperation and assistance under the right to health requires States to ‘respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means.’¹⁰⁰ This requires States to intervene politically and legally to ensure that third parties, such as the pharmaceutical industry or States that have not ratified the Covenant, do not have trade policies that violate access to affordable medicines in developing countries. In addition, States are required to refrain from imposing measures that restrict the supply of another State with adequate medicines.¹⁰¹ This could include refraining from imposing TRIPS-plus rules that would restrict the supply of affordable medicines in another country.

States are also obliged, particularly if they have sufficient resources, to facilitate ‘access to essential health facilities, goods and services in other countries.’¹⁰² This can be interpreted as meaning that State parties to the ICESCR, such as the members of the European Union, Canada or Switzerland, have a legal obligation to take steps to facilitate access to affordable medicines in developing countries.

Access to information and participation in decision-making

Due to the lack of transparency in trade negotiations, especially in bilateral and regional trade negotiations, it is important to consider which State obligations could ensure greater accountability of trade decision-makers. The obligations to ensure access to information and participation in public affairs are crucial in allowing citizens and civil society groups to monitor trade processes and ensure that IP rules being negotiated do not further undermine access to affordable medicines and the realisation of human rights.

State parties have a general obligation to ensure the freedom to seek, receive and impart information under Article 19 of the ICCPR;¹⁰³ additionally, under the right to health, there is an obligation to ensure the right to access information and ideas concerning health issues.¹⁰⁴ Furthermore, State parties to the CRC have an obligation to ensure the child’s freedom to seek, receive and impart information under Article 13(1) of the CRC, and an obligation to ensure access

⁹⁷ CESCR, General Comment No. 3: *The nature of State parties obligations*, UN Doc. E/1991/23 (14 December 1990), at para. 13.

⁹⁸ CRC, General Comment No.5: *General measures of implementation of the Convention on the Rights of the Child*, UN Doc. CRC/GC/2003/5 (27 November 2003), at para. 64.

⁸⁸ CESCR, General Comment No. 14., at para. 39.

¹⁰⁰ *Ibid.*, at para. 39.

¹⁰¹ *Ibid.*, at para. 41.

¹⁰² *Ibid.*, at para 39.

¹⁰³ HRC, General Comment No. 10.

¹⁰⁴ CESCR, General Comment No. 14, at para. 12.

of the child to information on his or her health under Article 17 of the CRC. State parties therefore have an obligation to ensure that information about trade policies and trade rules that affect the realisation of the right to health or the right to life are made public. It is particularly important that States ensure access to information relating to proposed IP rules in bilateral and regional trade agreements, in order to allow independent assessments of the effect of trade rules on human rights.

Article 25 of the ICCPR requires State parties to ensure participation in the conduct of public affairs.¹⁰⁵ This involves the conduct of ‘all aspects of public administration, and the formulation and implementation of policy at international, national, regional and local levels.’¹⁰⁶ This is echoed by the right to health, which requires access to information and participation of the population in health-related decision-making at the community, national and international level.¹⁰⁷ Moreover, under Article 12 of the CRC, States have an obligation to respect the views of the child in ‘all matters affecting the child.’ This involves opening government decision-making processes to children in a way that encourages the participation of the child in the ‘promotion, protection and monitoring of his or her rights.’¹⁰⁸ These participatory rights are crucial in ensuring greater accountability in trade decision-making processes, independence in human rights impact assessments of trade rules¹⁰⁹ and in ensuring that trade agreements are consistent with human rights standards.

Using international human rights mechanisms to make trade more accountable and human rights-consistent

In the current political climate, there is an urgent need to stall the proliferation of TRIPS-plus rules and to safeguard human rights from being undermined by trade rules. Independent monitoring of trade processes, especially bilateral and regional trade negotiations is particularly important. There are a number of avenues available at the national, regional and international levels to individuals and NGOs to challenge trade policy and trade rules that may be inconsistent with human rights obligations. These avenues range from national constitutional appeals, to providing submissions to regional mechanisms such as the African Commission on Human and Peoples’ Rights, the Inter-American Commission on Human Rights, or the European Court of Human Rights, and to the international human rights mechanisms of the UN.

This section will focus on the potential of international human rights mechanisms to monitor and challenge the impact of trade rules on the realisation of human rights, and will describe the experience of one NGO in using these mechanisms. The work of 3D → Trade - Human Rights - Equitable Economy (3D) will be considered as an illustration of how a policy-focused NGO has used international human rights law and mechanisms to make trade rules more accountable and human rights-consistent. 3D believes that human rights rules and mechanisms are invaluable accountability tools for trade policy, and chose to test this conviction by raising the issue of trade-related IP rules, access to medicines and human rights with the UN human rights mechanisms. The issue of IP, access to medicines and human rights was chosen because it was familiar to human rights advocates, and because it was probably the trade issue with the most clearly-recognised human rights implications.

The overall objective of 3D’s project on IP, access to medicines and human rights was to hold States accountable to their duties to ensure access to affordable medicines in a way that is human

¹⁰⁵ HRC, General Comment No. 25: *The right to participate in public affairs, voting rights and the right to equal access to public service (Article 25)*, UN Doc. HRI/GEN/1/Rev.7 at 194 (12 July 1996).

¹⁰⁶ *Ibid.*, at para. 5.

¹⁰⁷ *Ibid.*, at para 43.

¹⁰⁸ CRC, General Comment No.5, at para 12.

¹⁰⁹ CHR, *Analytical study of the High Commissioner for Human Rights on the fundamental principle of participation and its application in the context of globalisation*, Report of the High Commissioner, UN Doc. E/CN.4/2005/41 (23 December 2004).

rights-consistent. The project also had several underlying objectives. First, to enhance understanding within the human rights community of how trade impacts on human rights, through publishing concise, country-focused briefing notes, which would serve to indicate how to approach analysing these issues. Second, the work aimed to contribute to strengthening existing campaigns on access to medicines by demonstrating that IP rules {query – all IP rules? Would ‘some’ or ‘current’ be appropriate here?} are not only undesirable and immoral, but also incompatible with human rights law. Thirdly, the project aimed to demonstrate to developing country decision-makers that human rights standards can be used as ‘shields’ when faced with pressure to accept TRIPS-plus rules in trade negotiations. A final objective was to achieve greater accountability in trade policy and greater coherence between trade rules and human rights obligations.

3D is not a grass roots organization: its method of work is to intervene on policy issues by providing targeted information to individuals and organizations that can act as multipliers in disseminating a human rights-consistent approach to trade policy. Therefore, the results of 3D’s work with the UN human rights mechanisms was disseminated to policy-focused NGOs in the North and South and key decision-makers in international organizations, regional organizations and national institutions working on IP and human rights policy.

United Nations human rights treaty monitoring bodies

Rationale for raising trade-related issues in human rights treaty bodies

Treaty bodies are independent organs that monitor the application of international human rights treaties, such as the ICESCR, ICCPR and CRC. 3D chose to focus the majority of its IP and access to medicines work on these bodies, as they provide a high-profile international accountability mechanism where State policies are monitored. The fact that States are obliged to periodically report on the measures they have taken in order to implement their human rights obligations and answer questions in public on these measures – or lack thereof – is a valuable accountability mechanism.¹¹⁰ This public dialogue and questioning is particularly important when there is a lack of access to information and consultation at the national level.¹¹¹ Furthermore, the fact that treaty bodies encourage NGO participation and submissions, and often ask questions and make recommendations based on these concerns, facilitated 3D’s work. Most importantly, States have a legal obligation to take into account treaty body recommendations, which makes them critical tools for civil society. The treaty body process therefore emerges as a valuable mechanism to expose a human rights problem and achieve concrete recommendations that can support the ongoing efforts of advocates and decision-makers on a particular issue

Treaty bodies have been specifically requested to look at the issue of IP and human rights by other UN human rights organs. The UN Sub-Commission on the Promotion and Protection of Human Rights, in Resolution 2001/21, suggested that the CESCR and other treaty bodies ‘explore, in the course of reviewing State parties’ reports, the implications of the TRIPS Agreement for the realisation of economic, social and cultural rights.’¹¹² Moreover, a number of UN Commission on Human Rights resolutions have repeatedly invited CESCR to ‘give attention to the issue of access to medication and invites States to include appropriate information thereon in the reports they submit to the Committee.’¹¹³ However, treaty bodies and States have been slow to respond to these requests. The most notable response was the Statement on Human Rights and Intellectual Property

¹¹⁰ The obligation for State parties to submit periodic reports to the treaty bodies is enshrined in Article 16 of the ICESCR, Article 40 of the ICCPR, and Article 44 of the CRC.

¹¹¹ Leckie, S., ‘The Committee on Economic, Social and Cultural Rights: Catalyst for Change in a System Needing Reform’, in Alston, P. and Crawford, J., *The Future of UN Human Rights Treaty Monitoring*, Cambridge: Cambridge University Press (2000), p. 134.

¹¹² Sub-Commission on the Promotion and Protection of Human Rights Resolution 2001/21.

¹¹³ CHR Resolutions 2001/33, 2002/32, 2003/29, 2004/26 and 2005/23.

made by CESCR in 2001.¹¹⁴ Unfortunately, these UN resolutions and the CESCR Statement are little known outside specialist UN human rights circles and did not have much resonance with IP experts and decision-makers.

In order to give more exposure and relevance to the work of the UN human rights mechanisms on IP and human rights, 3D decided to encourage the treaty bodies to intervene on the issue of IP and access to medicines in such a way that their recommendations could provide useful tools to access to medicines advocates and decision-makers at the national, regional and international level.

3D's experience of using UN treaty bodies to make trade rules more accountable and human rights-consistent

In order to best achieve the objectives outlined above, 3D chose to submit briefings on countries coming up for review in front of the CESCR, the CRC, or the HRC. During 2004 and 2005, 3D made submissions on countries that were either reforming their IP laws, such as Uganda,¹¹⁵ or negotiating bilateral and regional trade agreements, such as Botswana,¹¹⁶ Ecuador,¹¹⁷ and El Salvador,¹¹⁸ or planning to enter into bilateral trade negotiations with the USA and European countries, such as the Philippines.¹¹⁹ Moreover, 3D also made a submission on two EU countries – Denmark and Italy¹²⁰ – in order to highlight the international obligations of developed countries regarding access to medicines and realisation of the right to health in developing countries. The next sections describe 3D's submissions on Ecuador, Botswana, Denmark and Italy, to illustrate how an NGO can raise a trade-related issue with a treaty body.

Ecuador

3D submitted a country briefing on Ecuador to be considered at the 32nd Session of CESCR in May 2004.¹²¹ Ecuador was selected because it began trade negotiations for a US-Ecuador Free Trade Agreement (FTA) in May 2004 and it was also participating in regional trade negotiations for a

¹¹⁴ CESCR *Follow-up to the day of general discussion on article 15(1)(c), Human rights and intellectual property*, Statement by the Committee on Economic, Social and Cultural Rights, UN Doc. E/C.12/2001/15 (November 2001).

¹¹⁵ 3D → Trade - Human Rights - Equitable Economy, 'Trade-related intellectual property rights, access to HIV/AIDS medicines and the fulfilment of civil and political rights – Uganda', March 2004. See http://www.3dthree.org/pdf_3D/3DHRCUgandaBrief04en.pdf (last accessed: 1 October 2005).

¹¹⁶ 3D → Trade - Human Rights - Equitable Economy, 'Trade-related intellectual property rights, trade in services and the fulfilment of children's rights - Botswana', September 2004. See http://www.3dthree.org/pdf_3D/3DCRCBotswanaSept04en.pdf (last accessed: 1 October 2005).

¹¹⁷ 3D → Trade - Human Rights - Equitable Economy, 'Trade-related intellectual property rights, access to medicines and the right to health – Ecuador', April 2004. See http://www.3dthree.org/pdf_3D/3DCESCREcuadorBrief04en.pdf (last accessed 1 October 2005) and 3D, 'International trade, health, and children's rights - Ecuador', September 2004. See http://www.3dthree.org/pdf_3D/3DCRCEcuadorBrief_Sept04.pdf (last accessed: 1 October 2005).

¹¹⁸ 3D → Trade - Human Rights - Equitable Economy, 'The impact of international trade agreements regulating intellectual property rights on access to medicines and the fulfilment of children's rights – El Salvador', February 2004. See http://www.3dthree.org/pdf_3D/3DCRCElSalvadorBrief04en.pdf (last accessed: 1 October 2005).

¹¹⁹ 3D → Trade - Human Rights - Equitable Economy, 'International trade, health and children's rights – The Philippines', December 2004. See, http://www.3dthree.org/pdf_3D/3DCRCPhilippines_Dec04.pdf (last accessed: 1 October 2005).

¹²⁰ 3D → Trade - Human Rights - Equitable Economy, 'Denmark and Italy, Trade-related intellectual property rights, access to medicines and human rights', October 2004. See http://www.3dthree.org/pdf_3D/3DCESCRDenmarkItalyBriefOct04en.pdf (last accessed: 1 October 2005).

¹²¹ 3D → Trade - Human Rights - Equitable Economy, 'Trade-related intellectual property rights, access to medicines and the right to health – Ecuador', April 2004.

Free Trade Agreement of the Americas (FTAA).¹²² These trade agreements risk putting Ecuador in a situation where TRIPS-plus rules may affect its ability to ensure access to affordable medicines and the realisation of the right to health, under Article 12 of the ICESCR.

3D's briefing explains how TRIPS-plus rules, such as patent extensions, limits on compulsory licensing and five year data exclusivity, could put Ecuador in a situation where it will no longer be able to ensure its obligation to ensure access to affordable medicines.¹²³ Moreover, the lack of access to information and consultation with civil society during the FTA negotiations is contrary to Ecuador's obligations under the right to health. The briefing concludes with a list of questions that the members of CESCR could ask the government of Ecuador, and recommendations they could make. These include the need to use TRIPS flexibilities, ensure access to information and participation in trade processes and to undertake an impact assessment of the effect of TRIPS-plus rules on access to affordable medicines in order to assess whether trade commitments will undermine human rights obligations.

When considering Ecuador's report,¹²⁴ three CESCR members raised the issue of IP and access to affordable medicines. The Ecuadorian representative to the WTO, who had been advised in advance that these questions were likely to come up, attended the CESCR session to answer the treaty body's questions. This was one of the few situations in which a trade representative has directly answered questions in front of a human rights treaty body. Following the public dialogue with the delegation of Ecuador, CESCR stated in its Concluding Observations that it was 'concerned about the enjoyment of the right to health by all people in the State party and particularly with regard to access to generic medicine'¹²⁵ and made the following recommendations in its Concluding Observations:

The Committee strongly urges the State party to conduct an assessment of the effect of international trade rules on the right to health for all and to make extensive use of the flexibility clauses permitted in the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) in order to ensure access to generic medicine and more broadly the enjoyment of the right to health for everyone in Ecuador.

The Committee strongly recommends that the State party's obligations under the Covenant should be taken into account in all aspects of its negotiations with the international financial institutions and other regional trade agreements to ensure that economic, social and cultural rights, particularly of the most disadvantaged and marginalized groups, are not undermined.¹²⁶

3D disseminated these recommendations to networks of human rights groups, access to medicines advocates and development NGOs in Ecuador, the Andean region and internationally.¹²⁷ 3D also sent them to international organizations such as UNAIDS, UNCTAD and OHCHR as well as to the Ecuadorian trade representatives. The purpose of distributing these recommendations so widely was to provide these advocates and decision-makers with authoritative human rights arguments, which assert that the State could not agree to IP rules which would put it in a situation where it would be forced to contravene its international human rights obligations present in a number of treaties, as described above.

¹²² Ecuador was still negotiating these agreements at the date of writing, October 2005.

¹²³ 3D → Trade - Human Rights - Equitable Economy, 'Trade-related intellectual property rights, access to medicines and the right to health – Ecuador', April 2004, para 4.

¹²⁴ Ecuador was considered by CESCR on 5-6 May 2004.

¹²⁵ CESCR, Ecuador, Concluding Observations, UN Doc. E/C.12/1/Add.100 (June 2004), at para. 30.

¹²⁶ *Ibid.*, at paras. 55 and 56.

¹²⁷ 3D → Trade - Human Rights - Equitable Economy, 'Access to Affordable Drugs: a Right no FTA can Ignore. UN Committee Warns Ecuador that US-Andean FTA Must Not Undermine Human Rights', Press Release, 18 May 2004. See http://www.3dthree.org/pdf_3D/EcuadorPress18May04_en.pdf (last accessed: 1 October 2005).

The CESCR recommendations on Ecuador were crucial to Ecuadorian civil society in their advocacy work. In particular, these recommendations were used in an open letter sent by a coalition of human rights and access to medicines advocates in response to a draft Presidential Decree that included TRIPS-plus rules,¹²⁸ attempting to pass them into Ecuadorian law before the end of the US-Ecuador FTA bilateral trade negotiations. This would have resulted in a situation of ‘fait accompli’, where it would not have been possible to argue that the FTA agreement was introducing laws that forced Ecuador to take measures that would be in violation of the right to health. The Ecuadorian chief trade negotiator at the time sent a written response to the *Centro de Derechos Económicos y Sociales* (CDES)-Ecuador, the NGO which coordinated the letter.¹²⁹ In his response the chief trade negotiator admitted that the proposed TRIPS-plus rules in the draft decree risked violating the Ecuadorian constitution, especially the right to health. The draft decree was not adopted and this letter was used by NGOs to lobby against possible TRIPS-plus rules in the US-Ecuador FTA.¹³⁰ This outcome was used as a precedent for other NGOs from the region and disseminated in regional campaign documents against bilateral and regional FTAs.¹³¹

Botswana

3D submitted a country briefing on Botswana to the 37th Session of the CRC in September 2004. 3D chose to focus on Botswana as it was negotiating a bilateral trade agreement with the USA, as part of the Southern African Customs Union.¹³² 3D’s briefing outlines how Botswana risks undermining its ability to provide access to affordable medicines, of which antiretroviral treatment for its national HIV/AIDS treatment programme, if it agrees to include TRIPS-plus rules in the US-SACU FTA.¹³³ Adhering to these rules could put Botswana in a position where it will no longer be able to take all the measures necessary to respect, protect and fulfil the child’s right to health and the child’s right to life. The report also emphasises the need to take into account the best interests of the child in all aspects of trade policy and to ensure access to information on trade negotiations that will affect children’s rights. The briefing proposes questions and outlines recommendations that the CRC could make to the government of Botswana in order to ensure that the rights of the child are given prime consideration in trade negotiations.

During the consideration of the report on Botswana,¹³⁴ the Chair of the CRC explicitly said that the outcome of the US-SACU FTA negotiations should not impede Botswana from producing or acquiring cheap medicines to treat HIV/AIDS. The Chair also wanted to know whether Botswana was considering providing itself with generic versions of antiretroviral medicines and whether South Africa was developing them. Although the delegation of Botswana did not reply to this

¹²⁸ *Centro de Derechos Económicos y sociales* (CDES), *Cuanto cuesta el derecho a la salud en Ecuador? Carta abierta al Presidente de la Republica de Ecuador*, [What is the Cost of Health in Ecuador? Open letter to the President of the Republic of Ecuador] 9 July 2004 (on file with author).

¹²⁹ CDES, *Medicamentos Genéricos y Derechos Humanos, DESC Para la Acción*, Boletín 1, September 2004. [Generic Medicines and Human Rights]. See <http://www.cdes.org.ec/biblioteca/biblioteca.html> (last accessed: 1 October 2005).

¹³⁰ CDES, *Ecuador: Jefe de equipo negociador TLC contrario al Decreto Ejecutivo. Genéricos son esenciales “para el derechos a la salud” y están por sobre intereses privados y específicos*, Press Release, 16 August 2004. [Ecuador: the Chief negotiator of FTA team is against the Executive Decree. Generic medicines are essential “for the right to health” and should be above private interests]. See <http://www.cdes.org.ec/biblioteca/biblioteca.html> (last accessed: 1 October 2005).

¹³¹ Centro Pro Juez, *Unfulfilled Obligations, Human Rights and Free Trade Agreements in the Americas*, 9 July 2004, at 22. http://www.centroprodh.org.mx/english/publications/publications/2004/alca_english_web.pdf (last accessed: 1 October 2005).

¹³² The SACU Member States were still negotiating an FTA with the USA at the date of writing, 1 October 2005.

¹³³ See 3D → Trade - Human Rights - Equitable Economy, ‘Trade-related intellectual property rights, trade in services and the fulfilment of children’s rights - Botswana’.

¹³⁴ Botswana was considered by the CRC on the 16 September 2004.

question or to the Chair's remark on the US-SACU FTA negotiations, it is important that such questions are on record in order to warn other governments that the Committee may question them on IP rules in trade agreements, and particularly FTAs.

In view of this dialogue with the Botswana delegation, the CRC made the following recommendation:

[T]he Committee also recommends that the State party ensure that regional and other free trade agreements do not have a negative impact on the implementation of children's rights and, more specifically, that these will not affect the possibility of providing children and other victims of HIV/AIDS with effective medicines for free or at the lowest price possible.¹³⁵

3D disseminated the recommendation to human rights groups, access to medicines advocates and development groups in Botswana, Southern Africa and internationally.¹³⁶ It was also sent to international organizations working on HIV/AIDS in Botswana, such as UNAIDS, WHO and the OHCHR.

The recommendations of the CRC on Botswana were useful for access to medicines advocates working against the inclusion of TRIPS-plus rules at the regional level, and especially in the US-SACU FTA negotiations. South African civil society groups; TAC and the National Labour and Economic Development Institute (NALEDI), disseminated the CRC recommendations to their networks and welcomed them as a 'pro-poor' approach to trade.¹³⁷ Although the recommendations have not been explicitly used in advocacy campaigns so far, they were welcomed by the Aids Law Project, South Africa,¹³⁸ as complementary to the South African constitutional requirements and the UN international guidelines on HIV/AIDS and Human Rights.¹³⁹ Moreover, according to the Trade Law Centre for Southern Africa (TRALAC), the CRC recommendations played a role in supporting Southern African trade negotiators in maintaining a negotiating position against TRIPS-plus provisions in the US-SACU FTA negotiations and supported the decision not to include TRIPS-plus rules in the FTA between SACU and EFTA countries.¹⁴⁰

Denmark and Italy

3D submitted a briefing on Denmark and Italy to the 33rd Session of CESCR in November 2004.¹⁴¹ The purpose of the briefing was to highlight the human rights obligations of EU Member States in relation to trade policy, and especially trade-related IP policy. The relevant obligations highlighted in the briefing include the obligation to ensure 'individually or through international assistance and cooperation' access to affordable medicines in developing countries, prevent third parties from violating the right to health in other countries, and ensuring that the actions of EU members in international organizations take due account of the right to health.¹⁴² The briefing focuses on the need to ensure that EU trade policy promotes TRIPS flexibilities and access to affordable

¹³⁵ CRC, Concluding Observations, Botswana, UN Doc. CRC/C/15/Add.242 (3 November 2004), para.20.

¹³⁶ 3D → Trade - Human Rights - Equitable Economy, 'Access to Affordable Drugs: Victims of HIV/AIDS Should Not Suffer From Trade Rules, UN Committee Warns Botswana that US-SACU FTA Should Not Undermine Access to HIV/AIDS Treatment', 4 October 2004. , See http://www.3dthree.org/pdf_3D/BotswanaCOPressRelease_en.pdf (last accessed: 1 October 2005).

¹³⁷ Emails from TAC and NALEDI, South Africa, October 2004, on file with the author.

¹³⁸ Email from the AIDS Law Project, South Africa, May 2005, on file with the author.

¹³⁹ UNAIDS, HIV/AIDS and Human Rights International Guidelines, Revised Guideline 6, UN Doc. UNAIDS/02.49E, March 2003.

¹⁴⁰ Email from TRALAC, May 2005, on file with the author.

¹⁴¹ 3D, 'Denmark and Italy, Trade-related intellectual property rights, access to medicines and human rights, October 2004.

¹⁴² Articles 2(1) of the ICESCR, as interpreted by General Comment No. 3 (1990) and Article 12 of the ICESCR, as interpreted by General Comment No. 14 (2000).

medicines in developing countries and that the implementation of the WTO General Council Decision is done in a human rights-consistent manner.

Although the then EU Trade Commissioner, Mr. Pascal Lamy, publicly committed not to make demands for TRIPS-plus rules relating to medicines in its bilateral and regional trade agreements,¹⁴³ the EU is promoting an IP enforcement strategy that requires states to achieve the ‘highest international standards in this area.’¹⁴⁴ 3D’s briefing stresses that the EU enforcement strategy should not undermine access to affordable medicines. The briefing also emphasises that technical assistance, provided by individual EU Members and the EU as a whole, must promote the full use of TRIPS flexibilities to ensure access to affordable medicines for all. The briefing ends with an outline of possible questions and recommendations that the CESCR could make to Denmark and Italy, as individual States and as Member States of the EU, including the need for access to information and increased participation in the EU trade decision-making processes, which lack transparency.¹⁴⁵

During the consideration of the reports of Denmark and Italy,¹⁴⁶ the members of CESCR asked the delegation what they were doing to ensure that developing countries can use all the flexibilities under the TRIPS Agreement to ensure access to affordable medicines. The Committee members also wanted to know what the positions of the governments of Denmark and Italy were in relation to the EU’s proposed regulation aimed at implementing the compulsory licensing mechanism of the WTO General Council Decision.¹⁴⁷ The Danish and Italian delegations replied by confirming their commitment to the WTO Doha Declaration on TRIPS and Public Health and the General Council Decision. In a written reply to the Committee, Denmark explicitly confirmed its commitment to ‘gaining maximum flexibility within the existing framework for developing countries and the least developed.’¹⁴⁸ Moreover, the Danish delegation said that the ‘WTO decision would be integrated swiftly into Danish national legislation. Every effort would be made to ensure that developing countries were in a position to take full advantage of the Doha Declaration.’¹⁴⁹

In view of the encouraging statements of the Danish and Italian delegations, the Committee did not make any recommendations on the issue of access to affordable medicines. This is problematic, because a recommendation emphasising the human rights obligations of developed countries regarding access to affordable medicines would have been a valuable tool for advocates working to ensure that developed countries do not impose TRIPS-plus rules on developing countries. Without a written recommendation it was difficult to encourage national NGOs to take up the issue with their governments and parliamentarians. The only NGOs that expressed strong interest in the outcome of the CRC dialogue were the national offices of *Médecins Sans Frontières*, Denmark and Italy. The outcome of this joint submission on Denmark and Italy therefore demonstrates that further work is needed to encourage treaty bodies to make recommendations on the human rights obligations of developed countries vis-à-vis developing countries.

¹⁴³ P. Lamy, ‘Speech of the European Commissioner for Trade at the International Conference on the 10th Anniversary of the WTO TRIPS Agreement’, 23 June 2004.

¹⁴⁴ European Commission, *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, 2005/C 129/03, 23 June 2004.

¹⁴⁵ In particular the 133 Committee, which elaborates EU trade policy. Ref, e.g. suggest: Written Question E-4036/00, Bart Staes (Verts/ALE) to the Council, (3 January 2001), 2001/C 261 E/020 *Official Journal of the European Communities*, 18/09/2001, <http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/ce261/ce26120010918en00210021.pdf> (last accessed: 1 October 2005).

¹⁴⁶ Denmark was considered by CESCR on the 10-11 November 2004, and Italy was considered on 15-16 November 2004.

¹⁴⁷ European Commission, *Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems*, COM (04) 737, 29 October 2004.

¹⁴⁸ CESCR, Denmark, Written Replies, 15 November 2004, on file with author.

¹⁴⁹ CESCR, Denmark, Summary Record, UN Doc. E/C.12/2004/SR.37, 16 November 2004.

United Nations Commission on Human Rights mechanisms

Special procedures: the Special Rapporteur on the right to health

The UN Commission on Human Rights has special procedures in order to investigate, monitor and report on thematic or country-specific human rights issues. One of the main mechanisms relevant to the issue of IP and access to affordable medicines is the establishment of a Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (Special Rapporteur on the right to health), currently Mr. Paul Hunt. The mandate of this Special Rapporteur includes making recommendations on appropriate measures to promote and protect the right to health, which includes access to affordable medicines.¹⁵⁰ The Special Rapporteur on the right to health chose to consider the impact of trade-related IP rules on the enjoyment of the right to health.¹⁵¹ During 2004 and 2005, 3D worked in close collaboration with the Special Rapporteur, providing him with information on the human rights impacts of the TRIPS Agreement and TRIPS-plus rules in FTA agreements.

The Special Rapporteur chose to visit the WTO for his first mission to highlight the impact of trade rules on the right to health, and to enter into dialogue with WTO Members.¹⁵² In his report, the Special Rapporteur recommends that ‘States be cautious about enacting ‘TRIPS-plus’ legislation without first understanding the impact of such legislation on the protection of human rights, including the right to health.’ He goes on to add that ‘wealthy 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.’¹⁵³ The Special Rapporteur raised similar concerns in a subsequent country mission, to Peru, in 2004, in that instance regarding the on-going US-Peru FTA negotiations. In a Press Release dated 5 July 2004 he expressly stated that ‘the US-Peru trade agreement must not restrict Peru’s ability to use the public health safeguards enshrined in the TRIPS and the Doha Declaration.’¹⁵⁴ Furthermore, in his report on Peru, he affirmed that:

The Special Rapporteur urges Peru to take its human rights obligations into account when negotiating bilateral trade agreements. He suggests that before any trade agreement is finalized assessments identify the likely impact of the agreement on the enjoyment of the right to health, including access to essential medicines and health care, especially of those living in poverty. All stages of the negotiations must be open, transparent and subject to public scrutiny.

In accordance with its human rights responsibility of international cooperation, the United States should not apply pressure on Peru to enter into commitments that either are inconsistent with Peru’s constitutional and international human rights obligations, or by their nature are WTO-plus.¹⁵⁵

¹⁵⁰ CHR Resolution, ‘The right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, E/CN.4/RES/2002/32, 22 April 2002..

¹⁵¹ P. Hunt, ‘The UN Special Rapporteur on the Right to Health: Key Objectives, Themes, and Interventions’, *Health and Human Rights: An International Journal* Vol. 7 No. 1 (2003), 18.

¹⁵² CHR, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Report of the Special Rapporteur of the Commission on Human Rights on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, Paul Hunt, UN Doc. E/CN.4/2004/49/Add.1 (1 March 2004).

¹⁵³ *Ibid.*, at para. 82.

¹⁵⁴ UN Press Release, ‘US-Peru Trade Negotiations: Special Rapporteur on Right to Health Reminds Parties of Human Rights Obligations’, 5 July 2004.

¹⁵⁵ The Special Rapporteur refers to ‘WTO-plus’ as including ‘TRIPS-plus’ rules Commission on Human Rights (CHR), *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 Peru, E/CN.4/2005/51/Add.3 (4 February 2005), paragraphs 50 and 51.

By focusing on the risks relating to TRIPS-plus rules in the Andean FTAs, and the human rights obligations of the USA vis-à-vis third countries, the Special Rapporteur has provided invaluable tools to advocates working on access to affordable medicines in Peru and the Andean region.¹⁵⁶

In addition to missions, the Special Rapporteur's mandate includes the ability to accept individual complaints of violations of the right to health. If the Special Rapporteur accepts a complaint he may send an urgent action communication to the State concerned, reminding them of their human rights obligations. These communications can be invaluable tools for human rights advocates, even if they are confidential until their publication at the CHR.

One of 3D's activities is to work with partners to encourage them to bring concrete examples, such as complaints relating to trade rules, to the attention of the different human rights mechanisms. 3D collaborated with a coalition of Thai NGOs and NGOs from EFTA countries in the submission of two requests to the Special Rapporteur on the Right to Health, in June 2005.¹⁵⁷ These requests urge the Special Rapporteur to send an urgent appeal communication to the governments of Thailand and the EFTA Member States reminding them of their obligations to ensure that IP rules in FTA negotiations do not undermine access to affordable medicines for all in Thailand. Also, the letters urge the Special Rapporteur to remind the Thai government and the EFTA Member States of their obligation to ensure access to information and participation in public affairs, including FTA negotiations.¹⁵⁸ Such an initiative can provide additional support and legitimacy to advocates and campaigners at the national level, as well as draw media and public attention to the risks involved in FTAs.¹⁵⁹

The resolutions of the United Nations Commission on Human Rights

Resolutions of the UN Commission on Human Rights can also be used to ensure that States are held accountable to their duties to ensure access to affordable medicines when negotiating and implementing trade agreements into national law. Moreover, these resolutions can provide tools to access to medicines advocates and developing country decision-makers in support of human rights-consistent trade policies. 3D participated in the 2005 Commission on Human Rights¹⁶⁰ in order to ensure that the resolution on access to medicines provided greater support to advocates and decision-makers. The final text of the resolution includes language that is more explicit than in previous years and requires States to undertake impact assessments of trade rules on human rights.¹⁶¹ The text explicitly refers to trade agreements and makes the following recommendations:

¹⁵⁶ R. Lopez Linares, 'La Salud Pública en riesgo, Los medicamentos en el TLC,' *Observatorio del Derecho a la Salud* 10, 2005, p.10. See http://www.aislac.org/pdf/otras_publicaciones/4_saludenriesgo_tlc.pdf (last accessed: 1 October 2005).

¹⁵⁷ FTA Watch, 'Request for an urgent appeal on the impact of strict intellectual property rules in free trade agreement (FTA) on access to affordable medicines in Thailand', June 2005, http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d_id=3 (last accessed: 1 October 2005) and *Déclaration de Berne* and *Liechtensteinische Gesellschaft für Umweltschutz* (LGU), 'Request for an urgent appeal to stop EFTA Member States (Switzerland, Norway, Iceland and Liechtenstein), from imposing TRIPS-plus rules in free trade agreements (FTAs) with Thailand', June 2005. <http://www.evb.ch/en/p25009762.html> (last accessed: 1 October 2005)

¹⁵⁸ FTA Watch, 'Request for an urgent appeal on the impact of strict intellectual property rules in free trade agreement (FTA) on access to affordable medicines in Thailand', Press Release, 15 June 2005. http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d_id=3 (last accessed: 15 November 2005)

¹⁵⁹ At the time of writing the Special Rapporteur had not yet informed the NGOs from Thailand and EFTA countries of his response to their request, September 2005.

¹⁶⁰ The 61st Session of the UN Commission on Human Rights took place from 14 March – 22 April 2005.

¹⁶¹ CHR Resolutions, E/CN.4/RES/2001/33, E/CN.4/RES/2002/32, E/CN.4/RES/2003/29, and E/CN.4/RES/2004/26.

Urges States to consider, whenever necessary, enacting appropriate national legislation in order to use to the fullest extent the flexibilities contained in the TRIPS Agreement and encourages States to take into account such flexibilities when entering into international trade agreements that may affect public health;

Calls upon States to conduct an impact assessment of the effects of international trade agreements with regard to public health and to the progressive realisation of the right of everyone to the highest attainable standard of health.¹⁶²

3D contributed informally to the drafting of the resolution, and disseminated information on its trade-related aspects to advocates and decision-makers working on IP and access to affordable medicines. This contributed towards giving greater exposure to the work of human rights mechanisms for a trade-orientated audience by emphasizing the fact that trade-related recommendations are also being negotiated in human rights fora.¹⁶³

Conclusion

The impact of the WTO TRIPS Agreement on access to affordable medicines is one of the first trade issues to be recognised as having clear human rights implications. It is also one of the first WTO issues to have been challenged by developing country governments backed by an unprecedented coalition of public-interest NGOs from the North and South. Since the adoption of the WTO Doha Declaration on TRIPS and Public Health and subsequent mechanisms, the TRIPS Agreement has become a reference point despite its numerous failings. This has been exacerbated by the appearance of even stricter IP rules in other trade agreements. Bilateral and regional trade agreements in particular have emerged as the main trade threats to access to affordable medicines and the enjoyment of human rights, making TRIPS appear to be the lesser evil.

The emergence of TRIPS-plus rules raises a number of questions about the ability of States to comply with their human rights obligations. This is particularly urgent and problematic, as TRIPS-plus rules restrict a State's ability to procure its most vulnerable groups with medicines at a sufficiently low cost in order to comply with the right to life and the right to health obligations. This is a question of life or death in the case of pandemics such as HIV/AIDS, tuberculosis or malaria. Moreover, the proliferation of bilateral and regional trade agreements that are negotiated in secret, without any proper consultation with civil society, raise strong concerns regarding access to information, consultation and participation of citizens in public affairs.

In the light of these political and legal developments, the NGO 3D → Trade - Human Rights - Equitable Economy tried to move the issue forward by seeking additional human rights tools that could help access to medicines advocates and developing country decision-makers in their efforts to quell TRIPS-plus rules. 3D's submissions to the UN human rights mechanisms, particularly the treaty bodies, were attempts to ensure greater accountability and transparency in the negotiation of IP rules. The submissions were also aimed at encouraging the treaty bodies to begin systematically looking at the issue of IP and access to affordable medicines. The treaty bodies began to take up the issue regularly and have made recommendations that were instrumental in helping access to medicines advocates and decision-makers to fight against the inclusion of TRIPS-plus rules in FTAs.

3D's work on IP, access to medicines and human rights emerges as an illustration of how human rights rules and mechanisms can support a more human rights-consistent approach to trade policy.

¹⁶² CHR Resolution, E/CN.4/RES/2005/23.

¹⁶³ ICTSD, 'Human Rights Commission Calls on States to Use TRIPS Flexibilities', *Bridges' Weekly Trade News Digest* 9 (13) (20 April 2005).

It has also confirmed that in order for policy work such as this to be effective, it has to be complemented by advocacy work at the national, regional and international level. One example of a regional initiative is the NGO submission to the Inter-American Commission on Human Rights on regional economic integration in the Americas which raised concerns about IP and access to medicines amongst other issues.¹⁶⁴ However, if anything is to change, these NGO initiatives must be accompanied by State political action, such as human rights impact assessment of trade rules before making any trade commitments. Human rights law and mechanisms can help to ensure greater accountability in trade processes, but in order for trade rules to be more human rights consistent, political action at all levels is fundamental.

¹⁶⁴ *Centro de Derechos Humanos 'Miguel Agustín Pro Juárez' (Centro Pro Juárez), Los Derechos Humanos en los Procesos de Integración Económica en las Américas*, Statement for the CIDH, October 2004. See http://www.choike.org/documentos/tlc_cidh_ddhh.pdf (last accessed: 1 October 2005).

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